The Decision to Notify Patients following a Dental Infection Control Breach

A Scoping Review Study of Historical Incident Outcomes and Guidance with development of a Novel Decision-Making Algorithm to support Public Health Incident Management.

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Abstract

Background

Following a healthcare incident which has created a risk of blood borne virus transmission, a patient notification exercise can be implemented to inform patients that they have been exposed to an unanticipated and unacceptable risk of harm as a result of medical error.

Those managing the incident must consider all the facts of the case as well as the negative and positive implications, before reaching a decision on whether a patient notification exercise is required. One of the goals of notification is to detect the presence of blood borne virus infection within the exposed patient population thus providing the opportunity for treatment. The risk of transmission, within this setting, however, is thought to be extremely low.

Patient notification exercises are thought to create stress for patients, carry significant financial costs and reflect poorly on the health service. Most notification exercises identify very few new blood borne virus diagnoses and almost never identify incident-related transmissions (Close et al 2013; Mason et al 2008; Conrad et al 2011; Blatchford et al 2000; Roy et al 2005; Henderson et al 2017). Detection of transmissions and the concept of transparency must be balanced against any negative effects created by the exercise.

Currently, incident management teams must make their risk assessment and decision regarding notification without the support of formal guidance and with no up-to-date synthesis of evidence from previous dental incidents.

One of the aims of this doctoral study was to design and present an evidence-based decision-making algorithm to aid the incident management team's decision-making process regarding patient notification, following a dental infection control breach.

Methods

This doctoral work comprises a scoping review study with three components: a stakeholder consultation, a review of the published and grey incident literature and a policy mapping exercise (Davis et al 2009).

In the stakeholder consultation, purposive sampling was utilised to seek out and record the responses of those with experience of managing United Kingdom dental incidents. Participants were interviewed using a specifically developed questioning route and semi-structured interview style.

The literature review was used to identify articles which either reported or focused on the management of (a) specific dental incident(s) or were considered to be an opinion piece on large-scale medical patient notification exercises. In

regards to the grey literature, the chief investigator was directed to unpublished United Kingdom incident reports by key contacts and organisations. One of the chief investigators' educational supervisors, Dr Roy had access to a number of Scottish reports through her role as senior epidemiologist within Health Protection Scotland and had historically been involved in the management of such incidents occurring in Scotland. The chief dental officers of each devolved United Kingdom nation were contacted and every health protection team across England, Wales and Northern Ireland were emailed. The UK Advisory Panel for Healthcare Workers Infected with Blood Borne Viruses (UKAP 2019) was also contacted and a list of the dental incidents for which they had provided advice, was supplied.

Four different data extraction forms were used to collect information from reports and articles based on incident type, with the intention of presenting qualitative data as a narrative synthesis and quantitative data in the form of graphs and tables.

In the guidance mapping exercise, an initial list of websites to search was formulated based on recommendations from stakeholder consultation participants, the medical college librarian and university public health lecturers. Further sites were included based on the chief investigator's personal knowledge and utilisation of the resource 'Grey Matters' (Canadian Agency for Drugs and Technologies in Health 2015). Guidance documents were included if their use was cited by those managing incidents or they provided guidance on a) how to grade/assess the risk associated with an infected healthcare worker/infection control incident *and/or* b) when to notify patients following an infected healthcare worker/infection control incident *and/or* c) when duty of candour/disclosure standards are triggered.

Results

One hundred and forty nine dental incidents from six developed countries occurring between 1990 and 2017 were identified. Around half of infection control incidents (48% of 40) went to notification compared to 14% of those involving infected healthcare workers (n=107). Infection control incidents account for an increasing proportion of those managed (3.6% from 1990-1999 but 35.8% from 2010-2017).

The stakeholder consultation, literature and guidance revealed that transmission risk was considered to be the most influential decision factor regarding patient notification, however, level of risk was rarely applied to incident management in a structured or consistent way. There was a consensus that, although very important, risk could not be calculated accurately and that at best, only qualitative descriptions such as 'low', 'very low' or 'negligible' could be applied (Mason et al 2008; Millership et al 2007; Unpublished reports 2001-2017).

Minimal information could be drawn from historical 'proven transmission' events as they are rare, occurred long ago and/or lacked contextual detail. The limited conclusions that could be drawn suggested that incidents involving syringe reuse, multi-dose vials, extractions and oral surgery settings present a greater risk of patient-to-patient BBV transmission.

Multiple sources suggested that if transmissions (patient-to-patient or healthcare worker to patient) have already been identified, or are strongly suspected, then notification and testing is necessary. However, of the four proven, reported dental blood borne virus transmissions since 1990, not one identified any further transmissions via their associated notification exercises. This suggests that any incident-related transmissions which require detection may all reliably be identified prior to the use of a patient notification exercise.

This review suggested that there was significant pressure to be candid with patients following an incident, a mantra which has arisen due to historical paternalism and an awareness of the new Duty of Candour legislation which may override any consideration of risk level (CQC 2014; GMC 2015; Scottish Government 2018). Decision makers often contemplated; what the public would want and their reactions to finding out an organisation had not been open with them. Unsurprisingly, notification was deemed essential when the public were already aware of an incident.

The professional and statutory Duty of Candour was often weighed against the perceived opportunity costs of conducting notification, the significant expenditure of time, staff and workload as well as the predicted psychological impact on patients and reputational consequences for the dental profession which could result in patients not seeking dental care.

Notification appeared to be conducted based on the need to err on the side of caution. Patient safety was the priority and with a challenging risk assessment, no guidance or information from other incident management teams and unclear Duty of Candour guidance, notification and testing was utilised to respect the importance of transparency and mitigate the risks of both not adhering to legislation and leaving patients undiagnosed.

Research gaps

Decision makers were not only hampered by an absence of guidance but also by an inability or struggle to ascertain what others have done in the past. This doctoral work discovered that within the United Kingdom there is no central repository for incident data, incident details are rarely published (15%) and there is a lack of sharing of lessons learned amongst public health teams. When reports are made available or their data are presented in a published journal article, no standardised way of reporting exists and there are inconsistencies in

both the amount and detail of information presented. There was great variability in the types of journal that featured articles on patient notification.

Creation of a central repository of 'blood borne virus transmission risk' incident information and an increase in publication activity with agreement on the most suitable type of journal is needed. Standardised data collection will facilitate comparison of homogenous incident outcomes.

Duty of Candour and its application to large-scale incidents and dental practices must be clarified. It is recommended that further guidance is formulated, by those who drafted both the Scottish and English 'Duty of Candour' legislation, to aid incident management team members in understanding its applicability to large-scale patient disclosure (Care Quality Commission 2014; Scottish Government 2018).

Findings from this doctoral study strongly support utilisation of a limited notification response. Limited notification can be seen as a compromise between the two options of conducting or not conducting a patient notification exercise. It involves adapting notification to reduce expenditure of resources or involvement of all practice patients. By notifying only those patients who are deemed to be at the highest risk, resources and time are saved with less patients having to undergo the distress of notification and testing.

Conclusion

Undoubtedly, there is a desire from those tasked with investigating and managing these incidents, for guidance that will support their deliberations on the need for patient notification. The work of this thesis showed that such guidance would be challenging to develop, not just because of a lack of evidence to support the impact of a patient notification exercise (both positive and negative) but also because these incidents are all unique, and the investigations nuanced. Consequently, the best that can be provided is an algorithm which will standardise the approach to the discussion by identifying the key factors that should be considered. This does not of course mean that similar incidents will result in a similar management strategy, but it would ensure that any course of action is based on a robust appraisal of relevant factors and can be justified on a scientific, ethical and/or pragmatic basis.

Findings from this doctoral scoping review study were incorporated into a novel process (the Patient Notification Exercise (PNE) post-Dental Decontamination Breach (DDB) Decision-Making (DM) algorithm). This research product is designed to guide the flow and structure of decision-making, reassure IMTs that all necessary factors have been considered and provide consistent justifications for

decisions made which, with reference to the algorithm, can easily be explained to third parties.

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Authors declaration

"I declare that, except where explicit reference is made to the contribution of others, this dissertation is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institution."

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Abbreviations

The following abbreviations are used throughout this thesis

ADA	American Dental Association
AGH	Advisory Group on Hepatitis
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
APIC	The Association for Professionals in Infection Control and Epidemiology
AR	Dr Alastair Ross
AWD	Automated Washer Disinfector
BASHH	British Association for Sexual Health and HIV
BBV	Blood Borne Virus
CADTH	Canadian Agency for Drugs and Technologies in Health
CDC	Centres for Disease Control
CDO	Chief Dental Officer
CFIR	Consolidated Framework for Implementation Research
CI	Chief Investigator
CJD	Creutzfeldt-Jakob Disease
CPI	Combined Practice Inspection
CQC	Care Quality Commission
EAGA	Expert Advisory Group on AIDS
ECDC	European Centres for Disease Control
GDC	General Dental Council
GDP	General Dental Practice
GMC	General Medical Council
HAART	Highly Active Anti-retroviral Therapy
HBV	Hepatitis B Virus

HBsAg	Hepatitis B Surface Antigen
HBeAg	Hepatitis B ‘e’ Antigen
HBcAg	Hepatitis B Core Antigen
HBcAb	Antibody to the Hepatitis B Core Antigen
HBsAb	Antibody to the Hepatitis B Surface Antigen
HBeAb	Antibody to the Hepatitis B ‘e’ Antigen
HCC	Hepatocellular Carcinoma
HCV	Hepatitis C Virus
HCW	Healthcare Worker
HIV	Human Immunodeficiency Virus
HPA	Health Protection Agency
HPS	Health Protection Scotland
HPT	Health Protection Team
IgM antibody	Immunoglobulin M antibody
IgG antibody	Immunoglobulin G antibody
IMT	Incident Management Team
IVDU	Intravenous Drug Use
JB	Professor Jeremy Bagg
KR	Dr Kirsty Roy
LBE	Look Back Exercise
LDU	Local Decontamination Unit
LG	Lorna Gordon
LSAE	Large-Scale Adverse Event
MSM	Men Who Have Sex With Men
MVLS	Medical, Veterinary and Life Sciences
NCCMT	The National Collaborating Centre for Methods and Tools
NHMRC	National Health and Medical Research Council

NHS	National Health Services
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NIPCM	The National Infection and Prevention Control Manual
NPSA	National Patient Safety Agency
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NSS	National Services Scotland
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PHE	Public Health England
PINE	Psychological Impact of Notification Exercises
PNE	Patient Notification Exercise
RCS	Royal College of Surgeons of England
RCT	Randomised Controlled Trial
SDCEP	Scottish Dental Clinical Effectiveness Programme
SHEA	Aids Committee of the Society for Hospital Epidemiology of America
SHPIR	Scottish Health Protection Information Resource
SICPs	Standard Infection Control Precautions
STD	Sexually Transmitted Disease
SVR	Sustained Virological Response
UK	United Kingdom
UKAP	UK Advisory Panel for Healthcare Workers Infected with Blood borne Viruses
USA	United States of America
VHA	Veterans Health Administration
VHPB	The Viral Hepatitis Prevention Board
WHO	World Health Organisation

Chapter 1. Introduction

1.1 Blood borne viruses

Blood borne viruses (BBVs) are spread via blood or bodily fluid contact with little to no transmission risk associated with saliva (Lala et al 2018). They are transmitted via broken tissues, mucous membranes or directly into the blood stream (Lala et al 2018). They include the hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). HBV and HCV replicate via the hepatocytes of the liver and can lead to hepatitis, cirrhosis and/or hepatocellular carcinoma (HCC) (Mahboobi et al 2013). HIV targets the helper T-cells of the host's immune system (Lamont et al 2019) and can lead to the development of opportunistic infections and cancers (WHO 2019[d]). Those who are infected may undergo months or years of undetected, asymptomatic disease with uncontrolled liver damage or immune suppression (Lala et al 2018).

For BBV transmission to occur from one person to another, a series of specific events must occur which result in an infected individual's blood entering the blood stream of an uninfected person. This may occur via a direct or indirect route. An infected person could bleed directly onto the wound or broken skin of an individual. Indirect transmission could occur via an object contaminated with an infected person's blood which then punctures the skin of the vulnerable person or contacts an open wound (Lala et al 2018). Blood-to-blood contact, however, does not always result in transmission. Chance of transmission depends on the type of blood borne virus involved, the viral load of the source (how many viral particles are circulating in their blood stream) the volume of blood inoculated and the immune status of the exposed person (Pfaender et al 2016).

1.1.1 Hepatitis B

1.1.1.1 Discovery, structure and survival

Hepatitis B virus (HBV) was discovered in the mid-1960s with the Australia antigen (Hepatitis B surface antigen) being identified approximately ten years later (Lamont et al 2019). The Hepatitis B surface antigen (HBsAg) is a protein found on the surface of the virus particle and is a serological marker integral to both the diagnosis and monitoring of HBV infection (Lamont et al 2019). In 1980, the complete HBV genome was sequenced and the virus was assigned to the Hepadnaviridae family (Lamont et al 2019).

Hepatitis B virus (HBV) is a DNA virus with a circular, partially double stranded genome (Lamont et al 2019). The genome, DNA polymerase and hepatitis B core

antigen (HBcAg) are encapsulated within a protein envelope - a lipid layer containing HBsAg (Lamont et al 2019).

It is generally acknowledged that hepatitis B virus can survive on surfaces for at least one week (WHO 2019[a]), however, recent evidence suggests that survival time may be much longer, with one study concluding that HBV infectivity only reduced by approximately 10% after 28 days at room temperature (WHO 2019[a]; Than et al 2019)

1.1.1.2 Morbidity and mortality

Many people may be unaware of becoming infected with HBV as 70% of those who contract the virus are asymptomatic (Trépo et al 2014). For those who develop symptoms, they appear following an incubation period of two to six months (Lamont et al 2019). Symptoms can last for one to three months (Lala et al 2018) and can include fatigue, nausea, abdominal pain, vomiting, dark urine, pale stools and jaundice (PHE 2017[b]; Gupta 2018).

Those that remain positive for HBsAg six months following infection and fail to develop the associated antibody (HBsAb) are considered chronically infected (Bowyer et al 2011). Fortunately, this is not the case for the majority of healthy adults (90-95%) who will clear the virus within six months, perhaps without issue or indeed knowledge that they were ever infected (Lamont et al 2019; Mahboobi et al 2010; Bowyer et al 2011).

Recovery with immunity depends on age and presence of co-morbidities, which in turn are dictated by the efficacy of the individual's immune system (Lamont et al 2019). Children between one and five and HIV-infected individuals have a 70-80% of chance of viral clearance whilst for neonates, this figure drops to only 5-10% (Bowyer et al 2011; Trépo et al 2014; Chu and Liaw 2016).

In chronic infection, damage to the liver is caused by the body's immune response (Lamont et al 2019; Trépo et al 2014) and is usually prolonged, varying in severity both over time and from person to person (Davison and Strasser 2014; Bowyer et al 2011). Whilst the annual rate of spontaneous recovery following diagnosis of chronic infection is 0.5-2%, 15-25% will develop hepatocellular carcinoma (HCC) or decompensated cirrhosis (Chu and Liaw 2016; Tang et al 2018; Davison and Strasser 2014).

Following acute HBV infection one percent of individuals develop fulminant hepatitis which, without liver transplantation, results in death in 80% of cases (Trépo et al 2014).

Even though subclinical infection and viral clearance is common, HBV is overall a very serious world health issue. HBV is a leading cause of HCC (Lamont et al 2019; Rantala and van de Laar 2008) and was reported to be the tenth most common

cause of death in a 2010 Global Burden of disease study (Mahboobi et al 2010; Trépo et al 2014). In 2015, 887,000 deaths worldwide were attributed to HBV infection (WHO 2019[a]).

1.1.1.3 Transmission routes and risks

HBV is transmitted via mucosal or percutaneous contact with the blood or other high-risk body fluids of an infected individual (Lamont et al 2019). In developing countries HBV is most commonly transmitted from mother-to-child during birth whilst in developed countries transmission via sexual contact and needle sharing are common (Lamont et al 2019).

HBV is the most infectious BBV and is estimated to be 75-200 times more infectious than HIV (Bowyer et al 2011). Following exposure to HBV-infected blood, depending on the viral load and Hepatitis B 'e' antigen (HBeAg) status of the source, transmission risk is cited as ranging from 5-30% (Coppola et al 2016; PHE 2014[a]; Health and Safety Executive 2019[b]), however, of out of 590 healthcare workers who were occupationally exposed to HBV-infected blood in the UK between 2004 and 2013, none developed HBV infection (PHE 2014[a]). The viral load of HBV-infected individuals can be high, with as many as 10^{10}-10^{12} infective particles per ml of blood meaning that exposure to extremely small quantities of blood can result in transmission (Lamont et al 2019).

Viral load may be significantly raised in the immediate period (approximately 2 months) following infection or if the individual in question is immunocompromised (Lamont et al 2019; Bowyer et al 2011). Being HBeAg positive or being infected with a pre-core mutant strain of the virus, also increases infectivity (Davison and Strasser 2014; Trépo et al 2014).

1.1.1.4 Prevalence

HBV is categorised into ten genotypes, A-J, with genotype A being most prevalent in northern Europe (Trépo et al 2014; Rantala and van de Laar 2008). Around one third of the world's population has been, at one time, infected with HBV (Mahboobi et al 2013; Trépo et al 2014) and currently, in 2019, it is estimated that 257 million people are living with the disease (WHO 2019[a]).

Rates of infection are highest in South America, Africa and Asia, continents in which 45% of HBV-infected individuals reside, with prevalences of 8-15% (Mahboobi et al 2010; Trépo et al 2014, Lamont et al 2019).

Countries with a low HBV prevalence (<2%) include Canada, the USA and Australia (Mahboobi et al 2010). In the UK, prevalence of chronic HBV is estimated to be 0.1-0.5% (Health and Safety Executive 2019[a]).

Although rates of HBV in developed countries are generally low, prevalence and genotype variation may be higher in those who have emigrated from high prevalence countries (Health and Safety Executive 2019[a]; Rantala and van de Laar 2008). A meta-analysis published in 2012 reported that the prevalence of HBV amongst refugees and migrants living in low prevalence countries was around 7.2% (Rossi et al). Prevalence in intravenous drug users (IVDUs) is also estimated to be significant and may be up to ten times higher than the average for any given country (Rantala and van de Laar 2008; Lamont et al 2019).

1.1.1.5 Testing

HBV markers within the blood are used to establish whether infection is present and, if so, the individual's stage of infection (Davison and Strasser 2014). Patients are initially tested for HBsAg which is detectable two to ten weeks post-exposure and indicates current infection (Tang et al 2018; Trépo et al 2014).

Although presence of HBsAg indicates current infection it does not indicate the patient's level of infectivity or whether they were recently infected (Lamont et al 2019). Viral load and presence of HBeAg are used to establish level of infectivity (Davison and Strasser 2014). Presence of the IgM antibody alone indicates recent or acute infection as it is the first antibody to be produced, later replaced by IgG antibody (Lamont et al 2019). Presence of antibodies to both the core and surface antigen (HBcAb and HBsAb) indicates resolved infection with immunity and presence of HBsAb alone indicates a history of vaccination (Lamont et al 2019; Davison and Strasser 2014).

1.1.1.6 Treatment

There is currently no cure for HBV. Treatment aims to reduce both viral load and replication, thereby lessening liver damage and the probability of progression to liver cirrhosis or cancer (Trépo et al 2014, Bowyer et al 2011). Decreasing viral load also reduces chances of onward transmission (Lala et al 2018).

Currently, in 2019, seven medications are licenced for the treatment of HBV (Bagg et al 2017). They include immunomodulatory drugs like interferon and nucleoside reverse transcriptase inhibitors (NRTIs) like Entecavir and Lamivudine (Bagg et al 2017). Although both forms of treatment may be effective in establishing sustained viral suppression, NRTIs are quickly becoming the favoured choice for treatment of HBV (Bagg et al 2017).

Interferon is administered via injection for a limited treatment course of approximately 48-52 weeks (Trépo et al 2014). It is associated with several side effects such as fatigue, depression and bone marrow suppression (Trépo et al 2014). Interferon's efficacy has been shown to be linked to genotype, with

infection most effectively treated in those with genotype A or B (Rajoriya et al 2017; Trépo et al 2014).

NRTIs are administered orally and result in fewer side effects (Trépo 2014). Unlike interferon, life-long treatment with NRTIs may be recommended (Lala et al 2018) with an attendant risk of drug resistance (Bagg et al 2017). However, this issue can be minimised through careful choice of first line medications, such as Tenofovir and Entecavir, which are known to result in less resistance (Bagg et al 2017).

Patients with HBV are likely to need life-long monitoring to assess liver health and drug efficacy (Bowyer et al 2011). Those with fibrosis or cirrhosis may need regular ultrasound scans or liver biopsies to promptly identify any developing tumours (Davison and Strasser 2014; Trepo et al 2014).

1.1.1.7 Prevention

An effective and safe HBV vaccine has been available since 1981 (Trépo et al 2014). In the UK, vaccination is recommended for those at high risk such as HCWs and haemodialysis patients (PHE 2017[b]). The vaccine has also recently been added to the UK's childhood vaccination schedule. All infants born since August 2017 have been offered the vaccine as part of a hexavalent, six-in-one immunisation (PHE 2017[b]).

If an individual responds to the vaccine, effective protection is provided for approximately 15 years (Trépo et al 2014). However, not all respond adequately to vaccination with approximately 5% of people not producing the required 10 mIU/ml of HBsAb titre (Mahboobi et al 2010; Trépo et al 2014).

Post exposure prophylaxis (PEP) for HBV is available in the form of vaccination or immunoglobulin which must be given ideally within 24 hours of exposure and no later than seven days post exposure (PHE 2017[b]).

1.1.2 Hepatitis C (HCV)

1.1.2.1 Discovery, structure and survival

HCV was discovered in 1989 (Pozzetto et al 2014). Before this time it was known as non-A non-B hepatitis (Westbrook and Dusheiko 2014). Although discovery occurred in the late 1980s, detailed information about the virus' genetic material was not gathered until 1999 when a newly developed process called the replicon system facilitated creation of full length HCV genetic sequences (Carrozzo 2014).

HCV is an enveloped, single-stranded RNA virus of the Flaviviridae family (Millman et al 2017; Lamont et al 2019; Pozzetto et al 2014). One of the most

significant features of HCV is its propensity to mutate rapidly in an attempt to evade the body's immune system (Lamont et al 2019). Mutations often involve errors which can enhance or even destroy the virus (Lamont et al 2019) and beyond sub-genotype, result in a range of quasi-species (Millman et al 2017).

HCV is categorised into six main genotypes (1-6) and multiple subtypes (Kamili et al 2012). Genotype 1 is the most common and accounts for approximately half of all HCV infection (Petruzziello et al 2016).

It is generally thought that HCV can survive for several weeks on dry surfaces (NHS 2018[b]) and has been shown to remain infective in saliva at room temperature for 3 weeks (Pfaender et al 2018). The virus is inactivated and/or killed by steam sterilisation at a temperature of 60°C that lasts for ten minutes or more and is easily killed through antiseptic, alcohol and peracetic acid use (Pozzetto et al 2014).

1.1.2.2 Morbidity and mortality

Following infection with HCV less than 25% of people will experience non-specific symptoms (WHO 2019[f]) which arise approximately 2 weeks to 6 months after infection (WHO 2019[f]).

Compared with HBV, progression to chronic infection is much more likely. 75-80% of those infected develop chronic HCV infection with associated risks of cirrhosis and HCC (Pozzetto et al 2014; Westbrook and Dusheiko 2014; Mahboobi et al 2013). Chronic infection is diagnosed based on the persistent detection of HCV RNA more than six months after infection (Cresswell et al 2015).

Once chronic infection is established the individual has a 16% chance of developing cirrhosis within 20 years and a 41% chance of its diagnosis within 30 years (Westbrook and Dusheiko 2014). Cirrhosis and HCC are more likely if the patient is older, male, overweight, has a high alcohol intake, has type 2 diabetes, or is co-infected with another BBV (Westbrook and Dusheiko 2014).

Presence of cirrhosis indicates a poor prognosis, with affected patients having an annual 1-5% and 3-6% risk of HCC and liver failure respectively (Westbrook and Dusheiko 2014). After liver failure is diagnosed, chances of patient death within the following year are 15-20% (Westbrook and Dusheiko 2014).

HCV is not only linked to HCC and fibrosis but other extra-hepatic diseases such as diabetes, non-Hodgkins B cell lymphoma, lichen planus and glomerulonephritis (Millman et al 2017).

HCV is the most common reason, worldwide, for patients requiring a liver transplant and 350,000 people die every year from HCV-related conditions (Westbrook and Dusheiko 2014).

1.1.2.3 Transmission routes and risks

HCV is less infectious than HBV but more infectious than HIV. Following a sharps injury[1], where the source patient is infected, Public Health England cite a 1 in 30 (~3%) chance of HCV transmission with the Health and Safety Executive outlining a 1-3% risk, (PHE 2014[a]; Health and Safety Executive 2019[b]). However, evidence from the literature suggests that seroconversion rates following occupational exposure may be lower. In 2002, Jagger presented evidence from 14 studies involving 11,383 exposed healthcare workers and the average seroconversion rate was only 0.5%. Similarly, in 2017, Egro et al published a study with 13 years' worth of data, which demonstrated an occupational exposure seroconversion rate of 0.1% out of 1361 healthcare workers. However, the seroconversion rate of 2.2% in Tomkins et al 2012 study, was more in line with Health and Safety Executive estimates.

Those at high risk for HCV include intravenous drug users, HCWs who perform exposure prone procedures (EPPs), dialysis patients, those who received blood transfusions before 1992, individuals born between 1945 and 1965 who engaged in drug use during the 70s and 80s, men who have sex with men (especially if they are already infected with HIV) and ethnic minorities with links to high prevalence countries (Leao et al 2006; Westbrook and Dusheiko 2014; Weaver 2014; Millman et al 2017; Creswell et al 2015; PHE 2018). Unlike HBV, HCV is not effectively spread from mother-to-child during birth or via sexual contact (Pfaender et al 2016).

Forty percent of diagnosed HCV cases do not have a proven, identified source (Mahboobi et al 2013) but a significant proportion of infection is linked to IVDU (Pozzetto et al 2014). In England it is estimated that half of IVDUs are infected with HCV (PHE 2018).

1.1.2.4 Prevalence

There are between 71 and 123 million people living with chronic HCV infection worldwide (PHE 2018; Westbrook and Dusheiko 2014; Pozzetto et al 2014). Developed countries have a lower HCV prevalence (<1%) compared to developing countries where it can be as high as 5% (Lamont et al 2019).

There are estimated to be 210,000 people living with chronic HCV in the UK (PHE 2018). The prevalence varies based on the devolved nation and associated proportion of high risk groups, such as IVDUs, residing there. In England and Wales prevalence is approximately 0.6% whereas in Scotland it is closer to 1% (Pozzetto et al 2014).

[1] A sharps injury or percutaneous injury is an incident, which causes a needle, blade (such as scalpel) or other medical instrument to penetrate the skin (Health and Safety Executive 2019[a])

Infection with HCV genotypes 1, 2 and 3 occur commonly in the U.S.A and UK (WHO 2017). Genotype 4 is most often found in Egypt (Lamont et al 2019) with genotypes 5 and 6 being associated with South Africa and Southeast Asia respectively (WHO 2017).

1.1.2.5 Testing

Patients are initially tested for the HCV antibody where a positive result is indicative of current or previous infection (Cresswell et al 2015). Presence of HCV RNA, detected through PCR, indicates current infection (Cresswell et al 2015). HCV RNA testing can be used 1-2 weeks following exposure (WHO 2017) but is not routinely performed as a first line test due to cost, resource and time implications (Cresswell et al 2015).

Unlike HBV, there is no specific HCV marker that indicates when infection likely occurred (Lamont et al 2014). Ways to establish if infection is recent have been developed and include measurement of viral load fluctuations, avidity testing[2] and immunoassays for the HCV core antigen (Kamili et al 2012).

1.1.2.6 Treatment

In the UK, the main treatment for HCV was historically a combination of pegylated interferon and ribavirin (Millman et al 2017). These drugs were given for approximately 24-48 weeks, depending on genotype but had significant side effects and variable efficacy (Millman et al 2017; Bagg et al 2017). A sustained virological response (SVR), defined as absence of HCV RNA at 24 weeks post-treatment (Carrozzo 2014), was achieved by around 50% of patients and was genotype dependent (Lamont et al 2019).

Recently developed direct acting antiviral drugs (DAAs) such as Sofosbuvir and Ledipasvir are effective in the treatment of all HCV genotype infections and result in little to no side effects or drug interactions (Weaver 2014; Bagg et al 2017). An 8-12 week course of treatment with DAAs results in over 90% of patients achieving a SVR (Millman et al 2017, Bagg et al 2017).

If achieved before any liver fibrosis or damage, SVR is associated with an elimination of risk of liver failure, portal hypertension and/or HCC (Westbrook and Dusheiko 2014). If cirrhosis is present, risks are still significantly reduced with a 20% reduction in risk of HCC development (Westbrook and Dusheiko 2014).

It is hoped that with the development of these new curative drugs, future, worldwide eradication of HCV is possible and the World Health Organisation aims

[2] Avidity testing measures the strength of bond between antibody and antigen which becomes stronger the longer the patient is infected (Shepherd et al 2018). A low bond strength or avidity indicates that infection likely occurred within the last four to six months (Shepherd et al 2018).

to remove HCV as a major public health threat by 2030 (Millman et al 2017; PHE 2018). It is important to note, however, that although these new DAA drugs are highly effective, controversy over high treatment costs have arisen and challenges remain in relation to reaching large numbers of patients in deprived areas (Bagg et al 2017; PHE 2018; Carrozzo 2014).

1.1.2.7 Prevention

Currently, there is no vaccine or effective post exposure prophylaxis (PEP) regimen available for HCV infection (Mahboobi et al 2013). A vaccine has been difficult to develop due to HCV's many genotypes and its propensity to mutate within the body (Millman et al 2017).

1.1.3 Human Immunodeficiency Virus

1.1.3.1 Discovery, structure and survival

Acquired Immune Deficiency Syndrome (AIDS) was first described in 1981 when five homosexual men were diagnosed with the rare condition *Pneumocystis carinii* pneumonia (CDC 1981). This condition was indicative of severe immunosuppression which was later discovered to be caused by infection with Human Immunodeficiency Virus (HIV) and associated depletion of their immune system's helper T-cell lymphocytes (Freed and Martin 2013; Lamont et al 2019).

Although identified in 1981, it was not until 1983 that AIDS was identified as being the final stage of HIV infection and the HIV virus was isolated and studied (Ghosn et al 2018). It has been theorised that HIV originated in chimpanzees and that a virus infecting these primates mutated to facilitate infection of humans. Humans had repeated contact with chimpanzees throughout history via hunting practices. The earliest evidence of HIV-infected human blood was sourced from a sample collected in the 1950s (Lamont et al 2019)

Like HCV, HIV is a single-stranded, enveloped, RNA virus (Pfaender et al 2016). HIV is part of the retroviridae family and has two strains, HIV-1 and HIV-2 (Lamont et al 2019). HIV-1 is the most common whereas HIV-2 is mainly localised to West Africa and has a better prognosis (Lamont et al 2019).

Of the three BBVs, HIV is the most fragile and does not survive for long outside the body (NHS 2018[a]). Most studies are linked to HIV's survivability in water and transplant tissues rather than in environmental blood spillages. HIV has been shown to survive in room temperature (20-25°C) wastewater for approximately 12 hours (Casson et al 1992) whilst another study showed that in 25°C water, infectivity dropped by 90% after one to two hours and by eight hours had dropped by 99.9% (Moore 1993). In 2000, a study showed that a temperature of

50°C for 30 mins resulted in a 1.12 log reduction of viable virus particles (Hernigou et al 2000).

1.1.3.2 Morbidity and mortality

HIV uses helper T-cells (CD4+ cells) to replicate, leading to their destruction and depletion (Maartens et al 2014; WHO 2019[d]). Helper T cells are vital to the immune response and so with a severely compromised immune system and helper T-cell numbers reducing over time, HIV-infected individuals are highly susceptible to a multitude of opportunistic infections and conditions such as tuberculosis, cryptococcal meningitis, pneumonia, candidosis and tumours (National Institute of Allergy and Infectious Diseases 2019; Maartens et al 2014; WHO 2019[d]; NHS 2018[a]). Regardless of treatment with antiviral medications, around half of HIV-infected individuals may also experience a varying degree of impaired neurological function as infection affects the central nervous system (Nightingale et al 2014).

There are generally three phases of HIV infection:

1. primary infection in which around 50% of individuals will experience flu-like symptoms such as fever, fatigue, headaches, a rash on the thorax and lymphadenopathy which may last for approximately one to three months before resolving (WHO 2019[d]; Lamont et al 2019; NHS 2018[a]).

2. a significant period of clinical latency (median=10-15 years) (Lamont et al 2019).

3. if untreated, a final progression to AIDS is associated with a very low helper T-cell count (Pfaender et al 2016). It is diagnosed based on the presence of HIV infection and one or more of a list of specific clinical conditions such as *Pneumocystis* pneumonia and Kaposi's sarcoma (WHO 2007).

Since the initiation of widespread infection, approximately 70 million people have been infected with HIV and around 50% of them have died (WHO 2019[c]). Mortality rates associated with HIV have, however, dramatically reduced in the developed world with the widespread use of effective treatment (Poorolajal et al 2016) but in areas such as Sub-Saharan Africa, where access to treatment is poor, the prevalence of HIV and associated deaths remains a major public health problem (Ghosn et al 2018) (Table 1). If not treated, HIV is fatal (Pfaender et al 2016) and most individuals will succumb to their condition 2-4 years after diagnosis (Poorolajal et al 2016).

Table 1: Number of deaths, in different countries, due to HIV infection

Country	Population size in 2017 (millions)[a]	Number of deaths due to HIV in 2017[b]	Percentage of population dying from HIV in 2017 (%)	Approximate numbers of deaths per defined sample
South Africa	56.72	110,000	0.19	1 in 500
Zimbabwe	16.53	22,000	0.13	1in 1000
South Sudan	12.58	12,000	0.09	1 in 1000
United republic of Tanzania	57.31	32,000	0.06	1 in 2000
Jamaica	2.89	1500	0.05	1 in 2000
Thailand	69.04	15,000	0.02	1 in 10,000
Cuba	11.48	<500	0.004	<1 in 25,000
Pakistan	197	6200	0.003	1 in 25,000
Mexico	129.2	4000	0.003	1 in 25,000
Ireland	4.784	<100	0.002	<1 in 50,000
Norway	5.258	<100	0.002	<1in 50,000
Denmark	5.77	<100	0.002	<1 in 50,000
Nepal	29.3	300	0.001	1 in 100,000
Italy	60.59	560	0.00009	1 in 1m
Australia	24.6	<200	0.00008	<1 in 1.25m
France	67.12	<500	0.00007	<1 in 1.5m
Philippines	104.9	760	0.00007	1 in 1.5m
Germany	82.79	<500	0.00006	<1 in 1.5m
Japan	126.8	<200	0.00002	1 in 5m

Red = Countries where 1 in <10,000 people died from HIV/AIDS in 2017
Orange = Countries where between 1 in 10,000 and 1 in 100,000 people died from HIV/AIDS in 2017
Green = Countries where less than 1 in 1 million people died from HIV/AIDS in 2017
a = World Bank Data (https://data.worldbank.org/indicator/SP.POP.TOTL)
b = World Health Organisation. (https://www.who.int/gho/hiv/epidemic_status/deaths/en/)

1.1.3.3 Transmission routes and risks

Sexual contact between men is a well-recognised mode of transmission but rates of heterosexual transmission are now high and indeed comparable to men who have sex with men (MSM) transmission in the UK (National AIDS Trust 2018). 46.4% of those being treated in the UK acquired their infection via sex between men compared to 46.2% who acquired infection via heterosexual contact. If not undergoing treatment for HIV infection, transmission from mother-to-child occurs, during birth, in around 25% of cases or via breastfeeding in 40% of cases (Pfaender et al 2016). Intravenous drug use (IVDU) remains a significant mode of HIV transmission (Ghosn et al 2018).

HIV is the least transmissible of the three BBVs. The chance of transmission following a significant sharps injury exposure is cited as 1 in 300 (0.3%) (PHE 2014[a]; Health and Safety Executive 2019[b]). This low rate of seroconversion is

supported by a recent review which reported that following assessment of 17 studies from 1986 to 2015, only 10 out of 7652 HCWs who were exposed to HIV-infected bodily fluids seroconverted (Nwaiwu et al 2017). Individuals with HIV are most infectious two to seven weeks post-infection (Lamont et al 2019).

1.1.3.4 Prevalence

In 2017 it was estimated that worldwide there were approximately 36.9 million people living with HIV and that around 75% of those who were infected lived in Sub-Saharan Africa where prevalence is around 4.1% (WHO 2019[b]). European prevalence was estimated to be 0.4% with the lowest rates of infection being found in the Middle-East and Asia (0.1%) (WHO 2019[b]).

In the UK, prevalence was estimated to be 0.16% in 2018 (Office for National Statistics 2018; National AIDS Trust 2018). It was also estimated that 1 in 14 of those infected are unaware of their condition (National AIDS Trust 2018) but 87% of the total number of diagnosed and undiagnosed UK cases are estimated to be on treatment with significant viral suppression and an associated negligible risk of transmission (National AIDS Trust 2018).

1.1.3.5 Testing

Fourth generation assays can be used to detect HIV antibody and the p24 antigen from 4 weeks post exposure (BASHH and EAGA 2014). If first line testing is positive, further diagnostic tests such as a Western Blot assay are conducted to confirm diagnosis (WHO 2019[d]; Parekh et al 2019).

1.1.3.6 Treatment

Since the mid-1990s the main form of treatment for HIV has been a combination of anti-retroviral medications referred to as highly active anti-retroviral therapy (HAART), with each drug targeting a different viral element or process (Lamont et al 2014; Bagg et al 2017). This treatment regimen is highly effective at reducing viral load to often undetectable levels but there is still no cure for HIV (Bagg et al 2017).

Earlier treatment results in better outcomes, longer life expectancy and reduced onward transmission (Bagg et al 2017). Current treatment is so effective that many HIV-infected individuals now have a close to normal life expectancy (Marcus et al 2016).

1.1.3.7 Prevention

There is currently no HIV vaccine as, like HCV, HIV frequently mutates, making vaccine generation difficult (Lamont et al 2019).

Post exposure prophylaxis (PEP) is available in the form of anti-viral medication which is ideally given within two hours of exposure. The PEP medicinal regimen is similar to that given for the long term treatment of HIV – Highly active anti-retroviral treatment (HAART) (British Association for Sexual Health and HIV – BASHH 2019). A combination of nucleoside reverse transcriptase inhibitors and interphase inhibitors are given for approximately 28 days (BASHH 2019). A risk-benefit assessment is advised before prescription as drug toxicity is high and side effects can be significant (BASHH 2019; Pfaender et al 2016).

1.2 Blood borne virus transmission in healthcare

The healthcare setting represents a unique environment where exposure of tissues and production of blood is combined with close quarters and complex interactions. Figure 1 shows the triangle of transmission, which identifies the possible routes of BBV transmission in healthcare (VHPB 2005).

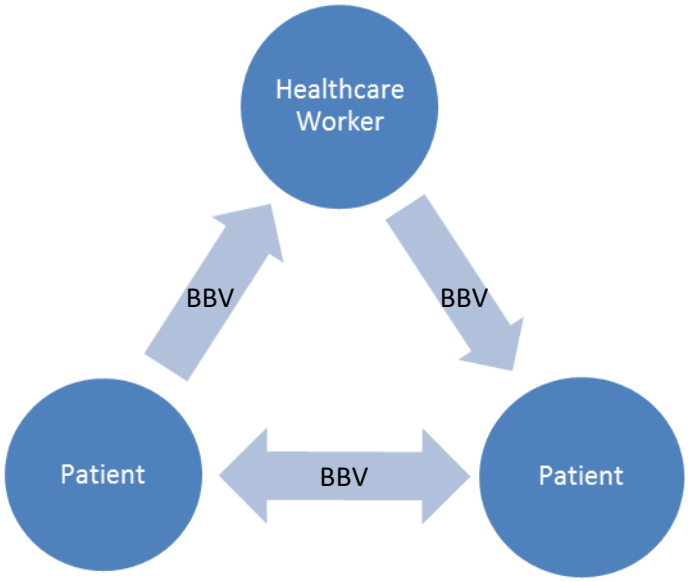


Figure 1: Diagrammatical representation of the possible pathways of BBV transmission in health care.

When describing the sequence of events required for transmission, the 'Swiss Cheese' analogy is often used. This concept relates to the specific events (ie. the holes of the cheese) which need to align for transmission to occur (Curran 2013). In a scenario where dental instruments have not been sterilised properly, for BBV transmission to occur, the following events would need to take place:

1. A BBV-infected individual is treated at the dental practice.

2. The infected individual undergoes an invasive procedure which results in instruments being contaminated with blood.

3. The instruments are not cleaned or sterilised sufficiently in order to remove/kill viral particles.

4. The next patient is susceptible to infection and also undergoes an invasive procedure with the contaminated instruments being used.

5. Following a significant exposure[3], chances of transmission occurring can be as high as 1 in 3 or as low as 1 in 300 depending on the type of blood borne virus involved and infectivity of the source patient (PHE 2014[a]; Health and Safety Executive 2019[b]). If the source patient is on anti-viral medication (which they are taking responsibly) chances of transmission will be negligible (Bagg et al 2017).

1.2.1 BBV transmission from patient to HCW

BBV infection can be transmitted to a HCW via a sharps injury which occurs whilst treating a BBV-infected patient. In England, Wales and Northern Ireland, from 2004 to 2013, 4830 events of significant occupational exposure were recorded (PHE 2014[a]). Of these, 71% were percutaneous needle stick injuries with 65% occurring during the clinical procedure, over half were in connection with a HCV-infected patient and 5-10% of all involved HCWs were dentists or dental nurses (PHE 2014[a]). None of the associated HCWs became infected with HIV or HBV but nine contracted HCV as a result of their exposure, reflecting a seroconversion rate of 1 in 285 (PHE 2014[a]). In total, since 2010, seven Scottish HCWs have been infected with HCV following occupational exposures (Health Protection Scotland and NHS Scotland 2018).

1.2.2 BBV transmission from HCW to patient

HCW-to-patient transmission is uncommon but can occur (Ward and Hartle 2015). In the UK between 1991 and 2015, 20 HCWs are known to have transmitted BBV infection to their patients (11 HCV, 9 HBV and 0 HIV) (PHE 2017[a]; Mawdsley et al 2005; Molyneaux et al 2000).

Transmissions of BBVs from HCWs to patients are most likely to occur during exposure prone procedures (EPPs) which are defined by the UK Department of Health as:

"Invasive procedures where there is a risk that injury to the worker may result in the exposure of the patient's open tissues to the blood of the worker. These

[3] a significant exposure refers to an event whereby a person is exposed to the blood of an individual known to be infected with a blood borne virus.

include procedures where the worker's gloved hand may be in contact with sharp instruments, needle tips or sharp tissues (eg spicules of bone) inside a patient's open body cavity, wound or confined anatomical space, where the hand or fingertips may not be completely visible at all times" (PHE 2016).

EPPs are further classified into three categories based on the probability of 'bleed back', which is defined as "the chance that following injury, the HCW's blood will contact the patient's exposed tissues" (Ward and Hartle 2015).

1.2.3 BBV transmission from patient-to-patient

Before current blood screening practices, BBVs were spread by organ transplantation (Gow and Mutimer 2001) as well as via contaminated blood and clotting factor transfusions (Prati 2006). In recent times, patient-to-patient healthcare associated transmission has been linked to dialysis, blood glucose monitoring and the reuse of multi-dose vials (Harling 2007; Duffell 2010; Kliner 2015; Garvey 2017; Johannessen 2018). Published literature indicates that since the year 2000, there have been at least 5 healthcare-associated BBV outbreaks involving 29 patients (Appendix 1).

1.3 Prevention of BBV transmission in the healthcare setting

As all three BBVs are spread via bodily fluid contact, their routes of transmission in healthcare are comparable. Steps taken to minimise spread of one virus will result in reduced transmission of all three.

1.3.1 Standard infection prevention and control

The World Health Organisation (2019[e]) defines infection control as "a scientific approach and practical solution designed to prevent harm caused by infection to patients and health workers. It is grounded in infectious diseases, epidemiology, social science and health system strengthening". The Department of Health outline that dental infection control includes "all aspects of the running of a dental practice: from attention to personal hygiene – hand-washing, masks, protective clothing – to the cleaning and sterilization of instruments and the maintenance of the equipment" (Department of Health 2013).

In addition to HBV vaccination and screening of blood products, advances in infection control processes since the 1980s have resulted in a drop in the number of healthcare-associated transmissions in developed countries. 'Universal precautions' were introduced in 1987 and were based on the concept that the "blood and certain body fluids of all patients [should be] considered potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens" (CDC 1988). These precautions have been

developed over time and today, in the UK, they exist in the form of 'standard infection control precautions' (SICPs). SICPs consist of ten categories of "basic infection prevention and control measures [which] reduce the risk of transmitting infectious agents from both recognised and unrecognised sources of infection" (NHS England and NHS Improvement 2019). They include hand hygiene, safe management of sharps and PPE use (NSS 2019[b]). SICPs should be applied to the treatment of all patients in the same way to minimise spread of infection with all patients' blood and body fluids being treated as potentially infectious (NSS 2019[b]).

1.3.2 Policies for identifying and managing BBV-infected healthcare workers

Policies exist in the UK to prevent BBV-infected healthcare workers from transmitting infection to patients. Guidance published by Public Health England stipulates that "any HCW who may perform exposure prone procedures (EPPs) and who has been diagnosed with a BBV infection must seek expert occupational health (OH) advice to enable appropriate occupational health care to be provided, and any restriction of working practice (if required) to be implemented" (2017).

NHS healthcare students and workers are screened for BBV infection prior to commencing a role where they will perform EPPs (PHE 2017[a]). HCWs infected with HCV are not permitted to perform EPPs whilst those with HIV and HBV must be continually monitored by both their physician and occupational health to ensure that treatment is consistently suppressing their viral load to a level where risk of transmission is negligible (PHE 2017[a]). BBV-infected HCWs working in the UK must also be registered on UKAP-OHR, a central confidential register, managed by PHE (PHE 2017[a]). Further information regarding specific viral load levels and UK working restrictions are provided in Table 41 (p207).

1.4 Dentistry

Dentists perform a range of procedures which vary in their propensity to produce blood or create risk of occupational injury. A plethora of re-usable instruments are used and then processed, with a high patient turnover. While the risk of transmission in these settings is considered low with current standards of infection prevention and control, transmission of BBVs (between patients, from patient to dental HCW and from dental HCW to patient) have been reported in developed country dental settings (Tomkins et al 2012; Oklahoma State Department of Health 2013; Robinson and Challacombe 1993).

1.4.1 Dental procedures

Dentists maintain patients' oral health through provision of advice to prevent disease, examination of the soft tissues, monitoring dentition development and growth, controlling gum disease, providing prosthetic tooth replacement options, managing the effects of dental trauma and, most commonly, treating the effects of tooth decay and/or infection via restoration, root treatment or tooth extraction.

No routine dental procedures fall into the highest risk EPP category (Category 3). Many are considered to be either Category 1, or indeed non-EPP (PHE 2016). Therefore, there are few procedures that could potentially result in a patient being exposed to the blood from a BBV-infected dental professional (Table 2).

Table 2: The general dentistry exposure prone procedure categorisation (PHE 2016)

EXPOSURE PRONE PROCEDURE CATEGORY	DENTAL PROCEDURE
LEVEL ZERO (NOT EXPOSURE PRONE) (NO RISK OF BLEED-BACK)	The taking of intra and extra-oral radiographs
	Visual and digital examination of the head and neck including soft tissue palpation
	Prescription of antibiotics or other drugs
	Routine oral examination, using mirror and any necessary probes
	All work associated with the construction or replacement of complete or partial dentures - excluding any prior surgical preparation of the hard or soft tissue
	Preventive procedures: oral hygiene instruction, fissure sealing, topical fluoride applications, saliva samples
	Taking impressions
	Topical application of, or irrigation with, therapeutic agents
	Suture removal where the hands or fingertips are completely visible at all times
	Supra-gingival or sub-gingival scaling of teeth using an ultrasonic/piezo-sonic scaler
	Polishing of teeth or restorations using a slow-speed hand piece with flexible polishing discs, polishing cups or brushes.
	Electro-cautery
	Use of laser when administered external to oral cavity
	Placement of dressings and temporary restorations not

	requiring tooth preparations
	Orthodontic procedures using removable appliances or aligner techniques e.g. Invisalign®, except where interdental stripping with an abrasive strip is required
	Re-implantation of tooth/teeth following trauma without bone removal
	Bleaching of teeth, excluding the use of any rotary instrument to provide access required for internal bleaching
	Botox or fillers for modification of facial aesthetics administered external to oral cavity
LEVEL ONE (LOWEST RISK OF BLEED-BACK)	Local anaesthetic injections
	Interdental stripping with a rotary device or abrasive strips for orthodontic purposes
	Biopsy of lip
	Suture of lip
	Polishing of teeth or restorations using finishing burs in high-speed handpieces
	Suture removal where the hands or fingertips are not completely visible at all times
	Supra-gingival or sub-gingival scaling of teeth using hand instruments
LEVEL TWO (INTERMEDIATE RISK OF BLEED-BACK)	Use of high-speed hand pieces for procedures such as intra-coronal restorations and crown and bridge work
	Polishing, finishing or removing overhangs from restoration
	Periodontal surgery
	Root canal therapy
	Root end surgery e.g. apicectomies
	Extractions of teeth including packing and suturing of sockets
	Orthodontic procedures with fixed appliances
	Placement of temporary anchorage devices in the context of orthodontic practice
	All other dento-alveolar surgery including: • surgical removal of impact/buried tooth/teeth; • surgical removal of complicated buried roots; • enucleation of cyst of jaw
	Surgical removal of intra-oral soft tissues, including biopsies

	Frenotomy/frenectomy of tongue
	Suturing of intra-oral soft tissue injuries
	Surgical placement of dental implant
LEVEL THREE (HIGHER RISK OF BLEED-BACK)	NONE
Bleed back – Following injury the healthcare worker's blood comes into contact with the open or exposed tissues of a patient.	

While dental treatment is considered to present a low risk of HCW-to-patient transmission, the risks of patient-to-patient transmission may be more significant. Rarely does a dental visit fail to result in some degree of patient bleeding, so there is a high chance that instruments, personal protective equipment (PPE) and environmental surfaces will be contaminated with blood, and in the absence of satisfactory infection control and decontamination, the potential for transfer to subsequent patients. Types of instruments that are regularly contaminated with blood during treatment are outlined in Table 3.

Table 3: List of commonly used dental instruments which frequently contact patient blood[a] accompanied by descriptions of how they are used

Periodontal probe	Used to measure probing depths around the gums, usually during routine check-ups.
Forceps, luxators, elevators	Used to extract teeth. Placed between bone and tooth, deeply engaging the sides of the tooth.
Endodontic files (should be single use)	Used to remove tissue from the root canals within a tooth.
Matrix bands (should be single use)	A metal band which is placed around the tooth to aid restoration of teeth using filling material. Often engages deeply around the gum line.
Local anaesthetic syringe carpule (should be single use)	Glass capsule containing local anaesthetic solution. Inserted into syringe. Can become contaminated with blood during injection as blood is aspirated back from the patient's tissues.
Local anaesthetic syringe needle (should be single use)	Attached onto syringe. Inserted into patients tissues during injection.

Periodontal hand scaler	Used to scrape away calculus both above and beneath the gum line.
Ultrasonic scaler	Oscillates at high speeds to break up calculus above and beneath the gum line. Projects water onto tooth surface during operation.
Rubber dam clamp	Used to hold a rubber sheet around the tooth, isolating it from saliva/contamination during root treatment and certain types of fillings. Engages the tooth at gum line level.
Scalpel, suture needle, scissors	Used for raising mucoperiosteal flaps to facilitate bone removal during surgical removal of a tooth or to take a biopsy.
Surgical hand piece and bur	Specific hand piece used to remove bone
a = All dental instruments may be contaminated with blood under specific circumstance. Table 3 represents those instruments most likely to be frequently/significantly contaminated.	

1.4.2 Dental infection prevention and control

Dentists, like all UK healthcare workers, are advised to follow Standard Infection Control Precautions (SICPs) when treating patients (section 1.3.1, p43) (NSS 2019[b]). To prevent patient-to-patient transmission of blood borne viruses, dentists must perform a number of tasks between patients which include appropriate disposal of clinical waste (including sharps), performance of adequate hand hygiene, changing of personal protective equipment and wiping down equipment and environmental surfaces with disinfectant based disposable cloths (Department of Health 2013; NSS 2019[b]).

Methods used to clean and sterilise re-usable dental instruments are based on their predicted contact with patient tissues, as described in the Spaulding classification which delineates items based on whether they will contact intact skin (non-critical), intact mucous membranes (semi-critical) or tissues beneath these surfaces (critical) (Spaulding 1968). Most dental instruments are considered to be critical items and therefore require sterilisation (Rutala and Weber 2013).

Steam is used within dental practices to sterilise instruments via the use of small, benchtop vacuum or non-vacuum sterilisers. Both international and European

standards define an adequate sterilisation process as one that produces an instrument with a less than 1 in 1 million chance of there being a viable micro-organism present on it (WHO 2016[a]).

Cleaning of the instrument before sterilisation is essential. Cleaning aims to remove, via physical and chemical processes, biological material which may be adherent to instruments, contaminated with prions and capable of inhibiting the steam sterilisation process (Walker 2014). Prions are abnormally folded proteins that reside primarily within the neural tissues (National Institute of Neurological Disorders and Stroke 2019). They are the causative agent of variant-CJD and are not denatured by conventional, dental, steam sterilisation (Walker 2014).

The processes of cleaning and sterilisation are encompassed within an overall process known as the decontamination cycle (Figure 2) (Black 2016). In general dental practice this process is conducted within a separate room dedicated to instrument processing; a local decontamination unit (LDU) (Black 2016).

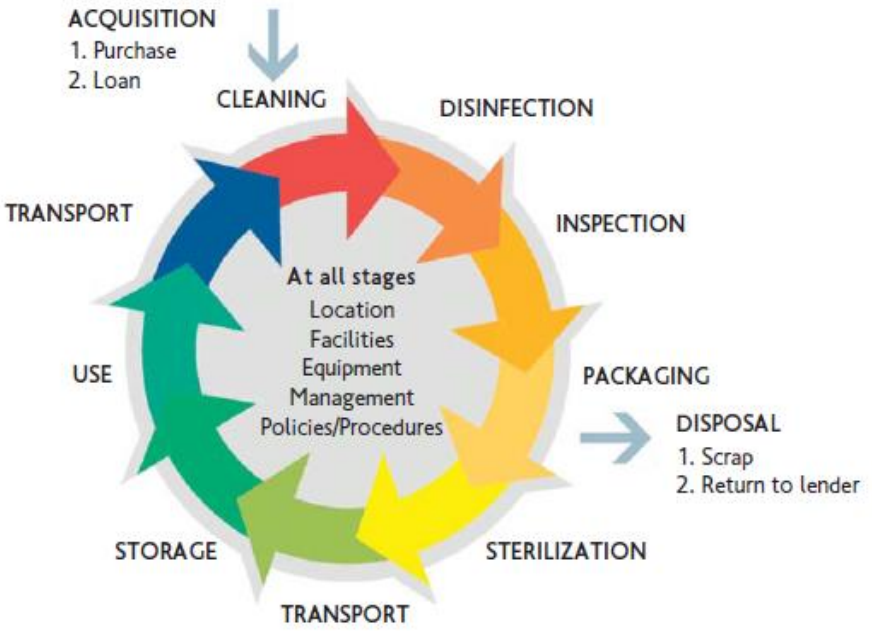


Figure 2: Dental instrument decontamination cycle (reproduced with permission, Bagg et al 2006)

The main aspects of the decontamination process include cleaning, disinfection and sterilisation. In dentistry, cleaning and disinfection are ideally achieved via use of an automated washer disinfector (AWD). An AWD has five stages; an initial flushing with cold water (<45°C) to remove debris, a washing stage which uses detergent and removes any remaining debris, a rinsing phase to remove the detergent, a thermal disinfection stage and finally a drying phase to remove moisture (SDCEP 2014).

Thermal disinfection is designed to destroy most viruses and all micro-organisms except spores (Rutala and Weber 2013). It is achieved by exposing instruments to

high temperatures for set periods of time (eg. 73-78°C for three minutes or 90-95°C for one minute) (Health Facilities Scotland and NHS Scotland 2013). Use of an AWD is considered essential in Scotland (NHS Scotland 2017) and best practice in England (Department of Health and Social Care 2013).

Before the widespread introduction of AWDs practices solely used manual or ultrasonic cleaning processes (Stankiewicz 2019). These processes involve washing instruments in a mixture of detergent and water at low temperatures (around 30-40°C, depending on detergent manufacturers' instructions) and do not result in disinfection of instruments (Shropshire Community Health Trust 2016). An ultrasonic bath is a chamber of water and detergent with transducers affixed underneath (Shropshire Community Health Trust 2016). These transducers create high frequency soundwaves which vibrate through the water and create bubbles which collapse, disrupting dirt and residue from the instruments (Shropshire Community Health Trust 2016). It is essential that the water in an ultrasonic bath is changed at least every four hours or when the fluid is visibly contaminated (SDCEP 2014).

Sterilisation is achieved in practice using a benchtop steam steriliser. The chamber must reach a specific temperature and hold this temperature for a set period of time under an appropriate level of pressure. There are a range of temperature/time combinations that result in sterilisation but the preferred, and most commonly used is 134-137°C for a minimum of three minutes at a pressure of 2.1-2.5 bars (SDCEP 2016).

1.4.2.1 Dental infection prevention and control monitoring and regulation

A plethora of decontamination guidance is available to UK dentists and is designed to aid them in meeting their legal requirements regarding instrument processing (Department of Health and Social Care 2013; Health Facilities Scotland and NHS Scotland 2013; SDCEP 2016). The legal obligations to use instruments which are safe at point of use are outlined in three key pieces of legislation;

- The Consumer Protection Act 1987
- The Medical Devices Directive (93/42/EEC)
- The Health and Safety at Work etc. Act 1974

(UK Government Legislation 1987; Council of the European Union 1993 and UK Government Legislation 1974)

In practice these require a number of checks be performed and recorded to ensure that decontamination equipment are working effectively and that specific sterilisation and disinfection parameters are met for example:

- All paper print-outs for each steriliser, washer disinfector and ultrasonic cycle need to be kept and at least one for each piece of equipment needs to be checked and signed every day (SDCEP 2016).
- Instruments need to be inspected after the washing/disinfection process to ensure no residue remains that will impede sterilisation (SDCEP 2016).
- If instruments are wrapped for the sterilisation process, any packaging indicators need to be checked for appropriate colour changes at point of use.
- Other tests include a daily steam penetration test for vacuum sterilisers and weekly cleaning efficacy tests for AWDs and ultrasonic baths (Health Facilities Scotland and NHS Scotland 2013).

In Scotland, dental practices are inspected by their NHS health board upon opening, at three yearly intervals and/or if there are specific concerns regarding standards (Jones 2018). These combined practice inspections utilise a detailed checklist with 111 items pertaining to infection control (NHS Scotland 2017). In 2016 unannounced inspections were introduced (The Scottish Government 2016).

In England, each year, a 10% sample of practices are inspected by the Care Quality Commission (CQC) based on a randomised selection or risk-related information gathered from organisations, stakeholders and patients (CQC 2018[a]). The CQC uses the 'Key Lines of Inquiry' framework which is designed to assess whether healthcare delivery is safe, effective, caring, responsive and well-led (CQC 2018[b]).

It is a legal requirement that all UK dentists be registered with the General Dental Council (GDC). Failure to adhere to GDC standards can result in a range of consequences, including being restricted from practising. GDC standards outline that dentists:

"must find out about the laws and regulations which apply to your clinical practice [...] This will include (but is not limited to) legislation relating to: [...] • health and safety • decontamination • medical devices"(GDC 2013).

1.5 Incident management

In Scotland, guidance recommends that an incident management team (IMT) should be responsible for the public health investigation and management of an incident. This multidisciplinary team will typically by chaired by an NHS consultant in public health (when community based) or NHS consultant in infection control (when hospital based) (HPS and Scot Gov 2017).

An IMT is normally established following a report of an infection control breach which could be brought to light in a multitude of ways: a report from a dental

nurse, a patient complaint or perhaps as a result of a routine inspection. The IMT must investigate the validity of any allegations and, if established to be credible, conduct a risk assessment which will aid in determining the risk management strategy which may include a PNE (Health Protection Scotland and The Scottish Government 2017).

PNEs, also known as large-scale adverse events or look-back exercises, involve informing patients that they have been exposed to an unanticipated and unacceptable risk of physical harm as a result of medical error (Dudzinski et al 2010). PNEs may be conducted following the diagnosis of a BBV-infected HCW and/or discovery of inadequate infection control practices (Dudzinski et al 2010). They may involve tens, hundreds or thousands of patients and often include encouraging patients to be examined or tested, to establish if harm has occurred (Dudzinski et al 2010). The goals of a PNE were described by a group of UK BBV expert panels in 2011 and include:

- providing "patients with information about the nature of the risk to which they have been exposed"
- detecting infection and providing "care to the infected person and advice on measures to prevent onward transmission"
- collecting "valid data to augment existing estimates of the risk of HIV transmission from an infected worker to patient during exposure prone procedures"

(AGH, EAGA and UKAP 2011)

Notification is a spectrum of communication which can range from a letter or phone call to provide information that requires no further patient action, to correspondence that strongly recommends testing.

If a PNE, with BBV testing, is deemed necessary, any patients with positive BBV results will be investigated further to establish if the infection control breach is the likely source of their infection. Presence of specific serological markers, avidity testing results (if available) and/or a history of recent seroconversion symptoms can indicate recent infection which can aid investigators in linking it to the breach.

If two or more infected individuals are thought to be linked, genetic sequencing can be used to establish the similarity between their viral strains and therefore how likely it is that transmission has occurred from one to the other, or that their infection shares a common source (Garvey et al 2017).

Myers (1994) explained that the similarity of different viral strains within an HIV-infected individual is between 95-100% and those between an infected mother

and her child are likely to be between 94 and 98%. In the Acer case, where six patients were infected with HIV, the dentist's and patients' sequences showed a 95-96% similarity whereas the dentist showed 84-94% similarity with local controls (Dickenson et al 1993). In 2007, an American investigation identified patient-to-patient transmission where patients had identical genetic sequence patterns in the viral regions compared (Redd et al 2007).

Genetic sequencing results should, however, always be considered alongside epidemiological evidence, as there is always a possibility that similarity could be down to chance alone (Garvey et al 2017). Unfortunately, genetic sequencing can only be conducted if an individual has viral DNA or RNA actively circulating in the bloodstream (Mason et al 2008).

1.6 Aims and research questions of this thesis

When a dental HCW is diagnosed with a BBV, there is clear guidance on when to notify patients, as well as support of the expert panel, UKAP (UKAP 2019; PHE 2017[a]). In contrast, there exists no clear UK guidance to assist IMTs when a dental infection control breach has occurred. Absence of guidance results in inconsistencies regarding incident response and patient notification across the UK. The decision to notify patients is particularly challenging, and involves careful consideration and a balancing of cost versus benefit (Weller 1999; Henderson et al 2017). There is a need to assess level of risk, often with inadequate information of what has happened and/or who is at risk, and consider what risks a *reasonable* patient would expect to be informed of (Weber and Rutala 2013).

One of the aims of this doctoral work is therefore to support the decision-making process regarding the need for patient notification following the identification of a dental infection control breach through the development and presentation of a decision-making algorithm. Evidence for this algorithm will be obtained by establishing what both experts and the literature can tell us about the decision to notify dental patients following an infection control breach in a developed country setting.

Evidence will be gathered via identification and analysis of historical dental 'BBV transmission risk' incidents (their contexts, investigations and outcomes), collation of the experiences and lessons learned by IMT leaders and examination of guidance available regarding the management of infection control breach incidents and patient disclosure.

Overall research question

What can both experts and the literature tell us about the decision to notify dental patients following an infection control breach in a developed country setting?

Sub-research questions

i. What are both the real and perceived problems created as a result of dental PNEs within developed countries?

ii. What are both the real and perceived benefits created as a result of dental PNEs within developed countries?

iii. What are the influential factors behind the decision to notify patients following a dental 'BBV transmission risk' incident?

iv. Do dental PNEs achieve that which they set out to do in relation to notification, testing, diagnoses made and identified transmissions?

v. What guidance and/or documentation currently exists to guide IMTs through the decision-making process of whether or not to proceed to a PNE, following a dental infection control breach?

vi. What research gaps lie within the field of dental PNEs that should be explored, in order to assist those in the decision of whether or not to proceed with one following a dental infection control breach?

Aims

i. To source and report on all dental incidents which may have resulted in the exposure of patients to a BBV transmission risk, within the dental setting in developed countries.

ii. To present evidentially supported arguments for and against the implementation of PNEs following incidents which have created a risk of BBV transmission within the dental setting.

iii. To identify and present current guidance related to the decision-making process of when to conduct a PNE following an infection control breach.

iv. To design and present an evidence-based decision-making algorithm which will aid IMTs with the decision of when to notify patients following a dental infection control breach.

1.7 Structure of this thesis

This thesis will consist of six main chapters (Table 4). The structure of the thesis is based around the scoping review study process, with each chapter addressing a different stage. They all however, contribute to the development of the evidence-based decision-making algorithm and the overall aim of the thesis; establishing what both experts and the literature can tell us about the decision to notify dental patients following an infection control breach.

Chapter two describes the methodological approach chosen and the development of a novel 16-step scoping review study process, based on stages outlined in both methodological publications and scoping review studies. Chapters three and four address the first and second objectives using intelligence derived from a stakeholder consultation exercise and literature review with collation of published and unpublished incident outcomes. Chapter five addresses the third objective by presenting findings from a guidance mapping exercise. Chapter six pulls together the intelligence derived from the stakeholder consultation and review of the literature and guidance to create an evidence-based decision-making algorithm. This is designed to be used as an *aide memoire* by public health consultants to establish if patient notification is the appropriate course of action following a dental infection control breach incident. Finally, Chapter seven summarises the findings of this doctoral research, derives conclusions and makes recommendations for further research

Table 4: Overall structure of thesis

Chapter 2 – Development of novel scoping review study methodological framework
Chapter 3 - Scoping review study stakeholder consultation
Chapter 4 - Systematic type review of grey and published literature
Chapter 5 - Policy mapping exercise
Chapter 6 – Results - Design of an evidence-based decision making algorithm to aid incident management team members with the decision of whether to notify patients following a dental infection control breach incident
Chapter 7 - Discussion

1.8 A focus on the wider dental patient notification exercise evidence base

Although the aims of this scoping review study are focused on the decision to notify patients specifically following a dental infection control breach, the research questions and chapter study designs focus on the wider dental patient notification exercise evidence base.

It was predicted that many of the findings and outcomes of wider incident types e.g. public anxiety caused, uptake of testing, would also be applicable to the investigation of a dental infection control breach.

The qualitative interview study and literature search process described in chapters 3 and 4 of this thesis, focus on any dental incidents which created risk of blood borne virus transmission (Figure 3).

The policy mapping exercise of chapter 5 includes guidance documents which give advice concerning large scale notification of patients following general medical incidents or adverse events (Figure 3).

Chapter 6 outlines the creation of an algorithm to aid IMTs in their decision of whether to notify patients following a dental infection control breach and the algorithm presented in section 6.4 reflects this goal but has a focus on infection control incidents which involve contaminated instruments/decontamination breaches (Figure 3).

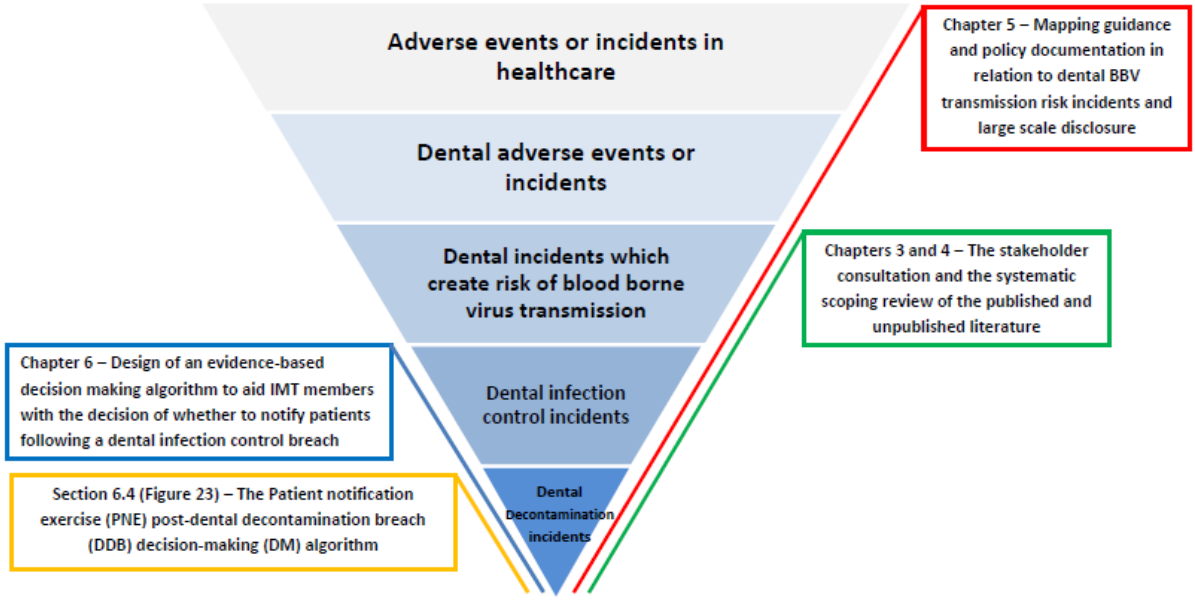


Figure 3: Focus of thesis chapters in relation to type of adverse event or incident

1.9 Publication arising from the work undertaken as part of this thesis

During the stakeholder consultation exercise, discussions with colleagues in NHS Ayrshire and Arran, highlighted a number of challenges identified and lessons learned from a large patient notification exercise associated with a dental infection control breach incident. These were written up and published to facilitate peer review learning (Appendix 2):

Henderson HJ, Hopps L, Roy KM (2017). Blood borne virus testing of 2250 patients in an unusual, repeated dental patient notification exercise: challenges faced and lessons learnt. *Public Health*. Vol 151 p74-80.

Chapter 2. Development of a novel scoping review study protocol

2.1 Introduction

Public health decision-making should be evidence based to ensure patient safety, maximise beneficial patient health effects and facilitate optimal use of resources (Harvey 2011).

When embarking on knowledge or evidence gathering research, methodological choices and interpretation of gathered data is influenced by the epistemological standpoint of the researcher i.e. how they separate truth from belief and know when an understanding of a fact has been reached (Sullivan 2010). Two broad schools of thought are presented in the literature regarding how knowledge exists, is discovered and interpreted – Positivism (or Realism) and Social Constructionism (or Relativism) (Sullivan 2010).

Positivism suggests that truths or facts can only be established based on direct experiences or observations. It favours quantitative data and argues that it is possible for science to be truly objective and free from subjective influences (Sullivan 2010).

Social Constructionism proposes that cultures, perspectives and context will always prevent true determination of fact and that examination of our perceptions of truths are the only way we can indirectly study them. Social Constructionism favours the study of language and is thereby suited to the interpretation of qualitative research study findings (Sullivan 2010).

Although two separate ideas are presented, in reality, these standpoints lie on a scale with extreme realism at one end and extreme relativism at the other. Researchers may elect to adopt a middle ground with certain aspects of each theory being appreciated (Sullivan 2010). Critical Realism is such a standpoint and, in this doctoral study, it was this approach which was chosen to guide both the decisions behind study design and interpretation of findings (Sullivan 2010).

Critical Realism is an approach which lies between the two extreme epistemological standpoints and suggests that even though we only have access to perceptions and social interpretations of facts, they do mirror the truth and that studying these perceptions can lead to meaningful conclusions that reflect fact (Sullivan 2010).

With the principles of Critical Realism in mind, it was important to consider the proposed research questions of this doctoral work, what type or types of study design would be suited to answering them and what interpretive assumptions would be made about any findings.

It was predicted that both quantitative and qualitative data would play a part in answering the proposed research questions. When assessing the implementation of a complex process such as large-scale patient notification, quantitative data such as numbers of diagnoses made or financial costs incurred would contribute to understanding the benefits and consequences created. However, this type of data in isolation would not be enough to understand the other complex human factors that result in positive or negative outcomes for example, degree of patient anxiety or what conflicting ethical concepts decision makers wrestle with when making their decision on notification.

A mixed methods approach was deemed suitable with language being studied to indirectly access the truths about how decision-making occurs and what the perceived benefits and negatives of notification are. This would be combined with an objective examination of numerical based incident outcomes.

The chief investigator actively observing or being involved in the management of a relevant dental incident was considered impractical as one could not predict when or where one would occur, or indeed if it would occur at all during the chief investigators doctoral study period. This approach would also only provide data related to one incident which would result in a weak evidence base for recommendations.

An examination and collation of historic incidents was deemed to be prudent as there was no evidence of such an exercise having been undertaken and the comparison of multiple incident outcomes would provide a richer evidence base with more data to support conclusions. A review of incidents, which captured the significant proportion of unpublished events, from across the developed world was considered, but how effectively would this answer the research questions being posed if we consider that these would simply be reflections of what the true facts are and would be greatly influenced by their contexts.

A mixed methods approach would support findings through triangulation of information gathered via differing approaches. If concepts were found to be reflected in published literature, stakeholder opinion and guidance it was deemed that that would provide a more robust argument for conclusions drawn based on a Critical Realism perspective.

A literature review which focused on dental incident management was determined to be a clear methodological choice for one part of the mixed methods study, but consideration had to be given as to what type of review would be appropriate.

Three types of literature review were considered potentially appropriate for this research: a systematic review, a realist review and a scoping review study (Grant and Booth 2009).

1. a systematic review requires a narrow, specific research question and focuses on high quality studies such as randomised control trials (RCTs).

2. a realist review aims to utilise a wide variety of literature sources and focuses on the context of an intervention; what works for whom, under what circumstances and why.

3. a scoping review study aims to provide a very broad picture of the literature and evidence concerning a subject. It is characterised by distinct study phases, presentation of the data without assessment of study quality and no limitations regarding information sources.

The main characteristics of the different approaches are summarised in Table 5.

A systematic review approach was deemed inappropriate as an initial search of the literature requiring examination (dental incident reports) suggested they were often not of a high quality and certainly never explored in an RCT context.

A realist review approach was also discounted as one of the aims of this work was not to examine the effectiveness of an intervention (large-scale patient notification) but, via creation of a decision making algorithm, consider whether it should be implemented at all.

Table 5: Comparison of systematic, realist and scoping review study features adapted from the table presented by Brien et al in 2010. (Pawson et al 2005; Berg and Nanavati 2016)

Systematic review	Scoping review study	Realist review
Focused research question with narrow parameters	Research question(s) often broad	Asking what works for whom, in what circumstances and how. Theory driven.
Inclusion/exclusion usually defined at outset	Inclusion/exclusion can be developed *post hoc*	Inclusion/exclusion usually defined at outset but can be iterative process
Quality filters often applied	Quality not an initial priority	Quality not an initial priority
Quantitative synthesis often performed	Synthesis more qualitative and typically not quantitative	Synthesis of both qualitative and quantitative data
Formally assess the quality of studies and generates a conclusion relating to the focused research question	Used to identify parameters and gaps in a body of literature	Used to assess complex policy interventions within a specific context

2.1.1 What is a scoping review study? Why was it deemed the ideal methodology to utilise?

Scoping studies are literature reviews which aim to map out key papers, sources and data relating to a broad subject, whilst identifying research gaps and

presenting findings within an up-to-date policy context (Tricco et al 2016; Anderson et al 2008).

The design of a scoping review study is suited to the exploration of a subject which is vast, complex and under-researched (Arksey and O'Malley 2005; Pham et al 2014). The area of dental incident management undeniably fits this description. It is:

Vast: as dental incidents occur all around the world with high variability in their management and with relevant evidence being found within a variety of sources.

Under-researched: as studies conducted in this field are currently limited in their amount, breadth and depth.

Complex: as the decision to notify is influenced by a multitude of factors such as transmission data, ethical arguments and economical considerations.

The scoping review study design facilitates the inclusion of multiple literature sources including grey literature (Levac et al 2010; Pham et al 2014). This is advantageous in the scrutiny of this topic as relevant dental PNE data are found within a variety of sources such as journal articles, opinion pieces and reports, both published and unpublished.

A scoping review study involves the examination of literature in relation to broad research questions (Levac et al 2010). Scoping review study research questions often begin with phrases such as "What does the literature tell us about..." (Daudt et al 2013) or "What is the extent of published evidence on..." (Brien et al 2010). The focus on the identification of positive and negative outcomes of a complex process (large-scale patient notification) and exploration of the many factors that influence a difficult and multifactorial decision (whether to conduct a PNE) could certainly be considered broad.

Scoping review studies typically do not assess the quality of the literature they identify and present (Armstrong et al 2011; Pham et al 2014; Victoor et al 2012). This is seen by some as a weakness of the method (Brien et al 2010; Grant and Booth 2009) but in fact this feature is ideally suited to the literature examined as part of this study as much of the literature on PNEs in dentistry exists in the form of historic governmental and health board reports. These reports are often a relaying of facts and as such are not suited to the rigorous examination of quality that would be conducted in the assessment of a clinical trial study paper for a systematic review.

2.1.2 A history of scoping review study development

Historically, scoping review studies were implemented as precursors to systematic reviews, but throughout the last decade they are more often being executed as extensive pieces of research in their own right (Davis et al 2009).

Comprehensive scoping review studies can take over a year to complete and those contemplating such a review are warned not to assume that they require any less time or resource input than a traditional systematic review (Armstrong et al 2011; Brien et al 2010; Pham et al 2014). Brien et al (2010) stated that scoping review studies are "often misinterpreted to be a less rigorous systematic review, when in fact they are a different entity".

A formal framework for the scoping review study methodology was originally devised by Arksey and O'Malley of York University in 2005 (Table 6) and has been enhanced by several researchers over the last ten years (Brien et al 2010; Daudt et al 2013; Levac et al 2010; Peters et al 2017; Rumrill et al 2010).

Table 6: Arksey and O'Malley's (2005) original scoping review study framework

1. Identifying the research question
2. Identifying relevant studies
3. Study selection
4. Charting the data
5. Collating, summarising and reporting the results
6. An optional consultation exercise

Arksey and O'Malley's (2005) framework was evaluated by Levac et al (2010) who made suggestions on how to break down and define the stages more clearly, making the framework more detailed and user friendly. Daudt et al (2013) examined each stage of the original framework with reference to the work done by Levac et al (2013) and provided recommendations as to what types of research questions were suited to a scoping review study methodology.

2.1.3 Scoping review study standards

There is virtually no guidance on how to report scoping review studies and no documents which provide direction on how to assess the quality of a scoping review study (Tricco et al 2016). The Joanna Briggs Institute in Australia did, however, publish a guide in 2015 on how to conduct a scoping review study which was updated in their most recent Reviewers Manual (Peters et al 2017).

Tricco et al (2016) have also stated that they plan to produce a scoping review study reporting checklist. This project can be found on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) website under 'Extensions in Development' with the current title 'The Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR)'.

2.1.4 Scoping review study aims

Arksey and O'Malley (2005) made the distinction between scoping review studies undertaken as an exploratory stage before a systematic review and those which are considered pieces of research in their own right. The former would focus on ascertaining the "extent, range and nature" of research within a specific field and aim to assess the value of conducting a full systematic review. The latter involves collation and publication of findings with identification of research gaps (Arksey and O'Malley 2005). The scoping review study conducted as part of this doctoral work fits into this second category.

2.1.5 Scoping review study stages

Anderson and his team (2008) commissioned many scoping review studies to gather evidence around healthcare service delivery and organisation. They outlined that scoping review studies are usually comprised of 1 to 4 distinct phases which include conceptual mapping, literature mapping, policy mapping and a stakeholder consultation (Figure 4) (Anderson 2008).

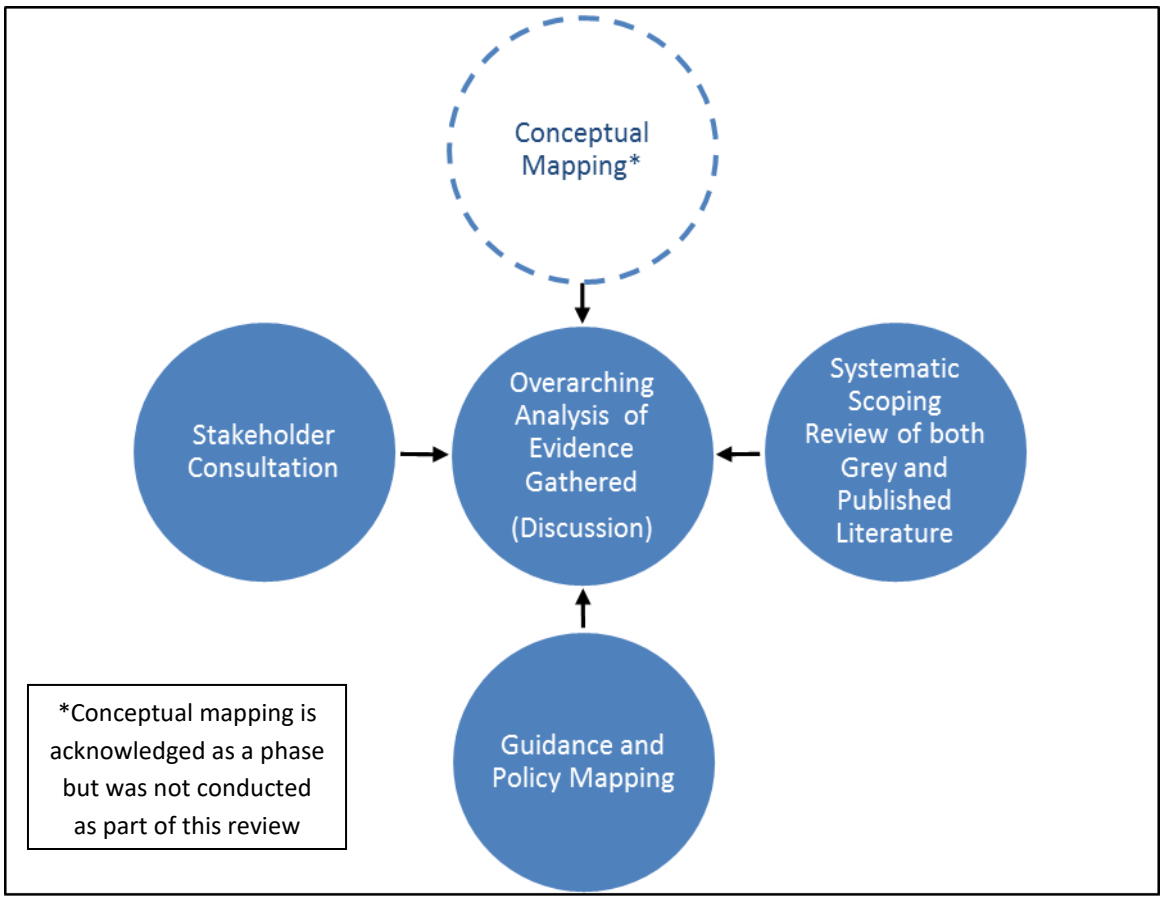


Figure 4. Stages of this doctorate scoping review study. (Adapted from figure presented by Davis, Drey and Gould, 2009)

With multiple, complimentary study phases, the design of a scoping review study was deemed to be ideally aligned with the mixed methods approach that was postulated when originally considering the overall doctoral methodology.

2.2 Methods

A simple, exploratory Google search was conducted to identify appropriate scoping review study methodological literature and healthcare-related scoping review study examples.

In addition to the formal protocol from the Joanna Briggs Institute (Peters et al 2017) and Arksey and O'Malley's original protocol (2005), seven key methodological papers and four scoping review study examples were identified and used to create a methodological framework to guide this scoping review study (Anderson et al 2008; Forbes et al 2007; Ross et al 2004; Victoor et al 2012; While et al 2005; Arksey and O'Malley 2005; Armstrong et al 2011; Brien et al 2010; Daudt et al 2013; Davis et al 2009; Grant and Booth 2009; Levac et al 2010; Peters et al 2017; Rumrill et al 2010).

All scoping review study stages recommended by the authors were merged and incorporated into a novel 16-step, methodological framework that was used in this doctoral project. Each stage of the process is set out in Table 7 along with an indication of where the results of each stage are presented within this thesis.

2.3 Results

Table 7: Novel scoping review study protocol

Stage of scoping review study and features	Reported in chapter/section	References
1. IDENTIFY AN OVERALL, BROAD RESEARCH QUESTION	**1.6**	**Armstrong et al 2011; Levac et al 2010; Rumrill et al 2010**
Examples include; "What has been published…" and "What factors determine whether…"		**Rumrill et al 2010**
PCC structured question ie: population, concept, context		**Peters et al 2017**
Identify sub-research questions		**Armstrong et al 2011; Brien et al 2010; Levac et al 2010**
Consider design and nature of outputs at completion		**Ehrich 2002; Levac et al 2010**

2. CREATE TITLE	**Title page**	
Should not be structured as a question and should include the term 'scoping review' or 'scoping study'.		**Peters et al 2017; Arksey and O'Malley 2005; Levac et al 2010**
3. PRELIMINARY LITERATURE SEARCH INCLUDING A SEARCH FOR OTHER SIMILAR SCOPING STUDIES/REVIEWS	**3.3.1, 4.3.1.1**	**Daudt et al 2013; Peters et al 2017**
4. COLLATE PRELIMINARY FINDINGS TO BE USED IN STAKEHOLDER CONSULTATION	**3.3.1, 3.5.3.2**	**Levac et al 2010**
5. STAKEHOLDER CONSULTATION EXERCISE	**3**	**Arksey and O'Malley 2005**
Utilise primary findings		**Brien et al 2010 Levac et al 2010**
Ask for key papers/studies		**Armstrong et al 2011**
Identify a key theme from discussion		**While et al 2005**
Ask about research priorities		**Levac et al 2010**
Ask about definitions/key search terms		**Armstrong et al 2011; Brien et al 2010**
Ask about key organisations/journals/websites to search		**Armstrong et al 2011**
Obtain opinions on validity and structure of study		**Levac et al 2010**
Consider roles, regions and purposive sampling		**Ross et al 2003**
Framework guided thematic analysis of transcripts		**Ross et al 2003; O'Brien et al 2009; While et al 2005**
6. DEVELOP SEARCH TERMS FROM KEY ARTICLES IDENTIFIED IN STAGE 3 AND STAKEHOLDER ADVICE	**3.5.3.1, 4.3.1.2**	**Peters et al 2017**
7. INCLUSION/EXCLUSION CRITERIA	**4.3.1.3, 4.3.1.4**	
Ideally not many initial limitations		**Armstrong et al 2011**

Search parameters can be altered *post hoc*		**Armstrong et al 2011; Brien et al 2010; Rumrill et al 2010**
Involve librarian in search strategy		**Brien et al 2010; Victoor et al 2012**
*Create and publish an a priori protocol**		*Peters et al 2017*
8. IDENTIFY RELEVANT STUDIES	**4.3.1.4, 4.3.2**	
Utilise at least 3 electronic databases		**Arksey and O'Malley 2005; Armstrong et al 2011; Peters et al 2017; Rumrill et al 2010**
Duplicate removal, title scan, abstract scan[a], full text scan[a]		**Peters et al 2017**
Full texts excluded with reasons		**Peters et al 2017**
Search reference lists of selected papers		**Arksey and O'Malley 2005; Armstrong et al 2011; Brien et al 2010; Peters et al 2017**
*Search citation histories of selected papers**		*Arksey and O'Malley 2005*
*Hand search key journals**		*Arksey and O'Malley 2005; Armstrong et al 2011; Brien et al 2010*
Contact authors if required		**Peters et al 2017**
Create system or plan for update to search		**Brien et al 2010**
Specific website/organisation searches		**Arksey and O'Malley 2005; Armstrong et al 2011**
Grey literature databases		**Armstrong et al 2011; Brien et al 2010; Daudt et al 2013; Ehrich 2002**
Papers suggested by experts/stakeholders		**Armstrong et al 2011; Forbes et al 2007**
Published books		**Rumrill et al 2010**
Use a reference manager programme		**Pham et al 2014**

Create flowchart based on PRISMA structure with narrative description of search process		**Brien et al 2010; Peters et al 2017**
No assessment of quality		**Arksey and O'Malley 2005; Armstrong et al 2011; Brien et al 2010; Grant and Booth 2009; Peters et al 2017; Rumrill et al 2010; Victoor et al 2012**
a = at least 2 reviewers, with meetings to discuss discrepancies in choices		**Brien et al 2010; Victoor et al 2012**
9. CHARTING THE DATA	**4.3.3, Appendix 14**	
Assign each paper a unique ID number		**Daudt et al 2013**
Create a data extraction form based on outcomes desired (can be altered later to reflect new discoveries)		**Levac et al 2010**
Can have multiple data extraction forms for different types of study/sources/concepts		**Levac et al 2010**
Team should meet to evaluate and pilot form(s) on 5-10 papers with further meetings to discuss discrepancies and refine design		**Daudt et al 2013; Levac et al 2010**
10. COLLATION OF QUANTITATIVE DATA	**4.4.3**	
Tabular and graphical summary of studies/sources characteristics eg. location, years, methods, journals, terms used etc.		**Peters et al 2017; Grant and Booth 2009**
11. NARRATIVE SYNTHESIS OF QUALITATIVE DATA	**4.4.2**	**Brien et al 2010; Davis et al 2009; Peters et al 2017; Victoor et al 2012**
12. POLICY/GUIDANCE MAPPING	**5**	**Davis et al 2009; Rumrill et al 2010**
Identify relevant websites to search through stakeholders, validated checklists etc.		**Brien et al 2010; Daudt et al 2013**
Identify inclusion/exclusion criteria		**Ross et al 2004**
Identify broad search terms		**Brien et al 2010**

Utilise website search boxes		**Brien et al 2010**
Manually search sites using links		**Brien et al 2010**
Alter inclusion/exclusion criteria *post hoc*		**Arksey and O'Malley 2005; Armstrong et al 2011; Brien et al 2010; Levac et al 2010; Victoor et al 2012**
Narrative synthesis of guidance/policy context		**Anderson et al 2008; Peters et al 2017; Ross et al 2004**
13. OVERALL RESULTS		
List of gaps in the research	**3.5.3.4, 3.6.3.3, 4.5.2.3**	**Levac et al 2010**
Recommend questions/methodologies for future research	**7.2.2, Appendices 22, 23 and 24**	**Levac et al 2010**
"provide advice on what kind of research products might be useful in the 'real world'"	**6**	**Anderson et al 2008**
Summarise and disseminate research findings	**3-6**	**Daudt et al 2013**
14. SYNTHESIS OF DIFFERENT STRANDS OF THE EXERCISE	**6, 7**	
Link results of guidance mapping, literature and expert opinion from consultation exercise		**Anderson et al 2008**
*15. SECOND CONSULTATION EXERCISE**	*N/A*	*Levac et al 2010*
*Validate outcome produced**		*Arksey and O'Malley 2005*
16. ADDITIONAL STEPS	**4.3.1.2 and reported throughout**	
Consult with stakeholders throughout		**Brien et al 2010 Daudt et al 2013 Pham et al 2014**
Iterative process		**Arksey and O'Malley 2005; Daudt et al 2013; Davis et al 2009**
Encouraged to report on your experience of doing a scoping review study		**Anderson et al 2008**

***White sections represent those steps which are recommended in the literature but were not executed as part of this study.**

2.4 Discussion

Use of the scoping review study methodology as a comprehensive search strategy and study in its own right is a recent practice. The scoping review study protocol presented here can therefore be used by those who wish to follow not only the steps laid out by Arksey and O'Malley in their original 2005 framework but incorporate adaptations presented by other authors (Brien et al 2010; Daudt et al 2013; Levac et al 2010; Rumrill et al 2010) and the Joanna Briggs Institute (Peters et al 2017). Creation of this framework aligns with the call for researchers to report on their experiences of using a scoping review study methodology (Anderson 2008).

2.4.1 Methodological choices

This doctoral scoping review study comprises three of the four key components identified by Anderson (2008): a stakeholder consultation, a review of the literature (both grey and published) and a mapping of relevant policy or guidance documents. Conceptual mapping was not deemed necessary as the main aspects of a PNE and its associated terminology were already well defined.

The scoping review study framework developed, incorporated most suggested stages in the key methodological papers identified. It did, however, acknowledge a number of stages but did not incorporate them. The creation of an *a priori* protocol (as recommended in the JBI protocol) was not included, as it was felt this would limit the ability to both utilise an iterative search strategy and modify inclusion/exclusion criteria *post hoc* as is suggested throughout the scoping review study literature (Peters et al 2017; Armstrong et al 2011; Rumrill et al 2010). The extent of the review was deliberately limited through the omission of certain stages such as the second stakeholder consultation (Stage 15) and the searching of literature citation histories (Stage 8) as the breadth of the review had to be balanced against the time available – this is an important step described by Daudt et al (2013). Within the scoping methodological literature, hand searching of key journals is recommended. This, however, was deemed to be inappropriate as dental incident data were discovered within a variety of journal types which differed in subject focus eg. infection control, public health, dentistry, hepatology, microbiology etc. (Table 36).

It is important to note that the literature search which influenced the content of the novel framework was not highly structured meaning that key methodological

documents may have been missed, however, this is considered unlikely as key documents were consistently identified from different sources.

2.4.2 Scoping review study strengths

Adopting a scoping review study methodology offers many advantages over the more traditional forms of literature review. First, scoping review studies do not put restrictions on the nature or quality of the studies that can be included in the review. Thus, published and unpublished heterogeneous data can be presented and made available for future reference. Second, scoping studies are not limited to a review of the literature alone. Incorporation of the stakeholder consultation means that results of the study can be tailored to the needs of the main research users, and increase the applicability and use, of research outputs (Anderson 2008, Colquhoun et al 2010, Daudt et al 2013), whilst inclusion of a guidance mapping phase places literature findings and stakeholder opinion within a policy context (Davis 2009). This approach lends itself well to the broad aim of this project; to establish what both experts and the literature can tell us about the decision to notify dental patients following an infection control breach in a developed country setting, and with such wide exploration and presentation of a topic it becomes easy to ascertain where further research is required.

Current guidance on the execution of scoping review studies is limited therefore publication of theses and studies that utilise this novel methodology are a beneficial addition to the evidence base and contribute towards the development of a standardised methodology (Brien 2010).

2.4.3 Scoping review study limitations

The limitations of such an approach should also, however be acknowledged. Similar to other forms of literature review, the results represent a snap shot in time where findings can quickly become out of date (Brien et al 2010). There is also the danger that studies may be missed and it is always important to consider that studies examined may be susceptible to the individual reviewer's bias (Pham et al 2014).

Pham et al (2014) emphasised that scoping review studies are "...a relatively new approach for which a universal study definition or definitive procedure has not been established". As such there remains a degree of confusion in relation to the purpose of a scoping review study (Daudt et al 2013; Davis et al 2009). This uncertainty coupled with the lack of a validated tool to assess the quality of scoping review studies, can limit the acceptance of the methodology and lead to questions regarding its credibility (Brien et al 2010; Davis et al 2009; Levac et al 2010, Pham et al 2014).

A further reason why scoping review studies may experience limited acceptance relates to the lack of a quality assessment phase for included studies (Brien et al 2010; Pham et al 2014). Accordingly, the results of scoping review studies must be interpreted with caution. Ehrich et al (2002) emphasised that the conclusions of a scoping review study are “indicative and suggestive rather than definitive”.

Chapter 3. Semi-structured qualitative interviews of those with experience of managing dental 'BBV transmission risk' public health incidents – A stakeholder consultation with use of a novel thematic analysis framework.

3.1 Introduction

A scoping review study stakeholder consultation exercise involves liaising with those your research is intended to aid (Colquhoun et al 2010) and is achieved via a range of methods from expert panels (Forbes et al 2007) and focus groups (Rumrill et al 2010) to conferences (While et al 2005) and one-to-one interviews (O'Brien et al 2010). Stakeholders can be patients, managers, policy makers, educators, researchers etc. (O'Brien et al 2010) and numbers involved can range from as few as ten participants (Brien et al 2010) to as many as 113 (While et al 2005).

Literature searching and networking strategies can be enhanced through stakeholders' suggestions of search terms, research contacts, literature sources and relevant organisations (Armstrong et al 2011; Forbes et al 2007). Stakeholders can also provide in-depth insight into a subject area thereby directly answering research questions or highlighting research gaps (Anderson et al 2008; O'Brien et al 2010).

In 2014, Pham et al conducted a review of scoping exercises which found that of 344 identified, 39.8% included a stakeholder consultation. Of these, 74.5% were conducted during the search strategy phase, 30.7% asked stakeholders to interpret preliminary findings and 25.9% involved interaction with stakeholders throughout the study. Arksey and O'Malley's original scoping review study framework (2005) described the stakeholder consultation as an optional step, whereas both Daudt et al (2013) and Levac et al (2010) agreed it is an essential component.

3.1.1 Related studies

Although not part of a scoping review study and not labelled specifically as a stakeholder consultation exercise, Maguire et al (2016[a]) examined the positive and negative aspects of the US Veterans Health Administration's large-scale disclosure policy through qualitative, semi-structured interviews with patients, leaders and employers who had been involved in a range of medical incidents, including one dental infection control incident. Focusing on two specific aspects of the notification process, communication and culture, data were analysed using the Consolidated Framework for Implementation Research (CFIR),

concentrating on three domains: ‘inner setting’, ‘intervention characteristics’ and ‘process’ (Maguire et al 2016[a]).

Maguire et al (2016[a]) reported that participants felt communication from higher management was often poor with staff feeling cut off from key information and uncertain about their job security during incident management. One of the largest costs of notification was reported to be loss of patient trust which was made worse by delayed communications, inappropriate vehicles of message delivery and first learning about the incident from the media rather than the involved health care organisation. Benefits of notification included the morality behind being transparent, respecting the patient’s right to know, the opportunity for organisational team building and the assessment of infection control with resulting improvements. Staff also expressed a desire to share their experiences with other organisations that may have yet to deal with such a scenario (Maguire et al 2016[a]).

Maguire et al (2016[a]) concluded their study by stating that there would be merit in identifying early indicators of an infection control breach, for example, an organisation’s culture and/or the content of historic safety reports, which could indicate an environment that could be more prone to the occurrence of breaches. They also stated that while US guidance indicated the types of incidents that required patient notification, they did not provide guidance on the manner in which they should be conducted. Consequently, they expressed a desire to develop a toolkit which would assist US IMTs in the execution of large-scale patient notification (Maguire et al 2016[a]).

3.1.2 Rationale for study

While many of the findings from Maguire et al (2016[a]) can be applied to a UK context, there are key differences in the delivery of healthcare between the US and UK, that may limit the applicability of the findings. The stakeholder consultation executed as part of this scoping review study would present insights into the challenges faced by IMTs from a UK perspective and provide a deeper insight into the influential factors and challenges relating to the decision to notify patients following a dental incident.

In addition, it was felt that conducting a literature search without guidance from those who have experience of managing these exercises would be unwise as they possess knowledge regarding terminology (that would help define search terms), details of unpublished incidents/grey literature, relevant guidance, websites and expert contacts.

As one of the aims of this doctoral study was to design and present an evidence based PNE decision-making algorithm, it was thought to be prudent to seek feedback from those who may utilise such a resource in the future. Furthermore,

networking with key research end-users would facilitate dissemination of the final research product.

3.2 Aims

i. To provide a deeper insight into the subject beyond that which the literature can provide, specifically regarding the influential factors and challenges relating to the decision to notify patients following a UK dental infection control incident[4].

ii. To facilitate obtaining further resources to aid in the (grey) literature scoping review study search such as publications, websites and expert contacts.

iii. To identify key search terms.

iv. To identify research priorities.

v. To receive feedback from stakeholders as to whether the design of the scoping review study research is valid and its anticipated outcomes useful.

3.3 Methods part 1

3.3.1 Participant recruitment

One-to-one interviews were conducted with UK public health staff with experience in the management of incidents which had created a risk of BBV transmission within the dental setting; either a dental infection control breach incident and/or discovery of a BBV-infected dental HCWs.

A list of potential participants was formulated using i) recommendations from Dr Kirsty Roy of HPS and ii) a list of authors of UK dental PNE publications. An attempt was made to include at least one participant from each of the devolved nations.

Participants were invited to take part in the study via an email with an attached Participation Information Sheet (Appendix 3). If the contact was happy to participate, emails were exchanged and an interview time and place were arranged. Participants were sent two documents to review before the interview:

1) A summary of preliminary research findings which was created following an initial exploratory literature search.

2) An outline of the aims, research questions and methods of the PhD project.

[4] Defined as those that created risk of/caused BBV transmission, in the dental setting, to patients (either from a BBV-infected HCW and/or inadequate dental infection control).

3.3.2 Questioning route design

A pre-prepared interview questioning route (Appendix 4) was designed based on the study's aims, the principles of a scoping review study stakeholder consultation as presented in the literature (Levac et al 2010; Daudt et al 2013; Brien et al 2010; Peters et al 2017; Rumrill et al 2010), information from qualitative interview methodology publications (Britten 1995; Kreuger and Casey 2000; Silverman 2013) and guidance from a University of Glasgow qualitative research expert (HH).

3.3.3 Study design

Following the consent process, participants were interviewed for approximately 90 mintutes. All interviews were audio recorded and structured around the pre-prepared interview questioning route mentioned above (Appendix 4).

Recordings were transcribed verbatim and any sensitive and/or identifiable information was removed. Transcriptions, in their anonymised form, were emailed to each participant to read and confirm content veracity (a respondent validation phase).

3.3.4 Ethical considerations

University of Glasgow MVLS Ethics Committee approval was sought and a research passport or letter of access was created and approved for each participating board/trust.

At the start of each interview, participants were given a detailed and comprehensive Consent Form to read (Appendix 5). Participants were asked to initial each consent form statement if they were comfortable with its content. Both participant and investigator then signed and dated two copies of the completed consent forms. One copy was given to the participant to keep for their personal records.

3.4 Methods part 2 – strategy for thematic analysis of interview transcripts

3.4.1 Framework guided thematic analysis

This study utilised a framework assisted thematic analysis method. Thematic analysis involves breaking qualitative data down to facilitate the identification of themes and patterns. In grouping similar concepts together, wider conclusions can be drawn from the data (Gale et al 2013).

Smith and Firth (2011) outline three different types of thematic analysis:

- “Socio-linguistic methods that explore the use and meaning of language such as discourse and conversation analysis”

- “Methods that focus on developing theory, typified by grounded theory”

- “Methods that describe and interpret participants’ views such as content and thematic analysis”.

The differences in methodology mainly relate to whether a deductive or inductive approach is taken. An inductive method involves the analysis of data with no predetermined theories or frameworks. The researcher ideally begins with no preconceptions of what the data will reveal allowing theories and/or themes to emerge from the data with repeated open coding (Gale et al 2013). A deductive approach involves coding the data around a pre-determined structure for example a framework or set of research questions (Gale et al 2013).

Thematic analysis of this study’s transcripts could be described as both deductive and inductive. As an initial step, the CFIR framework, was used to guide the deductive identification of themes. However, in an inductive manner, the chosen framework was altered and expanded to allow inclusion of emerging novel themes and concepts (Fereday and Muir-Cochrane 2006).

3.4.2 The chosen framework

The type of conceptual framework appropriate for the analysis of this data was considered. Insight was needed into the way a multifactorial, public health decision was made and/or the positive and negative aspects of a public health intervention.

Primarily four frameworks were considered, two of which related to public health decision-making; “a new transdisciplinary model of evidence based practice” (Satterfield et al 2009) and “a model for evidence-informed decision-making in public health” designed by The National Collaborating Centre for Methods and Tools (Ciliska et al 2008). Both of these frameworks were presented as Venn diagrams and outlined the influential factors in public heath decision-making. They included public health expertise, resources, local and organisational context, political preferences, population characteristics and best available research evidence (Ciliska et al 2008; Satterfield et al 2009).

The third framework was entitled the “Behaviour Change Wheel” (Michie et al 2011). This wheel, formed of concentric ringed sections, meant that central layers were always considered within an outer ring context. For example, the framework showed that behaviour is connected to capability, opportunity and

motivation but that these factors exist within an environment of education and legislation (Michie et al 2011).

The fourth framework, the Consolidated Framework for Implementation Research (CFIR), is highly detailed, presented in tabular form and comprises five main themes with 39 sub-themes (Damschroder et al 2009). It is traditionally used to assess the feasibility of introducing a new health-related intervention to an organisation (Damschroder et al 2009). Many of its categories are inspired by the context in which the intervention is being introduced (Damschroder et al 2009).

Although more suited to assessing the predicted success of a healthcare intervention, many CFIR constructs were applicable to the consideration of large-scale patient notification and, in fact it has already been employed for this purpose (Maguire et al 2016[a]).

3.4.3 The thematic analysis process

Data was coded and interpreted using an ever evolving form of the CFIR framework with new themes being added, removed, expanded and condensed based on the data. This process was guided by the Braun and Clarke (2006) method (Table 8). An example of how transcript extracts were coded and assigned to themes is presented in Appendix 6.

Table 8: Braun and Clarke's five stages of thematic analysis (2006)

Familiarisation with the data
Generation of Initial Codes
Searching for themes
Reviewing themes
Defining and Naming themes

Familiarisation with the data

The chief investigator (LG) transcribed all interviews verbatim to optimise familiarisation with the data. Transcripts were then carefully read and re-read, to not only increase knowledge of interview content (Braun and Clarke 2006) but to facilitate removal of information that may result in identification of specific individuals, boards or trusts.

Generation of initial codes

Raw transcript data was studied line by line and divided into 'meaningful segments' based on the CI's interpretation of where one concept ended and another began (Campbell et al 2013). Sections were labelled with initial thoughts and key ideas; a distillation of what the stakeholder was trying to convey.

Searching for themes

Codes were initially assigned to themes based on the CFIR framework. The framework having already been studied and interpreted to aid in its application to a dental patient notification exercise decision making process (Appendix 7).

Ideas or concepts were aligned with CFIR codes where applicable and where they were not, were grouped with other unassigned concepts.

Reviewing themes

Themes were continually reviewed in an effort to incorporate all ideas presented in the data and facilitate an understanding of the decision to notify and all its influential factors. Every time the thematic structure of the framework was deemed to have changed significantly thematic allocation was repeated from the beginning of the transcript data.

Defining and naming themes

A decision on the set of themes to be used for final coding of the data and presentation of results was made at the point when the chief investigator felt that all influential decision factors identified from the data had been incorporated into a clear structure of concepts and that extracts could be assigned to themes in an unambiguous and logical way.
The final NFBI framework can be seen in Appendix 8 and comprises six categories with 24 subcategories. Themes were created based on inspiration from the CFIR framework, feedback from coders and the interview data itself, with a focus on what specific factor influenced the interviewee in their decision-making.

To validate the applicability of the newly created NFBI framework to the data and reinforce that it is an accurate reflection of the ideas presented in the transcripts, it was prudent to assess the level of inter-coder reliability and agreement associated with its use. This process and its results, are outlined in Appendix 9.

3.5 Results

Narrative synthesis results are presented in section 3.5.2 under the six major NFBI theme category headings. Interpretation of the themes and explanations are accompanied by supporting interview transcript extracts.

Following presentation of the narrative synthesis, section 3.5.3 outlines further stakeholder consultation findings that were utilised to:

- facilitate literature searching
- enable effective and useful presentation of data
- validate utility of research outcomes
- identify research gaps and future research projects.

These 'further results' reflect the additional purposes of a scoping review study stakeholder consultation which go beyond the main aim of obtaining a deeper insight into the subject area.

3.5.1 Participant demographics

Those interviewed had experience of managing an incident which had created a risk of BBV transmission to patients within the dental setting. All participants interviewed were public health consultants, but one had progressed to a higher management role and another was specifically a dental public health consultant. In total, 11 participants were interviewed. Two worked in England, one in Wales and the other eight were based in seven different Scottish NHS boards. Number of years of experience within a public health consultant role ranged from 5 to 21 years ($\bar{x}$ = 11.5 years). The number of dental incidents managed by each participant ranged from one to six.

3.5.2 Narrative synthesis

3.5.2.1 Theme 1: Transmission risk

Table 9: Theme 1 – Transmission risk and its sub-themes

THEME 1: TRANSMISSION RISK	
T1 (Background prevalence)	Prevalence of BBVs in local/practice populations including levels of immunisation.
T2 (Profile of HCW)	Profile/Characteristics of HCW such as health status, infectivity, type of pathogen, skill level.
T3 (Incident details)	Incident details including nature of breaches, length of time patients at risk, types of procedures performed. Integrity of practice (which may create suspicion of further, more serious breaches).
T4 (Transmission risk estimation)	Evidence of transmissions having already occurred. Index/source patients identified via cross matching. Transmission risk estimation based on scientific evidence and outcomes of historic investigations.

Perceived transmission risk was reported to be the most influential factor behind the decision to notify (Table 9). Participants implied that often it was the only significant incident management aspect and reported that assessment of transmission risk was often considered a separate entity in the decision-making process, conducted before consideration of any other factors:

P – "if the risk was negligible and the answer was we really would not be expecting to find a case then the answer would probably be no [...] Cause [...] if you don't expect to find a case, why would you bother?"

P - "what we've tried to do [...] is to separate [...] the risk assessment with the decision-making."

Although respondents conveyed how influential the risk assessment was to the decision-making process, they did express concern over its reliability and accuracy *(T4 – Transmission risk estimation)* with no participant indicating a specific level of risk (i.e. a cut off) above which they would notify patients. The uncertainty surrounding risk assessment motivated many participants to call for more research concerning how proficient different decontamination processes are in the removal of blood and inactivation of viruses:

P – "it would be useful to have more information about the decontamination process itself, exactly, you know, which stage of the decontamination hasn't worked and so for example, if you're washing an instrument with detergent, does it deal with 99.9% of the viruses? Does it matter if they didn't get the heat treatment? So having a more detailed knowledge about each of the processes will give me more confidence in my risk assessment. I think that some of this (research) is missing."

The features of an incident were only cited as influencing the risk assessment in a general way *(T3 – Incident details)*. Only three specific scenarios that would definitively raise or lower the perceived level of risk were outlined. Higher risks were associated with re-use of multi-dose vials and if patients had been exposed to unsafe treatment conditions for longer periods of time:

P –"you can actually see how it's happening so, you stick the thing in and inject somebody [...] you're drawing it, you're leaving some of the blood in there [...] and then you go back and then draw another one [...] and that vial actually keeps [...] the virus, alive, you know, it's a medium"

P – "we recommend that the practice review their procedures to make sure it's just a one off accident so the more serious incidents are, in my experience, incidents where there has been a continuous problem and a failure of processing and monitoring"

In contrast, risks were considered lower if contaminated instruments had remained unused for a significant period of time, as viable BBV virus particles are known to not survive for long outside the body:

P – "cause we know that some of these things [...] they're not alive too long outside (the body) so even if they've not done it (decontamination) and maybe it's been sitting out for a long time, probably the risk of any organism remaining alive is low"

There was often uncertainty regarding the extent and severity of breaches that had occurred *(T3 – Incident details)*. Often incident management teams had no way of ascertaining that allegations represented an isolated event or were indeed even true. Suspicions of more extensive breaches were strengthened if the practice were uncooperative, had a history of poor conduct or were being investigated for other infractions such as fraud:

P - "if you're including things in the risk assessment that are a bit softer as well like, is this a good dental practice in terms of quality of care? [...] do your dental advisors say this is normally a really good dentist's practice? [...] he happens to be [...] a dental practice advisor [...] what do the recent inspections show? is it normally compliant?

have they got great training records to show they've trained all their staff and this has just been an error or a new locum or a...you know, what's [...] the overall context of this? Is it a bad failing practice or is it an exemplar teaching dental practice?"

Participants explained that uncertainty could also be caused by a lack of faith in the organisations that monitor dental infection control within general dental practice *(T3 – Incident details)*. Respondents made it clear that reports of good practice by those conducting inspections did not provide much reassurance around there being an absence of infection control issues:

P – "The impression was that having come in to an incident we couldn't assume that infection control was being monitored to any great extent."

Uncertainty surrounding allegations was considered an argument both for and against notification *(T3 – Incident details)*. Decision makers wished to err on the side of caution in response to uncertainty but the IMT may similarly be inclined to conduct notification if, in contrast, they felt as though the evidence against a practice was strong and allegations had been verified by a number of reliable sources:

P – "if it had just been somebody just coming and saying, you know, I observed this, it would have been given less weight....but here we had [...] evidence statements from other people in the practice that showed [...] that this was a systematic thing."

P – "So, I think we just had too much to say that there was potentially a risk here [...] because we had witnesses and because it was able to be verified and seen by people, we felt we had to do something."

Many participants associated the general field of dentistry with a minimal risk of BBV transmission due to the low number of high category EPPs conducted in comparison to other medical fields *(T3 – Incident details)*. They also felt that specifically UK dental treatment carried a lower risk than that provided in the US where use of sedation and performance of more invasive procedures, in the general dental practice setting, was perceived to be more common:

P – "in those ones (American dental incidents) [...] the circumstances [...] were such that, you know, transmission was probably more likely than in the common kind of circumstances that we [...] investigate because many of the (UK) dentists [...] tend not to deal with exposure prone procedures as compared to those ones which you have described in the U.S"

P – "it's important to look at actually dentists and dental practice cause dental practice is dental practice and actually, you know, the risk from a cardiothoracic surgeon to his patient is very different from the risk from a dentist because of the nature of the procedure."

The identification of index cases (BBV diagnoses established to be most likely linked to the incident in question) was outlined by participants to be a very clear indicator of whether to proceed to notification *(T4 – Transmission risk estimation)*. Respondents emphasised that, following the discovery of an infected HCW, UKAP utilise this investigation finding as a key factor in their decision regarding patient notification:

P – "largely with health care workers, whether they've transmitted or not is a material decision as to whether you do the notification exercise or not but particularly with the infection control failures often it's a theoretical risk actually without any evidence of transmission and there I think you might be much more nuanced in eh, the way you present it..."

Participants were generally aware that outcomes from historical dental incidents had indicated very low transmission risks but it was clear that more information was desired and, if made available, would be utilised in decision-making *(T4 – Transmission risk estimation)*. Participants expressed the need for an increase in publication of incident findings with one participant going on to say that a central repository for incidents and details of their management, which could be accessed by public health consultants, would be valuable. Another similarly expressed that a list of incidents, which outlined the breaches that had occurred, their associated risk estimations and IMT responses would be a useful resource:

P – "there should be a push for people to actually write up lessons learned from some of these incidents [...] Lessons learned [...] will help you so that when you're planning yours you can actually, ok, have that at the back of your, [...] once you've decided to go to a notification, what are the likely things they're going to face em, and then [...] people have done other things so how can you learn from other people"

P – "it is quite em, strange that we don't really have [...] a repository where all these things are...and a lot [...] of the ones that we do and this particular one, you know, should have been published...it just got stuck in (location) and never got released so there's a wealth of sort of, information and experience there that is sitting on a shelf somewhere and probably won't see the light of day"

P – "and based on what we're seeing from the UK ones, what are the behaviours that are leading to these notification exercises [...] what are the poor behaviours or practices that are leading to the notification exercises in the UK? and can we group them and begin to get an idea of risk given that we're not seeing evidence of transmission in the UK?"

Even though there may be no evidence of transmissions or index patients before notification, there will undoubtedly be a pool of potential source patients within the practice population *(T1 – Background prevalence)*. Respondents stated that a high background prevalence of BBV infection may make one more inclined to conduct notification:

> *P – "one other thing you take into account is [...] the background level of blood borne virus in the community [...] (in) certain parts of (the UK) the prevalence will be higher than others because of the deprivation and drug injecting users and so on"*

3.5.2.2 Theme 2: Perceived complexity

Table 10: Theme 2 – Perceived complexity and its sub-themes

THEME 2: PERCEIVED COMPLEXITY	
C1 (Predicted efficacy)	Predicted efficacy of notification (ability to contact patients, get them to take up testing, identification of diagnoses) also includes availability of and access to data. Profile of local area/population (ages, language barriers, mental capacity)
C2 (Gaps in knowledge)	IMT members' gaps in dental knowledge or experience
C3 (Profile of dental practice)	Levels of co-operation with investigation. Obstructive behaviour.
C4 (Public/media awareness)	Pre-notification exercise awareness of the incident by the public or media

Creation of the NFBI theme 'Perceived complexity' (Table 10) was inspired by several CFIR sub-constructs; 'patient needs & resources', 'compatibility', 'available resources', 'access to knowledge & information' and 'complexity'.

Although barriers to notification are not considered negative incident management outcomes *per se*, merely hurdles to be overcome, their presence and perceived impact could affect the feasibility of meeting PNE aims and thus perhaps influence the decision of whether to proceed with one.

Public health consultants, without a dental background, explained that assessing the risks associated with a dental incident could be complicated by a lack of technical, dental knowledge *(C2 – Gaps in knowledge)*:

> *P – "and then you need [...] the dentist, you know, supporting you to provide additional dental expertise, maybe with regard to, what, if there's infection control*

failure, type of procedure, how much risk does each procedure actually pose or different types of dental instruments, what are they used for [...] are they used for, you know, invasive procedures?"

Participants also reported that the unprofessional actions of a practice or individual can make notification more challenging and complex *(C3 – Profile of dental practice)*. Dental HCWs can delay the acquisition of patient notes or inspection of the practice. They can present false documentation, fail to share details of practice processes and generally be uncooperative in the identification of patients who may have been harmed:

P – "there's a loss of...a potential for loss of business sometimes that's why you find some of the organisations themselves are very reluctant to help [...] and [...] they can be obstructive [...] some of them are more em, you know, absolutely horrified something has happened, want to be open, want to sort it out"

Decision makers were shown to be influenced by their perception of whether notification would have the desired outcomes *(C1 –Predicted efficacy)*. IMTs were reported to consider whether all 'at risk' patients would be identified and contacted and if so, would messages regarding the incident and risks involved be effectively conveyed and understood? Would patients come forward for testing? Would infections linked to the incident in question be identified?

Contacting 'at risk' patients

An inability to identify the population at risk was reported to be a significant barrier in achieving comprehensive patient notification. Being unable to identify this population may be due, in part, to the difficulty in clarifying the specific length of time patients were at risk *(C1 – Predicted efficacy)*.

LG – "what kind of reasons would you expect for (IMTs) deciding not to notify patients?"
P – "one of the first is, if you can't identify your population at risk."

P – "multiple lapses of infection control were picked up but trying to establish how long this person had been doing this was difficult"

Respondents reported that failure to identify or contact the 'at risk' population could be caused by inaccurate or missing patient records *(C1 – Perceived complexity)*. Record inaccuracies could be the fault of the practice or created through patients moving and failing to update their information. A number of 'at risk' patients may also have died in the time between the incident and proposed notification:

P – "Well either, you can't contact them because they're dead em, or [...] (it's) much more difficult to narrow down their current address [...]. The really big ones go back into the dim past and the further you go back the more difficult it is to trace and identify people"

Participants emphasised that improvements were needed in relation to dental record quality and storage. One respondent proposed that research be conducted on how easily dental practices were able to generate lists of patients seen from specific time spans:

P – "...it would be quite valuable to, maybe it's just some audit work, around that? (dental record retrievability and comprehensiveness) [...] it's for dentists' reassurance themselves [...] if they fall into such an incident em and you say 'ok give us, we want a list' [...]. Can you please fax us a list of all of your patients that you've seen in the last 3 months. And, you know, some of them might think ok I'm gonna have to manually look through all of my records, and look at the dates, hopefully none of them are in that state now"

Participants also explained that health board or trust powers, in relation to accessing private patient notes, required clarification as permissions to obtain or view records were sometimes denied by dental practices:

P – "uncertainties around [...] do they have to pass us patient identifiable information and concerns around confidentiality until it's understood that actually we do have a role [...] in knowing individuals' names and what procedures they went under to [...] risk assess it. And it's all about explaining it so there can be lots of misunderstandings"

P – "as a private or self-employed business, apparently clinical records are the property of the practitioner"

The ability to contact all 'at risk' patients could be further complicated by patients residing in a variety of locations *(C1 – Predicted efficacy)*. The majority of 'at risk' patients could be local to the practice or spread far and wide across the UK depending on whether the incident affected patients seen in the recent past or those seen over an extended period of time:

P –"they get really nice and difficult when they cross more than one nation in the UK [...] and you've got to coordinate that."

The profile of the local area and/or practice population may complicate efforts to notify all 'at risk' patients *(C1 - Predicted efficacy)*. Careful consideration has to be given to the age, mental capacity and clinical health status of patients.

Participants emphasised that notifying terminally ill patients or those with severe mental incapacity would be inappropriate:

> *P –"they might be on the list but em they have either mental incapacity or the health situation is such that if they are notified it would worsen their situation, so, it is not worthwhile [...] so the people from that category are people who are mentally ill, people who are senile or elderly"*

Adaptation of the PNE process (limited notification) can be used to overcome challenges such as the inability to identify all patients who have been put at risk *(C1 - Predicted efficacy)*. Respondents suggested that one can begin with notification of those who can be identified and/or those deemed to be most at risk. If no BBV cases, linked to the incident, are identified from this initial pool of patients, the notification process can be concluded at that point:

> *P – "...then the other benefit of course is that em, if you start off with offering testing to patients most at risk and you don't get any transmission events [...] that gives you that reassurance not to extend beyond those most at risk, that's often an approach we use to sort of try and define a subgroup who may be most at risk to keep the costs down"*
>
> *P – "look, let's start off with (contact) the ones (patients) that we can, that we have easy access to, cause that was my plan, if we start with these, we do the notification exercise, if we find any evidence of transmission then yes we will have to [...] consider how we're going to obtain [...] the other records."*

One participant also explained that if a large percentage of 'at risk' patients could not be traced then local media could be used to disseminate incident information:

> *P – "we always think about other ways of [...] informing people, so that's where the press or the media comes in, sometimes if you have a large number of people that you can't tell where they've been em then the media bit about 'if you were treated about this time, by, you know, at this practice or so, so, then you may consider..."*
> *LG – "yeah, using them to get the message out and notify people"*

<u>Appropriate Communication</u>

Appropriately communicating the level of risk involved with an incident is also an essential aim of notification but was reported by participants, to be very challenging *(C1 – Predicted efficacy)*. Finding the right language to use in presenting the risk was difficult and striking a balance between encouraging the uptake of testing without causing alarm or distress was problematic:

P – "and while you might be able to get [...] a number, numbers don't mean much to people so it's how do you quantify to people and we debated about what does extremely low mean, what does very low mean, what does low mean?"

P – "it's also about the way the information is presented to people and the way you portray the risk [...] you might want people to be tested but you also don't want to be unduly worrying people and lots of worried well turning up so that's one of the things that's very difficult is how do you quantify the risk to the population?"

One participant highlighted the contradictory nature of conveying a very low risk in the letter, but conveying to the patient that the risk was still clearly high enough to justify notification:

P – "cause they're (notified patients) thinking well...oh I didn't know about this and well they've told me there's no risk but why are they writing to me to tell me there's no risk?"

Testing uptake

If challenges regarding contacting patients and conveying an appropriate message are overcome, participants explained that the predicted testing uptake may have an impact on your decision to conduct a PNE *(C1 – Predicted efficacy)*. Aspects of the incident, notification process or local population such as age, deprivation or ethnicity, may lead you to believe that the number of patients seeking out testing will be lower or higher:

LG – "What do you feel about that graph in terms of the amount of people that come forward for testing?"
P – "Em, well it's certainly a factor in em, deciding whether you're going to go ahead with one (a PNE) or not, if you think that a lot of people aren't going to come forward for testing"
LG – "As in, it wouldn't be worth it almost?"
P – "Yes"

P – "it (testing uptake) depends (on) [...] the population at risk cause sometimes in very, very deprived areas sometimes people [...] don't engage to the same degree as people possibly in more affluent areas who sometimes are more worried about their health, or take things more seriously but again these are impressions."

P – "anecdotally [...] (in relation to testing uptake) ethnicity appears to play a role, that may be related to whether people actually speak or understand English or not"

P – "I've also found that the age of the people you contact can play a role so with regards to children we tend to get a really good response rate (for testing), but with very elderly people, the response rate can be lower sometimes"

P – "I think the impact of getting a letter about your child might have a different impact to getting a letter about yourself [...] I suspect you would probably worry a lot more if you got a letter through your door about your child. Em, I think you'd worry more and I think you'd want to get them checked."

Factors which can be controlled by the IMT and could potentially affect testing uptake include the wording of the letter and both the number and manner of communication attempts. Factors out with the control of the IMT included patients making their own risk assessment of the situation, not trusting the organisation involved or not wanting to be tested because they are unclear or in denial about the risks involved:

P – "the community is also very clever, they have capacity to risk assess so sometimes, depending on which kind of community you're dealing with [...] you might be dealing with those who are able to risk assess and say "this is not serious, I'm not going to go, I'm not going to waste my time or I'm alright"

P – "some people don't want to know whatever is wrong with them and also that word 'I just don't want to know, don't tell me, I don't care whatever it is' and they don't want to know"

P – "lack of confidence, I would say [...] if the institution recently had a problem for instance and people are disenchanted or not happy with the way it is performing then people may not take it (the offer of testing) quite seriously."

Participants explained that if a low proportion of 'at risk' patients are tested, you can be less certain that transmission has not occurred with one respondent stating that patients who do come forward for testing may be those who are, for a number of reasons, less at risk of BBV infection:

LG – "when you read a report and at the end it says 'transmission was not proven', how confident do you feel in that recommendation?"
P – "If they used a decent set of criteria to determine that there was no evidence that transmission occurred then I would feel confident that transmission hadn't occurred in the group they tested but then I'd be thinking what about the other half or 60% or 70% or whatever."

P – "and then you also have to ask yourself [...] whether the patients who actually agree to be tested might be those that for a variety of reasons would be least at risk"

Participants contemplated the effect that different levels of knowledge about BBVs, or perceptions concerning these infections, may have on a patient's desire to seek out testing:

P – "if you say things like Hepatitis B or Hepatitis C I think the average UK person isn't very familiar with those infections because they disproportionately in the UK affect em either migrants or injecting drug users [...] most people, [...] will not have come across those infections so I think [...] when they hear they might have been exposed to it they're not as concerned, but you say HIV. Now everyone's heard of HIV [...] despite the fact that HIV is the one they're least likely to get, that's the one they're most worried about. So, sometimes it depends on what they're being tested for and if you say you're screening people for HIV the response might be higher than if you say you're screening people for hepatitis B or C"

P – "(For testing following notification) I guess some people will turn up, some people won't. Em, and it might be because [...] they have no idea of the implications"

They outlined that the language of the notification letter, especially in regards to how the risk is presented, can have a dramatic effect on uptake of testing. IMTs can use the letter's wording to encourage or discourage testing, depending on the perceived level of risk:

P – "I think that you would tailor your message towards what you perceive to be the risk [...] in a situation where you've got transmission, where you expect there might be other cases [...] you're gonna be giving a message that's gonna [...] more strongly encourage people to come forward for testing"

P – "but in the end it was only (a small number of) folk that came forward and we didn't letter them again [...] we were reassuring about it and [...] I guess if we were successful in our endeavour [...] nobody would have come forward because we didn't think they required testing, since the risk was so low but for anxiety reasons we felt it was useful to offer testing."

One participant elaborated on this point by stating that if you feel the risk is high further steps can be incorporated into the notification process such as utilising a recorded delivery process to send letters or telephoning patients.

Notification was deemed essential if the local area already had some knowledge of the incident in question, firstly to reassure patients and secondly to facilitate more control over the content of public messages *(C4 – Public/media awareness)*. Concern over the media leaking incident information first created time pressures in regard to incident management. Participants explained that it was highly important that in response to this sensitive and distressing issue, the public received the correct information and an accurate description of the associated low risks:

P – "the public are aware and em, you know if there's such a serious issue that I can't have my appointment for the next week or so, what's going on? So, you have to explain something"

P – "we knew that people who had been [his/her] patient, might be concerned because sooner than later it will become public domain so we'd rather they got the information from us rather than through the media [...] we don't always necessarily write because we think they're at risk. But you write to a certain extent, to manage the risk. Because, it's more important that people get the proper facts from us rather than being concerned about what they get in the media, so, there's a multi-purpose for writing to the patient"

Identification of transmission

The primary purpose of patient notification is to identify and consequently treat any patients who have acquired a BBV infection as a result of the incident under investigation *(C1 - Predicted efficacy)*. Respondents went on to explain that not only are BBV-infected persons rarely identified, but it can be very difficult to link any cases found, to the dental practice or HCW involved.

Respondents often compared the investigation of an infected HCW to that of an infection control incident. They stated that when dealing with an infected HCW, the investigation often begins with a blood sample to compare with any patient samples gathered later. With an infection control incident, however, two samples from two different patients are required to establish if transmission has occurred. If it is predicted that notification and testing will not result in the identification of a proven, linked transmission, then respondents explained a PNE may not be appropriate:

P – "they're (PNEs) unlikely to turn up anyone with a new infection so maybe there might be other reasons for doing them. Em, like reassurance"

P – "when you look at past experiences of PNEs [...] and [...] the results you then think well [...] the chances of actually finding you know, [...] infection that's actually related to transmission from the dental practice are probably very minimal"

P – "Sometimes it's very straightforward, particularly more recently if you've got a sample from the health care worker, they (the lab) can [...] sequence it, you get stuff from patients, they sequence it they [...] work out the probabilities....
LG – "yeah, cause you've already got that healthcare worker blood sample to start off with"
P – "you've got it to start with , eh, with the patient to patient stuff it is much more difficult at times isn't it to know, you don't have a complete, you've not tested everybody"

3.5.2.3 Theme 3: Benefits

Table 11: Theme 3 – Benefits and its sub-themes

THEME 3: BENEFITS	
B1 (Diagnoses)	Diagnoses made as a result of the notification exercise leading to earlier treatment and reduction of onward transmission
B2 (Reassurance)	Reassurance that no harm has occurred for patients already aware of incident, dental staff who made error and IMT
B3 (Spotlight on infection control)	Emphasises the importance of good dental infection control for dental HCWs. Highlights specific improvements needed.
B4 (Trust built)	Trust built, maintained or engendered through being open with patients and taking complaints seriously
B5 (Gathering further evidence)	An opportunity to gather further data so that dental transmission risk estimates become more accurate

Themes relating to the benefits of patient notification were inspired by the CFIR constructs of 'relative advantage' and 'cost' (Table 11). Many participants emphasised that the decision-making process essentially comes down to an assessment of the benefits versus the risks.

The opportunity to identify BBV-infected persons within the patient population was described as a key benefit of notification *(B1 – Diagnoses)*. Treatment, particularly if accessed early, can lead to a better prognosis for the patient or even resolution of their infection. Those who are aware of their infection can also employ precautions to prevent onward transmissions and being on treatment dramatically reduces viral load, further reducing the chance of secondary transmission:

P – "Well, if there is a likelihood of an incident resulting in transmission of blood borne viruses em, its critical in terms of patient safety, in terms of population health and wellbeing to conduct a notification exercise to identify people who have been infected and to put them on proper treatment and care. [...] so you can prevent onward transmission in the population"

P – "I think the benefit would be [...] if people have been exposed and infected, early diagnosis and with early diagnosis you're most likely to have a better outcome so for instance with HIV, if people are infected, it's good to get them early otherwise they

present late when they have symptoms, which could be 1-15 years later and when people have symptoms and they present late, you know, they tend to have more complications and, and, mortality is higher in that group"

P – "with HIV, if the viral load is undetectable em, chances of people transmitting is lower and that can only happen if you're on treatment."

Informing persons of their BBV infection was reported to always be prudent, but the identification of incidental BBV diagnoses (those unlinked to the incident) was not deemed to be a significant motive for conducting a PNE. One participant elaborated by stating that the detection of unrelated cases was merely an indication that another form of BBV screening within the community was needed:

LG – "So you would say the main benefits would be transparency and picking up cases related to the incident or cases in general?"
P – "Cases related to the incident, I mean, cases, cases in general is kind of a happy by-product of it but I would never do it for that reason because there's other systems in place for doing that."

P – "(If in another PNE) they identified 10 cases of blood borne virus whatever and two of them were definitely because of the dental incident and eight were not, I don't think that would be a good reason to do a PNE [...] how can we get to those people in another way? cause that kind of implies that we should be doing population screening"

The decision to notify patients could be influenced further by the contextual fact that there are now highly effective treatment regimens for those with BBV infections. Advancements in the treatment of BBVs, especially HCV, may encourage IMTs to proceed to notification, as any infections found (whether related to the incident or incidental) can reliably be treated in a highly effective way or even cured:

P – "with HIV at least you can have viral suppression and live an...well, an almost normal life, I mean, life expectancy is probably the same now with people with HIV and people who don't have HIV and people on treatment"

P – "I'd have thought maybe twenty years ago with hep C, you know, the benefit of actually identifying a patient would be much less than it is now.....Because now the treatment has 95% efficacy you know, you're just taking a tablet by mouth as opposed to giving injections with about twenty percent efficacy"

Respondents spoke of how notification can provide reassurance to patients, especially those who already have some awareness of the incident *(B2 – Reassurance)*. Participants commented that if transmission was not detected

following a PNE, the organisation who managed the incident and perhaps the associated dental practice could also be reassured:

> *P – "reassurance of the investigators, reassurance of the population that yes, while this happened, there is no risk to you, so, that, you get that sort of reassurance"*
>
> *P – "it may be higher risk than you appreciate so doing a PNE gives you that reassurance, if you find nothing then its fine."*

Publicity of the incident was theorised to have a beneficial effect on the dental profession's appreciation for infection control *(B3 – Spotlight on infection control)*. It was felt by respondents that the IMT's serious and detailed approach to the breaches involved would remind dental HCWs of the importance of infection control. This would hopefully lead to improvements in infection control standards and prevent occurrence of such incidents:

> *P – "there's also a positive of doing a patient notification exercises [...] which is really to focus the mind of dentists and dental practices on the importance of infection control because unfortunately there are still individuals out there who, you know, don't take it as seriously as it should be taken [...] it can also lead to either a local review or if there are issues that might affect more than one dental practice it may lead to a review of practices and ultimately have, and you might have improved patient outcomes, safer practice"*
>
> *P – "It also shows that you're taking it seriously from a regulatory point of view that em, infection control is important in clinical practice and there are risks that we're trying to mitigate against"*

Participants explained that by deciding to notify patients, the board/trust is able to demonstrate its commitment to transparency, putting patients first and taking complaints seriously *(B4 – Trust built)*. It was felt that a degree of mistrust towards organisations exists and that being notified as part of a PNE may either propagate this idea or conversely could increase patient trust:

> *P – "the other thing is to address a complaint because our incident came to light because of staff concerns in the practice and therefore we had to investigate and doing a PNE was one way of showing that we were investigating it thoroughly, taking them seriously rather than just"*
>
> *P – "I think actually it tends to build trust, you might lower trust initially [...] but I think in the long term actually it builds a better long term relationship"*
>
> *P – "in a sense it can instil confidence that people are being open, systems being open with patients"*

P - "I think there's a trust issue as well, really, you know, people are not trusting necessarily of governments, organisations or whatever."

It was reported by participants that publishing findings concerning PNEs would not only put a spotlight on dental infection control but would add to the evidence base concerning PNEs, specifically in regard to the level of risk created by incidents *(B5 – Gathering further evidence)*:

P – "if you look at the evidence, actually you think, well, why do we even bother, we shouldn't even be bothering because we've never documented anything. But, you know, the more evidence we can gather the more, we may be able to come to a position [...] to be able to look at this risk and actually say well, the risk is so low we don't actually (need to notify)"

P – "it's also a learning opportunity, you know, because as the evidence base accumulates you might be able in the future to pin point with more certainty which types of incidents are really putting patients at risk and which, you know, have less risk"

3.5.2.4 Theme 4: Negatives

Table 12: Theme 4 – Negatives and its sub-themes

THEME 4: NEGATIVES	
N1 (Anxiety)	The anxiety caused to notified patients and staff involved in incident
N2 (Resources)	Resources used e.g. time, money, staff. Workload and logistics. Opportunity costs.
N3 (Legal vulnerability)	Effect of notification on lawsuits filed.
N4 (Reputation of board/trust)	Reputational damage to organisation managing incident.
N5 (Reputation of dental profession)	Reputational damage to the field of dentistry which could result in reduced uptake of dental treatment and services
N6 (Reputation of involved dentist/practice)	Reputational damage to dental practice/individual involved resulting in loss of business and/or reduced patient base.

All participants were aware and concerned about the distress and anxiety caused to patients as a result of notification *(N1 – Anxiety)*. Some participants went on

to state that the anxiety caused was often not worthwhile, in light of the low risks involved:

P – "the anxiety that is generated you may find that eh, you have more damage to the population than you have helped them. Cause you have told them, you've kept them stressed and waiting eh, for results and you worried them, then at the end of the day, you tell, them oh, after all, there isn't anything. So that is not good"

P – "and I think if we knew the actual amount of distress that we were causing by letters and notification that would push us even more to not doing these things unnecessarily"

Participants emphasised that the severity of anxiety caused to a patient may be heightened if a specific BBV was involved or if they were already suffering from a great deal of stress or mental illness:

P – "I remember when HIV first came out and all the noise about it [...] and about how you could get it from your dentist"

P – "some people are probably at that point where their mental health is really strained or something so you don't really want to tip somebody into something that, you know, this (PNE) will trigger something"

Participants emphasised that anxiety is not only caused to patients but also those working at the dental practice associated with the incident:

P – "then of course you create anxiety to them (dental practice staff). Sometimes there's loss of earning as well [...] during that time they're not working or they're stressed, worried about the problem."

P – "it can impact on the wellbeing and the health of the (dental practice) staff there because they do lose staff, people leave. Em, you know, and the ones who are left, you know, have to sort of pick up the pieces so it can be, it can be a very difficult time [...] for them."

P – "We [the board/trust] can be seen to not be understanding of how hard they're working you know that actually 99% of the time things have gone very well [...] it can lead to individuals feeling very insecure and I presume it can lead to anxiety or even depression from a personal point of view and questioning of their, you know, work generally [...] and lead to problems with confidence, it can also presumably create problems within the practice amongst staff and lead to you know, blaming each other em, and if there were underlying issues it can just all explode, I guess."

Participants explained that they do not receive much, if any, feedback on how patients react to notification. Anxiety is presumed but neither the levels of

distress caused are known nor whether this distress impacts upon future uptake of dental treatment. Participants called for research in relation to these effects as well as exploration into how dental practice staff are impacted by incident management:

P – "so you're going to do that, and that's actually what would be really interesting (a patient questionnaire study assessing reaction to notification) because [...] unless you actually assess what a patient thinks of [...] when they get the letter, you're not going to know."

P – "the one thing [...] which would add a lot of flavour to your work [...] (is) trying to look at people who have gone through notification and they say 'you have received a letter telling you that you might have been exposed, how do you feel?"

Participants were aware that notification exercises are resource intensive. Staff, patient and laboratory time was the resource most frequently reported as being heavily utilised *(N2 – Resources)*. Respondents commented that financial costs were considerable and underestimated:

P – "we had at least two consultants, there was (person) and (person), consultant wise and then we had [...] health protection nurses [...] we had helplines and stuff so, I mean, at any one time there could have been 2/3 of them plus admin staff, big call on admin staff plus people at (organisation) that were helping us update addresses. People within the dental contracts team were also heavily involved at the time also the (organisation) people em because they had the contract with the practice, so they were supporting the incident also [...] there were people who had to take the bloods so they had to set aside the time for that em, and that involved clinical and admin people."
LG – "Yeah so it's a huge, huge operation"
P – "it was, it took over our work for quite a few days"

P – "they had to commission the testing clinics, they also commissioned the helpline and they had two full time project managers working on it plus just the weekly incident meetings, all that time and effort"
LH – "gosh"
P – "oh, a lot of money"

Although the significance of a PNE's financial cost was clearly acknowledged it was not shown to influence the decision-making process to proceed with one *(N2 – Resources)*:

P – "although it is a huge cost to the (board/trust) em, when it happens you just kind of, you just kind of get on with it and accept that its gonna cost you a lot of money and actually you don't really have a choice once you decide to go ahead so. It's not that the money's not an issue, cause it is an issue but it's kind of, it's sort of, the least of your worries because you're wanting to just get on and do it."

P –"and we did not take into account em the cost, we actually excluded the cost from our thoughts"

The majority of participants reported that it was more important to consider opportunity or indirect costs. By using time and money to conduct a PNE you are in effect diverting resources away from other projects:

P – "I'm a big believer in transparency but I think when transparency comes at a huge cost to those people and a huge opportunity cost to your team and your organisation where you're diverting money that could have bought you an awful lot more, for patients, I'm less swayed by that transparency argument now, not because I don't think you should be transparent but I think when it comes at a huge cost to patients, I don't think you've got a great argument for transparency in that situation."

P – "with everything we do, because we have limited resources there's always an opportunity cost so especially with big incidents like the one in (location), [...] a number of public health professionals, [...] when they were dealing with this exercise, they couldn't do, they couldn't spend the time on doing other things possibly even you know even preventative..."

Costs were reported to be difficult to calculate due to the many indirect costs to be considered. Expenditures were also often not monitored as they were not considered a priority when the main focus is on managing the incident correctly to protect public health *(N2 – Resources)*:

P – "well even [...] lab costs, there'll be a test cost but that probably doesn't include the scientists' time or the consultants' time to read all the results and to collate them together and present them back to the next IM team blah, blah [...] I think the NHS isn't set up to, to record costs very well"

P – "in the middle of an incident it's very hard to capture that stuff (financial expenditures), em and it's very difficult to gauge, it's not, it's not always your top priority so you may have missed that."

Participants explained that during a PNE the public's eye is focused on the organisation managing the incident *(N4 - Reputation of board/trust)*. One participant described how the need to manage the incident in a highly competent way, was even more important when the board/trust involved had historically been scrutinised by the public in relation to other issues:

P –"If you don't get it right it can lead to reputational issues em it sets the (board/trust) in this incidence in the spotlight [...] there's strong media, there are interviews and things that are needed."

P – "I can think of one (incident) that was years and years ago when we, we as a (board/trust) were under a lot of pressure because [...] we couldn't provide enough NHS dentists so there was recruitment issues [...] so there'd been a lot of adverse publicity about the (board/trust)'s provision of dental services and that came up in the discussions at the em, IMT as one factor why we needed to handle this properly and make sure that we didn't tarnish the reputation of the [board/trust] anymore with regard to dentistry and bad practice or unsafe practice"

Respondents explained that damaging the reputation of dentists and practices through a PNE may lead to patients avoiding seeking out future dental care. Some participants stated that the impact of this effect would be worsened in areas where general dental health was already poor and that the majority of patients already have a degree of fear towards dental treatment *(N5 – Reputation of dental profession)*:

P – "The other negative aspect [...] is the public confidence in the service because if they find lots of this adverse publicity, it might mean that a lot of people won't want to come and see the dentist for their routine check-up and so on"

P – "if you walk into a dentist for a lot of people there'll be an assumption that this is all tightly controlled. There's good governance in place and if I go here what I get is gonna be safe and then something like this happens and they suddenly go 'ok, if this can happen here, it can happen anywhere' and then potentially some people lose trust in dentistry and then they're maybe not getting the preventative work that they need.. And that worried me because I know what our department's trying to achieve in terms of oral health and it worried me that the two things were in conflict. Em, I didn't like that at all and I didn't like the thought that our incident happened in a community whose need for good oral health was really high."

P - "because a lot of people have a bit of a phobia or a fear of the dentist, sometimes it's hard enough to get people to go, you then throw into that, you might get infected, which could be what people believe, then you've just made things worse."

Respondents acknowledged that patient notification may have a dramatic impact on the reputations and revenue of involved dental practices *(N6 – Reputation of involved dentist/practice)*. Participants expressed sympathy for those practices where a genuine mistake had occurred as they felt that patients would not take this into consideration:

P - "It's bound to adversely affect their patient trust and that practice, especially if it's in the papers and things, they might well lose patients from, I've never, we've never gone back and assessed the impact of changed patient numbers or whatever but I'm sure that must happen, so it's not something to be taken lightly from the dental practices' perspective either."

P – "there's always reputational risks for the dental practice so even if there's no transmission events, just the fact that the patient has received a letter may actually not just affect reputation but the business, ultimately could even destroy the business so that's something which has to be taken into account."

P – "they will feel that people will blame them (the dental practice) for whatever reason [...] that it looks as if they've done the wrong thing whether they have or whether they haven't."

One participant pointed out that even if an incident involved only one dental HCW, the reputations of all those working at the practice may be affected especially when those managing the incident are trying to protect the HCW's confidentiality and patients are not told who specifically is associated with the incident:

P – "one tends to be at great pains not to say whether it's a dentist or a dental assistant or a dental whatever, they talk about a dental health care worker. So you don't know who it is and therefore it could be anyone of them so you might all feel a bit tarnished. So in the course of trying to protect [...] the individual then it can backfire on the other people within that practice."

Even though the reputational consequences for the HCW or practice involved are considered a negative PNE aspect, it was not reported to be a factor that would hold significance in the debate over the decision to notify *(N6 – Reputation of involved dentist/practice)*:

P – "you see protection of public health is the paramount so reputation for just a small [...] practice, it wouldn't be a priority"

One participant commented that reputational consequences could be fairly mild and predicted that over time the impact would be lessened:

P – "there were many people who did not believe that this (dental HCW) had done anything wrong so I suspect the practice would have carried on [...] the public have short memories."

Others stated that the notification letter can also be altered to mitigate reputational impact on the dental practice or HCW. Respondents explained that if an honest mistake had occurred and been reported swiftly, those managing the incident would be more inclined to try to protect the reputation of the practice and/or HCW involved through careful selection of the wording utilised in the notification letter:

P – "I think that (conducting a PNE) would be horrible, I think in that situation (where the practice have made a one off error which they reported swiftly), it would be

horrible for the practice and I think. You would hope that, cause that wasn't our situation, but you would hope you'd be able to kind of protect them in the sense of explaining to patients, [...] .You know, there's a way of wording it in terms of you know, these things happen and there'll be a full process put in place to ensure that it doesn't happen again and they're co-operating and all that type of thing."

3.5.2.5 Theme 5: IMT personal experiences/training

Table 13: Theme 5 – IMT personal experiences and its sub-themes

THEME 5: IMT PERSONAL EXPERIENCES	
IMT 1 (Personal experiences)	IMT members' experiences or training which may influence the decision to notify patients

The theme of 'IMT personal experiences' was inspired by the major CFIR construct; 'Characteristics of individuals' as well as the sub-constructs 'Knowledge & beliefs about the intervention' and 'Other personal attributes' (Table 13).

The data gathered via these interviews support the concept that the personal opinions and experiences of IMT members are likely to have an effect on the patient notification decision-making process. One participant emphasised the importance of making sure that people with the correct expertise and priorities are making the decision:

P – "you have to be really careful who's making that decision and that they're basically qualified to make the decision so [...] I suppose it's making sure you've got the right group of people to make that decision with you eh I guess em, to make sure you're making the right decision and not a decision based on either something that's not so relevant like cost or eh, em, reputation or something like that. You need to be making the decision only based on risk, risk to the patient"

Participants explained that they were able to draw on their knowledge from previous exercises to facilitate a more efficient notification process and commented that managing an incident gave them a new perspective on patient notification and would perhaps make them change their approach to decision-making in the future:

P – "I think, over time because we've done so many [...] there's, kind of, a greater understanding about what needs to be done and how it needs to be sorted..."

P – "so I think we've found ways to deal more efficiently [...] with the tracing of individuals [...] we've found ways of actually doing that in a much less labour intensive

way. Em, so the kind of electronic databases [...] stuff that can be done by machine rather than by individuals sitting in front of the screen so it's got a lot better."

P – "Knowing now what I know about all the other downsides to it, I wouldn't do it because I don't think we could argue it just in the interests of transparency"

P – "I remember at the time I was [...] content that we had to inform people, I could go along with that, I might not today but I could go along with it then. Cause I've been through the experience now"

One participant demonstrated that specific personal experiences could influence decision-making. They were particularly aware of the BBV-infected patients' plight, having treated such patients in the past and this, they felt, made them keener to notify patients and not risk leaving persons unaware of the presence of serious infection.

P – "I guess now you've asked me a really interesting question because right at the beginning of my career when I was (position) I did treat patients with hepatitis B [...] it's quite possible that that early experience of actually me providing their regular treatment and it's not a pleasant treatment..." "I still remember some of the individuals so yeah maybe that makes me a bit more interventional."

3.5.2.6 Theme 6: Standards

Table 14: Theme 6 – Standards and its sub themes

THEME 6: STANDARDS	
S1 (Ethical concepts)	Ethical concepts, norms/values in the medical profession/public health
S2 (Peers' actions)	Guided by peers, influenced by what others have done in similar circumstances
S3 (Outside organisations, experts and policies)	Influence of outside organisations, experts, government, higher management. Guidance documents, laws and policies
S4 (Public opinion)	Public opinion

The theme of standards is derived from the concept that decision makers may act in accordance with what is expected (Table 14). This may relate to current legislation and guidance or advice from experts, higher management and colleagues. IMT members may also be guided by certain principles and ethical

concepts, within the field of healthcare. This theme is inspired by the CFIR categories; 'peer pressure', 'external policies & incentives' and 'culture'.

Participants conveyed that there were three main concepts that guided their decision-making process: prioritising the health of the patient or population above all else whilst respecting the concept of transparency and the patients' right to know *(S1 – Ethical concepts)*:

> *P - "As far as I'm concerned when I make the decision I always consider the benefit to the [...] person that has been exposed to first"*
>
> *P – "I think also the kind of culture in health services [...] has changed and [...] if something happened that shouldn't have happened, I think that our culture now would be pretty much to tell people, unless it was so marginal and unimportant that there really wasn't anything to tell"*

Respondents explained that it was common to err on the side of caution and that a risk averse culture exists within healthcare:

> *P – "the organisation tends to err on the precautionary principle. We can't always be 100% certain so let's go for it so, more often than not the recommendation is [...] to go for a PNE unless as I said you are able to be quite certain that there wasn't really any sort of risk to the patients at all."*

They felt that, as a healthcare provider, they had a duty of care to patients and to not cause the harm that would be inflicted via the psychological impact of notification:

> *P - "personally I really don't want to unduly worry people and I think that can have a negative impact and it's a harm itself, first do no harm. Em, I think it's important that you make a balanced decision, including that in it."*

Respondents also explained that there exists a clear and obvious responsibility for NHS patients but the duty to notify, test and treat private patients was ill-defined:

> *P – "we had [...] a specific duty in regards to patients who had used that practice because they were using it as NHS patients but there were some patients who were completely outwith the NHS system and some of us argued that we had a duty to them too because as public health professionals we have a population duty therefore whether it's in a private facility or not, if there's a risk then we have a population duty."*

Respondents explained that IMT members were guided by their public health colleagues when it came to making the decision of when to notify patients *(S2 – Peers' actions)*. Being able to get help from colleagues appeared to be primarily linked to who you knew within the public health field:

P – "I did, as part of the sort of initial trying to make a decision [...] I did [...] send out a distress call to my colleagues to say 'Help! Has anyone done this before?' and I did get a response from colleagues in another area who directed me to a paper they had actually written"

P – "it depends on whether you know who to phone but [...] it's quite useful to chat through someone else and go actually I don't think we should escalate that"

One participant stated that having conducted a PNE, he/she was now regularly contacted by others seeking advice whilst another called for creation of a list, that public health consultants could access, which detailed persons who had managed different types of incidents over the years:

P – "I've had so many people come to me, asking me, when they've had similar things because they've found out through the grape vine that I've had an incident. So I find myself giving my experience to lots of other people who are then em, having the same thing."

P – "almost having like a, maybe like UKAP having somewhere where they have a list of everybody who's had (an incident) so, you can always go back if you wanted to"

Participants stated that consulting UKAP following discovery of an infected HCW was helpful and considered the norm *(S3 – Outside organisations, experts and policies)*. Participants explained that UKAP had a clear process for assessing infected HCW related incidents which benefited from patient input and the experience gained from assessing many other incidents:

P - "the reason that I like UKAP [...] is actually in the set up of that, patients are involved [...] in the decision-making and therefore you've kind of got that input, as well as [...] professionals etc. you've got that kind of consistency of approach"

P - "three involved infected dental practitioners so they were much easier [...] because UKAP has a process that at least makes it very easy for you to follow and you know what you're doing."

P – "No, I think conferring with UKAP ok, with their experience that is one critical thing so have we cross checked with them what would they think? So, yeah..."
LG – "So, if they supported your decision that would give you a bit more comfort, a bit more confidence"

P – "Oh yes, in fact yeah, this is what we did, we say look, we've reached this decision and we're gonna have to write to UKAP to confirm"

P – "I think with the healthcare worker stuff of course [...] there is UKAP [...] in essence they've decided, you know, what criteria they're gonna use they've got the decision makers they've got patients involved in that and they've got the consultation around that and I think that the healthcare workers actually what happens is much more standardised as a result of UKAP"

Participants explained that responses to infection control incidents may lack consistency as, unlike an infected HCW incident, there was no expectation or precedent for IMTs to contact UKAP *(S3 – Outside organisations, experts and policies)*:

P – "...but with the infection control stuff I think people may or may not seek (inaudible) advice (from UKAP) on that and make much less standard decisions really on that."

Two respondents described an unofficial, expert group which gathers in England and can be sought out for advice in relation to infection control incidents. Participants called for formalisation of this current group or creation of a group similar to UKAP, which could aid with the assessment of infection control breaches:

P – "the informal group that has already started that we are approaching, that group needs to be basically resourced and formalised into something like UKAP which .... so where they can then draw on expertise from all over the place eh, em, and then come up with the evidence and the guidelines and the toolkits and that would make it easier so we're not always reinventing the wheel anytime a new one comes along"

P – "it appeared that they had an unofficial group where they looked at these sort of incidents that were not your typical UKAP but involved decontamination incidents. So it's not an official group by any means, it's just a group of sort of, interested people with various sorts of expertise....so they actually did the risk assessment and made the recommendation [...] that we needed to do the notification exercise so, and you know, I was happy to go with them."

It was also emphasised by some participants, however, that outside experts or advisory organisations, may not truly understand the level of work that goes into conducting a PNE:

P – "there's been lots of eh, you know, internal politics that 'oh [...] they (the outside organisation) don't know what it takes to do these things [...] they just sit in a room and say, yeah, go forth and do a notification but actually that might knock down our service [...] we might have to put things on hold or we might have to get in extra staff to do this. So they're often not aware that they may make advice but that they can't

estimate the impact of what that's going to be so it comes down to you locally to say well, ok, that's the advice nationally but locally I don't think we need to do this"

P - "quite often we're asked to get advice from UKAP and my experience with UKAP is that they take the path of least resistance so, if in doubt, because, they don't have to do it themselves [...] actual notification exercises are done by the (board/trust) or the people at the sharp end, literally"

Participants reported that both management and government desired a transparent, proactive approach with notification of patients and therefore may be an influential presence in the decision-making process *(S3 – Outside organisations, experts and policies)*:

P – "Their views would be more towards going public rather than not going public because politicians, being politicians [...]. They want to be popular with the public therefore they take the views that, if in doubt tell them and that's the way things are moving and society's moving"

P – "Yeah, there was, amongst (higher management) here, not in (public health), there was a clear view that we should be doing something [...] and that even further than that we should be doing it proactively."

As previously mentioned, availability of guidance regarding the decision to notify following an infection control breach, is poor *(S3 – Outside organisations, experts and policies)*. Participants did, however, outline a number of documents which could be applicable when considering disclosure and general incident management. Duty of candour was mentioned by many participants although not always in the context of using it to support patient notification as there appeared to be confusion over its applicability and interpretation:

P – "you still don't have to do it just for duty of candour we can still say the risk is negligible, we think this would cause more harm than good so we're not doing it."

P – "so in the line of sort of, duty of candour, the need to tell people we told them it had happened but actually we assessed the risk to be so small we actually said but you don't need testing and I think we ended up testing a very small number of individuals who were not reassured..."

P – "I just happened to read it (duty of candour regulations) yesterday for other reasons [...] I was looking specifically for that (a clarification) in relation to another issue. Em, is the possible risk of harm enough for you to roll out a whole exercise? Or is, is it actual harm that it solely addresses? And it looks like it is wider than just actual harm."

Sources of guidance mentioned by participants included a document entitled 'Lookback before you Leap' (Cummins et al 2001), dental decontamination guidance, such as the Health Technical Memorandum 01-05, historical incident publications and instrument manufacturers' guidance. Participants also referred to resources produced by UKAP and the document published by the Scottish Government and HPS: 'Management of Public Health Incidents: Guidance on the Roles and Responsibilities of NHS Led Incident Management Teams' (2017):

P – "I haven't necessarily kept up with what the UKAP guidance [...] but that is one of the first things I would do."

P – "for Scotland we have the 'managing public health incidents' so dental health incident would be part of that"

P - "Public Health England has published generic guidance on how to deal with these types of incidents."

P – "And I would always refer to 'Lookback before you leap'"

P – "I suppose the only document I looked at were the [...] guidance for dental decontamination [...] HTM something"
LG – "HTM 01-05?"
P – "I did look at that to see if there was anything, you know, we could, sort of, that might say ok, this is good, this is bad [...] but, you know, that of course, that's a guide on best practice it doesn't actually tell you what to do when things don't go right, so, that wasn't really helpful"

P – "actually for the infection control stuff you know we would go back to [...] manufacturer's guidance [...] so if it's equipment or whatever there may well be some quite detailed stuff"
LG – "yeah cause they could tell you, kind of, variations on temperatures that are appropriate and things like that"
P – "yeah"

In general, however, participants called for more guidance on the management of infection control incidents and explained that the decision factors were more numerous and complex when considering patient notification following these types of incidents compared to assessment of a BBV-infected healthcare worker:

P - "I think with the infection control stuff, the risk assessment stuff is much more difficult, there's not a central way of doing that, probably the information's more difficult, there's many more variables, I think [...] then it sort of comes down to local judgement..."

P - "I would really like some sort of, something really concrete to come out of this [...] I would really like what we spoke about in terms of either a set of guidance or something around, here's the risk associated with...cause that's the big gap"

P – "working through em, a system for dealing with the infection failures because I think at the moment, there is a lot of variability, em and I think its understanding all the factors that come into the decision-making and have a process that allows us to do that more consistently but also then be able to justify what we've done"
P – "having some kind of guidance isn't it? [...] that we can look at in one format because right now we're probably going to various sources and stuff and whatever to try and collate things together and make an informed decision."

Participants stressed that the worst outcome of not proceeding to notification would be late discovery of an infected patient. Without knowledge and consequent treatment of their infection, the patient's condition would have deteriorated over time and prognosis may be poor at diagnosis. The public may be angry or concerned that notification and testing had not been conducted and the reputation of the board or trust involved may be significantly damaged *(S4 – Public opinion):*

P – "Yes and that is obviously a risk isn't it? Em, that when you do make that decision that you're not going to do a notification exercise and then somebody comes up, you know, a year later or something or whatever and says em, you know, em, I think I've caught something from this dental practice...oh dear."

P – "Well, there's the very low risk that someone actually did get it from there...or, or, there could be no other identified risk factors by which they got it and they could show that they'd had an invasive procedure in the time that we were aware there was a risk of inadequate infection control at that certain practice and so you, you could say that person might come back and say this is now ten years later, if you told me earlier, I could have dealt with this and not have cirrhosis now."

They also stated that not notifying patients may be misinterpreted by the public as the medical profession trying to employ a traditional and immoral paternalistic approach. What the public would say or think about incident management was clearly an important consideration when deciding whether to conduct a PNE:

P – "and if they then go why did the (board/trust) not tell us that things were wrong, you're on a really sticky wicket, to say, well, we decided for you, not to tell you because we didn't think it would be in your interest, that could potentially cause a huge mistrust of us"

P – "clearly the media (inaudible) they don't understand the niceties of why you didn't tell them, so I think and increasingly with the way the society's going this kind of allegation, nobody would like to be at the receiving end of it cause if your told that,

you know, you're the doctor with the decision and eh, it's a cover up, you didn't want to spend the money to tell people or you're playing, you're playing god, you're trying to be very paternalistic"

3.5.3 Further results

3.5.3.1 Using the stakeholder consultation to facilitate literature searching and guidance mapping

The purpose of these stakeholder interviews was not only to provide a deeper insight into the complex PNE process but also to facilitate a more complete and accurate scoping review study process. Participants directly suggested or provided access to incident reports, publications and guidance. They made recommendations regarding places to search for these documents (Table 15) and gave invaluable advice on the variations of terminology that should be used for database searching (Table 16).

Table 15: Organisations cited by stakeholder consultation participants for identifying incidents/expertise/guidance

Health Protection Scotland
United Kingdom Advisory Panel for Healthcare Workers with Bloodborne Viruses
Centres for Disease Control
Scottish Health Protection Information Resource (SHPIR)
Scottish Health Protection Network
European Centres for Disease Control
Eurosurveillance
Scottish Government
Public Health England (HPA, PHLS)
Communicable Disease Surveillance Centre
Informal PHE group
British Medical Association
General Dental Council
Medical and Dental Defence Bodies

Table 16: Terms suggested by stakeholder consultation participants for database searching

Incident	BBV
Health Care Worker	Hep C
Patient Recall	Dentist
Lapses	Dental Practice
Health Settings	Dental practitioner
Dental healthcare worker	Hepatitis B
Patient Notification Exercise	Hepatitis C
PNE	HIV
Lookback	Dental assistant
Dentistry	Dental Nurse
Notification	Blood borne virus transmission
Decontamination	Infection
Infection control failure	Transmission
Blood Borne Viruses	
Hepatitis	

3.5.3.2 Using the stakeholder consultation to facilitate effective data presentation and analysis

Participants suggested what data outcomes would be useful and ways in which they could be presented. They examined preliminary findings and provided insight into the potential reasons behind patterns shown or correlations identified. For example, participants explained that the significant variation in percentage of patients tested from incident to incident could be explained by differing language used in letters to encourage or discourage testing.

3.5.3.3 Using the stakeholder consultation to validate utility of research outcomes

The utility of this doctoral work was validated through comments made by participants. Many emphasised that the collation of incident outcomes was needed to inform future management of dental incidents and expressed interest in accessing the findings of the work (Table 17).

Table 17: Comments made by stakeholders regarding the validity and utility of this dental PNE focused PhD research

"I think it be useful, a good one, what you're doing, useful to pull together all the evidence to date of the incidents, why the incidents happen, what the incidents are, what they have done and the outcome. Cost/benefit as well and I think just having that information would be quite useful."
"and that's why I'm so supportive of putting all of this together.....you know, UK wide or worldwide, so that we can learn from them, it's absolutely crucial"
"although they are, you know, a pain to do but I think the more evidence and the more and that's why I think your piece of work is great, the more we can get out there to help people who are faced with it and I think the more we'll be able to tailor them and ensure that we are risk assessing them appropriately."
"I think the work in itself in trying to look at the literature and, you know, talk to people and come up with, you know, here's, you know, what needs to happen even if it's going to be a recommendation. Here is either a way by which we can gather up all the evidence that we've got already or here's a repository where we can start to put these things or, you know, even here's a template that you can put your report in and it collects all the information that would be helpful to other people em, you know, that could be done, or you know, recommendations for research, coming up with a toolkit, everything I...I just think the whole thing is just an area where you know there's lots of, lots of eh issues and you know, even just your synthesis of that evidence you've found em, you know, when you start and you don't have the time to go and search Medline and all the documents and try to make it up so what again, what we need is easily retrievable evidence that someone like yourself, who has been doing a PhD, is able to collate, somewhere where we can easily access it, that says, well, look here is all the evidence that we've got"
"no, just be pleased to see an outcome of it. And see them all, all the dental incidents collated, combined, compared."
"Em, well, I just, I look forward to, to reading the output, I think it will be very interesting."

3.5.3.4 Using the stakeholder consultation to identify research gaps and subjects for future research

Gaps in the field were outlined by participants and are presented as part of the narrative synthesis results. Table 18 summarises all issues which participants outlined as research gaps or suggested should be the focus of future studies.

Table 18: Issues or gaps in dental PNE research outlined by 11 participants involved in stakeholder consultation

Issue/gap	Number of participants who raised issue out of 11	Percentage of participants raising issue
Concerns re: the uncertain risk assessment.	8	73%
Desire for a standardised way of decision-making / guidance.	7	64%
Desire for a better evidence base.	6	55%
Desire for a closer look into monitoring and regulation of infection control in GDPs.	5	45%
What were dental staff's views on incident management?	4	36%
More studies on the ability of decontamination stages to remove blood/inactivate viruses.	3	27%
Data on which breaches / practices are historically linked to transmissions.	3	27%
Incidents need to be more frequently written up / findings disseminated.	3	27%
Cost analysis of notification process.	3	27%
Desire for patient feedback on experience / management of incident.	3	27%
Clarification on the duty to notify / take responsibility for private patients.	2	18%
Risks of transmission when HCW wearing gloves versus not wearing them.	2	18%
Need for a standardised system for writing up reports/better quality reports/reporting template.	2	18%
An assessment of the quality of dental HCWs infection control training.	2	18%
Exploration of the issue of staff having to whistle blow on their bosses, jeopardising their careers.	2	18%
Uncertainty surrounding the application of the duty of candour.	2	18%
IMT's not having powers needed to properly inspect / restrict / investigate practices.	2	18%
Desire for repository or database of incidents.	2	18%

During the interview, each participant was asked to specifically consider outcomes created by historic PNEs and outline which data from these older incidents would support them in their current decision-making. Each interviewee was given a list of outcomes and asked to pick the three types of data they would find the most useful (Table 19).

Table 19: Stakeholder consultation participant responses to interview question:
'To aid you in your decision you may want to consider the outcomes of previous dental notification exercises undertaken in the UK over the last ten years. In reference to the list of incident outcomes below, what are the three most important pieces of information that would inform your decision-making process on the need for a PNE in a 'minimal risk' incident?'

Data from historic incidents	Number of times selected by participants as being useful	Percentage of participants who selected option
The degree of psychological distress caused to patients.	8	73%
The number of new positive diagnoses that were found.	7	64%
What were notified patients' opinions on when they should be notified of these types of incidents?	5	45%
The number of those successfully notified who took up testing.	3	27%
How often is the 'patient's right to know regardless of risk' the main driver for undertaking a patient notification exercise?	2	18%
The percentage of those deemed to be 'at risk' who were successfully notified.	2	18%
How much did the letter alleviate notified patients stress?	2	18%
How much did contact with a dedicated helpline alleviate notified patients' stress.	1	9%
The monetary cost of undertaking the exercise.	1	9%
The effect the notification exercise had on patients' uptake of future dental services/care.	1	9%
Legal ramifications of exercise.	1	9%
The number of those that called the helpline.	0	0%
The number of those that requested/received counselling.	0	0%
The effect the notification exercise had on patients' levels of general dental anxiety.	0	0%
Degree of stress caused to staff managing the incident.	0	0%
Degree of disruption caused to the normal health board/trust workload during management of the exercise.	0	0%

3.6 Discussion

3.6.1 What this study adds

This stakeholder consultation exercise is the first to gather the thoughts and opinions of those who manage dental incidents within the UK using a novel tool developed to specifically assess the influential factors behind the decision to notify patients following a 'BBV transmission risk' healthcare incident.

This study was an important step in the design and development of much needed guidance in this area. The stakeholder consultation means that any guidance created as a result of this doctoral work, is based on stakeholder needs and incorporates the advice and experience of UK decision makers. Not only do findings from the stakeholder consultation enhance the scoping review study literature search and demonstrate the value of a decision-making algorithm but identification of research gaps may lead to future studies desired by UK stakeholders.

This study outlines the methodological process for conducting a stakeholder consultation as part of a scoping review study. The scoping review study methodology is a novel process and demonstration of its execution may be beneficial to others who may be interested in utilising its structure.

3.6.2 Methodological choices

Purposive sampling was utilised in this semi-structured, qualitative, interview study as the aim was to seek out and record the responses of those with experience of managing public dental incidents: a niche group of people within the health care system (Marshall et al 1996).

One-to-one interviews were conducted with participants in their place of work. This is a time consuming and expensive approach and on reflection, similar data may have been obtained in a focus group setting although participants would have had to travel to a central location from across the UK and their responses, especially if confidential in nature, may have been influenced by those around them. To save money and time the use of software such as Skype may have been valid, or engaging in secure email correspondence. However, the sensitive nature of the topics discussed may have made respondents less forthcoming with information in these less personal environments.

Furthermore, with each participant having such an in-depth and unique story to share, giving each a focused, protected period of time facilitated the gathering of higher amounts of quality information. In a focus group situation, time would be split between each participant and stronger voices may claim more of the allocated time. It was also felt that a one-to-one interview situation would be

easier for participants and remove a barrier to taking part, as the chief investigator could visit them at their place of work at a convenient time.

The questioning route was created with the consideration that these were to be what are described as 'elite interviews' – interviews of those with status and high levels of knowledge in relation to their field (Anyan et al 2013; Harvey 2011). It is suggested by Harvey (2011) that elite interviewees may frequently be approached by those in the media and thus may feel uneasy about the nature or reasons behind an interview. A great deal of consideration was given to the confidential information that may be discussed during this study's interviews as a significant proportion of incident information is not in the public domain. Harvey (2011) emphasised that you must attempt to gain the trust of an elite interviewee which is why, in this study, transparency and maintaining an open dialogue with the participant was considered a priority and also why a 'respondent validation' phase was included.

Recommendations by Kreuger and Casey, who in 2000 published 'Focus Groups: A Practical Guide for Applied Research', influenced the flow of the questioning route which began with shorter, broader, easier questions and progressed to focused, harder, key questions. Their advice also led to the inclusion of ordering activities, open style questions, grouping of similar questions and a question regarding interviewees' recommendations for improvements to the study.

The paper by Britten (1995) contained excellent guidance on good interviewing skills such as open body language, positive responses and relaying information back to the interviewee to demonstrate that you are listening.

3.6.3 Main findings

3.6.3.1 Lack of access to evidence/support

One of the key findings of this consultation was that IMTs must make a complex and multifactorial decision not only without access to guidance but also with no central repository where incident data can be accessed and with no formal channels for contacting others with similar experiences.

IMTs do not appear to share their investigation experiences amongst boards or trusts through any channels. Respondents reported that getting access to data concerning historic incidents is difficult because research is limited and report writing following incidents is not conducted consistently or in a standardised way. Even if reports are written by IMTs they are often delayed in their release, not comprehensive and not published.

In relation to infection control incidents, no panel or team, similar to UKAP, has been formally established to ascertain the risk and actions required. Not only

does this mean that IMT members do not have access to advisory support but there exists no assembled team of experts who could publish guidance, as UKAP have.

It appeared that should a board or trust find themselves managing an incident of a specific nature for the first time, they were somewhat on their own. Health Protection Scotland and Public Health England could provide support but obtaining relevant advice could come down to who the IMT members know within the public health network.

In regard to the benefits of notification, participants appeared to have a clear idea, based on sufficient evidence and personal experience, of how dental PNEs can benefit exposed patients. Negative effects, however, such as patient anxiety, reputational effects and impact upon dental care uptake, appeared to be based on educated assumptions and anecdotal evidence.

3.6.3.2 Main influential factors of decision

There was a consensus that risks were low but could not be calculated accurately due to a limited evidence base. The decision to notify, therefore, was not entirely based upon this estimation. Participants appeared to be under pressure to be open, regardless of the risk, and therefore focused on weighing the need to be transparent against the many negative outcomes of notification. Transparency was weighed against the opportunity costs of conducting notification, the significant expenditure of time as well as the predicted psychological impact on patients and reputational consequences for the dental profession which could result in patients not seeking out dental care. Respondents appeared to consider the importance of opportunity costs within the context of the NHS; an organisation currently under duress and in possession of limited resources.

Many other environmental factors were identified, with the decision to notify lying within numerous contextual layers (Figure 5). For example, consideration was given to the context of current scientific knowledge and existence of medical advancements. Participants explained that over time, the knowledge and experience accrued shows that transmission risks are low, supporting the idea that PNEs are not needed. However, advances in treatments for BBV infections could make the identification of infected persons more desirable as their disease can now be treated swiftly and successfully.

The decision to notify patients was complicated by legislative candour requirements. Participants had differing interpretations of the Duty of Candour guidance and how it applied to large-scale disclosure but most agreed that notifying patients would represent adherence to its principles. Pressure to be transparent was created by contemplating what the public would want, their

reactions to finding out an organisation had not been open with them and the current culture of transparency, which has arisen following times of medical paternalism. Public opinion was linked to presentation of the healthcare profession in the media, their changing perception of BBVs and their existing scepticism surrounding the integrity of government and organisations. Further pressure was created via the known opinions of government and higher management as well as the decision maker's own ethical standpoint.

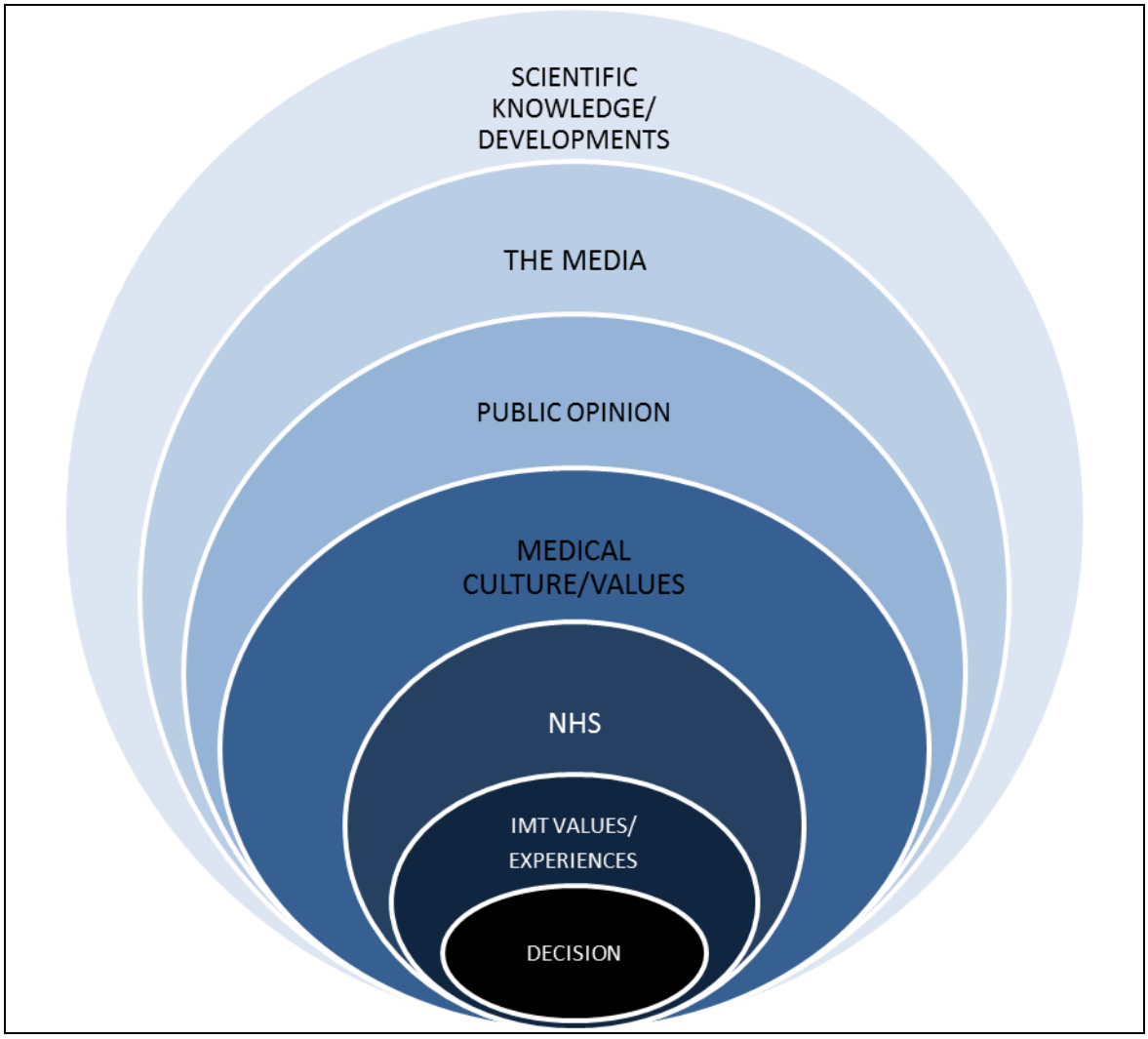


Figure 5: Stacked Venn Diagram showing the contexts within which the decision to notify lies.

3.6.3.3 Research gaps and issues

Paucity in the guidance available, for both the risk assessment and decision-making phases of incident management, was the main research gap outlined by participants. Participants called for this doctoral work to either include an initial draft of guidance or lead to the production of suitable documentation by others.

Many respondents expressed a degree of frustration at having to deal with incidents which may have arisen due to factors out-with the boards control e.g. a system of monitoring that has failed. Participants called for an evaluation of

how practices are monitored and how infection control training is delivered. Changes to education and monitoring, however, have recently taken place and it may yet be too early to detect the effects. In 2016, changes were made to the way in which inspections are conducted in Scotland, with boards now having the power to conduct unannounced inspections of dental practices (The Scottish Government). This may lead to practices addressing and maintaining IPC processes but could also lead to more breaches being identified. Changes within dental infection control teaching have also occurred with the University of Glasgow Dental School employing a decontamination expert to lead a programme of dental infection control teaching with its own separate examination (Anonymous 2011). This will hopefully lead to better infection control education and consequently less incidents.

Participants felt that exploration of the effectiveness of different decontamination stages would also aid in the creation of a robust risk assessment and expressed some confusion and frustration surrounding the allocation of certain roles/responsibilities following an incident. The participant who most often raised this point worked in England, where this appeared to be more of an issue. Perhaps the guidance; “Management of Public Health Incidents: Guidance on the Roles and Responsibilities of NHS led Incident Management Teams” eliminates this issue in Scotland.

3.6.4 Strengths

Interviewing each participant for a significant length of time and on a one-to-one basis facilitated the gathering of in-depth data. Interviews were conducted face-to-face as opposed to via telephone or email exchange. These aspects of study design facilitated the discussion of sensitive information and hopefully put the respondent at ease.

As consultants in public health, all participants had played a key role in the decision-making process regarding incident management and therefore could provide significant insight into its influential factors.

The stakeholder consultation was comprehensive in that three out of four of the devolved nations were represented. This ensured that the experience of stakeholders with differing perspectives arising from location factors and health service structure could be considered.

The same questioning route was used to guide all interviews. Consistency of questioning results in comparable responses and thus a more fruitful thematic analysis. A semi-structured interview style gives participants the freedom to discuss a plethora of issues without completely abandoning the goals of the interview and exploration of all research questions.

As an integral part of the scoping review study, the stakeholder consultation was beneficial in a number of ways. Firstly, presenting preliminary findings to interviewees facilitated the dissemination of early results to stakeholders and attainment of feedback on the utility of preliminary data. It provided an opportunity to learn how best to present current and future findings so that stakeholders will get the most from the data gathered. Participants provided explanations for correlations identified, gave advice on how to structure results and suggested data variables that merited comparison.

Secondly, the consultation proved to be a highly useful networking exercise. Many participants requested that they be sent any resulting publications and a link to the associated thesis meaning that a channel for disseminating your findings is already in place upon completion of the study.

3.6.5 Weaknesses

While the stakeholder consultation was comprehensive in that three of the four devolved nations were represented, many of this study's findings were based on incidents occurring in the Scottish healthcare setting as the majority of participants were working within Scottish boards. This may mean that the issues described by respondents may not be as applicable in England, Wales or Northern Ireland.

Given more time, a larger sample size would have been prudent to enrich and support findings. Only one participant believed that transparency outweighed all other considerations and that patients should be notified no matter the level of risk involved or negative consequences of notification. A larger sample size could have facilitated the inclusion of more respondents with this view.

As previously stated, all participants were consultants in public health meaning that the opinions and perspectives of those in other roles were not captured. The IMT is made up of those with a variety of roles: health protection nurses, local authority environmental health officers, communications officers, legal advisors, occupational health advisors, administration staff etc. Inclusion of those with an alternative IMT role would have strengthened this study.

Some participants were approached based on KR's awareness of their role and experience. It is possible that an awareness of KR's involvement in the study may have influenced participant answer content.

In regards to the development of the NFBI framework, presenting the results of inter-coder reliability in a 'percentage agreement' format is often seen as simplistic and may be criticised as it does not take into consideration coders selecting the same code by chance (Appendix 9). The effect of codes matching by chance, however, is thought to be lessened when a framework has many

codes, as was the case in this study. Use of advanced statistical calculations in this case was not appropriate as a) each code did not have the same chance of being chosen and b) all coders did not have the same type of background or levels of knowledge (Campbell et al 2013) (Appendix 9).

There is debate in relation to the validity of including an inter-rater reliability process in thematic analysis studies. Some argue that the expectation for researchers to interpret and code data in the same way is unrealistic whilst others support its use and suggest that it increases the transparency and credibility of a qualitative study (Armstrong et al 1997). It is hoped that the NFBI framework will be considered a useful research output in its own right and that an inter-rater reliability stage will provide evidence of its credibility as a tool (Appendix 9).

3.7 Conclusion

This stakeholder consultation shows the need for collation of incident data, creation of guidance and a study assessing the psychological impact of notification, all aspects which highlight the value of the aims and results of this doctoral work as a whole.

The stakeholder consultation explains some of the reasons why guidance does not currently exist, outlines the main influential factors that need to be part of guidance created and emphasises that consideration needs to be given to the context of decision-making.

Whilst research is limited, risk assessments remain uncertain and Duty of Candour is unclear, the IMT will need to consider a multitude of factors when dealing with a dental infection control breach. A structured decision-making algorithm will aid them in their endeavour. This consultation exercise was not only instrumental in its design but should facilitate its dissemination in the future through contacts made.

Chapter 4. A systematic scoping review study search of the published and unpublished literature concerning investigations of BBV 'transmission risk incidents' within the dental setting. A narrative synthesis with collation and presentation of dental incident outcomes

4.1 Introduction

The main body of a scoping review study comprises a systematic type review of the literature guided by stakeholder consultation findings (Davis et al 2009). This review focuses on the outcomes of 'BBV transmission risk' dental incidents that have occurred in the developed world between 1990 and 2017. It also examines literature which discusses the merits of conducting large-scale patient disclosure following a healthcare incident.

On examination of currently existing reviews, it was clear that early publications focused on the risks of HIV transmission from HCW to patient and revealed that worldwide, there have been only four reported instances of HIV transmission from HCW to patient: the Florida dental case and transmissions from a French nurse, French orthopaedic surgeon and Spanish obstetrician (Scully and Greenspan 2006; Mallolas et al 2006).

As both HBV and HIV are spread via contact with blood and bodily fluids, it was thought by reviewers that examination of healthcare related HBV transmission may provide clues as to the risks of healthcare associated HIV transmission (Chamberland and Bell 1992; Robert and Bell 1994). HBV transmission within healthcare was historically quite common. Between 1970 and 1994, 34 HCWs (including 9 dentists) transmitted HBV to 350 patients (Robert and Bell 1994). There has, however, not been a proven HBV transmission event from dentist-to-patient, within the developed world, since 1987 (Redd et al. 2007).

Later reviews reflected the emergence of publications which reported on the management of infection control breach incidents. Younai's 2010 review presented data on published, proven BBV transmissions in both US and UK dental settings and reported that between 1970 and 1987 there were nine clusters of HBV transmissions linked to dentists or oral surgeons. In regard to HCV, Younai (2010) reported that no proven transmissions, from dental HCW to patient or from patient-to-patient, had occurred, at that point in time, in the developed world.

A 2016 review by Cleveland et al focused on American incidents which had occurred after 2003 and resulted in proven transmissions: a 2007 patient-to-patient HBV transmission in New Mexico (Redd et al), a 2009 transmission of HBV to three patients and two volunteers of a temporary dental clinic (Radcliffe et al

2013) and transmission of HCV from one patient to another in Oklahoma in 2013 (Oklahoma State Department of Health).

An online worldwide outbreak database contains information on 3605 outbreaks caused by a plethora of pathogens occurring between 1936 and 2018 (Behnke et al 2019). The information available on dental incidents is, however, limited as many do not meet the definition of an outbreak and thus are not eligible for database inclusion. An incident having an associated scientific publication appeared to be a key factor in database inclusion and given that dental incidents rarely result in publication it is unsurprising that the database only held information for the 1990 Florida dental case and four pre-1990 HBV dentist-to-patient transmission incidents (www.outbreak-database.com).

Information is collated on healthcare related HBV and HCV outbreaks from 2007-2014 on the [a] website (CDC 2014; CDC 2009). This data source is limited as it focuses on American data and their definition of an outbreak ie: equal to or greater than two linked cases.

In conclusion, it is evident that there are very few recent, comprehensive reviews of dental BBV transmission risk incidents and that collation of these incidents and associated findings would be highly useful to those making the decision of whether to notify. Current reviews are limited by their American focus, 1990s context, concentration on HIV-infected HCWs and sole inclusion of incidents resulting in proven transmissions.

Literature reviews conducted as part of scoping review studies are guided by stakeholder consultation findings. This study's consultation found that, when deciding whether to notify patients, IMT members are likely to be guided by the experiences of other IMTs and outcomes of historic incident investigations (Chapter 3). These outcomes, however, are currently not easily obtained as dissemination of lessons learned from incident management is often poor or limited in reach.

This review presents evidence from investigations that occurred throughout the developed world covering both those that did and did not result in patient notification and those that did and did not result in proven transmissions. It provides insight into the potential benefits and negative consequences created by PNEs as well as describing the dental infection control breaches that have been linked to historical transmission events consequently highlighting those breaches or failures that should perhaps be considered higher risk.

4.2 Aims

i. To source and report on every published and unpublished dental incident[5] that has occurred within the UK since 1990 and whether it resulted in patient notification or not.

ii. To source and report on published dental incidents[6] that have occurred elsewhere within developed country settings, since 1990.

iii. To source and analyse published articles which discuss large-scale patient notification within a developed country context, post 1990.

4.3 Methods

Separate search strategies were employed to 1) identify all relevant published papers which discuss the management and outcomes of dental incidents and 2) identify unpublished dental incident reports.

4.3.1 Literature search

4.3.1.1 Preliminary search

A preliminary search was conducted to establish that no similar scoping studies already existed within the evidence base. Google and The International Prospective Register of Systematic Reviews (PROSPERO) (NIHR 2019) database was searched using the terms outlined in Table 20.

[5] Defined as those that created risk of/caused BBV transmission, in the dental setting, to patients (either from a BBV-infected HCW and/or inadequate dental infection control)
[6] As above

Table 20: List of terms used to search PROSPERO (NIHR 2019) and Google for similar studies or reviews to the one being executed and presented as part of this doctoral study

Terms used to search PROSPERO (NIHR 2019) for similar reviews
Scoping review AND Dental
Scoping review AND Transmission
Dental AND Transmission
Infection control AND Patient notification OR Dental
Dental AND patient-to-patient OR patient to patient OR healthcare worker to patient OR health care worker to patient
Dentistry AND blood borne virus OR large-scale adverse event OR hepatitis B OR hepatitis C OR disclosure
Dental AND hepatitis B, OR hepatitis C OR lookback OR look-back OR look back OR disclosure
Terms used to search Google for similar reviews
Scoping review HCV dentistry
Scoping review HBV dentistry
Scoping review HIV dentistry
Scoping review dental transmission
Scoping review patient notification
Scoping review look back
Scoping review large-scale adverse event
Scoping review disclosure

4.3.1.2 Search strategy

Database searching combined with suggestions from educational supervisors resulted in a small sample of initial key papers. The titles and keywords of these papers along with advice on terminology received during the stakeholder consultation (Table 16) and guidance from a University of Glasgow librarian facilitated development of a literature review search strategy comprising three separate searches. Each search is outlined in tables 21, 22 and 23 with Appendix 10 also presenting an example of the search strategy employed based on its use in the Ovid Medline database.

Search 1 focused on the variations of PNE terminology with a dental context (Table 21). It was inspired by publication key words such as 'dentistry', 'dental practice', 'notification exercise', 'look back' and 'patient notification' (Millership et al 2007; Irwin and Millership 2002) and titles such as "What are the costs and benefits of *patient notification* exercises following poor infection control practices in *dentistry*?"(Close et al 2013) and "Costs of a limited *patient notification* exercise following infection control failures in a *dental surgery*" (Conrad et al 2011).

Table 21: Terms used in 'search 1' of Literature Review

Dental OR	"look back*" OR
Dentist* OR	"large-scale adverse event*" OR
"Oral surger*" OR	LSAE OR
"Dental practice*" OR	LSAEs OR
Orthodonti*	LBE OR
	LBEs OR
	Lookback* OR
	(Notif* adj2 patient*) OR
	("medical error*" adj2 disclos*) OR
	("dental error*" adj2 disclos*)
Columns combined with Boolean term 'AND'	

Search 2 was influenced by the key words 'infection control' and 'decontamination' (Millership et al 2007) (Table 22). It aimed to capture those articles which may not specifically mention a transmission or notification exercise, such as the paper by Cheng et al (2013) "Management of an incident of *failed sterilization* of surgical instruments in a dental clinic in Hong Kong".

Table 22: Terms used in 'search 2' of Literature Review

Dental OR	Inadequate* OR	Decontamin* OR
Dentist* OR	Poor* OR	(infection* adj2 control*) OR
"Oral surger*" OR	Breach* OR	Clean* OR
"Dental practice*" OR	Improper* OR	Sterili#ation OR
Orthodonti*	Deficien* OR	Sterili*
	Fail* OR	
	Inappropriate* OR	
	Unclean* OR	
	Unsteril* OR	
	"not steril*"	
Columns combined with Boolean term 'AND'		

Search 3 focused on the description of the incident as a BBV transmission event (Table 23). This search was influenced by keywords such as 'BBV', 'transmission', 'HIV', 'AIDS' and 'blood borne virus' (Redd et al 2007; Irwin and Millership 2002; Comer et al 1991) and titles such as "Dental Healthcare-Associated *Transmission* of *Hepatitis C* – Final Report of Public Health Investigation and

Response"(Oklahoma State Department of Health 2013) and "Patient-to-patient *transmission* of *Hepatitis B* virus associated with oral surgery" (Redd et al 2007).

Table 23: Terms used in 'search 3' of literature review

Dental OR	Transmission* OR	BBV* OR
Dentist* OR	Infection* OR	HIV OR
"Oral surger*" OR	Infected OR	HCV OR
"Dental practice*" OR	Spread OR	HBV OR
Orthodonti*	Contracted	Hepatitis OR
		"Human Immunodeficiency" OR
		AIDS OR
		"Acquired Immunodeficiency" OR
		"Hep B" OR
		"Hep C" OR
		"Blood Borne"
Columns combined with Boolean term 'AND'		

These searches were conducted within three databases:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
- Embase 1947-Present, updated daily
- Web of Science Core Collection

Searches 2 and 3 were conducted on the 6th of June 2016 and search 1 on the 14th of June 2016. All three searches were continually updated until the 26th of January 2018.

British Library services were utilised as well as contact with authors to source full texts as necessary.

An iterative search strategy is advised in the execution of scoping review studies (Daudt et al 2013). Arksey and O'Malley (2005) emphasised that comprehensiveness and breadth are important and that inclusion/exclusion criteria can be "devised *post hoc*, based on increasing familiarity with the literature".

The limits of 'English language' and 'post-1990' were included later in the review process. All changes are shown in Figure 6, for example, articles

describing the 1990 Acer incident were excluded if published before May 1993[7]. The reference lists of included articles were searched for further relevant articles (Figure 7). A fourth search was also included: 'The Disclosure Search', which expanded the search to include general, rather than solely dental, large-scale disclosure literature (Figure 8).

4.3.1.3 Limitations

The following limitations were applied:

Published post 1990 AND Published in English Language

4.3.1.4 Inclusion/exclusion criteria

The following inclusion/exclusion criteria were applied:

Focus on discussion or management of (a) specific dental incident(s)[8] OR Be considered an opinion piece on large-scale PNEs. AND Must be presented in the context or setting of a developed country. AND If article focuses on the 1990 Florida Acer dental incident, must have been published post May 1993

4.3.1.5 Search strategy flow chart

The flowchart featured in Figure 6 outlines the main literature review process. For all search processes (Figures 6, 7 and 8), abstract scanning and scanning of full texts was carried out by two reviewers: the chief investigator (LG) followed by either Professor Jeremy Bagg (JB) or Dr Kirsty Roy (KR). Full text articles were excluded with reasons (Appendix 11, 12 and 13). The commercial reference management software package, EndNote®, was used to keep track of records.

[7] Only papers published after this date contained up-to-date figures on transmission findings as this is when transmission to the sixth and final patient was identified.

[8] Defined as those that created risk of/caused BBV transmission, in the dental setting, to patients (either from a BBV-infected HCW and/or inadequate dental infection control).

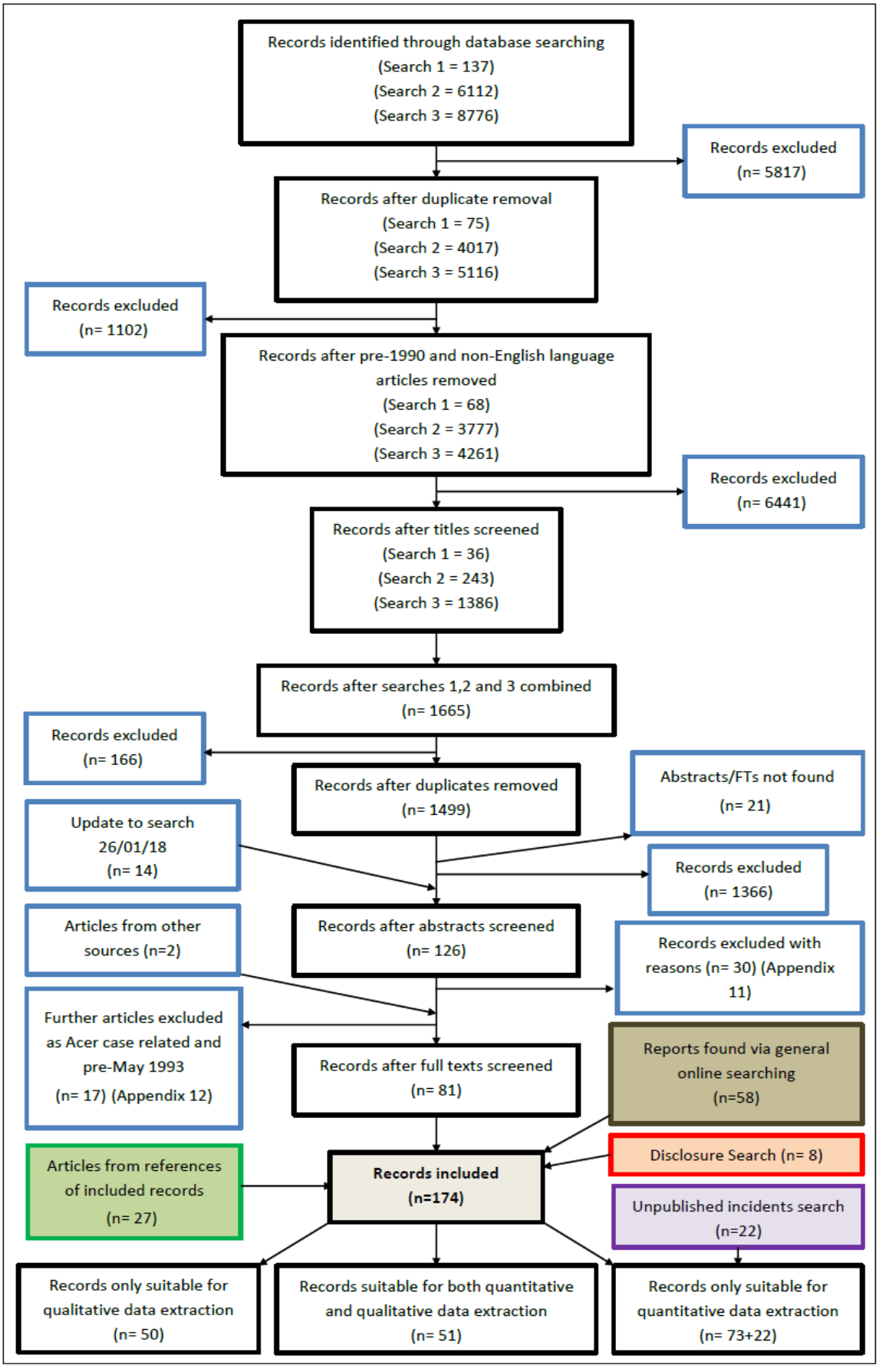


Figure 6: Flowchart outlining process for selecting relevant papers for analysis.

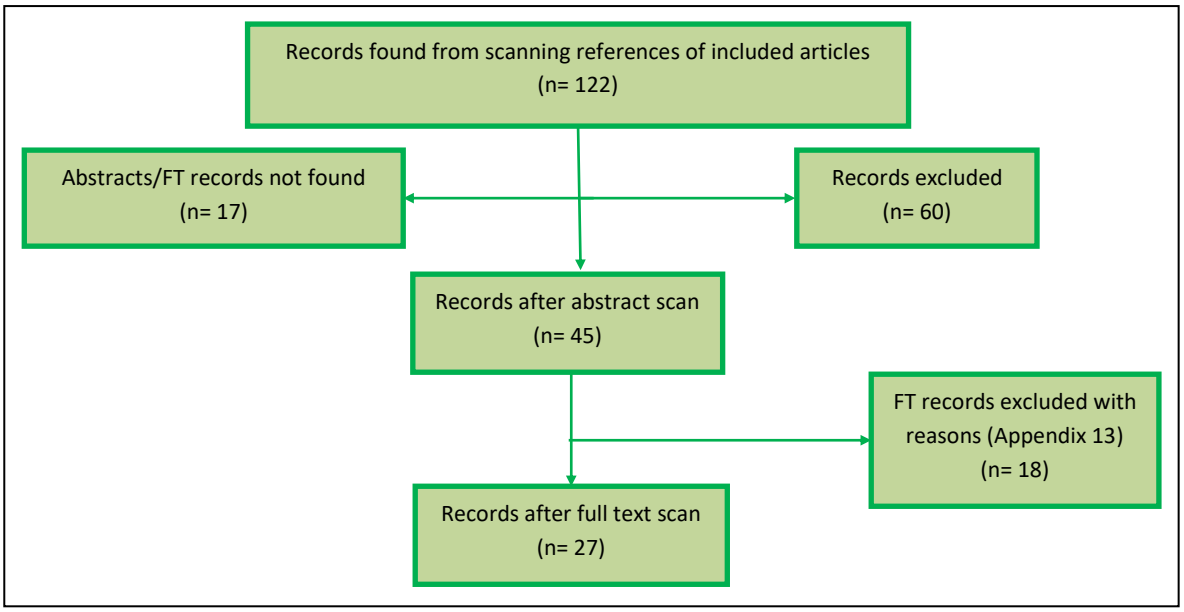


Figure 7: Flowchart outlining process for selecting relevant papers from reference lists of those articles identified through main literature review process - 'references of references' search.

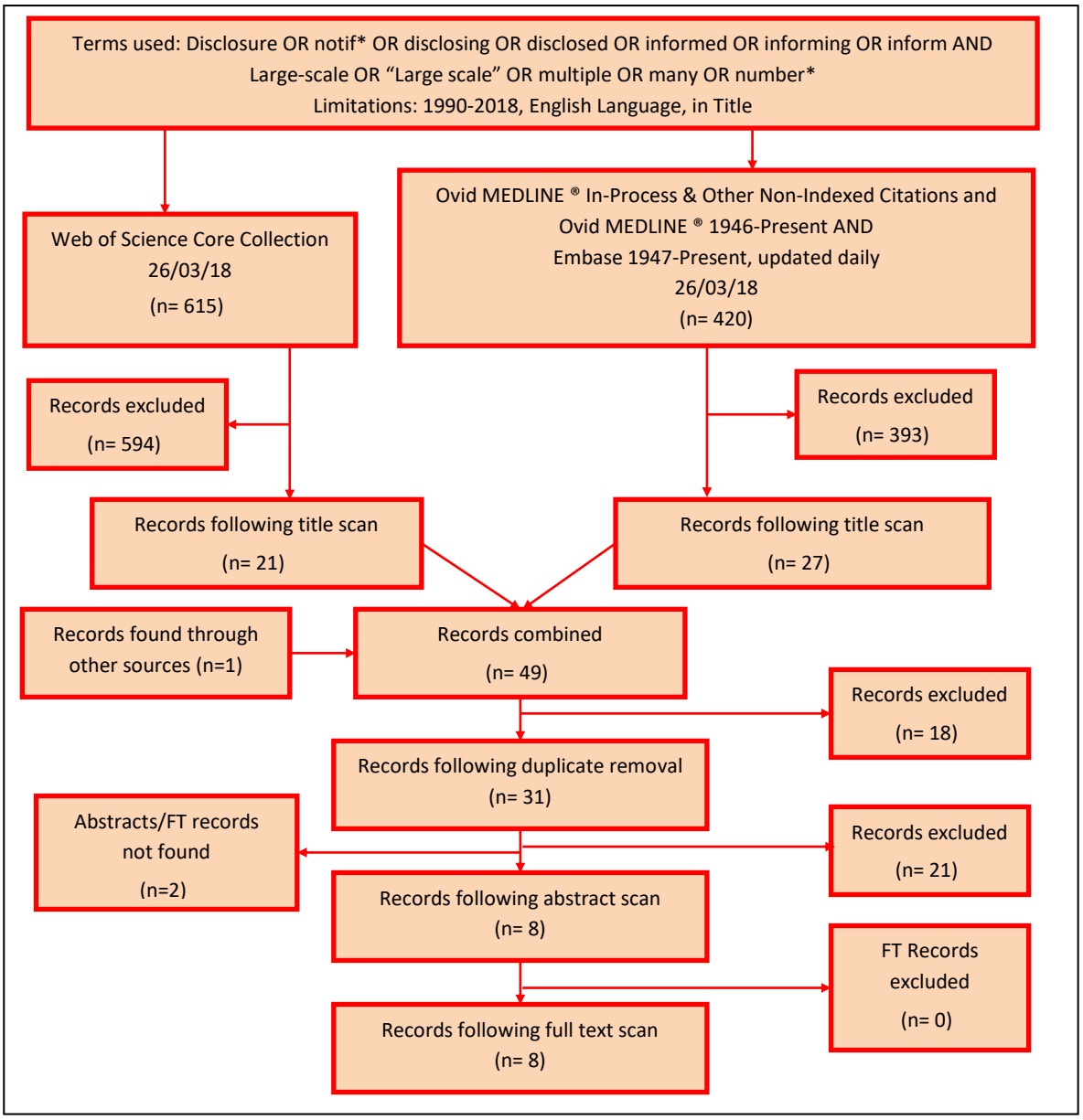


Figure 8: Flowchart outlining process for selecting relevant papers from 'The disclosure search'.

4.3.2 Unpublished incidents search

Unpublished, UK incident reports were identified via the following approaches;

1) Reports of incidents in Scotland were identified by one of this study's educational supervisors Dr Kirsty Roy, a senior epidemiologist within HPS who provides expert advice and support to public health teams responsible for managing incidents involving BBV-infected HCWs or dental infection control failures in Scotland.

2) The Chief Dental Officers of each devolved UK nation were emailed.

3) Every Health Protection Team across England, Wales and Northern Ireland was called or emailed.

4) The UK Advisory Panel for Healthcare Workers Infected with Blood Borne Viruses (UKAP) was contacted.

5) Those interviewed as part of the stakeholder consultation (Chapter 3) were asked if they knew of any relevant incidents.

4.3.3 Data extraction

Arksey and O'Malley (2005) referred to this stage as 'Charting the Data' and outlined that this process involves the application of "a common analytical framework to all the primary research reports" facilitating collection of "standard information on each study".

A single data extraction form was designed to record information on study location, year, focus, study design and type of journal used for publication (Arksey and O'Malley 2005).

A further four different data extraction forms were used to gather dental incident outcomes from the literature (Appendix 14). Their design was inspired by the four different types of dental incidents described (Table 24), this study's research questions and data items presented in previous reviews (Blatchford et al 2000; Cleveland et al 2016; Close et al 2013).

Table 24: The four types of forms used to facilitate extraction of dental incident outcome data

1: Identification of a BBV-infected dental HCW with notification of patients
2: Identification of a dental infection control breach with notification of patients
3: Identification of both a BBV-infected dental HCW and dental infection control breach with notification of patients
4: No notification of patients following a 'BBV transmission risk' dental incident

Suitability of the data extraction forms was tested via the CI and two research team members using the forms to collect data from the same eight publications, two from each incident category (Table 24). Each team member recorded data from the sample papers in isolation and without conferring. A meeting was held to establish whether the forms were resulting in consistent and predictable data extraction. Following this, second drafts of the collection forms were created and used to gather data on all incidents.

4.4 Results

The qualitative review findings are presented in the form of a narrative synthesis whilst incident outcomes, which were mainly quantitative, are collated and presented in the form of charts, tables and graphs with accompanying descriptions of findings and statistical analyses (performed using Microsoft Excel 2010®). Section 4.4.3 presents data on the broad characteristics of the PNE/dental BBV transmission literature.

4.4.1 Collation and presentation of dental incident outcomes

4.4.1.1 What dental incidents have occurred in the UK and other developed countries?

Information regarding 149 dental incidents, occurring within the developed world, was available from both published and unpublished sources (Figure 9).

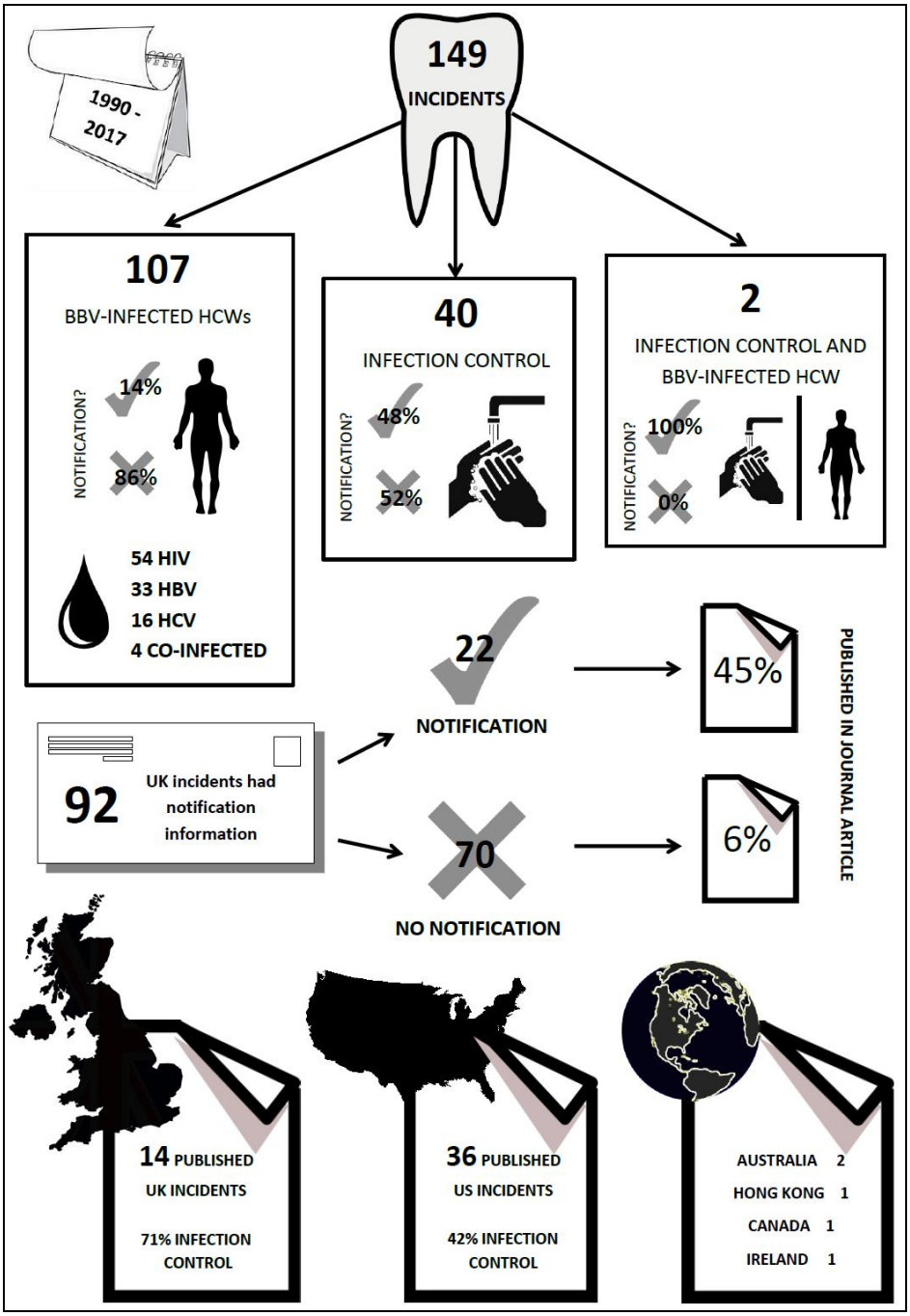


Figure 9: Diagrammatic summary of 149 dental incidents, which occurred within developed countries between 1990 and 2017, identified from published and grey literature. (Images sourced via Microsoft Office 2010® 'Clip Art' Function)

Using data from 148 incidents (one had no information on year of occurrence) Figure 10 shows how the proportions of incident types being managed, have changed over time. The total number of incidents being investigated appears to have risen from 1990-2017 and the proportion of incidents that relate to dental infection control has increased from 1990 to 2017. Dental infection control incidents made up 3.6% of all incidents from 1990-1999 but from 2010 to 2017 they accounted for 35.8%.

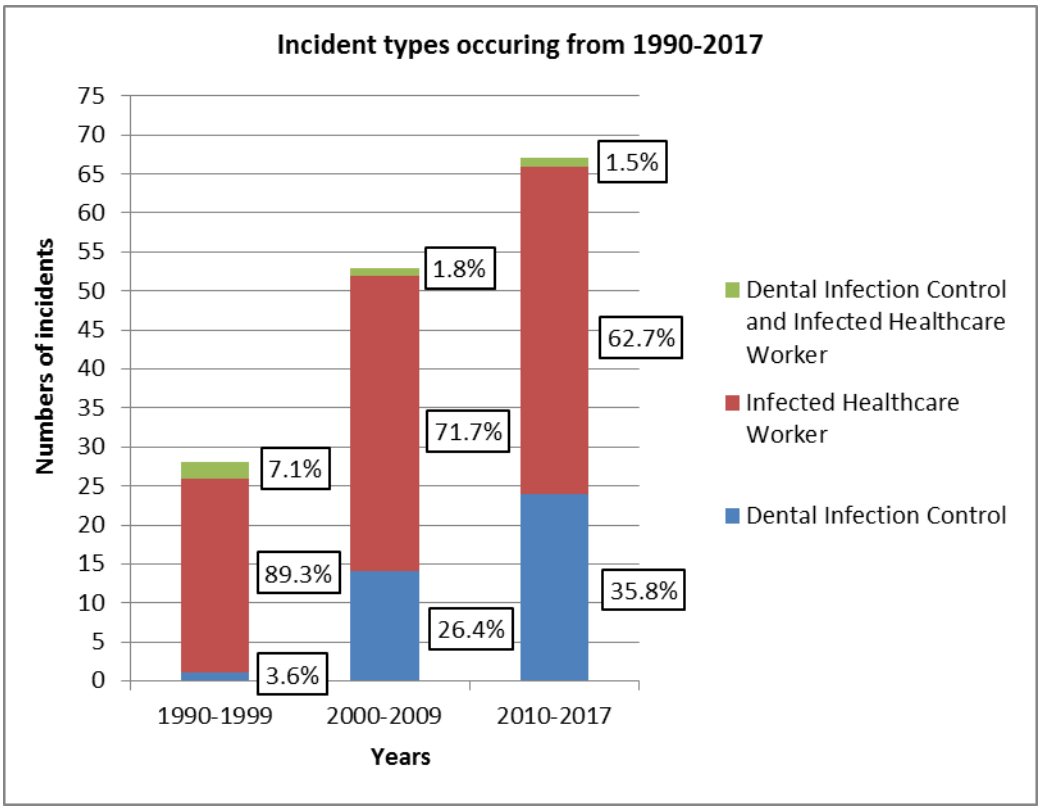


Figure 10: Stacked column chart showing the number of dental incidents occurring between 1990 and 2017.

Unfortunately, data beyond location, year, nature of incident and PNE use were unavailable for 54% (81) of the 149 incidents. Multiple attempts were made via email, telephone calls and letters to obtain this missing information, without success. Data from the 68 incidents for which sufficient information was available are presented hereafter and in Appendix 15.

There are four reported dental incidents that have resulted in BBV transmission from patient-to-patient or HCW-to-patient (Table 25).

Table 25: Dental incidents that were associated with at least one identified, proven transmission

Incident Details	Nature of Incident	Transmissions identified	Additional notes
2013 USA Dental Practice *(Oklahoma State Department of Health 2013)*	- "reuse of contaminated vials" - Use of older, rusted instruments that could not be sterilised properly. - Delegation of IV sedation to non-certified dental assistants. - "Lack of autoclave monitoring and maintenance." - Dental offices had no infection control plans. - No biological monitoring of autoclave for last 6 years. - Sterilization room unorganised and unclean. - Soaking of instruments in cold disinfection which was changed every 28 days.	1 patient-to-patient HCV	Index patient underwent tooth extraction, bone graft and implant placement under IV sedation; source patient had multiple extractions done under IV sedation.
2009 USA Temporary dental clinic in gymnasium *(Radcliffe et al 2013)*	- No barriers between operating areas - All operations in close proximity - Handpieces not sterilised between uses - Sterilised instruments left unwrapped - Patients brought their used anaesthetic cartridges from station to station	HBV to 3 patients and 2 volunteers	No one oversaw infection control at site. Outbreak occurred during time when there had been a seven-fold increase of reports of acute HBV infections in W.Virginia. Patient 1 – Extractions and prophylaxis Patient 2 – Extractions and restorations Patient 3 – Extractions Volunteer 1 – Escorted patients to waiting area Volunteer 2 – Maintenance of clean and dirty medical equipment

2002 USA Oral Surgery *(Redd et al 2007)*	- Unknown - "cross-contamination from an environmental surface is one possibility"	1 patient-to-patient HBV	Index patient had 7 teeth extracted; source patient had 3 teeth extracted.
1990 U.S.A Dental Practice *(Ciesielski et al 1994)*	HIV-infected dentist	HCW to 6 patients	Patients underwent exams, radiographs, extractions, scalings, LA administration, anterior composites, RCT, veneer, bridge and crown placement, gum resections. 4 of the 6 infected patients shared dental visit days but only 2 had invasive procedures done on the same day. Patient G shared no treatment days with the other patients and for Patient I, specific visit days were unknown.

4.4.1.2 Do PNEs achieve that which they set out to do?

A tripartite working group (AGH, EAGA and UKAP 2011) outlined the three main purposes of patient notification, following discovery of an infected HCW:

1) "Provide patients with information about the nature of the risk to which they have been exposed"

2) "Detect any HIV infection, provide care to the infected person and advice on measures to prevent onward transmission"

3) "Collect valid data to augment existing estimates of the risk of HIV transmission from an infected worker to patient during exposure prone procedures."

Although these aims related only to HIV-infected HCWs, intuitively, any large-scale patient notification following a 'BBV transmission risk' incident would have similar goals.

Review of the identified reports suggests that most PNEs meet the first aim as a high percentage of those put at risk following a dental incident can usually be contacted (65-100%, $\bar{x}$ = 89.9%) (Figure 11). Though there is some indication that as the number of 'at risk' patients increases, the percentage of those able to be notified decreases, with a moderate, negative correlation between number of

those deemed to be ‘at risk’ and percentage successfully notified, being observed (Figure 12).

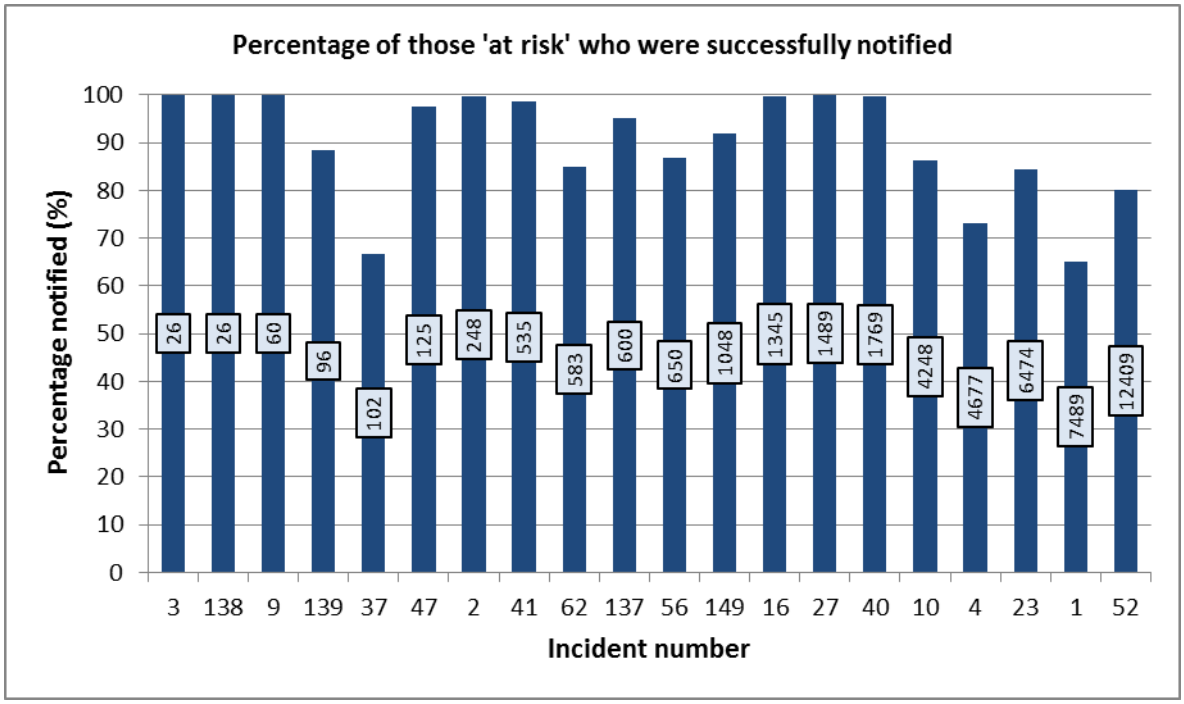


Figure 11: Bar chart showing percentage of patients who were deemed to be successfully notified out of all those deemed to be at risk in both infected HCW and dental infection control related PNEs.

(Each bar contains the total number of patients deemed to be at risk in each incident. In addition to those notified via letter, patients were deemed to have been ‘successfully notified’ if they learned about the incident via the media and consequently contacted the board/trust. A patient was deemed to have not been contacted if either the board/trust did not have the patient’s address and thus a letter could not be sent or if a patient’s letter was returned undelivered. The figure for the patients deemed to be ‘at risk’ was taken from reports with the removal of any patients who were discovered to be deceased).

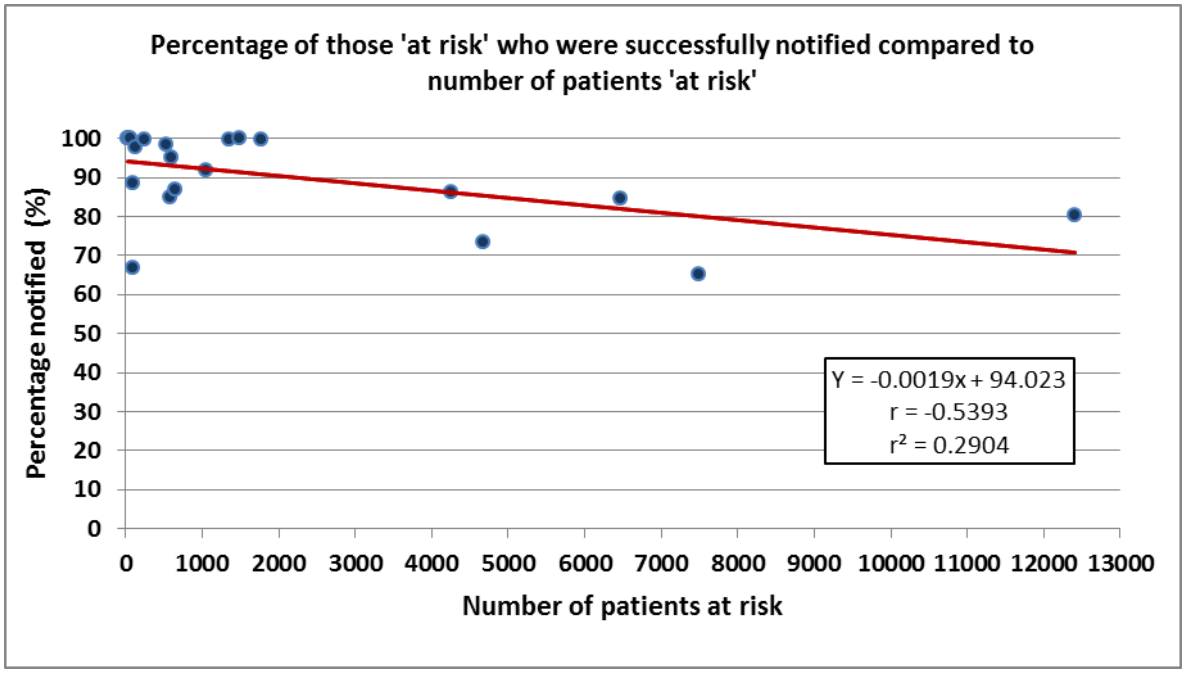


Figure 12: Scatter plot graph with linear trend line showing percentage of patients notified out of those deemed to be at risk against number of patients deemed to be at risk. Pearson correlation coefficient (r)= -0.5393, p=0.014 (r^2) = 0.2904.

With regard to the aim of detecting HIV (or other BBV) infection, this is dependent on the number of notified patients that are tested. Figure 13 shows that BBV testing uptake can be highly variable with a range of 3.5% to 100% of notified patients coming forward. Just over a third of incidents tested less than 50% of notified patients and a similar proportion tested over 80%.

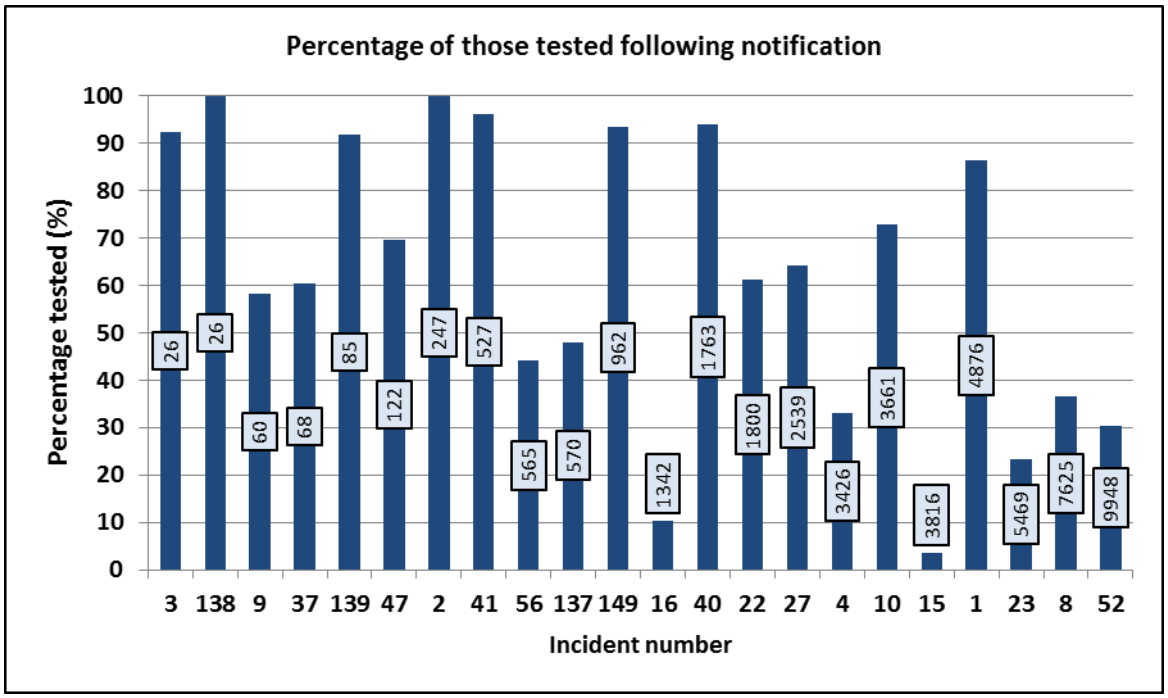


Figure 13: Bar chart showing percentage of patients who were tested out of those successfully notified in both dental infected HCW and dental infection control breach related PNEs. *(Each bar contains the total number of patients deemed to have been notified in each incident.)*

Uptake of testing also appears to have a moderate negative correlation with the number notified as the percentage of those coming forward for testing decreases with increasing numbers (Figure 14).

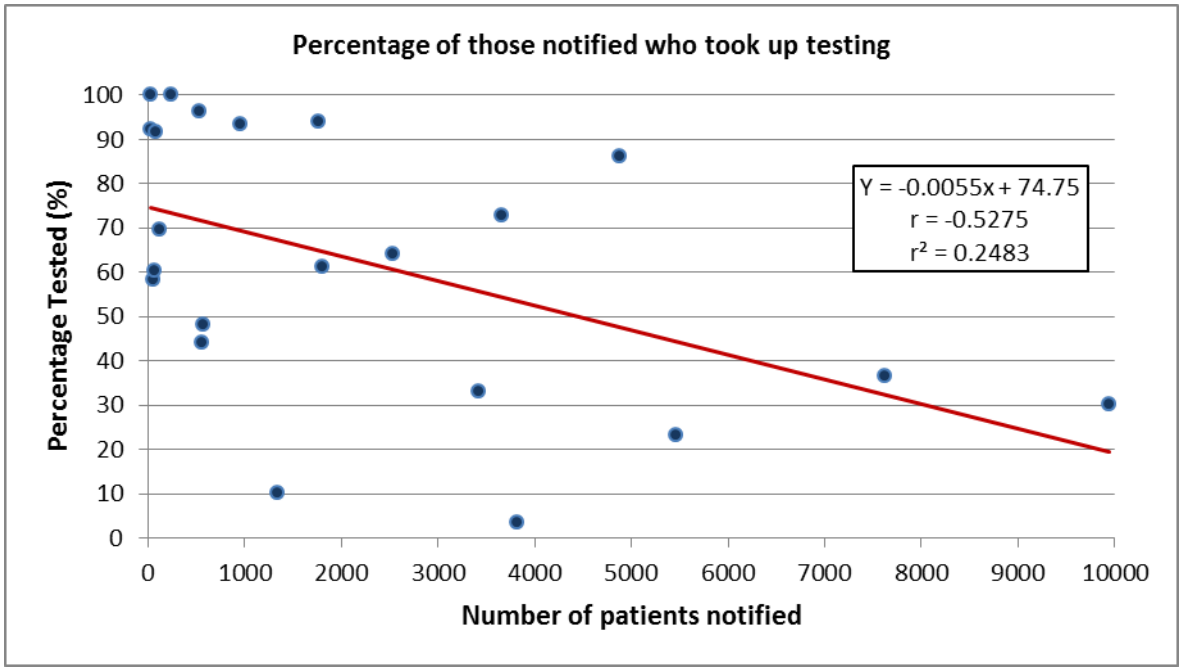


Figure 14: Scatter plot graph with linear trend line showing percentage of patients tested out of those notified against number of patients notified. Pearson correlation coefficient (r)= -0.5275, p= 0.018 (r^2) = 0.2483.

Stakeholder consultation respondents theorised that uptake of testing may also be connected to the language used in the notification letter. Unfortunately, only nine publications provided information regarding notification letter content.

Based on limited information, it appears as though there is no relationship between notification letter language and testing uptake (Table 26). A risk description of "extremely low" was associated with high testing uptake percentages of 96.2% and 94% whereas the potentially less reassuring description of "small" was associated with a lower uptake of 33.2%. The term "out of an abundance of caution the ADH recommends" resulted in a high uptake of 93.6%. These data, although limited, suggests that there are other factors at work and that language in the letter may not have significant effect on testing uptake. The only data item which exhibited a logical correlation, was testing uptake following patients being told "no further action is required on your part", which resulted in a low uptake of 10.2%.

Table 26: Percentage of those tested presented with description of risk in letter and language used in relation to advised action regarding BBV testing

Incident	Percentage tested (%)	Description of risk in letter	Language used to encourage/discourage/describe testing
41	96.2	"the infection risk is extremely low"	
40	94.0	"we believe the health risk is extremely low" "it was not possible to rule out the possibility that one or more patients were exposed to an infection"	
149	93.6	"It is important to know that at this time no illnesses have been linked to this situation and that we do not know whether you were actually exposed to infectious material. What has been identified thus far is only the potential for disease transmission."	Out of an abundance of caution, the ADH recommends that you be screened for infection.
1	86.3	"May have been exposed" "We do not know if you were personally exposed"	
10	72.8	"very low"	
47	69.7	we believe, based on the most current reliable scientific evidence, that the likelihood that you were infected with the HIV virus as a result of contact with this student is extremely low	"We strongly recommend that you be tested"
22	61.1	"reassure you that it is unlikely you have been infected" "you understandably are frightened"	"urge you to seek the free testing and counselling that is available" "For your peace of mind, I suggest you please contact the local health department for free testing and counselling"
4	33.2	"small" "impossible to estimate this risk accurately"	"the health board believes that patients should be informed and have the opportunity for appropriate counselling and testing for these infections"
16	10.2	"possible infection risk" "low"	"no further action is required on your part"

Table 27 presents data on the diagnoses identified as a result of 37 PNEs. It shows that of 21 exercises, which resulted in the diagnosis of at least one BBV-infected person, only in one third of cases was the incident conclusively excluded as the source of their infection (through identification of alternative risk factors and/or genetic sequencing).

Table 27: Diagnoses found following the testing phases of 37 PNEs including findings from further investigation of these identified infections.

Incident	Number tested for HIV	Number tested for HCV	Number tested for HBV	Diagnoses found, including prevalence in persons tested (%)	No of diagnoses that were new[h] to patients	New[h] diagnoses with other risk factors besides dental treatment	Was genetic sequencing performed for all relevant diagnoses? (new[h] diagnoses with no other risk factors)
1	4208	4209	4209	96 (2.28%) HCV[a] 6 (0.14%)HBV 4 (0.09%)HIV	63 HCV	at least 32 out of 63HCVs	N 44 HCV samples genotyped
2	247	247	247	11 (4.45%) HBV 0HCV 0HIV	NM	NM	NM
3	24	24	24	3 (12.5%)[b] HBV(res) 0HIV 0HCV	NM	2 out of 3 had RFs	N, the 1 HBV (res) with no other RFs was not genotyped
4	1137	1137	1137	1 (0.09%) HBV(res) 12 (1.29%)HCV 0 HIV	9HCV 1HBV	NM but 7 out of all 13 had RFs	8 out of 13 could be compared
8	2780	2780	2780	9(0.32%) HBV 4(0.14%) HCV	3 HBV and 3 HCV	6 out of 6 (but 1 extra HBV case diagnosed after treatment but not via PNE[c])	7 out of 13 positive cases (does not specify which 7 but one was patient[c]) no matches found
9	N/A	35	N/A	0 HCV	N/A	N/A	N/A
10	2665	2665	2665	11(0.41%) HCV 20(0.75%) HBV(res)[d] 0HIV	All new	at least 7 HCV had risk factors At least 9 HBV had risk factors	N 3 were not, but all had RFs

11	~750	~750	~750	0HBV 0HIV 0HCV	N/A	N/A	N/A
15	135	135	135	2(1.48%) HBV(res) 0HCV 0HIV	2 out of 2	2 out of 2 (1 from high incidence country, 1 extensive travel)	N/A
16	137	137	137	5 to 7	(e)	(e)	(e)
18	~2250	~2250	~2250	0HIV 0HBV <5(max 0.18%) HCV	<5 out of <5	NM	Y
19	4521	4521	4521	8(0.18%) HCV, 2(0.04%) HBV 0HIV	5 HCV	NM	NM
22	approx 1100	N/A	N/A	10(0.83%) HIV[f]	10 out of 10	4 out of 10	Y all 10, 6 with no RFs matched.
23	1279	N/A	N/A	28(2.18%) HIV	28	24 out of 28	N 2 out of 4 without RFs were not sequenced.
24	N/A	N/A	493	0HBV	N/A	N/A	N/A
25	61	N/A	N/A	0HIV	N/A	N/A	N/A
27	1631	N/A	N/A	0HIV	N/A	N/A	N/A
28	3096	N/A	N/A	0HIV	N/A	N/A	N/A
29	154	N/A	N/A	0HIV	N/A	N/A	N/A
37	41	N/A	N/A	0HIV	N/A	N/A	N/A
40	1658	1658	1658	NM	2 HBV, 2 HCV	NM	"did not find evidence of clustering"
41	507	507	507	7(1.38%) HCV 2(0.39%) HBV 0HIV	7 out of 7, 2 out of 2	NM	NM

42	389	389	389	5 HBV + 1(0.25%) HBV found as part of PNE	NM	0 out of 4 index pts had RFs, 5th lost to follow up. Extra HBV pt found through PNE NM.	N, 4 index pt compared all had genotype D and identical in partial sequence
47	85	N/A	N/A	0HIV	N/A	N/A	N/A
52	3011	3011	N/A	2(0.07%) BBV	NM	NM	NM
54	389	389	389	5(1.29%) HCV(res)	5 out of 5	NM	"no linked pairs were established"
55	37	N/A	37	0HIV (HBV NM)	N/A	N/A	N/A
56	248	249	248	1(0.4%) HIV[f] 3 (1.2%) HCV 19 HBV(res) and 1 HBV(active) (8.1%)	1/1 HIV, 1/3 HCV, 20/20 HBV	22 out of 22	NM
57	around 10,000[g]	around 10,000[g]	around 10,000[g]	17(0.17%) HBV 8(0.08%) HCV 1(0.01%) HIV	NM	9 had RFs, 9 had possible RFs, 8 had none	N
61	>500	N/A	N/A	0HIV	N/A	N/A	N/A
64	630	N/A	N/A	0HIV	N/A	N/A	N/A
110	899	N/A	N/A	0HIV	N/A	N/A	N/A
137	~274	N/A	N/A	0HIV	N/A	N/A	N/A
138	26	N/A	N/A	0HIV	N/A	N/A	N/A
139	78	78	78	0HIV 0HBV 0HCV	N/A	N/A	N/A
140	962	N/A	N/A	35(3.6%) HIV	NM	33 out of 35	N
149	900	N/A	N/A	5(0.56%) HIV	5 out of 5	4 out of 5	Y, all 5 different

a = 6 of these were household contacts of the dentist, not patients
b = If including source and index case (5/26), prevalence would be 19.23% HBV
c = Patient diagnosed after dental treatment but before PNE. Patient is not included in diagnoses found through the exercise. Patient's blood sample did undergo genetic testing and did not match the other

samples.
d = 1 person had both HCV and HBV(res)
e = “no new positive cases of blood borne infection were identified/detected/linked to the period of risk of the incident” (Unpublished report)
f = Includes index case
g = based on looking at overall New South Wales testing and seeing a 10,000 person increase from previous months.
h = patients were newly diagnosed and had not been previously aware of their infection or had their infection diagnosed before the PNE.

RFs = Risk Factors
NM = not mentioned
(res) = Resolved infection/viral clearance following infection. Viral particles are no longer circulating in the blood stream. Genotyping and/or genetic sequencing cannot be performed.
(active) = Active infection, viral particles and markers are circulating in the blood stream

During data extraction, incident outcomes were categorised as green, orange or red. Green values represented those data items that were clearly and consistently presented in the literature, red values denoted missing information and orange values represented information that had been contradicted or presented in an unclear manner (Figure 17; Table 27).

4.4.1.3 Influential factors behind the decision to notify patients

The stakeholder consultation revealed that the perceived level of transmission risk involved in an incident was the most important influential factor behind the decision to notify. Table 28 outlines numerical risk estimates presented in seven papers and reports.

Table 28: BBV transmission risk estimations presented in dental incident reports/papers

Incident	Quoted risk of HBV (eAg+) transmission	Quoted risk of HBV (eAg-) transmission	Quoted risk of HIV transmission	Quoted risk of HCV transmission	Quoted risk of overall BBV transmission	Was a PNE conducted?
5	0.00003 per 1000 pts seen	NM	0.000003 per 1000 pts seen	0.00006 per 1000 pts seen	0.000093 (almost 1 in 10,000) per 1000 patients seen	No
6	0.00003 per 1000 pts seen	NM	0.000003 per 1000 pts seen	0.00006 per 1000 pts seen	0.000093 (almost 1 in 10,000) per 1000 patients seen	No
7	0.00003 per 1000 pts seen	NM	0.000003 per 1000 pts seen	0.00006 per 1000 pts seen	0.000093 (almost 1 in 10,000) per 1000 patients seen	No
13	1 in 63,500	1 in 86,500	1 in 10,500,000	1 in 264,000	1 in 65,000 -1 in 52,000	No
14	1 in 59,000	1 in 63,000	1 in 118,000,000	1 in 1,224,000	1 in 60,000 - 1 in 56,000	No
17	NM	NM	1 in 26,000,000- 1 in 6,900,000	1 in 179,000- 1 in 48,000	1 in 117,000-1 in 31,000	Yes (but without recommendation for testing)
21	NM	1 in 800,000	1 in 300,000,000	1 in 25,000,000	1 in 770,000	No
NM = Not Mentioned						

Perceived transmission risk was associated with the nature of the breaches that had occurred. For the 42 incidents that involved infection control failures, nine did not contain enough detail to establish the precise breaches that had occurred. Figure 15 shows how frequently different breaches were associated with the other 33 incidents. Of these, 76% featured multiple breaches. The most common failure was use of unsterilised instruments (13/33) followed by poor disinfection (11/33).

A statistically significant association was not identified between breach type and notification (Fisher's Exact Test, $p = 0.561$) However, those that appeared most likely to result in notification included poor training, not changing gloves as regularly as required, absence of disinfection, poor sterilisation and the illegal practice of dentistry.

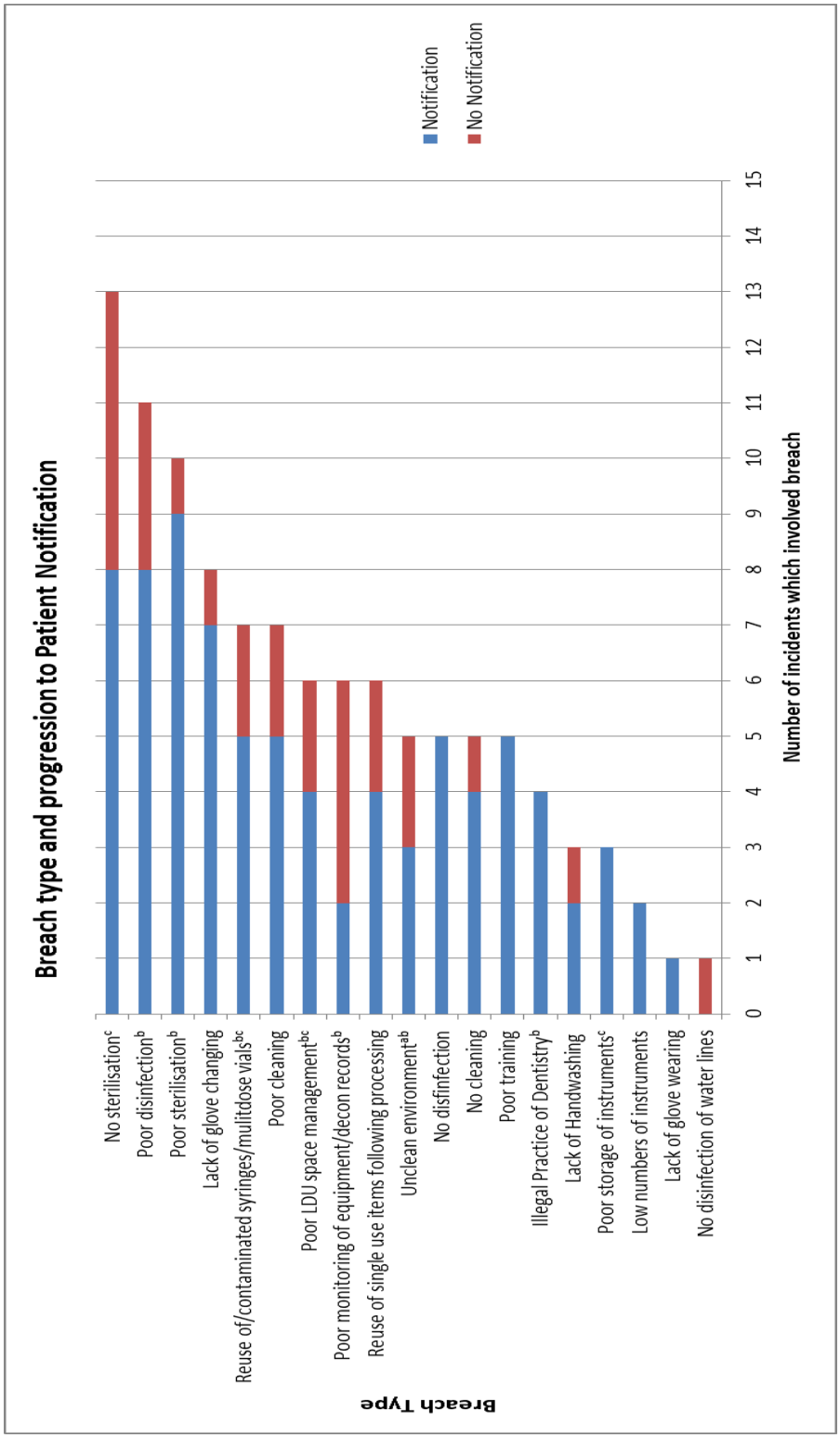


Figure 15: Number of dental incidents involving specific breaches and whether or not they proceeded to patient notification.

(AWD = automated washer disinfector. LDU = local decontamination unit. a= Breaches associated with a patient-to-patient HBV transmission in the U.S.A (Redd et al 2007) b= Breaches associated with a patient-to-patient HCV transmission in the U.S.A (Oklahoma State Department of Health 2013) c= Breaches associated with transmission of HBV to 3 patients and 2 staff members in the U.S.A (Radcliffe et al 2013) 'Cleaning' refers to manual cleaning or use of the ultrasonic bath, 'Disinfection' refers to use of an AWD. 'Poor disinfection' refers to improper AWD use/functioning or use of chemicals in place of an AWD. 'Sterilisation' refers to use of a vacuum or non-vacuum steam steriliser.)

Reasons given in the literature for notifying patients or not notifying patients are summarised in Tables 29 and 30. Each reason was assigned a broad, descriptive category to facilitate analysis.

Perceived transmission risk was the most frequently cited reason for both proceeding and not proceeding to notification following an infection control incident (Tables 29 and 30). Specifically, investigators decided not to proceed due to the low risks involved (77%) and the anxiety that would be caused to patients (38%). Proceeding to notification following an infection control breach was linked to the perception of high risk (39%), the desire to be transparent (22%) and advice from experts (22%).

Table 29: Reasons presented for not notifying patients. 13 dental infection control incidents for which data were available.

Incident Number	Likelihood of detecting transmission small/low risk	Distress/anxiety caused to patients	High Cost	Experience/Data/Literature around other PNEs	Lack of supporting evidence to confirm allegations	No known transmissions	In addition to breaches HCW not infected	Effect on trust between community and dental care	Alternative risk factors for diagnoses identified	Not mentioned	Other
5	✓	✓	✓								
6	✓	✓	✓								
7	✓	✓	✓								
12	✓				✓						
13	✓	✓		✓	✓	✓	✓	✓			✓ a
14	✓	✓		✓		✓	✓	✓			✓ b
21	✓										
33	✓										
34									✓		
35					✓						✓ c
58	✓										✓ d
59	✓			✓							
60										✓	
Total	**10**	**5**	**3**	**3**	**3**	**2**	**2**	**2**	**1**	**1**	**4**

a = Disbenefit versus benefit, predicted low uptake of testing
b = Practice had good records of adherence to standards. Similar recent decision made by peers
c = Low prevalence of BBVs in population
d = Minimally invasive procedures performed

Table 30: Reasons presented for notifying patients. 23 dental infection control incidents for which data were available.

Incident Number	Risks associated with breaches	Advice from experts/expert panels	Transparency/duty to notify/pts right to know	Already had proven transmission(s)	Guidance/ Policy/ Advice from experts	HCW also infected	Prevalence of local area higher	Uncertainty surrounding/ unusual case	Transmissions documented in past	Concerns regarding dental treatment quality	Treatment for BBVs now more effective/ better	Research opportunity	Procedures performed	Not mentioned
1				✓								✓		
2					✓				✓					
3				✓										
4														✓
8		✓					✓							
9	✓	✓												
10		✓				✓								
11			✓											
15	✓		✓											
16	✓													
17			✓											
18	✓							✓						
19	✓													
37			✓						✓				✓	
40			✓		✓									
42				✓										
45	✓					✓								
54	✓	✓												
56	✓	✓								✓				
57	✓						✓				✓			
62														✓
139								✓						
145														✓
Total	**9**	**5**	**5**	**3**	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**	**1**	**3**

4.4.1.4 Financial cost

Only 11 out of 44 incidents that proceeded to notification, presented financial cost information. Table 31 outlines the high costs associated with PNEs (range £14,958.90 - £488,609.94, $\bar{x}$ = £176,298.27). There appears to be no correlation between cost and numbers of those 'at risk' (r= 0.44 r^2= 0.19 p= 0.227) or number of BBVs tested for (r= 0.25 r^2= 0.062 p= 0.452) but there does appear to be a fairly strong, positive relationship between cost and numbers tested (Figure 16).

Table 31: Financial cost of notification exercises presented with number of those for which notification was attempted, number of patients tested and number of BBVs tested for.

Incident	Location	Attempted to notify	Numbers tested	Cost (£)	Number of BBV infections tested for
1	USA	5999	4209	488,609.94	3
8	UK	7625	3096	311,573.78	3
28	UK	5929	3096	300,000.00	1
19	UK	22000	4521	250,000.00	3
56	UK	591	249	180,000.00	3
18	UK	5100	2250	132,000.79	3
17	UK	5100	0	104,998.29	0
9	UK	60	35	85,936.00	1
11	UK	1500	750	40,000.00	3
27	USA	1489	1631	32,389.64	1
15	UK	3972	135	14,958.90	3
For US incidents, values have been converted to British pounds for inclusion in this table.					

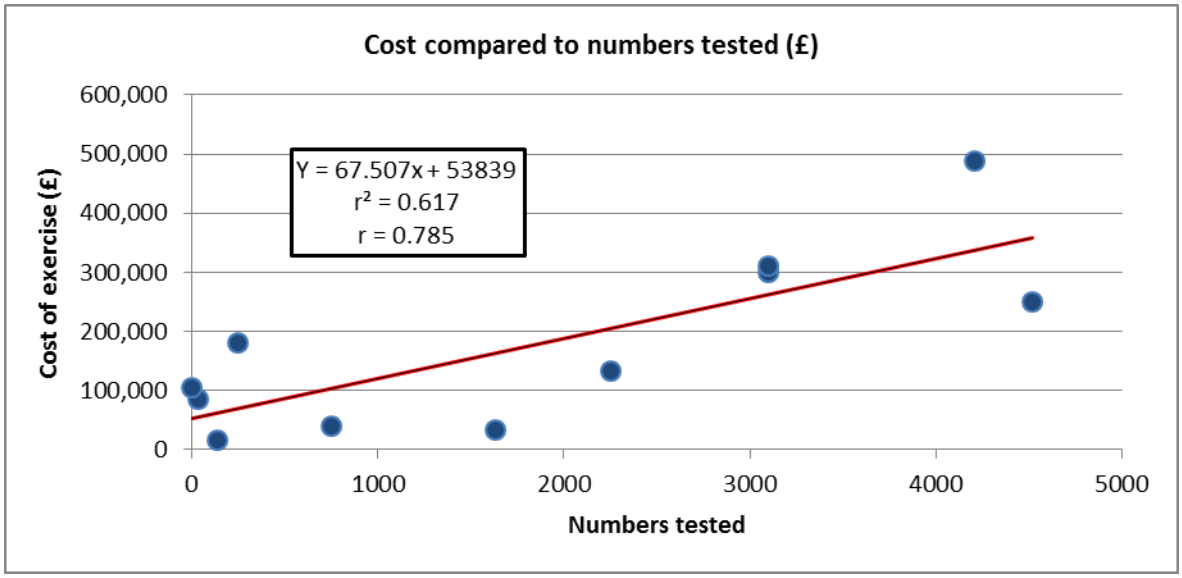


Figure 16: Scatter plot graph with linear trend line. Numbers of patients tested against financial cost of PNE. Pearson correlation coefficient (r) = 0.785 (r^2) = 0.617 p= 0.0041.

4.4.1.5 Missing and/or vague information

Incident data sources often presented vague information or had missing data. During data extraction, incident outcomes were categorised as green, orange or red. Green values represented those data items that were clearly and consistently presented in the literature, red values denoted missing information and orange values represented information that had been contradicted or presented in an unclear manner (Figure 17; Table 27).

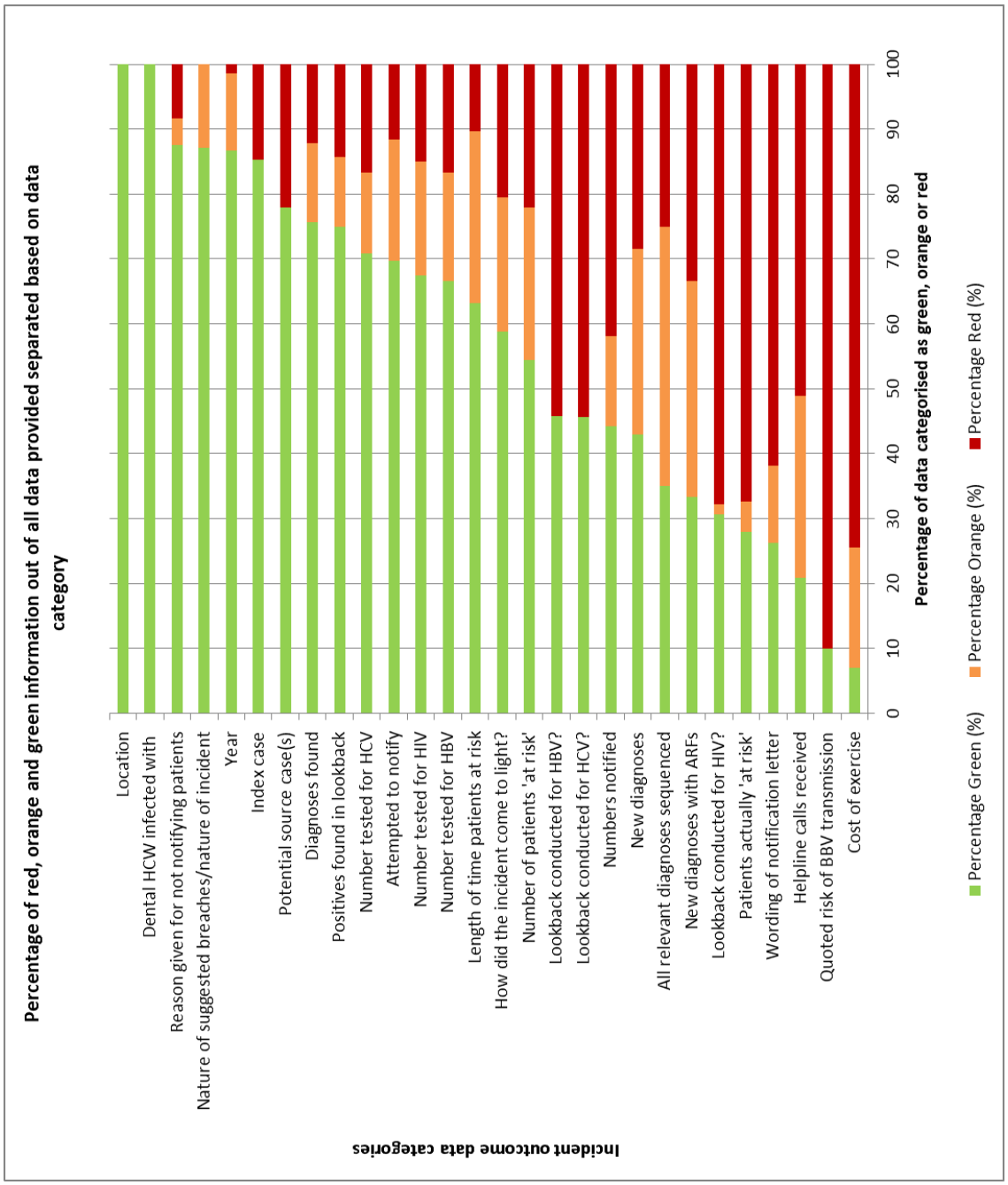


Figure 17: Incident outcomes and the frequency with which they feature in reports or publications.

Figure 17 demonstrates that information sources always presented clear data on where the incident had occurred and, when applicable, what infection the HCW had. A numerical estimation of the BBV transmission risk was most often missing from reports (90%) and when reported, a high proportion of information regarding sequencing and risk factors of identified infected patients was vague in nature (40% and 33% respectively).

4.4.2 Narrative synthesis

This narrative synthesis is structured around the factors, identified from the literature, as influencing the decision to notify patients following a dental 'BBV transmission risk' incident (Table 32).

Table 32: Structure of narrative synthesis

Influential Factor	Section
Context	4.4.2.1
Perceived Transmission Risk	4.4.2.2
Benefits of notification to the patient, the managing organisation and the wider scientific community	4.4.2.3
Negatives of notification to the patient, the managing organisation and the wider scientific community	4.4.2.4
Standards and expectations based on governing bodies, public opinion and actions of peers	4.4.2.5
Perceived Complexity	4.4.2.6
Design of Notification - Can the process be amended to lessen the impact of negative consequences?	4.4.2.7
Feedback on PNE outcomes	4.4.2.8

4.4.2.1 Context

Comer et al (1991) stated that decision-making is done in an environment of "evolving guidelines and regulations" with changes to "societal and professional philosophies".

The authors of the papers reviewed, highlighted that public fear surrounding HIV was particularly heightened during the mid-late 1980s (Pinching 2000; Hancocks 2006) and that reassurance following an incident was perhaps more important during this time (Taylor 1992). One may assume that fear was heightened in this era by a lack of knowledge and treatment options as well as the fact that

prognosis, following infection, was poor (Closen 1996), however, Taylor (1992) and Cottone et al (1992) suggested that public anxiety may also have been intensified at this time by reports of the Acer case transmissions (the 'Florida' dentist case). Currently, no papers provide concrete evidence to support the idea that the public's feelings are now more in line with scientific evidence which shows risks of transmission are low.

It is worth noting that the dental environments reported to be associated with BBV transmissions of the past, no longer reflect today's settings. Infection control standards have improved since the early 1990s with HBV immunisation of HCWs, glove use, separate LDUs, introduction of AWDs and an increase in the use of single-use items being just a few examples of modern-day improvements that reduce the risk of BBV transmission (Croser 2006; Cleveland et al 2016; Hancocks 2006).

Just as modern infection control practices may reduce risk and thus the need for PNEs, some argue that as BBVs can now be more effectively treated and managed, the justification for notification and identification of infected individuals is actually stronger (Weaver 2014; Hancocks 2006; Croser 2006).

Finally, the papers reviewed reported that decision makers may be influenced by trends in public opinion. Pinching (2000) outlined that the modern patient expects a decreased display of "professional paternalism" and a higher level of respect for their personal opinions and wishes. Maguire et al (2016[a]) stated that in recent times there has been "a call for open communication" when things go wrong. These ideas are reflected by the recently introduced statutory, UK organisational Duty of Candour (GMC 2015; The Scottish Government 2018).

4.4.2.2 Perceived transmission risk

The papers reviewed identified a number of aspects that contribute towards the perceived transmission risk associated with an incident. These included the nature of the infection control breach, the presence of index patient(s) or proven transmissions, the types of dental procedures being performed, the nature of the health care environment, the integrity of the practice or individual involved, the type of pathogen(s) involved, the background prevalence of BBVs in the community and the circumstances surrounding historic dental transmissions.

When assessing transmission risk one may wish to consider a calculated numerical estimation. Those provided in the literature, however, almost exclusively relate to the transmission of HIV from HCW to patient and are significantly out-dated (Appendix 16). Weller (1999) advised readers that estimations such as these represent an average and do not take account of

changing circumstances or context, for example, changes in the infectivity level of the HCW, performance of different procedures or variation in operator skill.

Alternative methods have been used historically to estimate HIV transmission risks numerically, including consideration of:

- Historical patterns of HBV transmission in healthcare. HBV is more infectious than HIV and similarly spread via blood-to-blood contact. There are more reports of HBV transmissions meaning a larger evidence base is available for analysis (Chamberland and Bell 1992; Robert and Bell 1994).

- How often transmission occurs in the other direction ie: from patient-to-HCW using figures associated with risk of transmission following percutaneous injury (0.3% HIV, 3% HCV, 30% HBVeAg+) (Closen 1996; Comer et al 1992; Millership et al 2007; Robert and Bell 1994).

Transmission risks were most often qualitatively described with IMTs concluding that BBV transmission risks associated with dental infection control breaches or infected dental HCWs were 'low' and more often 'very low', 'minimal' or 'negligible' (Mason et al 2008; Heuer 1992; unpublished reports 2001-2017).

4.4.2.2.1 Perceived transmission risk: details of past transmission events

<u>HIV-infected dental HCWs</u>

In 1990, David Acer, a dentist in Florida, was reported to have transmitted HIV to six of his patients. These transmissions were identified due to discovery of an index patient with no other risk factors followed by the detection of five other patients, who also had no alternative explanation for their infection (Ciesielski et al 1994). All six patients had viral sequences that closely resembled the dentist's viral strain and were distinctly different from local controls. (Further details regarding this extensively investigated and reported case are provided in Appendix 17).

Existence of this case, and specifically the uncertainty surrounding the precise route of transmission, has had a strong impact on the perceived risks of receiving treatment from BBV-infected HCWs (Longfield et al 1994; Comer et al 1992; Mishu and Schaffner 1994). The simple fact that transmission was proven to have occurred is enough evidence to support the concept that patients have been placed at some level of risk following discovery of an infected dentist (Irwin and Millership 2002; Weinstein and Keyes 1991). In fact, many reports of PNEs, which occurred not long after the Acer case, cited these transmissions as being their main reason for notifying and testing patients (Longfield et al 1994; Cohen et al 1992; Arnow et al 1993). More recently, however, this incident is used to

highlight the rarity of HCW to patient HIV transmission (Cleveland et al 2016; Croser 2006).

Authors advised that the Acer case should influence neither the understanding of HIV transmission risks in the dental setting nor the creation of policy and/or guidance (Hardie 1993) as: a) the route of transmission remains unknown, b) its investigation and findings are mired in a degree of mystery and c) it represents a cluster of transmissions. Chamberland and Bell (1992) explained that clusters "represent unusual and often incompletely understood events where the risk of transmission was greatly increased and cannot be used to estimate transmission risk across the board".

There have been many reports of PNEs executed in response to HIV-infected dentists that have not identified transmission. In the US, by the year 2000, of 22,579 patients treated by 66 HIV infected HCWs (29 of whom were dentists or dental students), no HCW-to-patient transmissions were identified (Croser 2006). Authors emphasised, however, that these results only represent approximately 20% of the infected HCWs' patients and that it is unclear which patients received more or less invasive procedures (Robert and Bell 1994). In the UK, 22 look-backs, which involved testing approximately 7000 patients, from 1988-2001, did not result in the discovery of any associated transmissions (Scully and Greenspan 2006).

HBV-infected dental HCWs

HBV transmission from dentist-to-patient has not been documented since 1987 (Cleveland et al 2016). From 1972 to 1986, however, there were nine HBV transmission clusters associated with ten dentists (Blatchford et al 2000), eight of whom were HBeAg positive, a marker of high infectivity. All had a high viral load, a history of sharps injuries and were performing invasive procedures without the use of gloves (Chamberland and Bell 1992; Blatchford et al 2000). In one case investigators could show a correlation between patient infection and numbers of extractions undergone (Ciesielski et al 1991). Evidence of these past, multiple HBV transmissions has been cited as a reason for the notification of patients (Longfield et al 1994).

HCV-infected dental HCWs

There has never been a documented transmission of HCV from dental HCW to patient (Condon 2008; Croser 2006; Cleveland et al 2016).

Patient-to-patient transmission

There have been three reported incidences of patient-to-patient transmission within the dental setting, all of which occurred in the USA. In 2002, HBV was

transmitted from one patient to another in an oral surgery setting. The index patient was treated two and a half hours after the source patient and both patients underwent multiple extractions with use of IV medications. Route of transmission in this case was never established but contamination of environmental surfaces was postulated (Redd et al 2007).

In 2013, 1,137 patients were treated in a temporary dental clinic, staffed by 750 volunteers over a two-day period. HBV transmission occurred amongst three patients and two volunteers, again with an unknown route of spread. The clinic was set up in a school gymnasium with no one allocated to oversee infection control, no barriers between treatment stations and with patients being asked to transport their own instruments and used anaesthetic syringes between stations (Radcliffe et al 2013).

In 2015, one patient-to-patient HCV transmission was identified following testing of patients treated at an oral surgeon's practice where multiple infection control breaches were discovered. The most likely mode of transmission was deemed to be re-use of contaminated vials (Oklahoma State Department of Health 2013).

UK investigators acknowledged that although these transmissions occurred out with the UK (where the delivery of dental service differs) they are proof that transmission can occur (Conrad et al 2011; Mason et al 2008; Henderson et al 2017).

Following UK based dental infection control breach incidents, published sources reveal that 8735 exposed patients have been tested with no identified transmissions to date (Conrad et al 2011; Close et al 2013; Roy et al 2005; Mason et al 2008; Henderson et al 2017).

Authors advised caution when estimating risks through consideration of historic transmissions, as they felt that the number of transmissions identified may be markedly under-estimated. Not all patients are tested and BBV infection can go undetected due to its asymptomatic disease course (Redd et al 2007).

4.4.2.2.2 Perceived transmission risk: proven transmission identified as part of initial investigation

Many authors suggested that PNEs are clearly indicated by the existence of proven transmission. In fact, decisions regarding patient notification are reported to be more complex and nuanced if there is absence of an initially identified transmission (Maguire et al 2016[a]; CDC 2019[a]). UKAP strongly advise notification if transmission has already been identified (Close et al 2013) and many authors outlined that this should be standard practice (Conrad et al 2011; Arnow et al 1993). Mason et al (2008) supported this approach by indicating that if a transmission or index case has not been identified the risk associated with an

incident is probably very low whilst Mishu and Shaffner (1993) postulated that as transmissions are likely to occur in clusters (such as in the Acer case) starting the investigation with an index patient or known transmission may be more prudent and fruitful than focusing solely on the infected HCW.

4.4.2.2.3 Perceived transmission risk: dental HCW/practice professionalism

Two cases demonstrate the importance of considering a practice's or individual's integrity and professionalism. In 2000, Roy and colleagues (2005) investigated the source of a patient's HCV diagnosis as it was suggested that dental treatment may have been the source of infection. Cross matching revealed no excess HCV infection in the practice population and there were no other samples with which to compare the index case's viral strain. The dentist had been removed from the dental register in 1997 and was being investigated for fraud. In 2001, the dentist revealed in court that they had used unsterilised instruments on patients. In light of this new information a PNE was initiated (Roy et al 2005).

A similar scenario arose in 2013 when allegations of re-use of single use items were made against a Scottish dentist (Henderson et al 2017). During the investigation of these allegations the practice was uncooperative and its actions suspicious. The practice delayed inspections and the IMT was provided with fraudulent documents. Staff appeared to have been coached in preparation for investigative interviews and expressed consistent, mimicked answers to questions. The IMT decided to conduct patient notification but not offer testing. Shortly after the notification exercise, confirmation of earlier allegations, including the addition of more serious ones emerged and the IMT was inclined to repeat the PNE, this time with the offer of testing (Henderson et al 2017). Both these cases demonstrate that evidence of fraudulent or unprofessional behaviour can indicate the need for a PNE as initial investigative details or allegations cannot be relied upon.

4.4.2.2.4 Perceived transmission risk: healthcare environment

It was suggested in some papers that the quality of infection control employed by those involved in incidents may be linked to the healthcare environment. Radcliffe et al (2013) outlined that locations such as temporary clinics may increase transmission risk as they are challenging to establish and run in a way that complies with infection control standards due to close quarters and poor water supply access whilst Comer et al (1992) suggested that a dental school environment is less concerning as infection control processes are likely to be compliant.

Three of the four recorded dental BBV transmission cases occurred in unique settings which do not mirror UK high street practice; two in an oral surgery environment (Redd et al 2007; Oklahoma State Department of Health 2013) and one in a temporary dental clinic (Radcliffe et al 2013).

4.4.2.2.5 Perceived transmission risk: nature of the dental procedures undergone by patients

Types of procedure undergone by patients rarely appeared to influence the response in the papers reviewed. Intuitively, however, procedures that are more invasive, resulting in greater exposure of patient tissues and production of blood, would be associated with a higher risk.

Performance of dental extractions may be linked to an increased chance of transmission. This procedure was associated with three out of the four proven BBV transmission cases. Both the source and index patients in the New Mexico and Tulsa cases underwent extractions as well as all three infected patients from the West Virginia investigation (Redd et al 2007; Oklahoma State Department of Health 2013; Radcliffe et al 2013) (Table 25).

The UKAP EPP categorisation assesses the risk of BBV transmission from HCW-to-patient. Procedures are graded not only based on the capacity for patients' tissues to be exposed but also the chances of HCW injury (PHE 2016). This categorisation is not necessarily applicable to assessing the risk associated with infection control breaches.

In the early 2000s, UK incident investigators acknowledged that the UKAP EPP definition of the time[9], meant all patients who had undergone dental treatment beyond examination with a mirror alone were considered 'at risk'. This meant that type of procedure became an irrelevant factor, with attempts to notify all exposed patients being made (Gaudoin 2000; Irwin and Millership 2002).

In 2008, a UK IMT chose to create its own categorisation of procedures when managing a dental infection control breach (Mason et al) (Table 33). The team did not, however, use this novel categorisation to establish which patients were to be notified but instead used it post-notification to establish if there was a connection between BBV infection and nature of procedures undergone (Mason et al 2008).

Similarly, Longfield et al (1994) used procedure data post-notification to report the percentage of patients, tested as part of their PNE, who had one of seven types of dental procedure. In fact, only in the reports of four out of the 44 incidents that resulted in notification, has procedure type been used to limit the

[9] In 2016, dental procedures were re-categorised, with many more procedures being classed as non-exposure prone (PHE 2016).

number of patients notified (Arnow et al 1993; Cottone et al 1992; People with AIDS Coalition of New York 1999; Fitzgerald et al 2010). More often papers reported assessing procedures after notification, to look for correlations or understand the scope of dental treatment performed by dentists (Dickenson et al 1993; Longfield et al 1994; Mason et al 2008). Table 33 outlines incidents where authors graded dental procedures and details of how these categories were utilised in the management or analysis of an incident.

Table 33: Dental incidents where IMTs categorised dental procedures performed on exposed patients. Presents information on how the categorisation was used to influence numbers notified or explore specific correlations.

Categorisation of dental procedures conducted	Type of incident	Did categorisation influence which patients were notified?	Country and Reference	Were the categories used in another way?
All procedures except exam with mirror, considered EPP	Infected HCW	No, attempted to notify all exposed patients. Decision of who to notify/test was not based on procedures.	Irwin and Millership 2002 UK	No
EPP determined by expert group. EPPs were defined as surgical extractions, dento-alveolar surgery, implant surgery and perio surgery	Infected HCW	Unknown. No patients were notified (unclear if this decision was based on procedures)	Condon 2008 Australia	No
All procedures except exam with mirror considered EPP	Infected HCW	No, attempted to notify all exposed patients. Decision of who to notify/test was not based on procedures.	Gaudoin 2000 UK	No
5 categories. Cats 3-5 included extractions, oral surgery procedures, periodontal procedures, prophylaxis and endodontic procedures.	Infected HCW	Yes, those who underwent cat 3-5 procedures notified with option to expand notification, to those who	Arnow et al 1993 USA	No

Cats 1 and 2 included any other procedures involving needles, high speed burs, sharp instruments and those that involved no sharp instrument use.		underwent cat 1-2 procedures, if transmissions found.		
EPP defined as surgical dental procedures, scaling and root planning therapy	Infected HCW	Yes, all patients who had their definition of an 'EPP'	Cottone et al 1992 USA	No
7 procedure categories. 1) oral surgery 2) periodontics 3) prosthodontics 4) endodontics 5) restorative 6) adjunctive 7) other	Infected HCW	No, attempted to notify all exposed patients. Decision of who to notify/test was not based on procedures.	Longfield et al 1994 USA	Established which patients took up testing in relation to the category of their procedure.
Three categories. Incidentally invasive (no sharp instruments except dental explorer, violation of oral mucosa does not happen frequently and injury to HCW is unlikely). Moderately invasive (non-surgical but violation of oral mucosa, use of sharp instruments including burs. Haemorrhage but no gross open wounds eg. non-surgical periodontal therapy, restorative dentistry and non-surgical endodontics.) Surgically invasive (open wounds, XLAs, flaps, excision of lesions)	Infected HCW	No, attempted to notify all exposed patients. Decision of who to notify/test was not based on procedures.	Comer et al 1992 USA	Established the proportion of dental procedures performed by the dentist that fell into each category.
3 categories. Non-invasive, minimally invasive and invasive. Non-invasive included advice, instructions, treatment	Infection control breach	No, attempted to notify all exposed patients. Decision of who to notify/test was	Mason et al 2008 UK	Established whether presence of infection was associated with a category of

planning with no periodontal assessment. Minimally invasive included xrays, denture production stages, fissure sealants, application of topical fluoride. Invasive covered all other procedures.		not based on procedures.		procedure.
NM	Infection control breach	Yes, only those who had extractions were notified	People with AIDS Coalition of New York 1999 USA	No
NM	Infected HCW	Yes, only "those deemed to be at possible medium-high risk of transmission" notified.	Fitzgerald et al 2010 Ireland	No
NM = Not Mentioned				

4.4.2.2.6 Perceived transmission risk: prevalence of BBVs in local population

The contribution of background prevalence of BBV infection to the overall estimated transmission risk is significant and was included in many risk assessment calculations reported in the papers reviewed (Millership et al 2007). Mason et al (2008) cited this as the main reason why risks associated with infection control breaches in the UK are low, rather than as a result of the nature of the breaches involved.

Documented transmissions have tended to occur amongst populations with a higher background BBV prevalence. The transmissions in West Virginia occurred at a time when there had been a seven-fold increase in the reporting of acute HBV infection in the state from 1997-2012 (Radcliffe et al 2013). The Tulsa HCV transmission investigation diagnosed 96 HCV-infected persons following testing of 4209, indicating a high prevalence of 2.3% (Oklahoma State Department of Health 2013). The Acer case PNE not only identified six patients thought to be infected by the dentist but four other cases out of 1,100 patients tested HIV-positive (Ciesielski et al 1991). In the same Florida area, following identification

of two other HIV-infected dentists, Jaffe et al (1994) identified 28 unrelated HIV cases out of 1279 tested and Dickenson (1994) identified 25 unrelated HIV infected patients out of 1192. These figures represent relatively high HIV percentage prevalences of 2.2% and 2.1% respectively.

Prevalence estimations were reportedly made based on knowledge of nationwide BBV infection rates, characteristics of the patient population involved and the proportion of undiagnosed cases (Henderson et al 2017). During the investigation of their incidents, Cheng et al (2013) were acutely aware that in Hong Kong HBV prevalence is high (1-8%) whilst Millership et al (2007) estimated that prevalence would be low in a mostly white and middle class population.

While some papers indicated that a high background prevalence of BBV infection can increase predicted transmission risk, others reported that high levels of population immunisation can reduce it. HBV immunisation was cited as the reason behind limited spread in two incidents, one in the US which found that of 25 patients tested, 16 had been immunised (Redd et al 2007) and one in Hong Kong which identified that 152 of 247 patients tested, had been vaccinated or previously infected with HBV, resulting in immunity (Cheng et al 2013).

4.4.2.2.7 Perceived transmission risk: type of pathogen involved

HBV is the most transmissible BBV followed by HCV and HIV (Irwin and Millership 2002; Croser 2006; Blatchford et al 2000; Close et al 2013). HBV is more environmentally stable (Robert and Bell 1994) and 100 times more infectious than HIV (Dental Protection Ltd 2002). However, as mortality rates were historically higher following HIV infection compared to HBV, the risks were considered comparable between the two viruses (Breo 1993; Shaw 2008). Older papers stated that the "severity of risk outcome contributes to the risk" (Iheukwumere 1997) and that the risk was low but "not so low as to nullify the catastrophic consequences of an accident" (Closen 1996). Arguably this is no longer the case with modern BBV therapy.

Following discovery of a dental infection control breach or infected dental HCW, those managing the incident are primarily concerned about the transmission of BBVs. Other relevant transmissible pathogens include herpes viruses, bacteria, fungi, parasites and prions (Scully and Greenspan 2006; Croser 2006; Cheng et al 2013). Millership et al (2007) and Cheng et al (2013) explained that the focus on BBVs is due to the fact that bacterial infections, if transmitted, will result in short-term, self-limiting illnesses. Furthermore, they may not even be detected during a PNE which takes place long after the incident in question. In contrast to a self-limiting, relatively low impact bacterial infection, Weaver (2014) highlighted that the majority of BBV-infected patients will be unaware of their infection, become chronic carriers of the disease and be at high risk for developing HCC and cirrhosis if they remain undiagnosed.

Millership et al (2007) acknowledged the possibility of prion transmission following a dental infection control breach. They stated, however, that estimating this risk is difficult and that no action, such as testing or treatment, can be taken by patients after they learn of their exposure (Millership et al 2007).

Cleveland et al (2016) highlighted that respiratory infection can also be a concern and may be spread through inhalation of pathogens during dental treatment (Cleveland et al 2016). In 2003, Legionnaires disease was transmitted via dental unit waterlines to an elderly, female patient in Italy, who, unfortunately, died as a result of her exposure (Cleveland et al 2016).

Cheng et al (2013) were clearly concerned about the risks of tetanus in their incident. The authors explained that tetanus vaccination was offered to exposed patients as transmission via dental treatment had been reported in the past (Ajayi and Obimakinde 2011) and because it can be fatal (Cheng et al 2013).

4.4.2.2.8 Perceived transmission risk: nature and/or severity of breaches

As previously outlined, in 2013, following a PNE associated with a Scottish dental infection control breach incident, new, more serious breaches were reported leading to a second round of notification, this time with testing being encouraged (Henderson et al 2017). The second set of reported breaches mirrored the first but included additional allegations of amalgam carriers and ultrasonic scalers not being sterilised (only surface wiped), as well as the re-use of endodontic files, burs, 3 in 1 tips and impression trays following processing (Henderson et al 2017). The decision to promote testing following discovery of these additional allegations shows that these specific breaches were deemed to be more serious meriting an enhanced response.

Breaches involving re-use of contaminated syringes have been associated with many nosocomial transmissions (CDC 2019[a]; Cleveland et al 2016; Shields 1995) and are connected to all four documented dental transmissions (Ciesielski et al 1994; Redd et al 2007; Radcliffe et al 2013; Oklahoma State Department of Health 2013) (Table 25).

4.4.2.3 Benefits of notification to the patient, the managing organisation and the wider scientific community

4.4.2.3.1 Benefits: diagnoses made

BBV diagnosis leads to earlier treatment for affected patients (Gaudoin et al 2000; Hébert 2015; Maguire et al 2016[a]; Blatchford et al 2000) with an associated improved disease prognosis (Radcliffe et al 2013) and reduction of onward transmission (Blatchford et al 2000; Gaudoin et al 2000).

Radcliffe et al (2013) emphasised that very early identification of an incident can also facilitate provision of PEP (for HIV and HBV). This is demonstrated in the management of the 2010 Hong Kong incident (Cheng et al 2010). Cheng and his team (2010) provided HBV prophylaxis following discovery of an infection control breach in a Hong Kong University dental clinic. The breach was identified very shortly after a 'one off' incident which put patients at risk for three days (Cheng et al 2010). Administration of preventative prophylaxis can be an added benefit of notification, but only if the incident has been recent and responses are rapid.

Dickenson (1994) outlined an additional benefit of detecting cases by stating that patients are better able to cope with their disease if they know the source of their infection. This is, in part, shown through Runnel's emotional description of the mental anguish suffered by Kimberly Bergalis (the first patient discovered to have been infected by Dr Acer) when she attempted to understand how she had become infected (Runnells 1993).

4.4.2.3.2 Benefits: using PNEs to highlight the importance of adequate infection control

Making the dental profession and public aware of PNEs can result in a renewed focus on infection control issues and policy. The Acer case resulted in changes to US policy and the proposition of new bills concerning the management of infected HCWs (Green 1992; Gerbert et al 1991).

Authors reflected on their incidents' causes and how a similar event could be prevented in the future, seeing the investigation as an opportunity for learning and improvement (Henderson et al 2017; Comer et al 1991; Eklund and Marianos 2013). Henderson et al (2017) reported that the IMT wrote a letter to the Scottish Chief Dental Officer detailing their concern that routine inspections had not detected any issues regarding the dental practice they later investigated. Pashley et al (1991) reported that after their PNE, infection control standards at the dental hospital had improved and patients were better at spotting issues. Cottone et al (1992) outlined that following their investigation, patient records were much improved and Maguire et al (2016[a]) emphasised how patients had noticed a cleaner, more organised clinic following their PNE.

Conversely, some papers reported that PNEs do not always have the desired effect of infection control improvement. Horowitz (1994[a]) and Gerbert et al highlighted that reporting of transmissions where the route of infection is unknown, can lead to dental HCWs actually losing faith in the compliant infection control methods they are currently employing. Gerbert et al (1991) showed that a significant proportion of dental HCWs do not necessarily respond to transmission reports in a significant way, with only 8% of dentists stating in

1991, that they would change or had changed their infection control practices as a result of the Acer case.

4.4.2.3.3 Benefits: reassuring patients

Many of the papers reviewed, identified the reassurance given to patients through notification and testing as another potential benefit of a PNE (Shaw 2008; Henderson et al 2017; Hancocks 2006; Blatchford et al 2000; Fitzgerald et al 2010). Pinching (2000) stated that this reassurance is even more important when the public are already aware of an incident but have been given an exaggerated or sensationalised description of the risks by the media.

4.4.2.3.4 Benefits: engendering/maintaining patient trust through transparency

Notifying patients was described by some authors as a way of demonstrating a commitment to transparency thereby preserving public trust (Dickenson 1994). Some stated that notification would maintain levels of trust in healthcare (Shaw 2008; Hébert 2015; Maguire et al 2016[a]). Others went further by stating that notification actually enhances and improves patient trust (Dudzinski et al 2010; Blatchford et al 2000).

Heuer (1992) demonstrated how the decision to notify can result in positive media headlines, such as "Northwestern Acts Wisely on AIDS case" whilst Taylor (1992) pointed out that transparency in an investigation's early stages could eliminate the risk of incident details becoming public knowledge via another route, which may create the impression that an organisation is trying to hide information from patients.

4.4.2.3.5 Benefits: PNEs add to the evidence base

In 1999, Weller highlighted that until sufficient evidence was gathered, it would not be possible to state definitively that risks were low and that negative PNE consequences vastly outweighed the need to notify exposed patients. Gathering further data to enhance our understanding of healthcare related BBV transmission, was, however, not perceived by authors as a key reason for conducting notification but an added benefit (Longfield et al 1994; Arnow et al 1993; Jaffe and Liberti 1995), facilitating easier decision-making and creation of policy in the future which in turn would promote utilisation of a PNE response in more specific, high-risk situations (Pinching 2000; Irwin and Millership 2002; Hancocks 2008; Fitzgerald et al 2010).

4.4.2.4 Negatives of notification to the patient, the managing organisation and the wider scientific community

4.4.2.4.1 Negatives: anxiety caused to patients and staff

Many papers outlined the significant anxiety that patients may experience following notification, but few supported their statements with objective evidence of its existence and/or severity (Shaw 2008; Croser 2006; Conrad et al 2011; Hébert 2015; Hancocks 2008; Martin 2006). Indeed, Pinching (2000) suggested that investigators may have a misplaced idea of the severity of anxiety caused, as their exposure to notified patients may solely involve handling complaints or dealing with a small proportion of acutely distressed patients.

The limited evidence provided in papers, both supported and refuted the idea that post-PNE patient anxiety is significant. In 2000, Blatchford et al posted a survey to patients who had been notified of an HBV-infected dentist. Results suggested that anxiety was less extreme than postulated in the literature, as only 15% reported feeling 'very anxious' on receipt of their letter, with 41% feeling 'slightly anxious' (Blatchford et al 2000). These percentages dropped further following contact with the helpline, which was established during the PNE for those affected (Blatchford et al 2000).

The literature review identified three other small studies that had been conducted in relation to anxiety following dental incident notification. These involved call handlers either making note of patients' demeanours or asking them directly about anxiety during helpline phone calls (Pashley et al 1991; Monteith et al 1995; Taylor 1992). Pashley et al (1991) reported that 58% of 153 patients were deemed to be calm, 28% were anxious and 14% angry. These results were mirrored in Taylor's study (1992) where the "vast majority" of patient reactions were deemed to be "favourable" and of around 500 calls, only 1% of patients were very upset, 17% were concerned/apprehensive and 82% had good reactions (Taylor 1992). In contrast to these findings, Monteith et al (1995) found that 74% of 130 patients who had been notified of an HIV-infected dentist reported feeling anxious on receipt of their letter, although in this case patients were asked directly about their feelings and no specific level of anxiety was recorded.

In 1996, Closen explained that the public were very unclear about the infectivity of HIV and subsequently both Shaw (2008) and Croser (2006) emphasised that there remained, a strong, public perception that it is an easily acquired infection. Byers (1993) stated that fear of HIV will not dissipate until a cure or vaccine is discovered whilst Shaw (2008) stated that it was "natural for people to be afraid of catching HIV" but reminded readers that the public's fears

surrounding transmission were not in line with scientific evidence, suggesting decisions should not be based upon predicted anxiety.

Dudzinski et al (2010) emphasised that they did not consider "temporary anxiety" "a significant argument against disclosure" and Canadian courts argued that the stress caused by notification is not as severe as that associated with a psychiatric illness (Hébert 2015). Although current evidence suggests that patient anxiety associated with notification is generally not extreme, there is evidence which suggests a small number of patients will suffer significant anxiety that may continue even beyond receipt of a negative BBV result (Dudzinski et al 2010). This concept is supported by Blatchford et al (2000) who reported that one patient out of 46 still felt anxious after receiving their negative blood test results and by Taylor (1992) who outlined that two out of 47 patients requested private counselling following PNE involvement. Finally, it is worth noting that a large number do often go on to sue the institution or dental HCW involved for the emotional distress caused (McDonald 2016).

Many authors outlined the ways in which anxiety caused by notification might be reduced through the manner in which it is conducted and the language used (Pinching 2000). Gaudoin et al (2000) recommended use of the term 'pre-test discussion' in place of counselling as they felt the latter term may cause more alarm. The impact of how the message is communicated has also been considered. Following a 1991 notification exercise in Manchester the High Court ruled that a letter was an inappropriate way in which to notify patients as it would cause more alarm than a face-to-face discussion, but this verdict was reversed on appeal (Pinching 2000; Blatchford et al 2000).

4.4.2.4.2 Negative: resource and opportunity costs

Dickenson et al (1993) and Mason et al (2008) outlined that the benefits of PNEs may be outweighed by their extensive costs. SHEA (1992) stated that unnecessary PNEs waste resources whilst Longfield et al (1994) explained that the decision to notify may be influenced by the availability of resources deemed necessary to conduct the exercise.

Only six published papers provided PNE cost estimations (Conrad et al 2011; Close et al 2013; Longfield et al 1994; Irwin and Millership 2002; Molinari and Nelson 2014; Robinson and Challacombe 1993). Molinari and Nelson (2014) reported that the Tulsa case of 2013 had cost over 1 million dollars whilst Robinson and Challacombe (1993) stated that the four year investigation surrounding the Acer case had cost approximately four million dollars. Irwin and Millership (2002) stated that their exercise cost "in excess of £300,000". Longfield et al (1994) were more specific, outlining costs of $45,200 and

presenting a list of what was paid for, although, they did not outline the actual cost of each specific aspect and explained that their estimation did not include salary costs for 49 staff members.

Two dental incident papers reviewed specifically focused on financial cost (Conrad et al 2011; Close et al 2013). In 2011, Conrad et al retrospectively calculated costs following a limited PNE. Each IMT member was provided with a questionnaire asking them to estimate the time they had dedicated to the exercise (Conrad et al 2011). Costs were calculated in terms of patients notified and patients tested and they compared these values to those of other exercises (Conrad et al 2011). They concluded that PNEs have high baseline costs and do not appear to be heavily dependent on number of patients involved (Conrad et al 2011). They explained that a dental PNE in Essex resulted in a cost of £80 per person notified out of 3825 patients compared to £1,562.47 per patient in their exercise, which involved the notification of 60 people. Conrad et al (2011) also concluded that the highest costs were associated with senior staff wages followed by legal advice and set-up/operation of the helpline.

In 2013, Close et al similarly found that staff costs were the most significant expenditure, accounting for 68.2% of their total estimated costs of £311,513.78. Unfortunately, the cost breakdown by Close et al (2013) was not as detailed as that presented by Conrad et al (2011), with simpler categories of 'staff costs', 'laboratory costs' and 'other costs'. Limitations of the study by Conrad et al (2011) included issues with recall (IMT members were questioned over a year after the first IMT meeting) and accuracy of staff wage costs, as pay scales were used to estimate these. Calculations by Close et al (2013) may be more accurate as data concerning staff time was accrued on a monthly basis. An additional aspect to Close et al's study (2013) was the consideration of costs incurred by patients who attended for testing, such as those related to travel and childcare, although not time off work.

It is not surprising that the papers reviewed identified staff costs as a major part of the overall costs associated with PNEs given that they require a significant amount of staff time. In Irwin and Millership's 2002 paper they explained that 36,000 records had to be examined in order to identify 5929 patients at risk. Extra staff, including IT consultants, had to be hired to create and manage both a new patient database and programme for handling calls and testing appointment requests, requiring 2020 hours of programming time (Irwin and Millership 2002).

While many authors considered the importance of opportunity costs, in the existing challenging fiscal environment for NHS health care (Croser 2006; Conrad et al 2011) none of the publications reviewed, presented data on the costs of diverting time and resources away from other potential healthcare projects.

Irwin and Millership (2002) postulated that this may be due to the predicted complexity involved in such a calculation.

Authors such as Green (1992) and Chamberland and Bell (1992) suggested that money could be better spent on prevention of the common BBV transmission routes such as sexual contact and IVDU. Shaw (2008), Dickenson et al (1993) and Close et al (2013) took the concept of amended funding allocation further by suggesting specific avenues of investment. Shaw (2008) suggested that more money should be spent on educating the public about low BBV transmission risks in healthcare whilst Close et al (2013) theorised that if diagnoses are found during PNEs, an alternative form of targeted BBV screening may be appropriate. Finally, Dickenson et al (1993) suggested that money should be put into assessing dental HCW adherence to infection control standards thus potentially preventing incidents from occurring in the first place. Even when healthcare is considered as a whole, Hébert (2015) pointed out that BBV transmission due to poor infection control is rare and from a numerical perspective is less significant than other healthcare lapses such as surgical, prescribing, diagnosis or communication errors.

4.4.2.4.3 Negatives: reputational effects to the dental HCW and/or practice

The experience of the infected HCW, specifically maintenance of their confidentiality, during and following a PNE, is the main focus of many articles (Byers 1993; Taylor 1992; Christianson et al 1993; Dental Protection Ltd. 2002; Weinstein and Keyes 1991; Comer et al 1991; Heuer 1992; Cottone et al 1992).

Unique features of the HCW or practice involved may complicate efforts to maintain confidentiality. For example, Byers (1993) explained that an investigation connected to a prison dentist resulted in breach of confidentiality as there was only one dentist working at the prison in question.

Longfield et al (1994) demonstrated, through the management of their incident, that an infected HCW's identity can remain unknown to the public if careful steps are taken during notification. Authors such as Irwin and Millership (2002) and Arnow et al (1993) explained how they avoided breach of the HCW's confidentiality through the preparation of legal injunctions and ensuring as many staff involved in handling calls or booking appointments remained unaware of the HCW's identity. Arnow et al (1993) also suggested that if a different institution to the one involved in the incident can manage the PNE, this will further protect the confidentialities of those involved.

Numerous authors outlined that should it become common for dental HCWs and practices to be subject to a plethora of negative consequences, following investigation of their infection or incident, they may be less likely to come forward with BBV infection related issues (Closen 1996; Christianson et al 1993;

Irwin and Millership 2002; Chiodo and Tolle 1992). As a result, not only could exposed patients remain un-investigated but infected HCWs would not receive appropriate management of their infection leading to deterioration of their condition and risks of onward transmission (Chiodo and Tolle 1992; Sampson 1991; Pinching 2000).

Authors also suggested that following a PNE, damage to the dentist's reputation may result in a reduction in patient numbers and loss of business (Green 1992; Croser 2006; Closen 1996; Christianson et al 1993). This may be an intuitive outcome of notification but there is very little evidence to support this concept. Wagner et al (2015) examined uptake of testing as well as use of general and dental treatment services at five Veterans Health Administration facilities following six PNEs, two of which were dentally related. Unfortunately Wagner et al (2015) did not have access to information regarding the individual patients who were involved in each PNE, therefore they could only examine total numbers of patients treated before and after the notification periods. At 12 months post-incident there had been a decline in patients returning for treatment but rates rebounded to normal levels by 18 months (Wagner et al 2015). Unfortunately they did not present information on the amount by which return rates had initially dropped (Wagner et al 2015). Taylor (1992) similarly reported a limited effect on their dental school patient base following their PNE. However, this may have been because patients were aware that the HIV-infected student was no longer delivering treatment (Taylor 1992).

In 1995, Thorogood described a survey in which members of the public were questioned about how they might react should they discover their dentist was infected with HIV. Thorogood (1995) stated that people have 'public' and 'private' responses (Thorogood 1995). The 'public' response is theorised to be more reasonable in nature, where being comfortable with treatment from an infected HCW is the 'correct' response (Thorogood 1995). Qualifying remarks, however, such as "it depends on how well I knew the dentist" or "assuming they take precautions" reveal that the participant does not want to appear naïve to the dangers of transmission (Thorogood 1995). The concept of 'public' and 'private' feelings being in conflict is aptly shown through a participant's response to the question of whether they would remain in an infected dentist's care: "I want to say yes, but it has to be no" (Thorogood 1995). Other studies clearly demonstrate that participants would leave the care of an infected dentist. For example, Christianson et al (1993) quote a study which revealed that only 32.5% of patients would remain with their dentist if they discovered they were infected.

4.4.2.4.4 Negatives: reputational effects on dentistry

Some authors postulated that following involvement in a PNE, patients may not only fail to return for dental treatment at the implicated practice, but avoid

utilising all dental services (Horowitz 1994[a]; Hébert 2015). This would mean that notification could lead to a decline in the dental health of the local area. Croser (2006) and Blatchford et al (2000) state that PNEs destroy the trust between patients and the dental profession whilst Close et al (2013) took this further by stating that confidence in the entire medical profession may be lost.

As with other perceived negative PNE consequences, a decreased uptake of general dental treatment is postulated by many authors, without much evidentiary support. Horowitz (1994[b]) suggested that the Acer case caused a reduction in dental attendance but provides no supporting evidence for this statement. Following the Acer case, Gerbert et al (1991) surveyed 168 dentists of whom only 2% reported that some of their patients had given the Acer case as a reason for cancelling their appointments, though 45% had wanted to talk about the case. Gerbert et al (1991) reported that the ADA had concerns that "patients may avoid the dentist due to a freak accident (the Acer case) that is not well understood" and that media headlines of the time read "many dental appointments cancelled after HIV report" and "medicine tries to calm fears over dental HIV spread report".

4.4.2.4.5 Negatives: reputational effects on those managing the incident

Reputational consequences to those managing the incident were exclusively discussed in US articles (Dudzinski et al 2010), particularly those involving dental schools (Pashley et al 1991; Taylor 1992; Heuer 1992) or the VA (Maguire et al 2016[a]; Elwy et al 2014). In two separate studies, Maguire et al (2016[a]) and Elwy et al (2014) found that loss of trust was perceived to be the most significant cost of notification in VA facilities. Elwy et al (2014) did however highlight that VA employees may have a biased outlook as they may exclusively be exposed to patients who are very upset and whose complaints they cannot adequately respond to as there was a reported lack of knowledge transfer throughout the facility.

Taylor (1992) and Maguire et al (2016[a]) discussed factors that could further increase the damage to an institution which included releasing information which at a later date has to be corrected or amended, result delays, poor letter content, negative media coverage and lack of detail regarding both what occurred and steps that have been taken to ensure it will not happen again.

4.4.2.4.6 Negatives: legal vulnerability

As mentioned earlier, patients may sue for the emotional distress caused by learning that they have been placed at risk of BBV infection and the consequent period of worry experienced whilst waiting for test results (Closen 1996; Hébert 2015). Two conflicting ideas are presented in the literature regarding

notification and its legal consequences. Hébert (2015) and Dudzinski et al (2010) theorised that notifying patients creates an increased risk of litigation whereas Shaw (2008), SHEA (1992) and Chafe et al (2009) advised that notification can be conducted in an attempt to mitigate or reduce an institution's legal vulnerability, since legal consequences may be more severe should patients subsequently discover they had not been notified.

There is limited information in the literature regarding the legal outcomes of patients suing for the emotional distress of notification. Henderson et al (2017) reported that, according to news reports, more than 800 patients were suing the dentist associated with the infection control incident in Scotland, in 2013. In two other cases, 38 patients sued a HIV-infected dentist's estate following his death in 1991 ('The Delaware Care') and six patients sued Northwestern University following patients being notified of an HIV-infected dental student ('The Northwestern Case') (Anon 1995[a]; Anon 1995[d]; Anon 1997[b]; Anon 1997[c]; Anon 1998). Detailed information on the litigation aspects are available for both the American incidents and outlined in Table 34 below.

Table 34: Two legal cases where patients sued BBV-infected dentists for the emotional distress caused by notification.

The Delaware case: Patients were suing the HIV-infected dentist's estate for alleged negligence, recklessness, battery, fraudulent misrepresentation and acting on false pretences. Patients' claims of battery were denied as they could not provide evidence of physical harm (Anonymous 1995[a]; Anonymous 1995[d]). It was also stated that battery is not a suitable claim in a class action suit, as each plaintiff must specifically outline what unconsented, offensive touching occurred (Anonymous 1995[d]). Battery, within the medical setting usually refers to a different procedure being performed than the one the patient consented to (Anonymous 1995[d]). Plaintiffs were unsuccessful as no physical harm was incurred and fears deemed to be unreasonable. There were those who disagreed with 'The Delaware case' outcome and believed that patients' fears were not unreasonable as the dentist was reported to have lesions on his arms, poor infection control standards and, after being advised to stop by a healthcare professional, continued practising (Anonymous 1995[d]; Anonymous 1995[a]; Anonymous 1997[a]). Justice Duffy stated that the risk was shown to be significant through the institution sending out notification letters (Anonymous 1995[d]). The Northwestern case:

Plaintiffs were suing for breach of fiduciary duty, intentional infliction of emotional distress, battery, common law fraud, breach of contract, negligent malpractice and dental malpractice (Anon 1997[b]).

Plaintiffs were unsuccessful initially as they could not prove that there was "a medically verifiable possibility of their becoming infected" (Anon 1997[b]; Anon 1997[c]). Plaintiffs were also unsuccessful on appeal as they could not provide 'proof of actual exposure' (Anon 1998).

'Proof of actual exposure' is defined as the plaintiff's ability to show that he or she actually came into contact with an infected person's blood or bodily fluids (Anon 1998). It is also described as the need for a plaintiff to show that "HIV was present in an alleged disease transmitting agent and that a medically accepted channel of transmission existed" (Anon 1997[b]). The battery claim was rejected as consent was not absent. The claim for consumer fraud was also rejected as treatment at the dental school was not a commercial enterprise but an educational facility. Duties would only be considered breached by the student and school if actual harm had resulted. Emotional distress was not deemed to be severe enough to merit claims (Anon 1997[b]; Anon 1998).

Authors make arguments for and against the legitimacy of claims by notified patients. Some say that the existence of the Acer transmissions makes fear of infection reasonable (Closen 1996) and that AIDS, specifically, is a disease dreaded and greatly feared by the public (Anon 1997[b]). Some, however, highlighted that the distress caused by notification is not comparable to a psychological illness (Hébert 2015) and that awarding damages for emotional distress sets a precedent of responding disproportionately to feelings that may be "trivial", "temporary" or "faked" (Anon 1997[b]). This would result in a higher number of claims (Anon 1995[d]), leading to more pay outs, increased insurance costs and less funding available to those who actually become infected as a result of these incidents (Anon 1997[b]). Some stated that the fears arising from notification are often based on a public misconception of the transmissibility of HIV. Awarding claims may therefore encourage patients to remain uneducated about the true risks of transmission (Anon 1997[c]; Anon 1997[b]; Anon 1995[d]).

Closen (2006) postulated that publicising large cases, where patients are awarded monetary compensation, will make other dentists more reluctant to breach standards or put patients at risk (Closen 1996). However, in conflict with this concept is the idea that severe legal consequences will discourage institutions from notifying patients (Anonymous 1997[b]; Anonymous 1997[c]).

4.4.2.5 Standards and expectations based on governing bodies, public opinion and actions of peers

4.4.2.5.1 Standards: perceived public opinion regarding incident and response

Members of the public value transparency (Chiodo and Tolle 1992) and have a strong desire to be notified following transmission risk incidents (Wagner et al 2015).

In 1992, Cohen et al assessed changes in public concern regarding dental HIV transmission, after investigation of the Acer case. Patients showed a strong desire to be notified, with 84.5% of 968 participants wishing to be told if their dentist were infected with HIV (Cohen et al 1992). In 1995, approximately 96% of 130 patients who called a PNE helpline, following being notified of a HIV-infected HCW, felt they had a right to be told of the incident (Monteith et al 1995). Later, in 2000, Blatchford et al sent questionnaires out to patients who had been notified of an HBV-infected dentist. Their results revealed that 93% of 291 participants felt patients should always be told (Blatchford et al 2000). Finally, in 2014 Elwy et al interviewed 27 patients who had been involved in a variety of PNEs, all of whom explained that although initially distressing, the VA followed the right course of action in notifying them of the incident (Elwy et al 2014).

Pinching (2000) described the existence of a 'blame culture' in which someone always needs to be found responsible for mistakes and that generally, the public do not trust those in professional roles. Some authors acknowledged that patients may be concerned about healthcare professionals choosing a paternalistic course of action which reflects historical medical practice (Closen 1996). To address this, several authors cited avoiding paternalism, as a reason to notify (Blatchford et al 2000; Breo 1993; Henderson et al 2017; and Chiodo and Tolle 1992). Hébert (2015) suggested that even following notification, patients may remain sceptical and question whether disclosure is being conducted to promote patient safety or mitigate legal vulnerability. Maguire et al (2016[b]) in their analysis of historical press reports, identified that the media may fuel scepticism by frequently reporting that managing organisations were being secretive or hiding the truth, especially if notification had been conducted more than 75 days post-incident.

4.4.2.5.2 Standards: medical ethics, norms and values

Authors referred to widely acknowledged medical standards and ethical concepts such as patient autonomy (Iheukwumere 1997), non-maleficence (Blatchford et al 2000), professional duty of care (Conrad et al 2011; Hancocks 2008) transparency (Maguire et al 2016[a]) and a commitment to always putting patients

first (Weaver 2014). Hébert (2015) emphasised that the ethics concerning disclosure of errors to single patients are clear but become much more nuanced and complex if an incident involves many patients.

Dudzinski et al (2010) outlined both the duty-based and utilitarian ethical schools of thought. A duty-based approach requires fulfilment of one's pre-established duties no matter what the consequences. A utilitarian approach involves ascertaining which course of action would result in both minimal harm and maximum benefit for those involved (Dudzinski et al 2010). They argued that both approaches support disclosure but that the utilitarian theory is more easily challenged in a large-scale patient disclosure case (Dudzinski et al 2010). The authors concluded that disclosure should be the norm unless a strong, ethically based case can be made against it (Dudzinski et al 2010).

Some authors referred to general strategies used within medicine to determine the amount of information that patients need to know. Shaw (2008) explained that, in surgery, the most common and serious risks are disclosed. Chiodo and Tolle (1992) explained that disclosure of every risk is highly impractical and unnecessary, citing that a risk equal to or more likely than 1 in 10,000 was a common threshold used for surgical risk disclosure. Iheukwumere (1997), however, explained that surgical risk should not be based on a numerical estimation but whether it is deemed to be material to either the HCW or the patient. Basing the decision on the patient's idea of a material risk is less paternalistic and referred to as the 'reasonable patient standard' (Closen 1996).

Although not an ethical concept, a norm outlined in the literature was 'erring on the side of caution' when risks were uncertain (Iheukwumere 1997), with health service managers often being described as 'risk averse' (Pinching 2000). Calculations of risk were always done with a margin of safety (Millership et al 2007) as was the case in the exercise described by Henderson et al (2017) where notification was triggered by allegations that could not be refuted and were thus assumed to be true.

4.4.2.5.3 Standards: guidance and/or policy

No official decision-making or risk assessment tool is available to UK IMT members when deciding whether patients should be notified following a dental infection control incident. Maguire et al (2016[a]), Chafe et al (2009) and Dudzinski et al (2010) highlighted that guidance on notification following a localised incident, affecting one patient, is clear and available but is limited in relation to large-scale disclosure. Closen (1996) stated that the CDC's policy of investigating incidents on a "case by case" basis, a stance shared by UKAP, results in varied IMT responses. Dudzinski et al (2010) suggested that if harm has occurred, disclosure is clearly warranted whereas guidance on 'near miss'

incidents is unclear. Although authors called for the creation of guidance (Henderson et al 2017; Millership et al 2007), Mason et al (2008) cautioned that this is an area "where judgement […] rather than merely the application of rules and regulations" may be required.

A small number of authors reported that adherence to guidance and/or policy influenced their decision to notify (Appendix 18). When discussing VA facility incidents, Hébert (2015), Elwy et al (2014) and Maguire et al (2016[a]) all reported that the organisation possessed very clear policies, such as VHA directive 2008-02, which favour disclosure of incidents to patients, even if patient harm is not obvious, severe or yet present. VHA decision makers are guided by both ethical considerations and a suggested numerical threshold for notification: "when 1 patient or more of 10,000 patients is expected to have a short-term or long-term health effect that would require treatment or cause serious illness if untreated" (Dudzinski et al 2010). Dudzinski et al (2010) and Hébert (2015), however, pointed out that this threshold may be difficult to utilise in practice as investigators are often unaware of the number of patients who have been harmed until after notification and testing have occurred.

As UKAP only provides advice concerning infected HCWs (UKAP 2019), most UK investigative teams turned to groups of experts or public health organisations such as Health Protection Scotland (in Scotland) or the Health Protection Agency (HPA) (in England and Wales) following infection control incidents.

4.4.2.5.4 Standards: expert panels, organisations and/or peers

Many IMTs made their decision on patient notification following consultation with experts and/or appropriate organisations. American investigators often took advice from the CDC and the ADA (Cottone et al 1992; Jacob 1991; Comer et al 1991). In the UK, when investigating an infected dental HCW, advice from UKAP (or EAGA in the days before UKAP was established) was always reported to be sought by the IMT (Gaudoin et al 2000; Irwin and Millership 2002; Mason et al 2008). Martin (2006) highlighted that once received, UKAP's advice is "considered mandatory by most". In regards to a dental infection control incident English and Welsh IMTs occasionally took advice from the HPA (Conrad et al 2011; Close et al 2013). There were also reports of UKAP being consulted following infection control incidents where dental HCWs were practising illegally, suggesting that they occasionally give advice slightly outwith their remit (Unpublished report 2007).

Although only a small number of authors reporting an incident specifically mentioned being guided by how incidents had been managed in the past (Cottone et al 1992; Heuer 1992; Millership et al 2007), 11 of the 20 published incident articles provided details of other dental investigations. This suggests

that even if not specifically outlined, the majority of teams (61%) are probably influenced, to some degree, by what others have done in the past.

SHEA (1992) outlined an additional way in which the historical incident literature might influence decision makers. They stated that frequent publication of articles related to those incidents which resulted in notification, over those that did not, gives the impression that a PNE is, or should be, the standard response (SHEA 1992). Of 56 articles published in relation to a specific incident between 1990 and 2017 only five per cent focused on incidents that did not trigger notification (Condon 2008; York and Arthur 1993; Millership et al 2007).

4.4.2.6 Perceived complexity

4.4.2.6.1 Perceived complexity: predicted efficacy of PNE

Both Dudzinski et al (2010) and Chafe et al (2009) emphasised that incident management is filled with challenges, which extend far beyond the initial aim of ascertaining who is at risk. Whilst the literature indicates that a greater perceived complexity associated with incident management does not influence the decision to notify there is some evidence that suggests that if the logistics of notification appear simpler, the team may be more inclined to pursue notification. The perceived ease of conducting a PNE may be influenced by: the involvement of only a small number of 'at risk' patients (Taylor 1992; Cheng et al 2013), patient data being easy to access and/or of high quality (Dickenson et al 1993; Heuer 1992; Longfield et al 1994) or the time period for which patients were placed at risk being clearly defined (Longfield et al 1994).

Authors reported that missing or incomplete patient records represented a barrier to patient notification (Henderson et al 2017; CDC 2019[a]; Radcliffe et al 2013; Merchant 2014; Hanley 2013). Reasons behind IMT's being unable to locate and utilise patient details included: general poor record keeping (Merchant 2014), the number of patients who regularly join and leave dental practices (Irwin and Millership 2002), failure of patients to register with GPs (Irwin and Millership 2002), patient records not having an accompanying NHS number (Irwin and Millership 2002) and, in one case, destruction of patient records by the dental HCW (Roy et al 2005). Specifically, authors reported that most often it was very difficult to ascertain what types of procedure patients had undergone (Chamberland and Bell 1992; Irwin and Millership 2002; Weller 1999). In Roy et al's incident, information was only available on when patient treatment plans started and ended, based on centralised, payment information, with no specific details on the procedures conducted (2005).

Irwin and Millership (2002) explained that those managing incidents often must obtain permissions from the HCW or involved dental practice to access them.

This issue was encountered by Roy et al (2005) who were unable to obtain details from legal investigators regarding the specific way in which instruments were deemed to be 'unsterile' following a dentist's admission of their use in court.

Patient records are not the only forms of information that may be unavailable to IMTs. In both the Acer and West Virginia cases investigators could not observe or record the quality of infection control practices, as the clinics were no longer providing patient care (Chamberland and Bell 1992; Radcliffe et al 2013).

Once attempts have been made to notify all 'at risk' patients, the ability to detect transmission is further inhibited by limited testing uptake (Jaffe and Liberti 1995). Testing is rarely conducted for more than 50% of notified patients (Henderson et al 2017; Gaudoin et al 2000; Close et al 2013; Jaffe et al 1994). Irwin and Millership (2002) pointed out that once extensive resources are dedicated to conducting a PNE, concentrated efforts must be made to test as many of those 'at risk' as possible whilst Weller (1999) explained that poor testing uptake results in an underestimation of risk associated with these incidents.

A potential connection between wording of the notification letter and testing uptake was reported by Close et al (2013). Exposed patients from two separate districts were notified of an infection control breach, with different letters being sent to each area resulting in uptake percentages of 21% and 53% (Close et al 2013). Henderson et al (2017), who had to repeat their PNE, reported that no patients, of 5100 contacted in the first exercise, requested testing whereas in the second round (following alterations to the letter which now advised testing), uptake was 44%.

Dickenson et al (1993) suggested that low testing rates may be due, in part, to elderly or physically impaired patients being unable to make the trip to the testing clinic, though Longfield et al (1994) showed no relationship between age and testing uptake.

Wagner et al (2015) found that African Americans were significantly less likely to return for testing (OR of 0.74 for HCV, 0.46 for HIV and 0.66 for HBV) compared to white patients. Hébert (2015) postulated that this difference may reflect a lack of trust in the healthcare system or perceived lack of access to it.

In addition to the potential effects of age and race, Longfield et al (1994) showed that methods of notification may have an effect on testing uptake. Patients notified by letter were 11 times more likely to come forward for testing than those who had been notified in another way (Longfield et al 1994). Testing

uptake was also positively associated with a history of more and/or recent dental visits (Longfield et al 1994).

PNEs primarily aim to identify transmissions that may have occurred as a result of an incident but they are rarely discovered (Shaw 2008; Croser 2006). Millership et al (2007) emphasised that the costs of notification must be balanced against the likelihood of detecting transmissions. In fact, no patient-to-patient transmission has ever been identified in the UK following a dental incident.

Millership et al (2007) likened the process of identifying transmissions to searching "for a needle in a haystack". Infected patients may not present themselves for testing as they do not consider themselves to be infected, with symptoms often being absent or mild (Radcliffe et al 2013). Furthermore, to prove transmission has occurred, the viral genetic sequences of two infected individuals need to be compared (Millership et al 2007). Millership et al (2007) presented risk assessment calculations for three incidents that they decided did not merit notification. They predicted the probability of detecting one transmission pair in eight different scenarios (Millership et al 2007). These scenarios reflected differences in number of patients seen each day, length of time patients were at risk and testing uptake (Millership et al 2007). They estimated that in all scenarios the chance of detecting a transmission pair was less than 1.00 (Millership et al 2007).

Even if infections are identified, linking them to the incident can be challenging. Samples often cannot be obtained for all infected patients, restricting the comparison of viral genetic sequences (Jaffe et al 1994; Mason et al 2008). Also, for those who show evidence of past BBV infection, genotyping or sequencing cannot be performed as viral particles are no longer present in the bloodstream (Mason et al 2008). Radcliffe et al (2013), in their investigation, described how low viral titres meant that only partial or limited genetic sequencing could be conducted.

Even following genetic sequencing, the concept of a proven transmission can remain under debate. Identification of transmission relies on the presence of a strong relationship between genetic sequences, backed up by convincing, epidemiological evidence (Cleveland et al 2016). Viruses mutate over time so if a long period of time has passed since the incident, sequences can be harder to link (Radcliffe et al 2013). Debate over sequencing conclusions can most clearly be seen in relation to the Acer case. Here, sequences were examined many times by multiple research teams using differing methods and local controls (Crandall 1995).

One of the aims of notification is to provide patients with "an accurate description of the risk" to which they have been exposed (Maguire et al 2016[a]). Risk communication can be very challenging (Wagner et al 2015). Chiodo and Tolle (1992) explained that "accepting risks in life can be purely subjective and logically inconsistent". Breo (1993) proposed that if HIV is mentioned, patients become solely focused on their fear of contracting AIDS, blinding them to all other messages. Both Gaudoin et al (2000) and Closen (1996) highlighted the contradiction in attempting to communicate low levels of risk when it is evident that the risk clearly merited notifying the patient.

Elwy et al (2014) showed that patients preferred notification via telephone whilst Dudzinski et al (2010) suggested a compromise; notifying those at higher risk of infection verbally and using a letter for those at lower risk. This represents a balance between the economically prudent process of sending a letter and the personable, but resource intensive, action of speaking face-to-face (Elwy et al 2014).

4.4.2.6.2 Perceived complexity: Media influence and local area knowledge of an incident pre-PNE

Local residents may already have some knowledge that an incident has occurred. This may arise through discussion within the community (SHEA 1992), news reports (Maguire et al 2016[b]) or the release of information related to GDC fitness to practice hearings (Henderson et al 2017). Many investigators cited the importance of notifying patients before any media leaks (Wagner et al 2015; Maguire et al 2016[b]; Irwin and Millership 2002). The media were portrayed in a negative light and described as being a highly inappropriate vehicle for disseminating information about an incident. Pinching (2000) explained that the media can "fuel anxiety with misinformation" and a Dental Protection report (2002) outlined that the media take a "scare mongering approach, rather than a reasoned, scientific based consideration of all the facts". This approach by the media was reflected in headlines that were published following the 2014 Ayrshire and Arran incident eg: "Dentist who sparked HIV scare for 6,000 patients and infected four with Hepatitis C by using dirty equipment" (Davies et al 2016). Note the mention of HIV as the media are aware of the public's disproportionate but heightened fear of this infection (Henderson et al 2017). Furthermore, the statement that four patients contracted HCV as a result of their treatment is incorrect (Henderson et al 2017).

Some authors argued that when conducting patient notification, media involvement is unavoidable (Dudzinski et al 2010) although Conrad et al (2011) reported that their incident generated no media interest and both Taylor (1992) and Heuer (1992) explained that bigger, contemporary and unrelated media

headlines may mean an incident story goes unnoticed. Fitzgerald et al (2010) emphasised that a quick response with rapid testing of exposed patients causes a swift reduction in press coverage.

In light of the media's strong influence authors recommended early establishment of a proactive, positive relationship with the press (Maguire et al 2016[a]; Elwy et al 2014; Comer et al 1991; Gaudoin et al 2000). Taylor et al (1992) demonstrated an excellent level of preparedness in relation to media communications associated with their incident. They approached a reporter with whom they had a good relationship and provided their own video footage of clinics and sound bites for use in reports.

In 2016[b], Maguire et al conducted a study to assess how VA incidents were described and presented in the media by reviewing and analysing historic reports. Their main aim was to establish if the messages that the VA organisation wanted to disseminate were being relayed by the media (Maguire et al 2016[b]). Maguire et al (2016[b]) found that the media often reported delays in response and testing whilst claiming that the VA were clearly not learning lessons from past incidents as breaches were recurring. Overall, however, 77% of 148 reports were reassuring and 76% described the cause of the incident but only 39% of reports encouraged patients to seek testing and 4.7% included elements of an apology (Maguire et al 2016[b]).

Both Wagner et al (2015) and Jaffe et al (1994) suggested that media channels can be utilised to improve and amplify the notification process. Roy et al (2005) and Merchant (2014) described incidents where local media was used to reach out to those patients for whom contact details were unavailable. Cohen et al (1992) however, suggested that the media may only be successful in reaching those who are more educated, older and white.

4.4.2.7 Design of notification - can the process be amended to lessen the impact of negative consequences?

In responding to the need for notification whilst acknowledging the costs of the exercise, a balance can be struck through adaptation of the process (Conrad et al 2011). Limited notification saves resources and reduces the number of patients who are made anxious (Weller 1999; Arnow et al 1993) whilst meeting the duty to disclose (Conrad et al 2011). It potentially limits reputational effects on the practice involved, as less people in the community are made aware of the incident and facilitates a faster response as there are fewer patients to notify (Arnow et al 1993). Weller, however, warned readers that notifying only those at risk could still create substantial media interest and result in large costs (Weller 1999).

The most common limitation employed was reduction in numbers of patients notified based on risk or ease of contact. In the incident reported by Henderson et al (2017) only those patients currently registered with the practice were notified and Dickenson et al (1994) only contacted patients who were identified as residing in the local area. In some cases patients were only notified if they were treated shortly after a potential source patient (Redd et al 2007; Conrad et al 2011) whilst others were notified based on the procedures they had undergone (Fitzgerald et al 2010; Cottone et al 1992; Arnow et al 1993). In one incident, the CDC advised that the patients of an HIV-infected dentist need only be notified if they were treated during a two week period when he had dyshidrosis (blisters on his hands) or if the dentist had incurred a sharps injury during their procedure (Byers 1993).

Close et al (2013) explained that a single attempt to notify patients was acceptable if the risk was low whilst Weller (1999) suggested that all patients who underwent an EPP should be notified but for those deemed to be at higher risk, BBV testing should be specifically encouraged.

The greatest deviation from a conventional PNE was described by York and Arthur (1993). Their investigation, following the discovery of three HIV-positive navy dentists, involved no patient involvement or testing beyond that which all navy personnel received routinely (York and Arthur 1993). Regular testing of navy personnel meant records could be thoroughly examined as part of the investigation (York and Arthur 1993). Patients who had received a negative HIV test before dental treatment and a positive one after, were investigated (York and Arthur 1993). All patients in this group had other risk factors for their infection (York and Arthur 1993). The authors also indicated that if a transmission had been identified the investigation would have been extended (York and Arthur 1993).

4.4.2.8 Feedback on PNE outcomes

It is not easy to assess the true effectiveness of PNEs. Often the large number of patients involved limits the follow-up that can be done to ascertain whether everyone was successfully notified (Chafe et al 2009) or why some patients did not get tested (Hébert 2015). IMTs are often unaware of the true extent of the damage that has been caused by their PNE and some have questioned what methods are available to measure this (Wagner et al 2015).

4.4.3 Characteristics of the body of literature

Scoping review studies seek not only to analyse and collate study findings but provide general information on the ways in which the research field is explored and presented through publication providing "a descriptive overview of the reviewed material" (Pham et al 2014). They present data on publication characteristics such as the focus or topic of papers identified, approaches or methodologies used, study types, countries of origin, and years in which papers were published (Colquhoun et al 2010; Brien et al 2010; O'Brien et al 2010).

This section provides a general description of the body of literature regarding dental healthcare related BBV transmission and PNEs. Tables and charts alongside descriptive text outline the features of the published literature in this field.

There were 105 journal articles identified in this review that addressed dental BBV transmission or large-scale patient notifications, The line graph in Figure 18 shows that the number of journal articles published, peaked during 1993 and was in decline from the mid-1990s to early 2000s. In recent years, publication activity has been low with an average of two publications per year from 2000 to 2017.

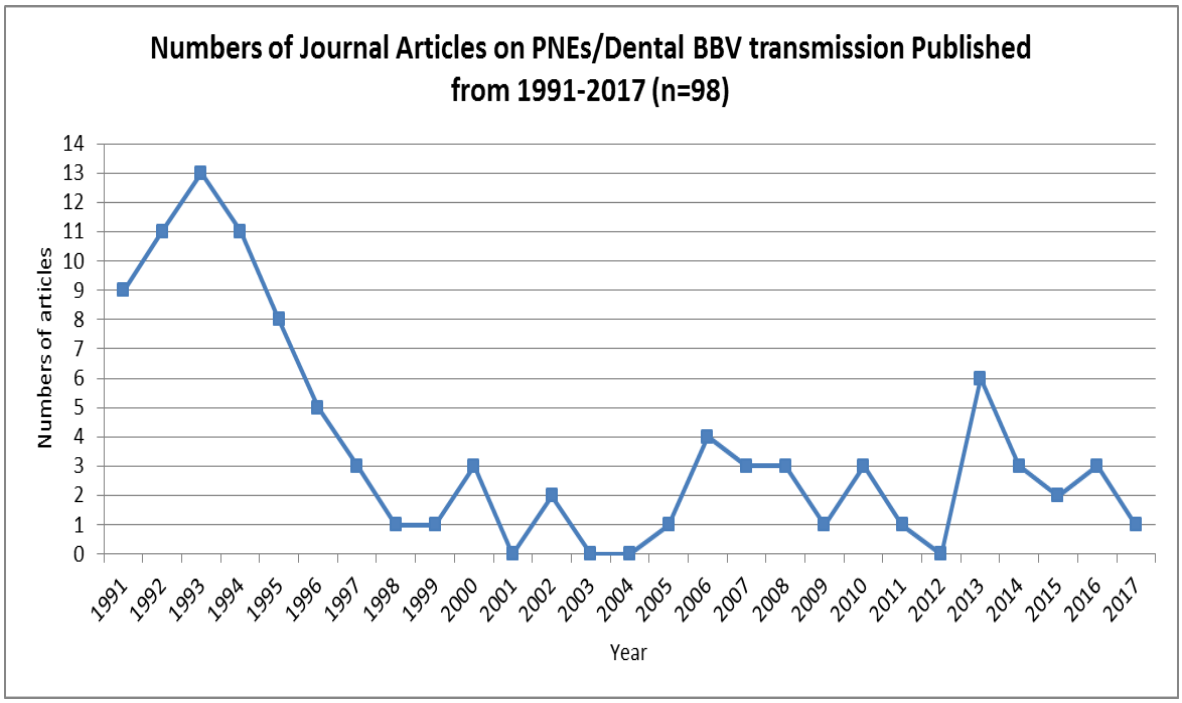


Figure 18: Line graph with markers showing the numbers of articles that were published in journals, relating to dental BBV transmission or large-scale patient notification, from 1991-2017 within a developed country setting. *(7 articles were excluded as they were either erratums or news articles.)*

The large number of articles published between 1991 and 1995 can be linked to two prominent cases involving infected dental HCWs. Of the 52 journal articles

published between 1991 and 1995, 27% were related to the Acer case and 12% described the case of an infected dental student from the Medical College of Georgia.

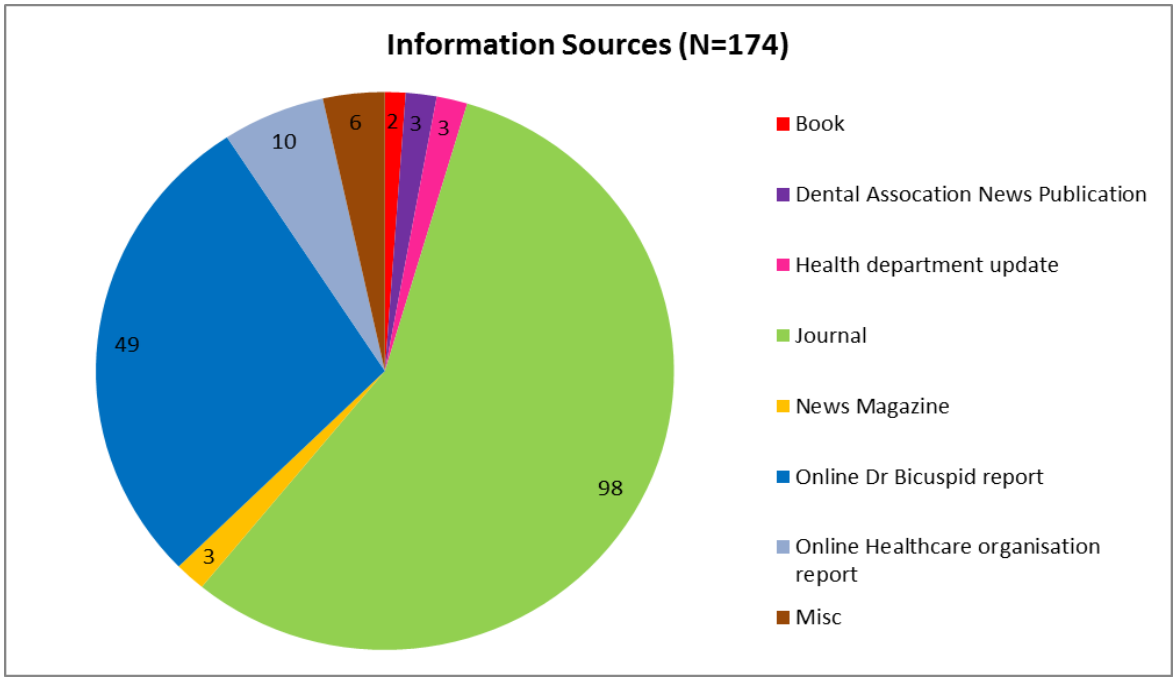


Figure 19: Pie chart showing the different information sources used to gather articles or reports on dental BBV transmission or large-scale patient notification.

The majority of articles (n=98) were sourced from peer reviewed journals but as Figure 19 shows, a wealth of information was obtained from the website Dr.Bicuspid.com, an American dental news site run by an editorial board of dentists and dental specialists. It describes itself as a "free, member-driven website dedicated to general dentists, specialists, and other dental professionals" (Dr Bicuspid).

From the early 1990s to the present day there has been a shift in the type of incidents being reported. There were 39 infected dental HCW articles published between 1990 and 1999 whereas only five were published from 2000-2017. In comparison, the number of articles describing infection control incidents has increased. There were none from 1990 to 1999 whereas nine were published between 2000 and 2017. The number of publications describing decisions made not to notify has remained consistently very small over the years (three in total between 1990 and 2017).

Many of the papers identified were simply descriptive reports whilst others were opinion pieces discussing the merits of notification. Researchers would occasionally aim to explore a specific PNE phenomenon whilst investigating and reporting on their incident (Table 35). Of the seven articles which reported on a specific incident and had an additional focus, two involved an economic evaluation, three focused on the needs and issues of the infected HCW and two

looked at the relationship between types of procedures performed and infection rates, one of which used a nested case-control study approach.

Table 35: Formats of journal articles that provided information on large-scale patient notification and/or dental healthcare related BBV transmission (n=105).

Study Type	Number of journal articles
Editorial/opinion piece/letter	41
Case report	18
News article/update/Dental association news	10
Review	8
Case report with specific focus or additional study element	7
Questionnaire study	6
Legal case description	5
Phylogenetic analysis study	3
Interviews of stakeholders with thematic analysis of qualitative data	2
Thematic analysis of media content	1
Case-control study examining patient behaviours following notification	1
Abstract	1
Erratum	1
Conference proceedings	1

Table 36 shows that there is significant variability in the types of journals that publish articles regarding dental 'BBV transmission risk' incidents and the outcomes of their associated investigations.

Table 36: Number of articles which contained information on dental incident outcomes and the types of journal they were found within.

Types of journals that contained articles which reported on dental incident outcomes/Dental 'BBV transmission risk' incidents (n=84/98*)	
Journal Type	**Number of articles**
Medical	18
Dental	16
Dental Association	13
Dental Education	7
Public Health	5
HIV/AIDS, Infectious Disease Medical Ethics AIDS policy and law Infectious Disease/Public Health Law Review Lymphology Immunology Research Science Virology	<5
*7 Erratum and News articles excluded	

Table 37 outlines the terminology used in titles of journal articles which discuss the pros and cons of large-scale patient notification in the medical setting. Table 38 outlines the terms used in titles of papers which discussed dental 'BBV transmission risk' incidents.

Table 37: Terms used in titles of journal articles which primarily discuss large-scale patient notification (n=13/98*)

Title Term	Number of article titles containing term
Disclosure, Large-scale	5
HIV, Notification, Disclosing	3
Dental, Healthcare	2
Infection control failure(s), Error, Transmission, Large-scale, Lookback, Look-back, Multiple, Honesty, Dentistry, Health care, Dentist(s), Surgery, Warn, Unsafe injections, Patients	1
*7 Erratum and News articles excluded	

Table 38: Terms featured in the titles of journal articles and books which discuss/report on (potential) dental BBV transmission (n=85/100*)

Term included in title	Number of article titles containing term	Percentage of articles/books containing term
HIV OR AIDS OR Hepatitis OR Infection OR Virus	74	86%
Dental OR Dentist(s) OR Dentistry	52	60%
Transmission	21	24%
Patient(s)	20	23%
Worker(s)	11	13%
"Health care"	10	12%
Exercise, HIV-infected, HIV-positive, Case(s), Risk, Student, Investigation(s), Positive, Surgery, Infected, Health-care, Office, Failure, Failed, Infectious, Management, Look-back, Practice(s), Clinic, Ethics, Pathogen(s), Personnel, Incident, Told, School, Oral, Test(s), Testing, Public, Blood-borne, Clustered, Protection, "Right to know", Professional(s), Transmitted, "Blood borne" , Invasive, Procedure(s), Provider(s), Surgeon, "Looking back", Doctor(s), Healthcare, Practitioner, Sterilization, Instruments, Unsterilized, Equipment, Testing, Poor, Notifying, Status, Seropositive, Seroconversion, Patient-to-patient, Medical, Contact, Messy, Alert(s), Violation, Ethical, Legal, Professional-to-patient, Announcement	<10	<10%
3 article titles did not contain any of the terms presented in this table, these included; 'Above All Do no Harm' (Merchant 2014), 'Take a lesson from Tulsa' (2013) and 'Written Off' (2006).		
*7 Erratum and News articles excluded		

Even though the literature review aimed to collate information from journal articles published in developed countries, the UK and US were the main two countries of origin for publications identified (Figure 20).

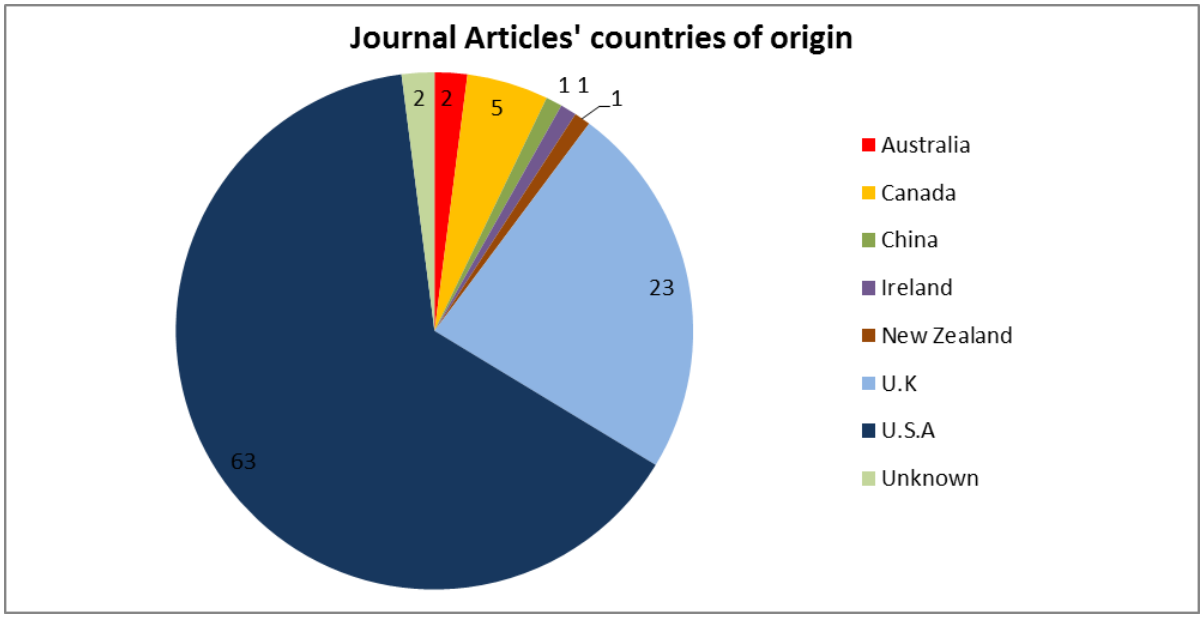


Figure 20: Pie chart presenting information on journal articles country of origin. *(7 articles were excluded as they were either erratums or news articles.)*

4.5 Discussion

4.5.1 What this study adds

There are a small number of published papers and databases in which incident outcomes have been collated. These resources, if not outdated, are often limited in their breadth and tend to exclusively collate incidents that resulted in transmission, involved HIV-infected HCWs and/or occurred in the US (Cleveland et al 2016; Shields 1995; Chamberland and Bell 1992; Robert and Bell 1994; Samaranayake 1991; Ciesielski et al 1994; Younai 2010).

This review was novel in its aim to source and report on all published, dental incident outcome papers from the developed world. It also represents the first study of its kind to attempt to collate information on all dental incidents managed within the UK, regardless of whether they led to publication or patient notification.

A collation of incidents such as the one presented here gives stakeholders quick and easy access to the historical evidence base, allowing decisions to be made more quickly with confidence that their conclusions are based on past outcomes and experiences.

This review reveals the positive and negative aspects of notification, the degree to which PNEs meet their intended aims, the factors which influence the decision to proceed to patient notification and some of the field's research gaps.

4.5.2 Main findings

4.5.2.1 Evidence to support the existence/significance of positive and negative PNE outcomes

There is limited evidence to identify with certainty the positive and negative consequences of notification. The perceived existence of these consequences by decision makers is based on intuition and anecdotal evidence. For example, it is natural for one to assume that making the public aware of an incident will damage the reputations of the dentists and/or practices involved. However, there is only one published study which examines this phenomenon and its finding, that reputational effects may be limited and short term, may only be applicable to a large establishment such as a VHA facility (an environment not necessarily reflective of smaller, UK, high-street dental practices). Similarly the assumption that many patients will experience severe anxiety upon being notified of an incident is supported by evidence which is out-dated, limited and contradictory (Blatchford et al 2000; Pashley et al 1991; Montieth et al 1995; Taylor 1992). Certainly, no published evidence exists to support the idea that patients would avoid dental treatment following involvement in a PNE, yet this is a prudent and unsurprising concern of some decision makers.

Damage to the reputation of those managing incidents was only discussed in American papers. This may be linked to the fact that management of US incidents is often handled by those who have, in part, been responsible for the breaches/errors as opposed to in the UK where incident management is handled by an external board/trust. It may also reflect the idea that healthcare in America is associated with financial gain.

Financial costs associated with undertaking a PNE appear to be high and unpredictable. Their values do not correlate with numbers of patients ‘at risk’, numbers notified or numbers of BBVs tested for and only show a potential, weak correlation with patients tested. When costs are reported, which occurred only in 25% of incident reports, calculations are often missing key elements, presented in a vague manner or represent estimations with no standardised way to report them. Even when comparable cost categories are examined there appears to be high variability, suggesting that costs are dependent on many complex factors that are currently not understood. Using current data, decision makers would only be able to make a rough estimation of how much a PNE would cost.

Until further research is conducted, especially regarding feedback from notified patients, many of the positive and negative outcomes of notification will be based on common sense, personal experience and expert opinion.

4.5.2.2 Influential factors

Chafe et al (2009) stated that the difficulties associated with notification included “seeking legal advice, locating and contacting patients” and “not knowing all the facts” as well as “the real or perceived political pressure to limit communication or shift blame to specific people”. When discussing the decision to notify patients following unsafe injection practices, a CDC case study paper advised that “evidence, ethics and economics” should be considered (CDC 2019[a]).

Absence of a correlation between breach type and progression to a PNE suggests that either other influential factors are at work or more likely that adequate evidence does not exist to support a decision based on breach type. Most likely it is a combination of the two. Basing the risk estimation on the nature of the breaches that have occurred may also be unwise as it is clear that risk of transmission is not always mitigated through good infection control as HBV patient-to-patient transmission occurred in a New Mexico oral surgery clinic where infection control standards were considered high (Redd et al 2007).

Types of dental procedure performed did not appear to influence the decision to notify. This may be because, under historic BBV-infected HCW guidance, virtually all dental procedures were considered to be EPPs. It may also be related to the time that would be required to categorise patients or the poor quality of dental records which would not facilitate this process.

Assessment of infection control and adherence to standards has always been an important consideration in incident investigation. However, recent cases, described by both Roy et al (2005) and Henderson et al (2017) highlighted the need to take a closer look at general integrity of the dentist or practice involved. Evidence shows that being uncooperative with investigators or additional charges of fraud could indicate more widespread or serious breaches.

Limited conclusions could be drawn from historical ‘proven transmission’ events as they are rare, occurred a long time ago, lack contextual detail and/or are related to HBV, the most infectious BBV, thereby creating an exaggerated perception of risks involved. One must acknowledge that BBV transmission from a dental HCW to a patient has not occurred since 1990 (Ciesielski et al 1991). Before this time, HBV was the main virus of concern. In the modern dental setting, risks concerning BBV transmission from HCW-to-patient appear to have been mitigated through immunisation of HCWs and use of appropriate PPE. Patient-to-patient BBV transmission in the dental setting is more concerning as it has occurred recently (three times in the past 20 years) (Redd et al 2007; Radcliffe et al 2013; Oklahoma State Department of Health 2013). These cases of proven transmission unfortunately do not provide much insight into which breaches should be associated with the highest risks as their circumstances are varied with a significant degree of speculation as to their causes. The limited

conclusions that can be drawn suggest that incidents involving syringe reuse, multi-dose vials, extractions or oral surgery settings are most concerning.

Historical incident outcomes support the concept that dental related BBV transmission rarely occurs and risks are low. Those BBV-infected patients identified are usually established as being incidental i.e. unlinked to an incident via genetic sequencing results or, more frequently, because they have alternative risk factors for their infection. Excluding incident-related transmission based on alternative risk factors should be conducted with caution as with thorough investigation, almost everyone could be established as having some form of BBV risk factor. One must therefore remember that transmission rates may not be as low as evidence suggests if a) not all 'at risk' patients are tested and b) patients are routinely excluded based solely on having alternative risk factors.

It is unclear how much numerical risk estimations influenced the decision to notify patients. These estimations appeared to only be presented when notification was not done (Millership et al 2007; unpublished report 2014; unpublished report 2015) suggesting that they are used more often to support the decision that non-disclosure is suitable due to low risks rather than to specifically tip the decision towards or away from PNE implementation.

Decision makers may wish to consider the predicted efficacy of their planned PNE. In regard to the capacity for PNEs to achieve their aims, it was comforting to see that IMTs were usually able to notify a large proportion of 'at risk' patients. Testing uptake, in contrast, was shown to vary greatly and often be less than 50%. Stakeholders highlighted, however, that low uptake may not reflect IMT failures. If the team believes the risks associated with the incident to be low and primarily wish to reassure patients rather than promote testing, low testing uptake may reflect a suitable outcome.

4.5.2.3 Research gaps

Both the literature review and stakeholder consultation phases of a scoping review study have the shared aim of highlighting research gaps in the field and making recommendations for future studies. This literature review certainly identified a plethora of research gaps within the evidence base. Authors highlighted the need to explore specific PNE factors such as the anxiety caused to patients (Hancocks 2008) or the financial and opportunity costs of the notification process (Mason et al 2008).

The absence of suitable infection control PNE decision-making guidance is an issue encountered more frequently as infection control breaches are shown to account for an increasing proportion of dental incidents. Why is this the case? It seems highly unlikely that dentists' standards of infection control are worsening.

It is more likely that detection of issues has improved or that as infection control standards have risen more dental practices are found to be in breach of regulations with previous, less stringent practices no longer being accepted.

Not only are decision makers hampered by an absence of guidance but also an inability to ascertain what others have done in the past. A large proportion of UK incidents do not result in publication (87%). This value is also most likely an under estimation as many of the unpublished incidents were identified through contact with UKAP an organisation focused on management of infected HCWs. A lack of publication activity means that lessons learned and incident data are not disseminated to decision makers. Even when incidents were published there appeared to be no standardised way of reporting dental incidents and there were inconsistencies in both the amount and detail of information presented. There was great variability in the types of journal that featured articles on patient notification.

Incident information was commonly presented either in a vague manner or not at all. The most likely information to be missing included the calculated risk of BBV transmission (missing in 82-93% of cases) and the cost of the exercise (missing in 74% of cases). The most common information to be presented in a vague format were data concerning the investigation of identified diagnoses. It was often very difficult to ascertain the steps that had been taken following diagnoses of patients to disprove or prove a link to the incident in question. Information regarding the total number of diagnoses found was usually present, however, information regarding whether diagnoses were new to the patients (28%), whether these newly diagnosed cases had alternative risk factors for infection (33%) and/or sequencing performed (40%) was often vague or presented in a complex manner. Creation of a standardised reporting framework would be helpful. The data extraction forms created for this doctoral project (described in section 4.3.3 and presented in Appendix 14) could serve this function.

Those managing incidents also highlighted issues with both identifying and classifying ‘at risk’ patients using dental records. Irwin and Millership (2002) called for there to be a minimum level of patient information that must be recorded by dental practices as generally records examined in incident investigations were found to be poorly maintained and/or difficult to obtain at all.

4.5.3 Strengths

This type of broad literature and evidence overview gives the reader access to an extensive summary of the subject area and allows researchers to see clearly both those studies that have been undertaken and the further research that is needed. A single resource which collates and describes a large proportion of dental incidents will benefit decision makers who do not have time to review all available evidence following discovery of an incident.

A scoping review study strategy meant literature for this review was not limited by quality, source or publication status. This provides access to a larger volume of data with greater variability – an especially important factor when presenting data on a subject which has a low amount of high quality research. Although not a traditional systematic review, this study still utilised a systematic strategy facilitating replication of methods and increasing user confidence in the comprehensiveness of its results.

4.5.4 Weaknesses

All reviews have the common weakness of becoming instantly outdated once they are completed and published. However, one of the main weaknesses of this review was the inability to source further information in relation to 54% of incidents. This is thought to be due to a number of factors such as the low number of incidents that result in publication (14/108 UK incidents), the lack of a central repository or database where incident data are stored and, finally, the possibility that boards or trusts may have been reluctant to share incident reports or details with the CI, a relatively unknown contact. This final theory is supported by the fact that, based on UKAP data, there were many UK dental incidents for which boards and trusts would have had information but the majority of calls and email requests sent to all UK IMTs, for incident details, did not prompt a response.

A large proportion of the reviewed literature was old (79% of 105 journal articles were published more than ten years ago), but this was simply the nature of the information available and was an issue that could not be mitigated. It may mean that some findings may be influenced by an older context and not necessarily applicable to the management of a modern incident.

Both the meta and narrative synthesis of this review collate and present concepts together. However, caution should be exercised when drawing conclusions from these data as all incidents are managed within greatly varying contexts, for example the year, location or nature of incident. A significant

proportion of the incidents presented occurred in the 1990s (19%) and/or in the USA (24%).

When interpreting the results readers should also be aware that key incident data within reports were often estimated, vague or missing. This means that not only should results again be interpreted with caution but also that high-level statistical analysis was neither feasible nor appropriate.

4.5.5 Methodological choices

A developed-country setting literature searching limitation was considered appropriate as population prevalence of BBV infection and dental infection control practices would be comparable to the UK and therefore any outcomes would be appropriate in influencing future UK guidance (Mahboobi et al 2013; Scully and Greenspan 2006). The limitation of 'post 1990' was chosen based on the concept that, before this time, infection control practices were more lax. Glove wearing, use of steam sterilisers and being immunised against HBV was not commonplace in the early to mid-eighties (Burke and Wilson 1989; Smith et al 2007; Scully et al 1993). Gordon et al (2001) conducted a systematic review which examined the changes in infection control practices throughout the developed world from 1980-1999. They explained that:

"Since the mid-1980s, recommended measures such as the wearing of gloves, masks, and the autoclaving of handpieces have been reviewed regularly [...] In particular, the concept of universal infection control, whereby all patients are treated as potential carriers of pathogenic micro-organisms, has become accepted best practice." (Gordon et al 2001)

Scully and Greenspan (2006) highlighted that in 1982 HBV vaccination became available to HCWs and that from 1983 to 1992 there was a 74% increase in HCW vaccination. Upon consideration of the literature and expert advice, 'post 1990' was deemed to be a prudent time limitation as this represents the beginning of an era of enhanced infection control and greater understanding of BBV transmission risks.

Often multiple sources were used to extract data related to incidents with certain facts or figures occasionally contradicting one another. The figure chosen to be presented was decided upon based firstly on the quality of the source (ie: a peer reviewed journal was considered to be a more reliable source than an online news update) and secondly on the frequency of its presentation in different sources. More than half (53%) of infection control incident reports or publications lacked sufficient detail concerning the breaches that had occurred. This meant that discerning the exact infection control or decontamination step or steps omitted was difficult and a degree of interpretation was needed. For

example, the phrase “use of unsterilised instruments on patients” intuitively indicated that instruments were not entered into any stage of the decontamination process before being used on a subsequent patient, but the statement is open to interpretation (Roy et al 2005). There was a plethora of issues when estimating, collating or presenting the financial costs of notification. Reports rarely outlined financial costs and when they did, great discrepancies could be found between their calculation and reporting styles. A number of reports had categories such as ‘other costs’ which were ambiguous (Close et al 2013). Some reports included staffing costs (Conrad et al 2011; Close et al 2013) whilst others did not (Longfield et al 1994) and the ways in which notification was achieved varied greatly from incident to incident.

4.6 Conclusion

Current evidence is clearly limited and it is difficult to ascertain the true impact of the different positive and negative PNE outcomes. Future research, however, does not need to explore every factor, only those which the literature shows will actually impact upon the decision to proceed to patient notification. These can be summarised as the risk of transmission, the anxiety caused to notified patients, the concept of transparency and resource allocation.

No significant correlations were identified amongst incident features rendering prediction of future outcomes by IMTs difficult. Collation and comparison of incident data was challenging due to vague and/or inconsistent reporting as well as incidents being highly contextual.

Although these issues are present and important to consider, guidance is needed, even if it is based on limited evidence. Those in the field must work with existing evidence and decision makers will benefit from the provision of a useful guide to complement their expert opinion.

Chapter 5. Mapping guidance and policy documentation in relation to dental 'BBV transmission risk' incidents and large-scale disclosure

5.1 Introduction

A policy mapping exercise, executed as part of a scoping review study, provides an opportunity to place stakeholder opinion and literature review data within a contemporary policy context (Anderson et al 2008). It has been defined as both a process which is "designed to identify the main documents and statements from government agencies and professional bodies that have a bearing on the nature of practice in that area" (Anderson et al 2008), and an exercise which "might have the objective of mapping how policy documents provide advice and guidance around" a specific subject (Peters et al 2017).

To facilitate the design of an appropriate decision-making algorithm, mapping and analysis of dental PNE guidance was deemed essential. It was anticipated that inspiration for the content and design of the algorithm would almost certainly be drawn from the extant guidance.

5.2 Aims

i. To establish the amount, detail and focus of guidance that currently exists in the area of large-scale notification following medical incidents.

ii. To aid in the creation of a decision-making algorithm[10] by identifying any relevant guidance content or design that could be adapted for use.

5.3 Methods

Although a significant number of scoping review studies make reference to policy mapping few give specific detail regarding its execution. Keating et al (2006) simply listed the medical databases searched and terms used whilst Ross et al (2004) provided more detail on their identification of relevant documents and extension of their search to include the references of identified documents. Ross et al (2004) utilised a framework for thematic analysis of policy content and graded each piece of guidance based on its applicability to their study aims.

[10] An algorithm which will guide the decision-making process of when to proceed to patient notification following a dental infection control incident.

5.3.1 Search strategy

Using recommendations from experts, stakeholders, the Medical, Veterinary & Life Sciences (MVLS) College Librarian and University Public Health lecturers as well as the CIs personal knowledge and utilisation of the resource 'Grey Matters', 102 websites were identified for searching (Appendix 19). Grey Matters is essentially a list of healthcare data websites and is described as a practical tool for searching health-related grey literature (CADTH 2015). A simple Google search was also conducted and reference lists of all source documents were scanned for further guidance of relevance.

A systematic strategy was developed for searching the sites identified. Specific terms were consistently used within the search boxes of each website, to identify relevant guidance. This was followed up by a manual search of the site. Twenty four detailed terms were used and if low numbers of results were generated, eleven broader terms were used (Table 39). The Google search was conducted using not only the 24 detailed search terms but six additional terms (Table 39).

A spreadsheet was used to record the search terms used, the sites searched, the dates they were searched, any documents found that appeared to fit the inclusion/exclusion criteria and any issues or problems encountered.

Table 39: Search terms used in 102 healthcare organisation websites to identify guidance documents related to the decision to conduct a dental PNE

Detailed search terms	Dental patient notification
	Dentist patient notification
	Dentistry patient notification
	Oral surgery patient notification
	Dental transmission
	Dentistry transmission
	Dentist transmission
	Oral surgery transmission
	Dental large scale adverse event
	Dentist large scale adverse event
	Dentistry large scale adverse event
	Dental incident report
	Dental look back exercise
	Dentistry look back exercise
	Dentist look back exercise
	Dental patients notified
	Poor dental infection control
	Poor dental decontamination
	Dirty dental instruments
	Dental infection control breach
	Poor dental cross infection control
	HIV dentist
	Hepatitis B dentist
	Hepatitis C dentist
Broad search terms	Dentistry
	Dentist
	Dental
	Blood borne virus
	Transmission
	Oral Surgery
	Patient notification exercise
	Look back exercise
	Large scale adverse event

	Incident management
	outbreak
Extra terms used for Google search	Public health incident management guidance
	Patient notification exercise guidance
	Look back exercise guidance
	Dental BBV transmission
	Dental patients at risk of HIV
	Dental patients at risk of hepatitis

5.3.2 Inclusion/exclusion criteria

All guidance identified that met the following criteria was retained for further analysis:

- It gave advice on how to grade/assess the risk associated with an infected HCW/infection control incident

OR

- It gave advice on when to notify patients following an infected HCW/infection control incident

OR

- It gave advice on the threshold for duty of candour/disclosure

AND

- It was published by a healthcare organisation or is a document reported to have been used by stakeholders in the assessment or management of a relevant incident

AND

- It applies to / was published in a developed country setting / context

AND

- Was published post 2000

Guidance was excluded if it:

- Was published/written by authors rather than an organisation UNLESS directly used or recommended by a consultant/individual who has managed an incident

- Featured no risk assessment or advice on notification and was not considered disclosure/candour guidance

- Was a general document on adverse event/clinical incident management UNLESS it included risk assessment/grading/matrix

- Was only applicable to a small, localised area such as a single NHS trust or board.

- Had been made obsolete by new documentation (excluding open disclosure guidance)

5.3.3 Data analysis

Following application of the exclusion/inclusion criteria, summaries were created for each document. Consideration was given to their focus, whether they included a risk assessment/matrix/severity grading tool, whether they outlined factors which could be considered when deciding whether to notify patients following an infection control incident and whether they gave guidance on when and when not to notify patients.

If a document referred to a risk assessment tool but did not include it, a note of the tool was made and incorporated into the final results/discussion (Appendix 20).

Documents were separated into five categories to facilitate interpretation and analysis:

- General guidance on managing/grading public health incidents or outbreaks
- Guidance on the management of BBV infected healthcare workers
- Open disclosure/Duty of Candour guidance
- Guidance on the implementation of PNEs/Lookbacks
- Management of a specific infection control breach incident

5.4 Results

Initial searching resulted in the identification of 226 potentially relevant guidance documents (Figure 21). Following application of the inclusion and exclusion criteria 49 documents from 10 countries were deemed eligible for inclusion in the narrative synthesis (Figure 22).

No UK guidance exists to aid IMTs with decision-making regarding large-scale patient notification following an infection control breach incident. General guidance on incident management is available but it does not provide detail on the risk/benefit analysis that needs to be done when considering a PNE. The relevant guidance documents identified as part of this policy mapping exercise are either sourced from another developed country or, more commonly, simply linked to the general subject area.

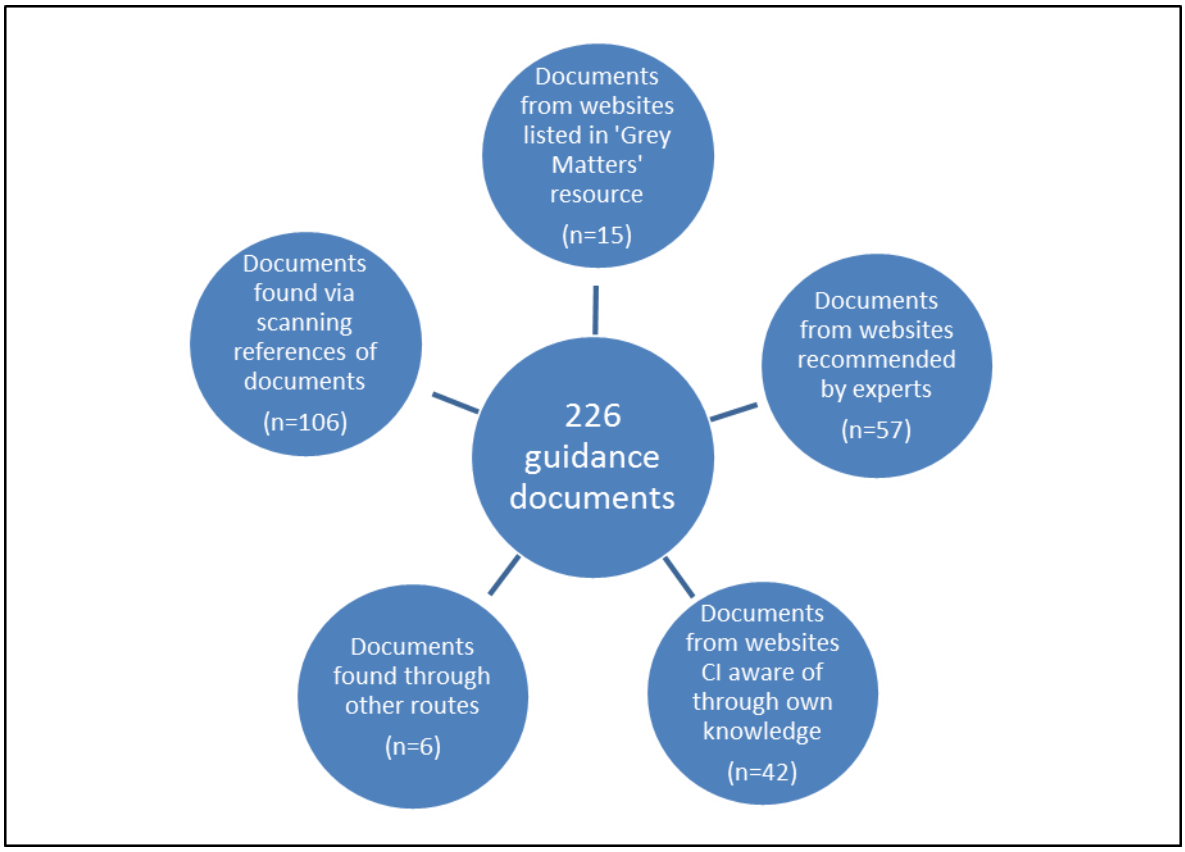


Figure 21: Radial diagram showing number and sources of all identified guidance documents

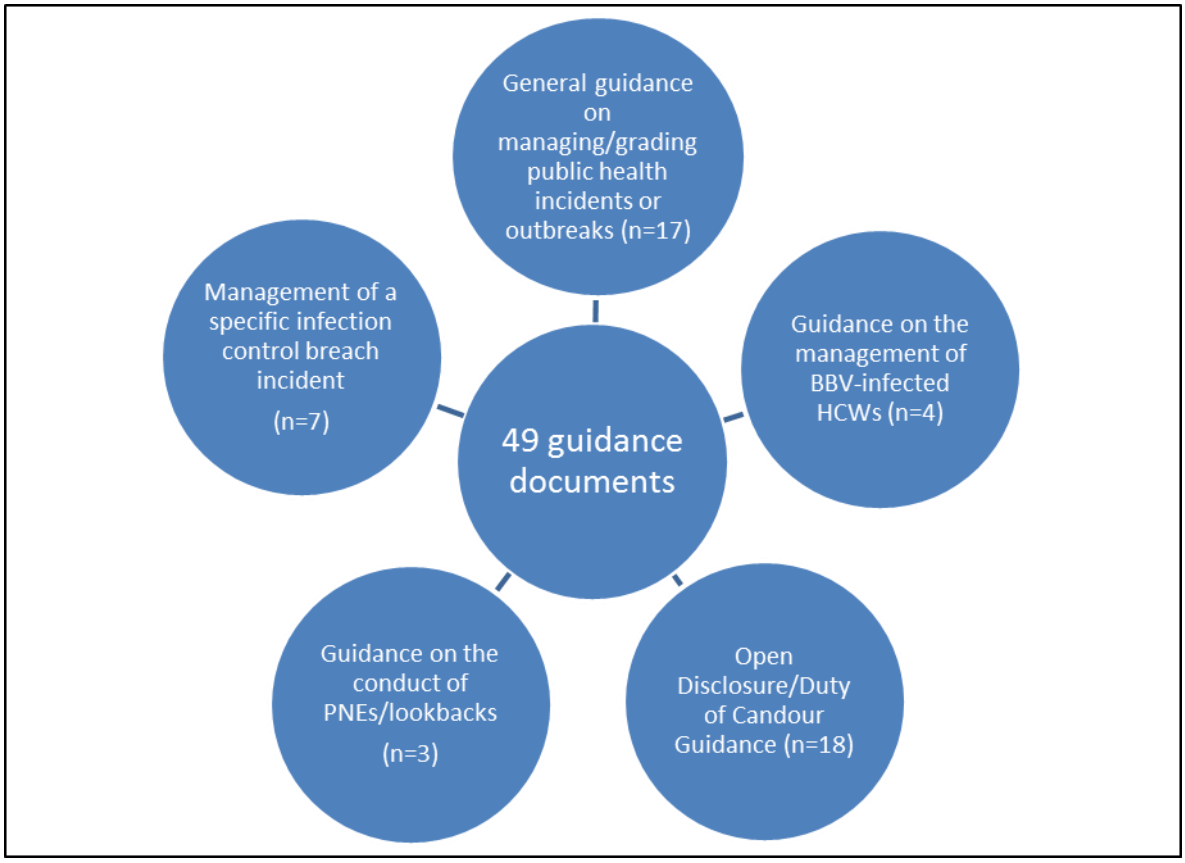


Figure 22: Radial diagram showing the numbers of each type of guidance document selected for analysis based on main focus.

5.4.1 General guidance on managing/grading healthcare associated infection incidents or outbreaks

General guidance was identified which gave advice concerning both healthcare associated infection/outbreaks and, more broadly, the management of all incidents which could affect public health, including food outbreaks and environmental hazards.

Guidance on the subject of general public health incident management was identified from European authors Schroder-Back et al (2014), the UK (Health and Safety Executive 2001) and each of its devolved nations (NSS 2019[a]; Healthcare Improvement Scotland 2018; HPS and NSS 2017[a]; HPS and NSS 2017[b]; Scottish Government 2008; PHE 2014[c]; Public Health Wales 2014; PHA 2018; Health and Social Care Board 2016) as well as Ireland (Health Service Executive 2017) Australia (New South Wales Government 2014; Australian Government – NHMRC 2010) and the USA (Conway et al 2011). Both the European Centre for Disease Prevention and Control (ECDC 2011) and the World Health Organisation (2016[b]) also published relevant documentation.

When considering applicable guidance, a dental infection control incident could be considered a clinical adverse event (Conway et al 2011; Healthcare

Improvement Scotland 2018), significant adverse incident (Health and Social care Board 2016), healthcare infection exposure incident (NSS 2019[a]; HPS and NSS 2017), public health incident (HPS and Scottish Gov 2017) or healthcare associated infection risk (Scottish Government 2008) making many general guidance documents potentially relevant.

Most guidance contained a toolkit for assessing the risk associated with an incident. A risk value or grading was most often created based on combining scores within a grid related to the predicted or actual impact of an incident and the likelihood of it occurring or recurring (HIS 2018; Scot Gov 2008; ECDC 2011; Australian Gov-NHMRC 2010; Health and Social Care Board 2016; HSE 2017; NSW Gov 2014). The incident grading was used to establish, in the majority of cases:

- whether certain expert teams should be assembled (HPS and Scot Gov 2017; Public Health Wales 2014; Public Health Agency 2018)
- who the incident should be reported to (HPS and NSS 2017; Public Health Agency 2018)
- timescales for addressing issues (ECDC 2011; PHE 2014[c])
- whether it should be declared a certain type of incident eg: a serious adverse event, an outbreak (Public Health Wales 2014; Health and Social Care Board 2016).

Specific incident grades never directly influenced decisions regarding informing patients. However, elements incorporated into the grading tool, such as resources and staff required, number of patients affected, predicted media/public interest and potential patient harm are certainly applicable to a patient notification decision (HSE 2017; PHW 2014; HPS and Scot Gov 2017; PHE 2014[c]; Scottish Gov 2008). Appendix 20 presents data on the toolkits identified including the guidance documents they are from, what they aimed to measure and the nature of advice given depending on the grade or level of risk associated with the incident. In essence, the risk assessment tools presented in these documents are simply a guide to aid decision makers in understanding the severity of the scenario with which they are dealing and therefore how swiftly and intensely risks should be managed or controlled.

As well as risk assessment matrices and incident grading systems, these documents provided advice concerning the importance of both sharing lessons learned following incident management (HPS and Scot Gov 2017; Public Health Wales 2014) and keeping accurate records of decisions made and the reasoning behind them (HPS and Scot Gov 2017). Guidance included reporting templates and advice on the minimum amount and type of information that should be collated following an incident (NSS 2019[a]; HPS and NSS 2017; Conway et al 2011). For example, if an incident is classed as being ‘amber’ or ‘red’ using the NHS

Scotland HIIAT tool, a Healthcare Incident Infection Outbreak Reporting Template (HIIORT) must be completed (HPS and Scot Gov 2017).

An additional and unique document which was classed as providing general incident management guidance was published by Schröder-Bäck et al in 2014. They proposed using key ethical questions under seven headings to support ethically based, public health decision-making (Table 40).

Table 40: The Seven Principles of Public Health Ethics as described and published by Schröder-Bäck et al 2014. Reproduced with permission.

Non-Maleficence

- Will no one be harmed by the proposed intervention?
- Are especially children prevented from harm?

Beneficence

- Is the intervention of any good to every single person taking part in this intervention?
- Overall, for both non-maleficence and beneficence, is it possible to assess whether more benefit than harm is produced by intervening (or not intervening) and, if so, on what side (benefit or harm) does the equation finally fall?

Health Maximisation

- Is the proposed intervention effective and evidence-based? Does it improve population health?
- Does it have a sustainable, long-term effect on the public's health?
- Is there a community added value to the proposed intervention?

Efficiency

- Is the proposed intervention cost-effective?
- Awareness of scarcity of public money; saved money can be used for other goods and services.

Respect for Autonomy

- Does the intervention refrain from employing coercion and manipulation? Does it foster free choice?
- Is there really 'informed consent' to take part in the intervention?
- Is self-responsibility not only demanded but also possible for every person?
- Are privacy and personal data respected?
- If the intervention is paternalistic, is this justifiable?
- Does the intervention promote the exercise of autonomy?

Justice

- Is no one (including third parties) stigmatised, discriminated against or excluded as a consequence of the proposed intervention?
- Is the institution proposing the intervention publicly justified and acting transparently?
- Is the proposed intervention not putting sub-populations at risks of being

excluded from social benefits and/or universal access to health care?
- Does the intervention exacerbate social and health inequalities (inequities)? Does it fight inequalities (inequities)?
- Does the intervention consider and support vulnerable sub-populations (e.g. migrants)?
- Does the intervention promote rather than endanger fair (and real) equality of opportunity and participation in social action?
- Does the intervention refrain from eroding a sense of social cohesion and solidarity?

Proportionality

- Is the intervention the least infringing of possible alternatives?
- Are costs and utility proportional?

5.4.2 Guidance on the management of BBV-infected HCWs

Guidance which provides direction following the identification of an infected HCW often includes advice concerning risk assessment and decisions regarding patient notification (Henderson et al 2010; PHE 2017[a]; Australian Government Department of Health 2018; Queensland Health 2013). It was postulated that reviewing this guidance may provide some indication as to the elements that should be assessed following an infection control incident and the factors which may influence the decision to notify.

Much of this guidance attaches level of risk to the infectivity of the HCW, the type of BBV involved and the nature of the procedures performed (Queensland Health 2013; Australian Gov Dep of Health 2018; Henderson et al 2010; PHE 2017[a]). In the context of a dental infection control breach this would equate to the infectivity of any potential source patient identified and the types of dental procedure undergone by both source and exposed patients. However, following an infection control breach, one must remember that in comparison to most BBV-infected HCW incidents there is a risk of all three BBVs being transmitted.

In 2017, a useful, integrated guidance document was published by Public Health England. It combines and updates a number of historical documents regarding the management of infected HCWs within the UK (PHE 2017[a])[11].

5.4.2.1 Types of procedures performed

UK guidance indicates that risk of transmission from HCW to patient only exists if EPPs are being conducted (PHE 2017[a])[11]. An EPP describes a procedure where there is a risk of HCW injury with consequent bleeding into patient tissues as

[11] This guidance was updated in 2019

sharp instruments are used, the worker's fingers are not visible at all times and the patient's tissues are exposed (PHE 2017[a]). EPPs are separated into three categories with Category 3 procedures being the most invasive and risky eg. cardiothoracic surgery (PHE 2017[a]). There are no dental procedures which are classed as Category 3 EPPs but almost all dental procedures are EPPs (PHE 2016).

5.4.2.2 Type of BBV infection

Infected HCW guidance also bases level of risk on the specific BBV involved (Henderson et al 2010; PHE 2017[a]). This is shown, in UK guidance, through the differing working restrictions imposed on BBV-infected HCWs based on the nature of their infection (PHE 2017[a]). A HCW infected with HBV or HIV may perform EPPs depending on viral load, uptake of treatment and monitoring whereas if positive for HCV, the HCW may not conduct EPPs (PHE 2017[a]). In Australia, regulations are stricter, with BBV-infected HCWs not being allowed to perform EPPs under any circumstances (Queensland Health 2013; Australian Gov Dep of Health 2018). The US appears to have less restrictive regulations, as HCWs infected with any BBV may perform EPP Categories 1 and 2 as long as certain criteria are met, such as double gloving and seeking advice from an expert panel (Henderson et al 2010).

5.4.2.3 Viral load

The risk surrounding treatment from an infected HCW, and therefore their working restrictions, are shown to be strongly linked to their viral load and associated level of infectivity (Tables 41 and 42).

Table 41: Working restrictions placed on UK BBV-infected HCWs based on viral loads (PHE 2017[a])

Virus	Acceptable (very low) viral load. HCW can conduct EPPs	Viral load needs to be confirmed through repeated testing. If still above acceptable level, HCW must cease conducting EPPs	Viral load indicates HCW must immediately stop conducting EPPs
HBV	<200 IU/ml[a]	200-399 IU/ml[b]	≥400 IU/ml[c]
HIV	<200 copies/ml[d]	200-999 copies/ml[e]	≥1000 copies/ml
HCV	Cannot perform EPPs		
IU/ml = International Units per millilitre of blood			
a = In the updated 2019 guidance this value has been changed to <60 IU/ml b = In the updated 2019 guidance these values have been changed to 60-199 IU/ml c = In the updated 2019 guidance this value has been changed to ≥200 IU/ml d = In the updated 2019 guidance this value has been changed to <50 copies/ml e = In the updated 2019 guidance these values have been changed to 50-999 copies/ml			

Again, US regulations are shown to be less restrictive as if viral load is low enough, BBV-infected HCWs in the US may also conduct Category 3 procedures (Henderson et al 2010).

Table 42: Working restrictions placed on American BBV-infected HCWs based on viral loads (Henderson et al 2010)

Virus	Acceptable (very low) viral load which means HCW can conduct EPPs cat 1, 2 and 3*	Viral load which means HCW can only conduct EPPs cat 1 and 2*
HBV	$<10^4$ GE/ml	$\geq 10^4$ GE/ml
HIV	$<5x10^2$ GE/ml	$\geq 5x10^2$ GE/ml
HCV	$<10^4$ GE/ml	$\geq 10^4$ GE/ml
GE/ml = Genome equivalents per millilitre of blood		

** as long as HCW adheres to certain criteria*

Guidance also indicates situations or findings that would increase risk of transmission from a HCW that would similarly apply to a source patient. If they are HBeAg positive or carry a pre-core mutant version of HBV transmission risks will be higher (PHE 2017[a], Henderson et al 2010)[12].

5.4.2.4 Infected HCWs - the need for patient notification

Infected HCW guidance not only gives risk assessment and monitoring advice but also gives specific guidance regarding the need for patient notification.

UK

In response to a BBV-infected HCW, the key influential factor contributing to the decision to notify, is whether a probable, iatrogenic transmission has already been identified (PHE 2017[a]). If so, notification of all patients, regardless of EPP category, covering the entirety of the HCW's employment history (or at least back to the date of their most recent negative test, if available) is advised (PHE 2017[a]). If there are no identified transmissions, consideration of other factors such as quality of infection control and the health status of the HCW is advised (PHE 2017[a]). Physical conditions such as skin lesions or mental impairments such as dementia may increase risk of transmission. Presence of these factors along with the HCW's infection, indicate the need for a PNE (PHE 2017[a]). Specific advice regarding HIV-infected HCWs is given[12]. It states that even if there are no identified transmissions or reports of poor infection control, a PNE must still be conducted for those patients who underwent Category 3 EPPs (PHE 2017[a])[12].

In general UK guidance advises that every assessment of an infected HCW should be done on a case by case basis and that responses should be "practical and proportionate to the risk of transmission" (PHE 2017[a]). Generally they advise

[12] This is no longer outlined in the PHE guidance which was updated in 2019

that when making the decision to notify, cross matching findings, the nature of the procedures conducted and expert advice are important (PHE 2017[a])[13].

Australia

Australian guidance similarly advises that generally, each scenario should be considered on a case by case basis (Australian Government DoH 2018; Queensland Health 2013). Their guidance states, however, that if an infected HCW is found to have been conducting EPPs, patient notification is generally indicated (Australian Government 2018; Queensland Health 2013). Flexibility regarding this point, however, is shown through later advice. Authors explain that if there is no identified probable transmission, notification should be restricted to those patients who underwent Category 3 EPPs (Australian Government 2018; Queensland Health 2013). If there is a suspected transmission or presence of additional factors, such as poor infection control or HCW impairment, all patients who underwent an EPP of any category should be notified (Australian Government DoG 2018; Queensland Health 2013).

USA

CDC guidance provides a list of situations involving infected HCWs where patient notification would be prudent (Henderson et al 2010):

- A HCW has been conducting Category 3 procedures with a viral load higher than is permissible (Table 42).
- There is strong evidence of an identified, associated transmission.
- The specific clinical specialty and types of procedures conducted are associated with a higher transmission risk.
- There is a history of frequent sharps injuries or high rates of postoperative infection.
- Presence of poor infection control.
- The HCW has physical or mental impairments which may increase risk of transmission.

5.4.3 Open disclosure / duty of candour guidance

Key guidance regarding the decision of when to notify patients following an incident was found within documents which discussed the requirements for open disclosure or circumstances which trigger an organisational, statutory duty of candour.

[13] If there is no index case/ probable transmission, cross matching is no longer advised as part of the PHE guidance which was updated in 2019

5.4.3.1 Duty of candour within the UK

The Duty of Candour, which now applies to both England and Scotland, places a legal requirement on both NHS health care organisations and providers to be open with patients when things go wrong (CQC 2014; RCS 2015; GMC 2015; Scottish Government 2018). Statutory Duty of Candour in both Scotland and England does not apply to individuals who have a professional, but not statutory, duty to be candid (CQC 2014; RCS 2015; GMC 2015; Scottish Government 2018).

In 2014, Statutory Duty of Candour was introduced in England for health service bodies (CQC 2014). Its implementation was in direct response to recommendations made following investigation of an English NHS Foundation Trust and its resultant report, the Francis inquiry (Francis 2013). In 2015, the duty was extended to all English facilities which provide NHS healthcare (RCS 2015; GMC 2015). The requirements of the English Duty of Candour differ depending on whether the incident involves a 'health service body' eg. NHS trust or 'registered person' eg. a dental practice (RCS 2015; GMC 2015). For health service bodies, a notifiable incident includes both incidents that have resulted in harm and those that (in the reasonable opinion of a healthcare professional) could result in harm (RCS 2015; GMC 2015). For 'registered persons' the duty only applies to incidents that have caused harm (RCS 2015; GMC 2015). Failure to comply with the English Duty of Candour can lead to a criminal conviction, which is not currently the case in Scotland (UK Faculty of Public Health 2019).

In 2018, Scotland implemented the Duty of Candour (Scottish Government 2018) which is set out in the Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016. The Scottish Duty of Candour closely mirrors the English duty with minor differences e.g. the health care professional who assesses whether harm has occurred, or could occur, must not be linked to the incident in any way (Scottish Government 2018). The Scottish duty applies to NHS boards and service providers in the same way, with both needing to notify patients if harm has or could have occurred (Scottish Government 2018). The Scottish Government website does outline, however, that 'could result in' is akin to the term 'likely to result in' and state that "if the registered health professional thinks that it is unlikely that harm will occur, then the duty of candour procedure need not be activated" (Scottish Government 2018).

5.4.3.2 Other disclosure guidance documents

Pivotal disclosure guidance documents were identified in relation to a number of developed countries: Australia, New Zealand, Canada, the USA, Scotland, England, Ireland and Denmark. Common themes identified from these guidance documents included the ethical imperative to notify patients, basing the notification decision on levels of patient harm, considering the potential for future patient harm following an incident and the benefits of reducing litigation

and increasing patient trust (AHRQ 2016; VHA 2018; Danish Society for Patient Safety 2008; Health Service Executive 2013; Health and Disability Commission 2009; Australian Commission on Safety and Quality in Healthcare 2014; Health Quality Council of Alberta 2006; College of Physicians and Surgeons of Ontario 2003; Canadian Patient Safety Institute 2011; Canadian Medical Protective Association 2017; Nova Scotia Health 2005; NPSA 2009; Healthcare Improvement Scotland 2015)

The decision to notify patients following a 'no harm' or 'near miss' incident is mostly described as discretionary (Health Quality Council of Alberta 2006; College of Physicians and Surgeons Ontario 2003; NPSA 2009; AHRQ 2016). Some guidance does refer to the concept of potential or future harm (Health Quality Council of Alberta 2006; CEC 2014; VHA 2018; CMPA 2017) but varies in how it is described or quantified. As previously outlined the Scottish Duty of Candour guidance document states that a notifiable incident includes those that "could result" in specific outcomes (Scottish Government 2018). The Canadian Patient Safety Institute (2011) stated that "disclosure must occur if there is a risk of potential future harm" and that "if potential for future harm exists [the] decision depends on future likelihood of important clinical consequences". Patient notification thresholds from the examined guidance are outlined in Appendix 21 alongside specific advice given regarding multi-patient disclosure or assessment of potential, future harm.

5.4.3.3 Ethical/professional duty to be open with patients

While many documents provided thresholds for prompting a notification, they also advised that each situation should be judged on a case by case basis. Furthermore, while recognising that duty of candour had introduced a legal requirement to notify, the ethical arguments for notification, following a greater variety and severity of occurrences, were still strong (GMC 2015; CQC 2014; RCS 2015; Scottish Government 2018). The guidance also reminded healthcare providers that the professional duty of candour remains applicable and has been both advised and encouraged for decades and that open disclosure comes hand in hand with a move away from the historical paternalistic medical culture (Healthcare Improvement Scotland 2015; Royal College of Surgeons 2015; Care Quality Commission 2014; Health and Disability Commission 2009; Canadian Medical Protective Association 2017; The Scottish Government 2018; Agency for Healthcare and Research Quality 2016; Health Quality Council of Alberta 2006).

5.4.3.4 Multi-patient disclosure

In some countries open disclosure documents specifically indicated that their use was solely relevant to incidents involving single patients (AHRQ 2016; Australian Commission on Safety and Quality in Healthcare 2014; CQC 2014; College of

Physicians and Surgeons Ontario 2003; GMC 2015). In addition, the advisory content of many other documents implied that their use applied only to single patient incidents through outlining approaches that would only be possible when disclosing to a single patient. For example, the CQC (2014) advised that disclosure should always be undertaken verbally and ideally in person. Both the Agency for Healthcare Research and Quality (2016) and New South Wales Health (2014) outlined that notification must take place within 24 hours of an incident being identified. New South Wales Health (2014), along with the Australian Commission on Safety and Quality in Health Care (2014), stated that preferably the patient should decide both whether harm has occurred and what level of harm merits explanation, a process not possible when managing an incident involving hundreds or thousands of patients.

No UK guidance refers to multi-patient disclosure, but three documents published by Irish, Australian and Canadian organisations presented brief, general advice for these types of incidents (CEC 2014; Canadian Patient Safety Institute 2011; Health Service Executive 2013). Essentially, they stated that all incidents should be managed on a case by case basis, seeking advice from relevant experts whilst undertaking "a complex weighing of clinical probabilities and ethical obligations" (Canadian Patient Safety Institute 2011).

Notification of multiple patients is advised by the Health Service Executive (2013) when "likelihood of exposure is high". When lower, consideration of a number of factors is required such as the "ethical obligations" of the organisation (Health Service Executive 2013). Both the VHA (2018) and Nova Scotia Health (2005) provide more detail in relation to the decision-making process to follow when multiple patients are involved in an incident. The Nova Scotia Health framework (2005) outlines that response options should be established through "brainstorming and facilitated discussion of stakeholders" and encourages users to reflect on "ethical principles at play" and "institutional core values". It also advised that decision makers consider the issues from multiple perspectives eg: "the harmed or potentially harmed individuals" as well as "society at large".

5.4.3.5 Disclosure of adverse events to patients – VHA guidance

The VHA (2018) provides detailed guidance on disclosure of adverse events and recommends that an initial panel conducts a thorough investigation of the incident, including site visits and assessment of evidence. The resulting risk assessment is used to inform one of three recommendations: 1) that patient notification is required, 2) that it is not necessary, or 3) that the risk is uncertain and further discussion and assessment are needed (VHA 2018). The latter recommendation triggers assembly of a second panel – the Clinical Review Board (VHA 2018). This panel explores "the probability and severity of harm resulting from the adverse event" as well as considering "salient ethical

principles; risk of harm to patients and potentially-affected third parties; benefit and burden of disclosure to patients, including medical, psychological, social, or economic; impact on the institution's perceived integrity and its capacity to provide care and treatment for all patients; as well as applicable policy and relevant precedent" (VHA 2018). A list of salient questions is provided for consideration and presented in Table 43.

Table 43: Questions featured in VHA guidance – Disclosure of Adverse Events (2018)

VHA (2018)
1. DO WE HAVE ALL THE IMPORTANT FACTS RELEVANT TO THE DECISION?
2. HAVE WE INVOLVED EVERYONE WHO SHOULD BE PART OF THIS DECISION?
3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES?
4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY LIKELY HARMS?
5. DOES THIS DECISION ESTABLISH A GOOD MODEL FOR FUTURE DECISION-MAKING?
6. HOW WOULD THIS DECISION LOOK TO SOMEONE OUTSIDE THE ORGANIZATION?

5.4.4 Guidance on the implementation of PNEs / lookbacks

Three pieces of guidance were identified which mainly focused on the conduct of PNEs (Health Service Executive 2015; Cummins et al 2001; NSW Gov 2007). These documents mirror the open disclosure and duty of candour documents, by outlining which experts should be approached for advice, the roles of those on the IMT and how the final report should be structured (Health Service Executive 2015; Cummins et al 2001; NSW Gov 2007).

Irish guidance had more of a PNE decision-making focus as it clearly presented the key criteria that should be considered when deciding whether to proceed to patient notification (Health Service Executive 2015) (Table 44). The guidance stated that patients must have 1) been exposed to some form of hazard and that 2) "a means of amelioration exists" i.e: treatment (Health Service Executive 2015). The authors stated that concern for patient safety must be balanced with the need to ensure the PNE does not cause widespread distress (Health Service Executive 2015).

Table 44: Key criteria to consider when making decisions regarding patient notification following a healthcare related incident (Health Service Executive 2015)

- The potential extent of the issue and the level of exposure to the hazard
- Evidence of harm that has occurred
- The likelihood of future harm occurring
- The potential and actual (if relevant) outcomes of the issue (eg. undiagnosed and therefore untreated HCV infection)
- Severity of potential outcome (HSE impact table 2014 can be used to rate)
- The potential cohort of service users affected (number of patients affected, ages, category of service user)
- The manner in which harm would be ameliorated (e.g. repeat investigation /onward referral for treatment)

5.4.5 Management of a specific infection control breach incident

Seven guidance documents focused directly on the management of an infection control breach (Patel et al 2008; USAF DECS 2009; CDC 2012; Anon 2016; CDC 2019[b]; CDC 2015; Weber and Rutala 2013). All were published in the US. Two of these documents were included in this synthesis as they were reported to have been used by public health stakeholders in the past, but were in fact peer reviewed scientific papers as opposed to formally developed guidance (Patel et al 2008; Weber and Rutala 2013).

The CDC (2012), US Airforce (2009) and Californian Dental Association (Anon 2016) all used the article by Patel et al (2008) as a basis for their guidance. The process guides the user to assign an incident to one of two risk categories:

- category A, where there is a clear and significant risk to patients
- category B when the risk is low, uncertain or hypothesised (Patel at al 2008).

If Category B is chosen, consideration of other factors, such as public concern, the duty to disclose and potential harm caused to patients by notification, is advised (Patel et al 2008). Notification is advised regardless of which category is chosen, the only difference being the recommendation that a category B incident may not merit testing of patients (Patel et al 2008). It is made clear that use of this process is only applicable when there is no associated known transmission event, as that would clearly indicate a high-risk scenario with a need for patient notification and testing (Patel et al 2008). Patel et al (2008) advised that since there is significant uncertainty linked to a quantitative

calculation of risk in these situations, a qualitative consideration of risk is more appropriate.

Just as Patel et al (2008) highlighted that an identified transmission event indicates a higher risk, and thus an enhanced response, so too did the CDC (2012) advise that following discovery of syringe re-use or contaminated multi-dose vials, notification is imperative.

The method described by Patel et al (2008) represents one of the two main processes presented in the literature for assessing infection control incidents. Weber and Rutala (2013) outlined a 15 step process with three key stages which relate to the decision to notify patients (steps 7, 10 and 12). In step 7, the authors encourage the reader to consider if the breach in question could actually lead to patient infection (Weber and Rutala 2013). They explained that decontamination processes, especially sterilisation, have wide safety margins meaning small deviations from the programmed process may not represent a significant danger to patients (Weber and Rutala 2013). Step 10 involved assessing if harm had already been caused, for example by testing specific patients and/or examining medical records (Weber and Rutala 2013). In reference to step 12, Weber and Rutala (2013) stated that "if it is determined that the failure could result in adverse patient events, then patients should be notified".

Weber and Rutala (2013) outlined that when the risk of patient infection is extremely low, notification may not be justified. The authors suggested that a risk of less than one in one million would meet this criterion and that in the medical field, pre-procedure, patients are generally not advised of risks which have a less than 1% chance of occurring (Weber and Rutala 2013).

Further, relevant guidance was identified on the CDC website in the form of a healthcare investigation checklist, although this resource is specifically designed to assess an incident where investigations have begun with identification of a single index patient and only targeted testing of connected patients is recommended (CDC 2015).

5.5 Discussion

5.5.1 What this study adds

This review represents the first known attempt to comprehensively map guidance that may support the decision-making process in relation to the notification of patients following a dental infection control breach. The findings of this mapping exercise serve as both the inspiration for the novel decision-making algorithm, presented in Chapter 6, and a list of guiding documentation which is easy for stakeholders to access and utilise.

5.5.2 Main findings

In general, existing public health guidance provides a broad overview of the stages involved in incident assessment and management but detail is needed regarding the decision to notify multiple patients of an incident.

Many of these documents apply to a variety of healthcare contexts, some of which differ greatly to the scenario of a UK board or trust faced with a dental infection control incident. Examination of this type of general incident management guidance, however, still provided inspiration for the structure of the dental, PNE decision-making algorithm as its advice mirrored the elements needed in such a toolkit:

- A risk assessment
- Advice regarding communication with the public
- Ethical considerations
- Who should be involved in incident management and any decisions made?

Many of the grading systems identified emphasised the factors that should be considered when assessing the impact that an incident will have. These elements would similarly apply to a dental infection control breach and included the degree of patient harm, resources required, number of patients affected and negative publicity created. These grading systems also demonstrated the main way in which risk is assessed, namely a comparison of impact and likelihood. Even though little guidance on the decision to notify was provided, these documents presented a good selection of toolkit structures which helped to inform the design of the novel toolkit presented in Chapter 6.

The applicability of most disclosure guidance was limited by the advice that notification be undertaken when a specific level of, or, indeed, any degree of harm had befallen the patient (Healthcare Improvement Scotland 2015; Agency for Healthcare Research and Quality 2016; Australian Commission on Safety and Quality in Healthcare 2014; College of Physicians and Surgeons Ontario 2003; Health and Disability Commission 2009; Nova Scotia Health 2005). Following an infection control breach, a number of patients may have been exposed to a risk but may not necessarily have incurred any harm. Knowledge of harm having been caused can usually only be established after notification and testing has already taken place hence it cannot be used pre-PNE to establish the need for one.

It was postulated that the restrictions placed on BBV-infected HCWs based on type of virus, viral load and procedures conducted, could be used as a guide to indicate which infection control breaches may carry higher risks.

British guidance suggests that the highest risk of transmission is associated with HCV-infected HCWs, including dentists, who are advised that under no

circumstances are they permitted to perform EPPs. HIV is also given special consideration, even though it is the least infectious of the BBVs. Patients who have been treated by a newly discovered and unmonitored HIV-infected HCW and undergone category 3 EPPs, must be notified, regardless of other factors such as identified transmissions or poor infection control (PHE 2017[a])[14].

In the UK, HCW viral loads of ≥400 IU/ml and ≥1000 copies/ml for HBV and HIV respectively were shown to be associated with a high risk as at this level, dentists were instructed to immediately cease performing EPPs (PHE 2017[a])[15]. American HCWs, whose viral load is above a certain level (HBV >10^4 GE/ml, HIV >$5x10^2$ GE/ml, HCV >10^4 GE/ml) are not allowed to perform category 3 procedures (Henderson et al 2010). This suggests that following an infection control breach, any source patient with comparable viral load levels would similarly generate a high risk of transmission.

The category of EPP that had been performed was shown to be important, as notifying patients of HIV-infected HCWs (HCV, HIV, HBV in Australia) was only advised if they had specifically undergone category 3 procedures. This is advised regardless of any identified, potential transmissions (PHE 2017[a])[16]. In a dental infection control breach scenario this may equate to a higher risk being associated with incidents where the dentist had been performing procedures with a greater propensity to produce blood and/or expose tissues.

The applicability of these guidance documents to a dental infection control breach is, however, limited. First, it would not be possible to base a risk assessment on whether EPPs have been performed as 1) virtually all dental procedures are categorised as such, 2) in dental practice there would always be a mixture of EPP 1 and 2 procedures performed and 3) EPP categorisation is designed to specifically assess the risk associated with treatment delivered by an infected HCW not an infection control breach. A higher risk could perhaps be attached to breaches occurring in specialist dental practices, where category 2 procedures, such as implant placement, are regularly conducted.

In an infection control breach, the type of virus involved would be an irrelevant risk assessment factor, as all three BBVs can be transmitted. Being guided by viral load values in an infection control breach scenario is also unlikely as many breaches are discovered or reported late, with patients having been exposed many months before. The viral load of a potential source patient, at the time the breach is discovered, will be unlikely to reflect its level at the time of patient exposure.

[14] This guidance was updated in 2019
[15] As above
[16] As above

In consideration of the decision of whether to conduct patient notification following identification of a BBV-infected HCW, all guidance clearly states that identification of a suspected transmission indicates the need for a PNE. If a potential transmission has not been identified, guidance asks us to consider other factors, such a poor infection control or the HCW's physical or mental impairments. In the context of an infection control breach, if we consider the infected HCW to be equivalent to a source patient (perhaps identified via cross matching) then poor infection control, associated with an identified source patient, would be grounds for conducting a PNE.

Significant differences in guidance were observed based on country. Regarding the management of BBV infected HCWs, Australia's guidance was the most restrictive and presented a low threshold for proceeding to patient notification. In contrast to Australia and the UK, the US places lower levels of restriction on infected HCWs. This is surprising as, apart from France and Spain, the USA is the only other country to be linked to HIV transmission from HCW to patient (Ciesielski et al 1994). Restriction variations may be due to unknown political and social influences on the levels of risk accepted by patients from different countries.

With an absence of guidance on whether to conduct a PNE following an infection control breach, UK IMTs may be influenced by open disclosure/duty of candour guidance. Guidance on when open disclosure is required following a healthcare related incident tended to be general and vague. This is understandable as healthcare incidents can be highly variable in relation to their nature and context.

Through interpretation of the UK Duty of Candour legislation, it appears that a dental practice in England would only need to notify patients if harm had occurred following an incident, whereas in Scotland both incidents that had caused, or could cause, harm would trigger the duty (CQC 2014; RCS 2015; GMC 2015; Scottish Government 2018).

The VHA's guidance, Disclosure of Adverse Events (2018), was found to be the most relevant and useful piece of guidance as it presented a clear pathway of decision-making for stakeholders to follow. The structure and content of this guidance was highly influential in the creation of the toolkit presented in Chapter 6 of this thesis.

While some of the guidance identified did present information on the different thresholds for open disclosure/duty of candour (Appendix 21), it is important to note that many of these documents give advice based on incidents affecting single patients and do not refer to, or address, the challenges faced when notifying multiple patients.

Applying open disclosure guidance to a healthcare incident, where it is not yet known whether patients have come to harm, can depend on the interpretation of terms used. UK duty of candour guidance indicates that a patient should be notified if "in the reasonable opinion of a health care professional" the incident "could result in" harm (CQC 2014; RCS 2015; GMC 2015; Scottish Government 2018). One can appreciate the challenge in interpreting subjective terms and attempting to establish, for example, what level of likelihood is connected to the phrase "could result in".

In relation to the management of an infection control breach, very specific and relevant guidance was outlined by Patel et al (2008) and Weber and Rutala (2013). These documents, however, still possessed numerous limitations. Patel et al (2008) gave very clear guidance on the incident details that should be recorded and considered but then categorised incidents into only two broad types: A and B. Both type descriptions were fairly vague and open to interpretation with a simple penultimate step entitled "decision regarding notification and testing" (Patel et al 2008). Weber and Rutala focused more on how to assess and manage the incident rather than how to make a decision regarding patient notification with the twelfth step of their process entitled "consider patient notification".

5.5.3 Strengths and weaknesses

This is the first systematic policy mapping exercise to assess guidance on the management of general public health incidents, infected HCWs, infection control breaches, lookbacks and open disclosure. It was highly comprehensive with special consideration being given to specific documents that were recommended, or already being used, by public health decision makers. This mapping exercise had a detailed and systematic approach which facilitates repeatability and reassures the user that the subject has been covered extensively.

A broad range of guidance was identified and a list of relevant documents, summaries and desired advice can be accessed and utilised swiftly by stakeholders.

While comprehensive, it is possible that some documents have been missed. This, however, was considered unlikely as the strategy utilised a great number of different sources. It should also be noted that the guidance mapping exercise, executed as part of a scoping review study, involved no quality assessment phase. This means that documents did not undergo in-depth analysis. Stakeholders may therefore be extracting findings and advice from guidance which is poorly produced and/or based on weak evidence.

Finally, the currency of advice provided in guidance can quickly become outdated as documents and policies are constantly being updated. For example, following completion of this scoping review study, a piece of highly relevant UK guidance was updated in July this year (PHE 2017[a] updated July 2019). This updated guidance now stipulates that a cross matching exercise is no longer required following the identification of a BBV-infected HCW, with no associated transmissions, or index patients (PHE 2017[a] updated July 2019). Also, "a patient notification exercise (PNE) will only be recommended if transmission is identified through an index case report, or if the local risk assessment identifies factors that increase the risk of BBV transmission from the HCW" (PHE 2017[a] updated July 2019). The updated 2019 guidance includes changed viral load ranges which indicate when a BBV-infected healthcare worker should cease performing exposure prone procedures and/or undergo additional testing. The updated guidance also no longer associates an increased transmission risk with those HBV-infected healthcare workers who are HBV 'e' antigen positive or who carry a pre-core mutant version of the virus (PHE 2017[a] updated July 2019).

5.6 Conclusions

In summary, no document gave clear guidance on the decision to notify multiple patients following an infection control breach. Nearly all relevant guidance advised using clinical judgement and a case-by-case approach when responding to a large-scale public health incident. No quantitative thresholds were provided and when the risks were considered low or uncertain most guidance eventually led the user to a general list of complex factors that should be considered. This can limit the utility of these documents as the user is still left with a difficult and multi-factorial decision. Following detailed examination, however, several conclusions can still be drawn, which may aid those in their decision to notify patients following a dental infection control breach:

- If a potential, probable transmission is identified, which appears to be linked to the incident in question, notification is deemed essential.

- Identification of a source patient alone could be a strong indication for notification, especially if that source patient has a high viral load, underwent a more invasive procedure and/or is HBeAg positive or carrying a pre-core mutant strain of HBV.

- Duty of candour is not an automatic indication to notify patients in a large-scale adverse event scenario and depends on the IMT's interpretation of how likely it is that patient harm, in this case infection, has occurred.

- The risks given to patients before surgery could be used as a guideline for the threshold figure of when to notify patients or as specifically suggested by Weber

and Rutala (2013), a 1 in 1 million chance of transmission, could be used as the lower limit for initiating a PNE.

- Re-use of multi dose vials or syringes is a high-risk breach that should result in patient notification.

- Consideration should be given to breaches which have historically been connected to transmissions within the dental setting.

- Certain decontamination stages, such as sterilisation, have very wide safety margins and therefore one should consider the nature of the breach and whether instruments have been partially or fully processed.

Chapter 6. Design of an evidence-based decision making algorithm to aid incident management team members with the decision of whether to notify patients following a dental infection control breach incident

6.1 Introduction

Healthcare guidance ensures that patients consistently receive high-quality, evidence-based care (NICE 2019). Adhering to guidance reassures healthcare providers that their treatment planning is appropriate and that their legal obligations are being met (NICE 2019). Guidance also helps to ensure that resources are allocated to the most effective and prudent healthcare interventions (NICE 2019).

Appropriately developed guidance should be created via a number of key steps. A topic which addresses a gap in guidance and is considered a priority for improvement of patient care should be identified by relevant stakeholders (SDCEP 2019). It is then common for a scoping review study to be undertaken to establish the quality and amount of evidence available in the subject area as well as the feasibility of guidance development (SDCEP 2019).

Following a more in-depth review, a multi-disciplinary team often referred to as a steering or guidance development group will convene to write the guidance based on the highest quality evidence available (SDCEP 2019). When there is an absence or lack of this high-quality evidence "other published literature and unpublished work may be sought" and "where authoritative evidence is not available, the guidance development group may decide to make recommendations based on expert opinion" (SDCEP 2019). Following development, guidance documentation is often disseminated for stakeholder consultation, facilitating the assessment of feedback from a much larger cohort of the professional community (SDCEP 2019). Once guidance is finalised and published, a set period is established for review of the documentation eg. every five years (SDCEP 2019).

It is theorised that UK IMTs would benefit from the development of decision-making guidance in relation to the need for implementation of a PNE following a dental infection control incident. Guidance would create consistency in IMT discussion across the UK and improve consistency of incident response to similar infection control breach scenarios. Guidance would also provide reassurance that all appropriate factors were being considered in regard to patient safety, ethical considerations and resource allocation. Those who authored papers regarding UK dental infection control incidents frequently expressed a desire for creation of guidance:

"Given that the decision to notify is a crucial part of management of such incidents, health protection teams would benefit from a decision-making tool to help assess the need for patient notification and testing where risk to patients is low. This would allow a robust assessment of all the relevant factors including potential risks, based on what is known from the existing evidence about the probability of a transmission event, and harms involved in notifying patients (or not notifying patients)." (Henderson et al 2017).

"To ensure consistent practice within the UK the National Institute for Health and Clinical Excellence should produce guidance on PNEs for the NHS [...] which will combine a robust economic evaluation with the views of stakeholders including patients." (Mason et al 2008).

"There is no UK guidance, however, on whether patients should be notified when they have been exposed to dental instruments which may have been contaminated with a BBV [...] In the absence of national guidance, decisions must be made in individual situations on the level of risk considered acceptable." (Conrad et al 2011).

As high-level evidence is not currently available in the area of PNE implementation, especially in regard to infection control breaches, it was prudent to gather evidence from a number of different sources: the published and grey literature, expert opinion, current related guidance and stakeholder opinion. The decision-making algorithm presented in this chapter (Figure 23) represents a collusion of all evidence and data collected as part of each stage of this doctoral study's scoping review study.

6.2 Aim

This chapter focuses on addressing the fourth aim of this doctoral study (chapter 1.6): to design and present an evidence-based decision-making algorithm which will aid IMTs with the decision of when to notify patients following a dental infection control breach.

6.3 Methods

Key aspects considered in the PNE decision-making process were ascertained, and placed in order of importance, based on evidence from the literature and stakeholder input. Decision factors were allocated an order in the algorithm's flowchart design, based on their importance and capacity to influence decision-makers. The algorithm was designed in consultation with the CI's educational supervisors who provided expert advice on dentistry, BBV transmission and incident management.

The algorithm utilises grading systems in phases 3 and 4. These types of matrices are presented in many other guidance documents as a method of assessing risk associated with medical incidents by applying a number or colour to an incident based on different risk related factors (Appendix 20).

The algorithm is designed to be a guide for discussion and source of recommendations rather than as a prescriptive checklist resulting in an absolute outcome. This was considered an appropriate design feature as evidence is limited and incidents will always have unique contextual aspects.

Within the algorithm assessment of risk is incorporated in a number of ways. As a reflection of the process reported to be followed by stakeholders, degree of risk is addressed before any other incident factors in the toolkit. Decision makers are guided to consider specific scenarios initially for which study findings revealed a potentially greater need for patient notification. These included the presence of any transmissions/index patients or use of multi-dose vials/re-use of syringes.

Even though the literature reveals that it is not currently conducted in a consistent or significant way by IMTs, the algorithm advises decision makers to consider the nature of both the procedures conducted and breaches that have occurred. American guidance documents published by Patel et al (2008) and Weber and Rutala (2013) incorporated such considerations and UK stakeholders expressed a desire for more guidance in this area with a reported lack of knowledge regarding the ways in which dental instruments are used or exposed to blood in general practice. A matrix was devised by the CI which was based on personal knowledge of dental practice, decontamination processes and BBV transmission. The matrix evaluates the propensity for specific dental instruments to come into contact with blood, to retain blood on their surfaces and encourages users to consider broadly if any attempt at cleaning, disinfection or sterilisation has been made.

As the literature reflected an inclination to proceed to notification when it was predicted that the PNE process would be easier, perhaps due to a limited number of exposed patients or comprehensive and organised patient notes, this was incorporated into the decision-making algorithm. Decision makers were guided towards patient notification if the number of those exposed was less than 50. This value was somewhat arbitrarily chosen but was also based on the numbers of patients normally involved in historic incidents and the fact that both Cheng et al (2013) and Taylor (1992) cited the low numbers of patients involved in their incidents (250 and 47 respectively) as being influential in their decision to notify, due intuitively to the associated minimal resource requirements.

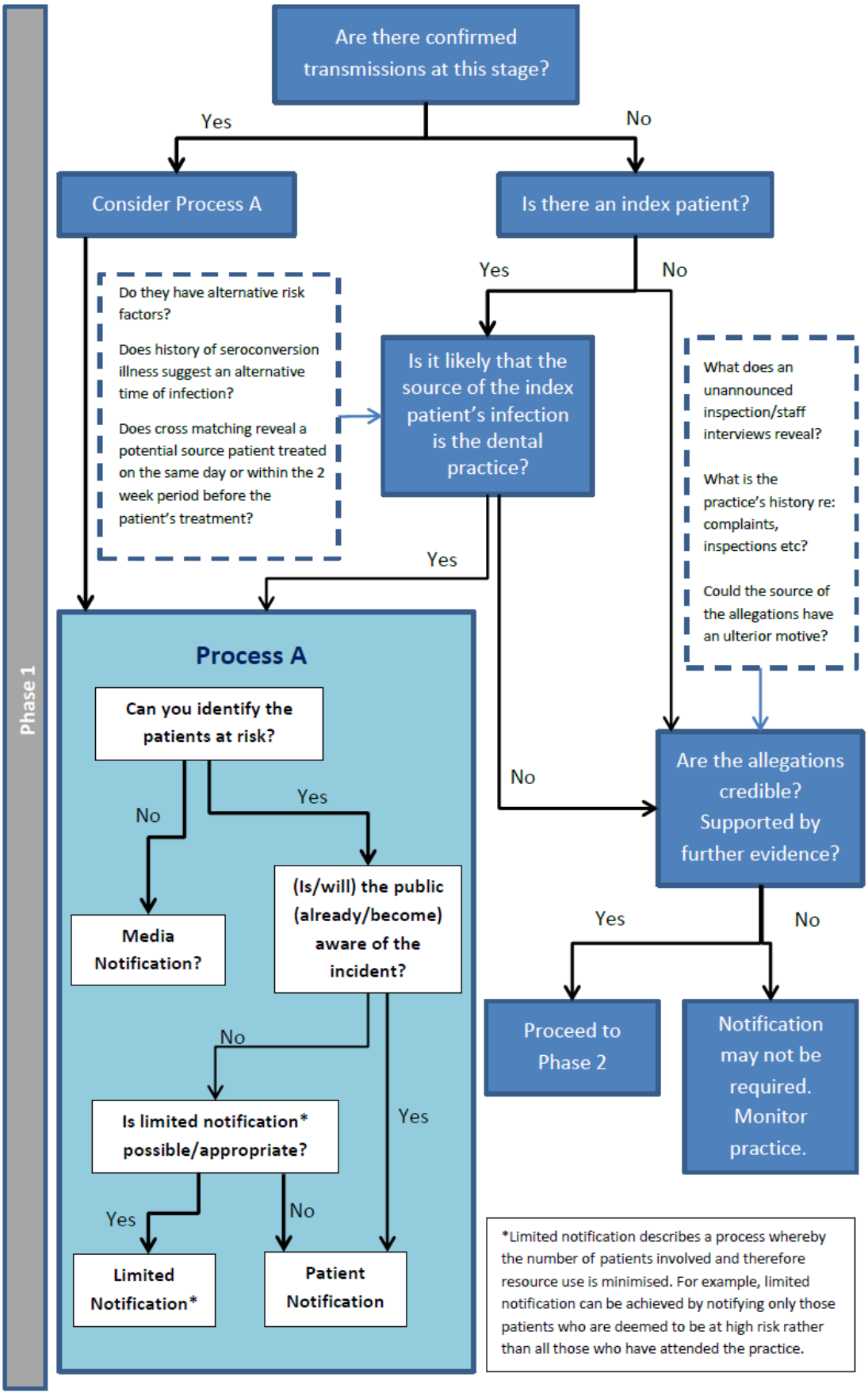
The numerical values presented in the toolkit were chosen based on literature findings. Dudzinski et al (2010) outlined that the VHA use a numerical risk cut off

value of 1 in 10,000 when considering notification of patients. Values were also based on the management of historical incidents by UK IMTs where notification was associated, in one case, with a calculated BBV transmission risk value of 1 in 31,000 (unpublished report 2013) but not conducted following risk assessments with results of 1 in 52,000 (unpublished report 2015) and 1 in 56,000 (unpublished report 2015).

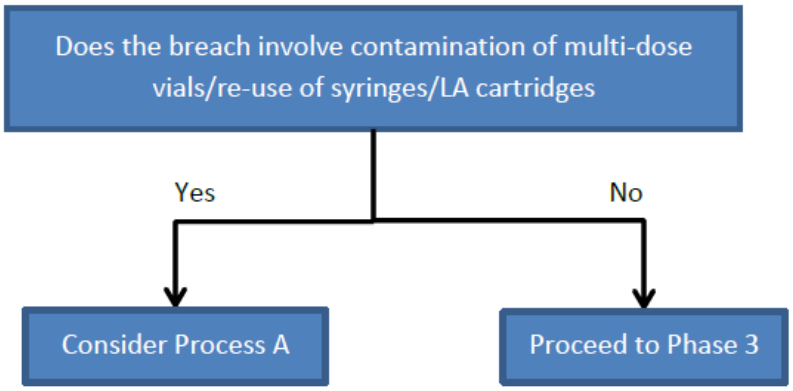
Ethical arguments for and against patient notification were incorporated into the algorithm as they were shown to be very important to decision makers. In the stakeholder consultation, participants conveyed that there were three main ethical concepts that guided their decision-making process. These included 1) prioritising the health of the patient or population above all else, 2) valuing transparency and 3) respecting the patients' right to know. Participants explained that they felt that, as healthcare providers, they had a duty of care to patients and to not cause the harm that would be inflicted via the psychological impact of notification. Within the literature, authors referred to widely acknowledged medical standards and ethical concepts such as patient autonomy (Iheukwumere 1997; Blatchford et al 2000), non-maleficence (Blatchford et al 2000), transparency (Maguire et al 2016[a]) and a commitment to always put patients first (Weaver 2014). Some articles were entirely based upon the ethical discussion of whether large-scale notification should be conducted following a low risk health care incident (Hébert 2015; Pinching 2000; Weller 1999; CDC 2019[a]; Dudzinski et al 2010; Fromson and Kenney 2010; Chafe et al 2009; Blatchford et al 2000). The ethical questions posed in VHA guidance (2018) and the ethical principles outlined by Schröder-Bäck et al (2014) were instrumental in the design and inclusion of the ethical questions posed to decision makers at the end of the algorithm.

The algorithm presented in this chapter will aid incident management teams with the assessment of dental infection control breach incidents but only in relation to those which involved dental instrument processing breaches. It is not currently designed to assess incidents which purely involved other types of breaches such as limited handwashing, glove use or environmental contamination.

6.4 Results:

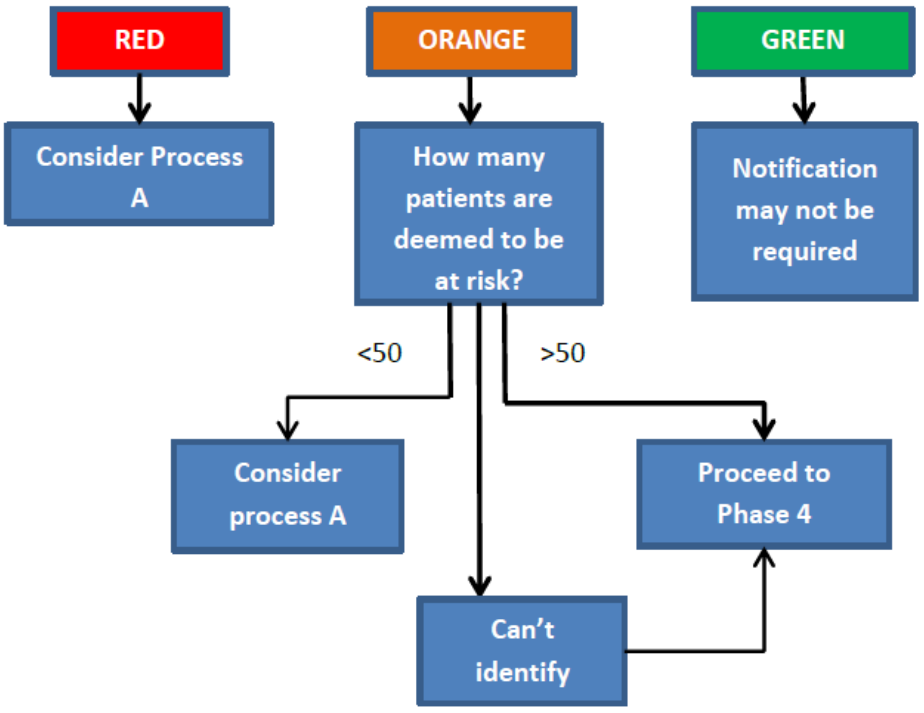

Phase 1
Are there confirmed transmissions at this stage?
Yes
No
Consider Process A
Is there an index patient?
Yes
No
Do they have alternative risk factors?
Does history of seroconversion illness suggest an alternative time of infection?
Does cross matching reveal a potential source patient treated on the same day or within the 2 week period before the patient's treatment?
Is it likely that the source of the index patient's infection is the dental practice?
What does an unannounced inspection/staff interviews reveal?
What is the practice's history re: complaints, inspections etc?
Could the source of the allegations have an ulterior motive?
Yes
Process A
Can you identify the patients at risk?
No
Yes
Media Notification?
(Is/will) the public (already/become) aware of the incident?
No
Yes
Is limited notification* possible/appropriate?
Yes
No
Limited Notification*
Patient Notification
No
Are the allegations credible? Supported by further evidence?
Yes
No
Proceed to Phase 2
Notification may not be required. Monitor practice.
*Limited notification describes a process whereby the number of patients involved and therefore resource use is minimised. For example, limited notification can be achieved by notifying only those patients who are deemed to be at high risk rather than all those who have attended the practice.

Phase 2



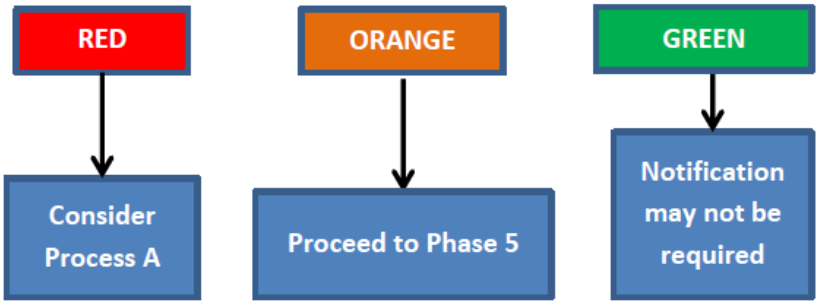
Phase 3

Characteristics and Status of Instruments			
Instrument Intricacy?	High[a] (3)	Medium[b] (2)	Low[c] (1)
During use, how frequently will the instrument contact blood?	Regularly[d] (2)	Infrequently[e] (1)	Almost never[f] (0)
Process	Unclean[g] (2)	Partially Cleaned[h] (1)	Processed through an AWD* and/or sterilised (0)
Score	7,6 = RED 5,4 = ORANGE ≤3 = GREEN		



Phase 4

Integrity/Quality of practice	Poor (2)	Fair (1)	Good (0)
Setting	Oral surgery or Temporary clinic (2)	General high street practice (1)	Dental school/teaching clinic (0)
Numerical risk estimation	High[i] (3)	Medium[j] (2)	Low[k] (1)
Score	7,6 = RED 5,4,3 = ORANGE ≤2 = GREEN		



Phase 5

Consider the number of children involved in the incident. If high, will parent anxiety be greater than it would have been had they themselves been exposed? Is it right to have children undergo testing following a low risk event? Is the potential for infection and its outcomes more significant when children are involved?

Does the health service have a responsibility to exposed patients if breaches were not detected through routine inspection?

Is paternalism in this case justified?

Notification respects patient autonomy and their decision of how they wish to respond to the risk.

Patients cannot provide informed consent to take part in a PNE.

Does notification respect patient privacy and personal data?

Is notification and testing an intervention that will result in certain persons being stigmatised, discriminated against or excluded?

Do patients have a right to know, no matter the level of risk involved?

Will a higher net benefit or net harm to patients, result from notification?

What is the predicted expenditure of money and staff time? What other public health projects will suffer/be delayed as a result?

Has the incident occurred in an area where dental health is poor and where an increased fear of attendance may amplify this issue?

Does this decision reflect one that has been made by others under similar circumstances?

Suffixes

a = Dental instruments with narrow lumens, threads and/or grooves such as endodontic files and burs (excluding polishing cups and discs) and saliva ejectors

b = Dental instruments which are not considered 'solid' instruments and may be challenging to clean such as matrix bands, aspirator tips, impression trays, hand scalers, cord packers, dental dam clamps, excavators, extraction forceps, scalpels, suture needles, tweezers, conservative restoration (cons) kits

c = Dental instruments which are considered 'solid' with smooth surfaces which are easily cleaned such as curing lights, dental mirrors, probes, dental dam frames, radiographic film holders, patient visors, cheek retractors, ultrasonic tips.

d = Examples include dental probes, dental dam clamps, extraction forceps, endodontic files, cord packers, scalpels, suture needles, aspirator tips.

e = Examples include impression trays, instruments for manipulating restorative materials, dental mirrors

f = Examples include curing lights, composite compules, amalgam carriers, dental dam frames, mirrors for photographs, radiographic film holders

g = Have not undergone any form of cleaning whatsoever before being used on a subsequent patient

h = Have undergone any form of cleaning, decontamination or sterilisation even if only includes rinsing under the tap, wiping with disinfectant/alcohol wipe or steeping in disinfectant.

i, j, k - Chance of any BBV transmission occurring	
Description	Numerical Risk Estimation
High (i)	1 in 2 – 1 in 10,000
Medium (j)	1 in 10,001 – 1 in 49,999
Low (k)	1 in 50,000 or lower

*AWD = Automated washer disinfector

Figure 23: Patient notification exercise (PNE) post-dental decontamination breach (DDB) decision-making (DM) algorithm

6.5 Discussion

The algorithm presented in this chapter represents the first piece of published guidance designed to aid UK IMTs with the decision of whether to proceed to notification following a dental infection control breach. It is influenced not only by the published literature but guidance from other developed countries, stakeholders and unpublished incident data.

6.5.1 Algorithm design

First and foremost, those utilising the algorithm are asked to consider if there is evidence of transmission associated with the incidents. Index patient presence was incorporated into the toolkit despite some sentiment that identification of all affected patients may occur during the pre-PNE investigation, without the need for a PNE. However, there is currently not enough evidence to support this idea and it is still a prominent decision factor currently used by UKAP and IMTs.

Those utilising the algorithm are also guided to consider the numerical estimation of BBV transmission risk associated with the incident. Inclusion of this stage was carefully considered. As previously outlined, currently, stakeholders do not significantly base their decision regarding disclosure to patients on these values but they did express a desire to do so and recognised that these estimations could potentially be very useful following further research. Uncertain risk assessments are caused by a multitude of factors. Firstly, there is a lack of research into the effectiveness of different instrument decontamination steps and their ability to remove blood or inactivate viral particles. Secondly, incident publications rarely present numerical risk data and when they do, figures are often outdated or irrelevant (Closer 1996; Millership et al 2007; Shaw 2008; Weller 1999). Finally, IMT members are often uncertain as to the extent and exact nature of the breaches that have occurred, therefore they cannot be incorporated into the risk calculation in a meaningful way.

Numerical estimations were still included in the toolkit as it was felt that should the IMT members reach the end of the decision-making process, having considered a multitude of other factors, and still be uncertain as to the need for a PNE, these values can be used as a final step, either to reassure stakeholders that the risk is low and therefore notification is not required or conversely that the risk is high and a PNE is needed.

The algorithm's numerical risk thresholds are partially based on historical incidents' risk assessments and whether they progressed to patient notification. The fact that notification was or was not historically associated with certain numerical risk estimations does not mean that these were the main influential

factors behind the decision to notify as other factors may have been responsible for the IMTs decision.

A flowchart structure was considered appropriate as it lends itself well to the process of decision-making. It allows a measured response with the concept that a definitive decision may be made based on the result of a first, highly important question or, if necessary, a series of questions which decrease in level of perceived importance. Flowcharts were found to be incorporated into a number of relevant decision-making guidance sourced from the UK and other developed countries (VHA 2018; Healthcare Improvement Scotland 2018; Health Service Executive 2015; New South Wales Government 2007; Public Health Agency 2018).

6.5.2 Strengths and weaknesses

The algorithm incorporates a wide range of decision factors and goes beyond an assessment of risk alone meaning that users can be certain that their discussion has touched on all salient points. Outside of the risk assessment, users are asked to consider the feasibility of limited notification, the credibility of the allegations made, the number of patients involved and the potential ethical motivations behind notification.

Given the lack of evidence identified in the scoping review study, especially in regard to the nature of infection control breaches and their associated transmission risks much of the algorithm is based on expert opinion and the incident management experience of a limited number of stakeholders. Some of the algorithm questions may also be open to interpretation or unanswerable due to limited incident information, and ultimately users may still be faced with a series of ethical questions which are challenging to answer and fail to resolve IMT indecision. Nonetheless, the algorithm provides a framework to lead discussions and ensure actions are deliberated and justified.

As previously outlined, the algorithm is only suited for use in situations where it is postulated that dental instruments have not been properly cleaned and/or sterilised. It is not suited to the evaluation of incidents involving other infection control breaches such as a lack of handwashing or glove changing. This decision reflects the nature of the evidence available, the current design of relevant guidance and the expertise of the chief investigator.

The stakeholder consultation revealed that decision makers desire more guidance specifically on the assessment of decontamination processes and how effective they may be in removing blood and thus reducing risk. Evidence from the literature highlighted that risk assessments are undertaken with consideration of the percutaneous risk of transmission; a risk only associated with instrument use (Millership et al 2007; Unpublished reports 2001-2017).

UKAP and Public Health England gave guidance on the types of procedure that are considered more invasive with greater exposure of tissues and hence one can extrapolate which instruments are associated with higher risks (PHE 2016). Having a dental background meant that the chief investigator was suitably placed to provide guidance on dental instrument use. Experts (KR and JB) advised that breaches out with instrument contamination, are not the priority in a risk assessment as they are considered to be much lower risk events.

In summary, it was decided that currently, inclusion of non-instrument based infection control breaches was not appropriate. The evidence base assessed was not deemed to be strong enough to support it. It is currently very difficult to assign a qualitative or quantitative risk to a non-instrument associated infection control breach as the evidence base does not appear to provide examples of this process or enough information to facilitate its creation.

The algorithm needs further evaluation (and piloting). A second stakeholder consultation, such as that suggested in Table 7 (step 15), could serve this purpose. It is important that this algorithm is evaluated and validated by a greater number of those working in the field. It will also need to be reviewed on a regular basis as the evidence base changes and grows.

Chapter 7. Discussion

7.1 What this doctoral study adds

It appears that infection control breaches occurring in the dental setting are being reported and managed with increasing frequency within the UK (5 from 1990-1999, 15 from 2000-2009 and 25 from 2010-2017). In the US, there have been three recent dental incidents resulting in BBV transmission to seven patients (Redd et al 2007; Oklahoma State Department of Health 2013; Radcliffe et al 2013). UK IMTs currently have access to neither an up-to-date collation of dental incident outcomes nor guidance regarding the decision of whether to notify patients following a dental infection control breach. In response to this lack of evidence and absence of guidance, this doctoral work aimed to 1) source and report on all dental incidents which may have resulted in the exposure of patients to a BBV transmission risk in developed countries, thereby creating a repository of dental incident outcome data and 2) design and present an evidence based decision-making algorithm, based on stakeholder input, literature evidence and current guidance, which will aid IMTs in the decision of whether to notify patients following a dental infection control breach.

This is the first study of its kind to collate both published and unpublished UK dental incident data and to present information regarding both incidents that led to notification and those that did not. It is also the first study to gather input from UK IMT decision makers regarding PNEs and map the available guidance concerning the decision to conduct large-scale notification of patients following a healthcare incident.

This study generated a multitude of research outputs. Use of the scoping review study methodology as a comprehensive search strategy and study in its own right is a recent practice. The scoping review study protocol presented in Chapter 2 can therefore be used by those who wish to follow not only the steps laid out by Arksey and O'Malley in their original 2005 framework but incorporate adaptations presented by other authors (Brien et al 2010; Daudt et al 2013; Levac et al 2010; Rumrill et al 2010) and the Joanna Briggs Institute (Peters et al 2017) over the last ten years.

The NFBI framework (Chapter 3) represents a novel tool for thematic analysis of transcripts in studies which aim to assess the influential factors behind the decision to notify patients following a 'BBV transmission risk' healthcare incident.

The data extraction forms used to gather information from incident reports (Appendix 14) can be used by those managing incidents to record the details of their incident. Use of these forms would create standardised data gathering which, in turn, could facilitate inclusion of incident data onto a central database and easier comparison and collation of incident outcomes.

Data gathered from stakeholders, the literature and guidance documentation were used to create the decision-making flowchart presented in Chapter 6. This algorithm, desired by decision makers, represents the first UK guidance of its kind. It will aid those who have to make the difficult decision of whether to notify patients following a low risk incident and hopefully reduce inconsistency in the PNE decision-making process.

7.2 Methodological choices

The scoping review study approach provided the solution for a scenario in which it was difficult to collate data from multiple heterogeneous sources, varying in quality and ease of acquisition. Conducting extensive scoping review studies as pieces of research in their own right is a fairly new concept. Due to the lack of standardisation and formal guidance, elements from various scoping review studies described in the literature were used to create a novel process, encompassing information from multiple sources (Chapter 2.3).

The theoretical elements of a scoping review study are clear but can be challenging to implement in practice. With no limitations on quality and source, the resulting volume of data can be immense, meaning that one must carefully consider the search limitations and the amount of data that can be processed in a defined length of time. The search process should be iterative but also systematic. Both specific search steps and numbers of articles can be difficult to organise and eventually present in a clear manner, when inclusion and exclusion criteria are in flux.

Since there is no incorporated quality assessment phase, conclusions should be interpreted with caution and meta-analysis of any quantitative data would be ill advised. However, without the stringent parameters of an RCT based systematic review or meta-analysis, scoping review studies represent an opportunity to provide broad overviews of subject areas where current research is limited but needing to be examined and made applicable to real world scenarios.

7.3 Strengths and weaknesses

The strengths and weaknesses of each specific study phase are discussed within each relevant chapter. However, upon consideration of the scoping review study as a whole, it represents a one stop source of information for those who are faced with management of an incident involving a dental infection control breach. None of the three scoping review study components presented here have been conducted previously and their execution resulted in a plethora of research outcomes, including the derivation of a proposed and desired decision-making algorithm. This review clearly highlights gaps in the current evidence base meaning that future research can be targeted and useful.

As the research questions and inclusion criteria of scoping review studies are very broad in nature, the volume of literature generated during their preparation is substantial. A balance must therefore be struck between the breadth of the review and the time available (Daudt et al 2013).

There are undoubtedly a number of unpublished, relevant incidents that were not included in this review as not every UK IMT provided a response to inquiries. Collation and comparison of incident data within this study was very challenging as the reporting of data was highly variable due to the absence of standard reporting methods and differing sources of information. On certain occasions, interpretation of which data values to include was needed which may have introduced inaccuracies. As the quality of included studies was not assessed and data were limited, high level statistical analysis was also not possible.

7.4 Main findings

7.4.1 Factors which contribute to the decision regarding large-scale patient notification following a 'BBV transmission risk' dental incident.

This scoping review study identified many different factors that IMTs considered in relation to the decision to notify patients following an infection control failure. The influence of the factors, however, varied between incidents, with some having more bearing than others, and certain factors being considered important to some decision makers but not to others.

The scoping review study revealed that stakeholders considered the most important factor influencing the decision to notify patients to be the risk of transmission associated with an incident. However, the level of risk, especially in the form of a numerical estimation, was rarely applied to incident management in a structured or consistent way, potentially because of the challenge in determining the exact nature and extent of breaches, and hence risk to patients, in the dental setting. There was a consensus that risks could not be calculated accurately and that at best; only qualitative descriptions such as 'very low' or 'negligible' could be applied. Decision makers acknowledged that transmission risks in dentistry are generally low due to the nature of the procedures conducted and the low number of reported dentally related BBV transmissions.

Although clearly influential, conclusions could not easily be drawn from historical 'proven transmission' events as they are rare, with most occurring long ago and/or lacking contextual detail. BBV transmission from a dental HCW to a patient has not occurred since 1990 (Ciesielski et al 1994). Patient-to-patient BBV transmission in the dental setting is more concerning as it has occurred

three times in the past 20 years (Redd et al 2007; Oklahoma State Department of Health 2013; Radcliffe et al 2013). The circumstances of these cases are varied with a significant degree of speculation as to their causes. The limited conclusions that can be drawn suggest that incidents involving syringe reuse, multi-dose vials, extractions and oral surgery settings may be most concerning (Figure 25).

Multiple sources suggested that if transmissions have already been identified, or are strongly suspected, then notification and testing is undoubtedly necessary (Figure 25). However, of the four proven, reported dental transmission events since 1990, no further transmissions were identified via their associated PNEs. This suggests that transmissions are all reliably detected prior to the use of a PNE. However, the decision not to notify when you have such clear evidence that a risk exists through presence of an index patient, would need to be clearly justified.

Stakeholders indicated that there was significant pressure to be candid with patients following an incident, a mantra which has arisen due to historical paternalism and an awareness of the new Duty of Candour legislation, which potentially overrides any consideration of risk level. Stakeholders considered what the public would want and their reactions to finding out an organisation had not been open with them. Unsurprisingly, notification was deemed essential when members of the public were already aware of an incident (Figure 25).

A reluctance to rely completely on numerical estimations combined with a limited 'historical transmission' evidence base, an inability to ascertain the true extent of breaches and consideration of Duty of Candour made incident risk level a somewhat moot factor in the decision-making process.

Transparency was often weighed against the negative outcomes of notification: perceived opportunity costs, the significant expenditure of time, staff and workload as well as the predicted psychological impact on patients and reputational consequences for the dental profession which could result in patients not seeking out oral health care.

Currently, however, one cannot identify with certainty the severity and impact of negative PNE consequences. It is assumed, for example, that many patients will experience severe anxiety upon being notified of an incident but evidence to support this is limited and contradictory (Blatchford et al 2000; Moneith 1995; Pashley 1991; Taylor 1992). Certainly, no published evidence exists to support the idea that patients would avoid dental treatment following PNE involvement, yet this is a prudent and unsurprising concern of decision makers.

Many conflicting ideas or theories were outlined regarding the effects of notification (Figure 24). For example, it was postulated by some authors and

stakeholders that patients would lose trust in an organisation that had informed them of an incident, but others stated that trust may actually be enhanced because the organisation has been open and honest. Without evidence, decision makers were unclear if notification resulted in a net increase or decrease in patient trust.

Until further studies are conducted, especially regarding feedback from notified patients, many of the positive and negative outcomes of notification will be based on common sense, personal experience and expert opinion.

Guidance on when open disclosure was required following a healthcare incident tended to be vague. When given, notification thresholds were presented in a qualitative rather than quantitative manner and most disclosure guidance based the requirement for notification on the concept of patient harm already caused. Use of these documents for PNE decision-making in an infection control breach scenario is therefore impossible as one cannot know for certain whether harm (BBV transmission) has occurred before notification and testing. One could also argue that the anxiety-based harm caused by notification is ironically tantamount to the 'harm thresholds' for notification presented in the guidance and legislation.

Guidance for implementing the Duty of Candour legislation within the UK was clearly on the minds of decision makers (Figure 25) and indicated that a patient should be notified if "in the reasonable opinion of a health care professional" the incident "could result in" harm (CQC 2014; GMC 2015; RCS 2015; Scottish Government 2018). This terminology is very much open to interpretation. Careful examination of a Scottish Government (2018) website figure revealed that "could result in" equated to the term "likely to result in" leaving the decision maker to contemplate when the outcome of patient harm, following an incident, should be considered more likely than not. Furthermore, it is important to note that Duty of Candour guidance makes no distinction between an incident involving a single patient or many patients. Adhering to Duty of Candour and implementing a notification exercise following a large-scale adverse event involving many patients, may be logistically challenging.

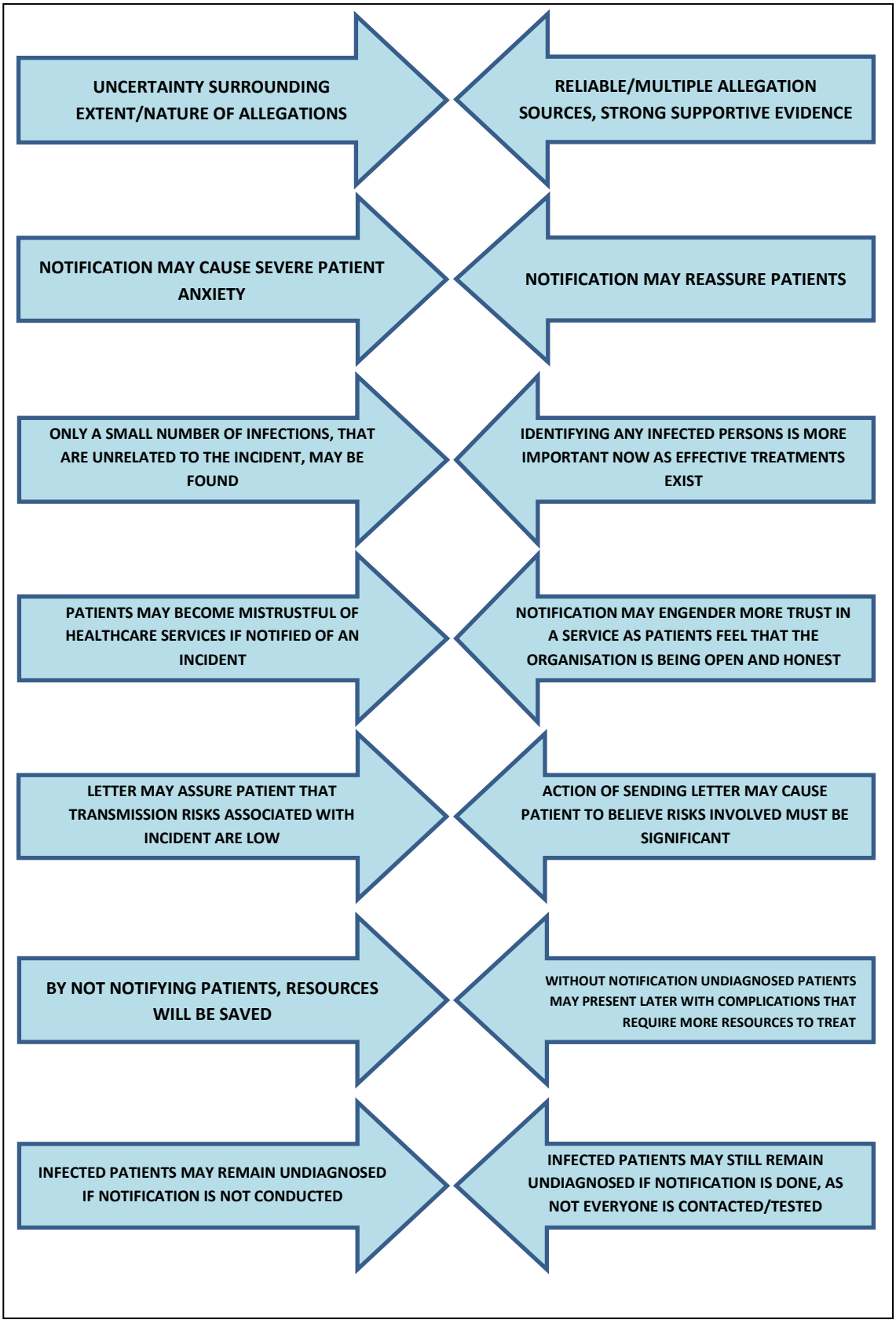


Figure 24: Visual representation of the decision factors and/or PNE features that are in direct conflict and/or contradict one another.

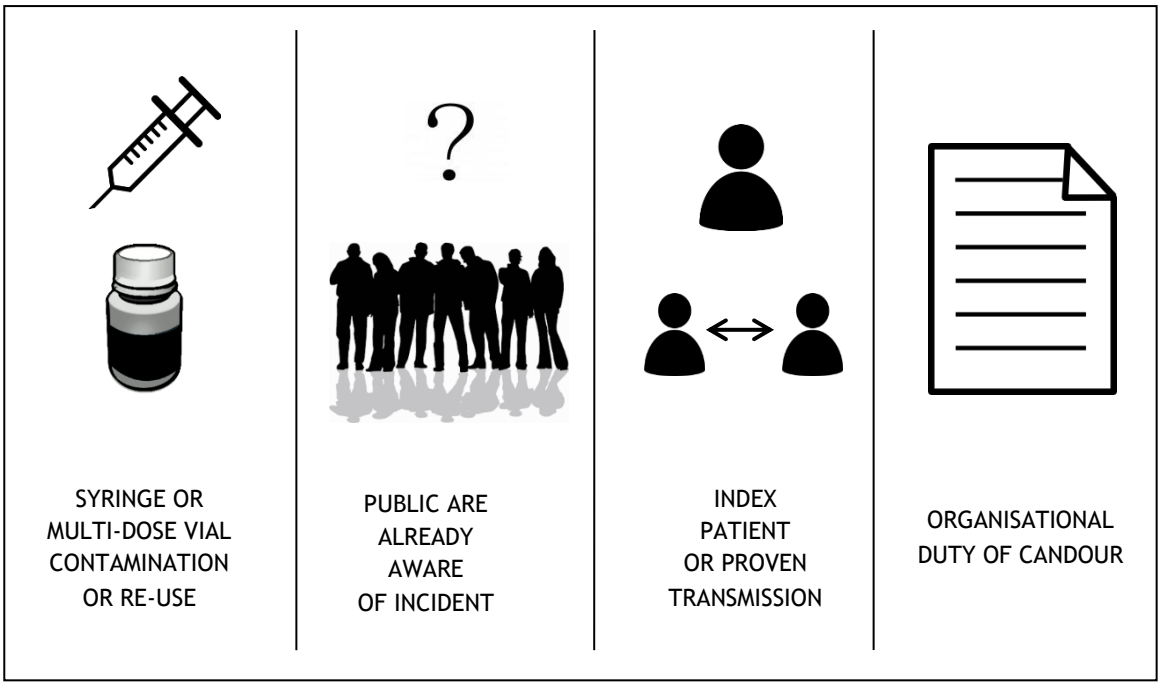


Figure 25: Visual representation of factors which appeared to strongly indicate the need to notify and test patients following a dental incident as reported by authors of incident literature and stakeholder consultation participants. (Images sourced via Microsoft Office 2010 'Clip Art' Function)

Additional influential factors included consideration of the involved practice or dentist's professionalism. Recent cases (Roy et al 2005; Henderson et al 2017) highlighted the need to take a closer look at general integrity of the dentist or practice involved. Being uncooperative with investigators or additional charges of fraud could indicate more widespread or serious breaches and therefore a need for notification due to an increased transmission risk.

Stakeholder consultation participants indicated that if it was predicted that execution of a PNE was going to be made easier in some way e.g. due to accurate records or a low number of 'at risk' patients, one may be more inclined to conduct notification. This was not however, really reflected in the literature or guidance.

Financial and opportunity costs, although acknowledged to be significant, were not influential to the decision to notify. The focus was on appropriately responding to the risks created by the incident and ensuring patient safety. Consensus was that cost should not be a highly influential decision-making factor and attaching importance to it may be perceived to be immoral, going against the concept of a patient-focused response. However, diverting resources away from other projects and towards a PNE will affect patient care. It could be argued that NHS time and money is taken away from programmes of work which may benefit larger numbers of patients than a PNE ever would.

In summary, notification appeared to be conducted based on the need to err on the side of caution. Patient safety and autonomy were the priorities and with a challenging risk assessment, no guidance or information from other IMTs and unclear Duty of Candour guidance, PNEs appeared to be utilised in order to mitigate the risks of not adhering to Duty of Candour legislation and/or leaving patients undiagnosed. Decision makers are in conflict over the need to be transparent and non-paternalistic whilst responding appropriately to risks, minimising harm caused through patient anxiety and potentially wasting resources.

7.4.2 Research outputs

The main output of this doctoral study is a novel decision-making algorithm: The Patient Notification Exercise post Dental Decontamination Breach (PNE post-DDB) Decision-Making Algorithm (Figure 23). This resource is designed to be used by IMT members when deciding whether to notify patients following a dental decontamination breach. Its design is inspired by the needs of those interviewed as part of the stakeholder consultation (Chapter 3), the dental incident literature analysed as part of the comprehensive literature review (Chapter 4) and current guidance in the subject area (Chapter 5).

The results of this doctoral study also include the scoping review study protocol presented in Chapter 2.3, the NFBI thematic analysis framework presented in Appendix 8 and the Incident data extraction/reporting forms presented in Appendix 14.

7.4.3 Conclusions and recommendations

Anderson et al (2008) outlined that not only can a scoping review study identify research gaps but it can also outline future prudent research questions or study designs. The following lists conclusions, areas for further study and recommendations identified through the scoping review study undertaken for this doctorate.

1. Paucity in the guidance available, for both the risk assessment and decision-making phases of dental infection control incident management, was the main research gap outlined by authors and stakeholders. The absence of suitable guidance in this area is an issue encountered more frequently as infection control breaches were shown to account for an increasing proportion of dental incidents (10.7% during 1990-1999 to 37.3% during 2010-2017). Use of general incident management grading systems, in their current form, does not result in clear messages regarding the decision to notify patients. Many of the grading systems emphasise the factors that should be considered when assessing the impact that an

incident will have and provide a broad overview of the stages involved in incident assessment and management, but further detail is needed, especially regarding the decision to notify patients. The decision making algorithm presented in this thesis should be piloted in response to a relevant scenario so that stakeholders can provide feedback on its utility and facilitate any necessary changes/improvements (Figure 23).

2. Not only are decision makers hampered by an absence of guidance but also an inability or struggle to ascertain what others have done in the past. There is no central repository for incident data, incident details are rarely published and there is a lack of sharing of lessons learned amongst public health teams. A large proportion of UK incidents do not result in publication (87%). This lack of publication activity combined with experiences not being shared internally amongst IMTs, means that both lessons learned and incident data are not disseminated to decision makers, resulting in inconsistencies in responses to similar UK dental infection control breaches. When reports are made available or their data are presented in published journal articles, no standardised method of reporting exists and there is great variability in the types of journal that feature articles on patient notification. Findings from this doctoral study support either the creation of a central repository of 'BBV transmission risk' incident information or an increase in publication activity with agreement on the type of journal most suited for presentation of such articles. Either way, standardised data collection needs to be encouraged to facilitate comparison of homogenous incident outcomes. Standard data collection forms, such as those presented in Appendix 14, should be distributed for use by UK IMTs and considered by public health journals as the minimum data set required for publication.

3. Use of the decision-making algorithm presented in Chapter 6 is encouraged. The algorithm is designed to guide both the flow and structure of decision-making, reassure IMTs that all necessary factors have been considered and provide consistent justifications for decisions reached, which can be communicated to third parties easily with reference to the algorithm. As VHA guidance outlines, the decision process should be "documented in a way that can be easily referenced for any similar future cases" (2018). Although useful, the algorithm is based on the limited, available evidence that currently exists and therefore will require regular reassessment and review including the consideration of wider infection control breaches such as glove use or hand hygiene.

4. The Duty of Candour and its application to large-scale incidents and dental practices must be clarified. It is recommended that further guidance is formulated, by those who originally drafted the Organisational

Duty of Candour legislation, to aid IMT members in understanding its applicability to large-scale patient disclosure.

5. A great number of papers, which discuss large-scale patient notification, referred to the significant, predicted psychological impact that being informed of the risk of BBV infection, will have on patients (Shaw 2008; Croser 2006; Conrad et al 2011; Closen 1996; Hébert 2015; Hancocks 2008; Martin 2006; Blatchford et al 2000; Pashley et al 1991; Monteith et al 1995). On examination of historical incident reports the most commonly quoted reason for not proceeding with patient notification, after 'low transmission risk' and 'absence of associated transmissions', was concern regarding the distress/anxiety that would be caused (Table 29). In the stakeholder consultation, the 'degree of psychological distress caused to patients' was the most commonly reported incident outcome for which participants desired more research data (Table 19). As an addendum to the scoping review study, a study proposal was developed to examine the psychological impact of patient notification following a dental incident, the 'PINE' study. Appendix 22 outlines the process used to develop the questionnaire designed to gather information on the psychological impact of being notified of a dental incident – a 'think aloud' interview process. Comments on the usability and appropriateness of the questionnaire were gathered from study volunteers and used to shape the design of the questionnaire in iterative stages. Appendix 23 outlines a proposal for the PINE study (Psychological Impact of Notification Exercises). It is proposed that the questionnaire, developed through the 'think aloud' study process, would be posted to those involved in a notification exercise. Recommendations regarding study design, sample size and data analysis are given. The questionnaire itself is presented in Appendix 24.

6. Authors and stakeholders highlighted the need to explore the financial and opportunity costs of the notification process. Cost was never the sole influential factor behind the decision not to notify patients but was shown to be important. A detailed cost evaluation is needed to truly understand specifically the opportunity costs of not pursuing other healthcare projects such as alternative means of testing or aiming to further improve dental infection control. A cost evaluation would also ideally convey the money saved through earlier detection and consequent earlier, and thus less intensive, treatment of BBV infections.

7. Participants in the stakeholder consultation felt that exploration of the effectiveness of different stages in the decontamination cycle would aid in the creation of a more robust risk assessment. An awareness of the effectiveness of different processes in the removal of blood from instruments or inactivation of viruses would allow an assessment to be

made as to how serious the omission of a particular step or steps is, in terms of transmission risk. One must consider, however, if pursuit of a stronger risk assessment is worthwhile when there will always be uncertainty caused by not knowing exactly how a procedure was done/breach occurred and based on the concept that Duty of Candour may override any risk assessment.

8. Findings from this doctoral study strongly support utilisation of a limited notification response where possible. Limited notification can be seen as a compromise between the two options of conducting or not conducting a PNE. Limited notification involves adapting the process in a manner which reduces expenditure of resources or involvement of all practice patients. Limited notification has numerous benefits. By notifying only those patients who are deemed to be at the highest risk, IMTs somewhat adhere to the principles of Duty of Candour whilst resources and time are saved with less patients having to undergo the distress of notification and testing. The parameters of a limited notification process are also flexible based on initial exercise findings. Should any diagnoses connected to the incident be identified during an initial phase of notification and testing, further patients can be contacted. This means that a measured response in relation to the risks involved can be made. It is also important to note that no reports were identified during this scoping review study which described a negative response by exposed patients who later discovered that they had not been notified – one of the key concerns when considering limited notification.

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Appendix 1: Published BBV healthcare associated outbreaks occurring in the UK between 2000 and 2018.

Year	Setting	Number of patients involved in outbreak[a] (healthcare associated transmissions only)	Suspected mode of transmission	Reference
2002	General Medical Wards / Surgery	5 HBV (Source patient transmitted HBV to 4 patients)	Source to patients A, C and D – Unknown, but stayed on same ward. Source was in isolation when sharing a ward with patients C and D. Source to patient B – Both had abdominal surgery performed on the same day by the same surgical team. Patient B operated on directly after source patient but in different theatre. Theorised that surgeon's head torch may have been vector for transmission.	Harling et al 2007. Passage from India: an outbreak of hepatitis B linked to a patient who acquired infection from health care overseas.
2004 to 2006	Care Homes	18 HBV (3 outbreaks[b]. Outbreak A involved 7 residents of the same care home, plus another resident from a different care home. Outbreaks B and C were also linked to care homes: 3 linked cases in one, 7 in the other.)	All cases linked to BGM device use. In outbreak A, BGM devices were known to be shared in the care home with 7 linked cases.	Duffell et al 2010. Five hepatitis B outbreaks in care homes in the UK associated with deficiencies in infection control practice in blood glucose monitoring
2011	Renal Ward	2 HBV (HBV/HCV co-infected source patient transmitted to one other patient)	Source and index patient shared same renal ward for 6 days and were in adjacent beds. Both had CKD and insulin dependent diabetes. Both underwent frequent BGM. Ward was found to have "poor hand hygiene [practices], visible contamination of blood glucose testing equipment and other shared equipment with blood, visible blood within the procedure room and lack of clarity of ward cleaning procedures. [...] the ward was cramped and cluttered with equipment. There was also a high	Kliner et al 2015. Identification, investigation and management of patient-to-patient hepatitis B transmission within an inpatient renal ward in North West England.

			turnover of patients." "source patient had an open surgical wound on his diabetic foot, which he would not allow staff to dress appropriately. The patient repeatedly removed the dressings and frequently contaminated the floor and his bed linen with blood. Although this blood was promptly cleaned [...] He also would not stay around his bed space to prevent contamination of the environment and frequently sat on the index patient's bed."	
2014	A&E department	2 HCV (1 source patient transmitted to one other patient)	"Although the exact route of transmission could not be determined [investigations] indicated that the most plausible explanation was surface contamination of shared equipment, particularly the blood gas analyser, combined with staff failing to change gloves after each procedure and perform hand hygiene." "	Johannessen et al 2018. Molecular and epidemiological evidence of patient-to-patient hepatitis C virus transmission in a Scottish emergency department.
2017	Renal Ward	2 HCV (1 source patient transmitted to one other patient)	Source and index patient shared 16 days of treatment on the ward. Inspections revealed poor hand hygiene frequency and technique with inappropriate PPE. Elements of the environment and care equipment were soiled with blood.	Garvey et al 2017. Use of genome sequencing to identify hepatitis C virus transmission in a renal healthcare setting.

A&E – Accident and Emergency
BGM – Blood Glucose Monitoring
CKD – Chronic Kidney Disease
HBV – Hepatitis B Virus
HCV – Hepatitis C Virus
PPE – Personal Protective Equipment

a = defined in this table as two or more linked cases
b = Two events considered 'outbreaks' in this article where not considered as such in this table. One case was incorporated into outbreak A and the other only involved identification of a single HBV positive resident.

Appendix 2: Blood borne virus testing of 2250 patients in an unusual, repeated dental patient notification exercise: challenges faced and lessons learnt. Henderson et al. 2017

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Original Research

Blood borne virus testing of 2250 patients in an unusual, repeated dental patient notification exercise: challenges faced and lessons learnt

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ABSTRACT

Objectives: The objectives of this study were to ascertain the risk created for patients of two dental practices where infection control was found to be inadequate, and if the risk was deemed to be significant, initiate an investigation involving notification and blood borne virus (BBV) testing to establish if any patient-to-patient BBV transmissions had occurred as a result of these infection control breaches.
Study design: A case study.
Methods: A public health investigation and patient notification. Investigations involved practice inspections, staff interviews and examination of invoices. The practices were not fully cooperative during the investigation and provided misleading information regarding the allegations. This led to two patient notification exercises, as more serious breaches were uncovered following the first notification exercise. Risk assessments of BBV transmission likelihood were undertaken and informed the nature of the advice given to patients.
Results: The health board wrote to 5100 patients informing them of the situation. BBV testing was offered in the second notification exercise and 2250 patients opted to be tested for HIV, hepatitis B and hepatitis C. There were no new cases of HIV or hepatitis B but less than five patients were found to be positive for hepatitis C. None of these cases were proven to have contracted their infection as a result of the dental infection control lapses.
Conclusions: This incident was unusual in that the practice was found to be repeatedly and knowingly putting patients at risk, and attempts were made to cover up breaches during the investigation. In future, health boards would benefit from a risk assessment tool to aid decision making regarding notification exercises, and whether testing is indicated where risk to patients is low. This would help ensure that notification exercises do more good than harm.

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Introduction

Maintaining consistently high standards of infection prevention and control is vital in dentistry, as failure to do so results in the risk of patient-to-patient transmission of blood borne viruses (BBVs), such as hepatitis B, hepatitis C and HIV. There have been instances of such transmission outwith the UK.[1,2] In Scotland there are several pieces of legislation to which dentists and dental practices must adhere, including the Consumer Protection Act (85/37/374/EEC)[3] and the Medical Devices Directive (93/42/EEC).[4] 'The National Health Service (General Dental Services; Scotland) Regulations 2010' state that the dentist 'shall provide proper, sufficient and safe premises, equipment, instruments and procedures'.[5] To support Scottish dentists in complying with the requirements, guidance has been published by the Scottish Dental Clinical Effectiveness Programme.[6] A key infection control document is 'Decontamination into Practice' with three parts; part 1 Cleaning of Dental Instruments (2007), part 2 Sterilisation of Dental Instruments (2011) and part 3 Management of Decontamination in Dental Practice (2014). Equivalent guidance has been produced for dentists elsewhere in the UK by the Department of Health,[7] though it is important to note that there are some differences, specifically in relation to the sterilisation and re-use of certain dental devices such as endodontic files and matrix bands, which is not acceptable in Scotland. Compliance in Scotland is monitored through Combined Practice Inspections, carried out by National Health Service (NHS) boards on a three yearly basis with inspectors ensuring standards are met, using a checklist of approximately 300 essential items.[8] Up until 1st April 2016, these inspections were preannounced. Prior to 2016, health boards had no powers to conduct unannounced inspections where there were significant concerns about a practice.

Infection control breaches can come in various forms, from the steam steriliser failing to reach adequate temperatures during its cycle (a mechanical error), to the failure to process dental instruments through the decontamination cycle at all (a human error). Breaches are not always erroneous. When incidents of poor infection control come to light, the allegations should be investigated and the risk to patients assessed. This will inform any control measures required to protect patients from infection, and can be an opportunity for learning and improvement. While there is no specific guidance to support the public health management of dental incidents specifically, guidance describing the generic organisational arrangements for managing public health incidents and the roles and responsibilities of Incident Management Teams (IMTs) is available in Scotland. The guidance is entitled, 'Management of Public Health Incidents, Guidance on the Roles and Responsibilities of NHS led Incident Management Teams (updated 2013)'. When managing such situations, the results of previous patient notification exercises undertaken in the UK following infection control breaches in the dental setting can prove very informative. To date, such exercises have provided no evidence of BBV transmission between patients tested due to poor infection prevention and control practices in a UK dental setting.[9–12] Infection transmission cannot be completely ruled out, as no more than half of 'at risk' patients have been tested in any previous exercise. It has been argued by some authors that patient notification is not usually justified when risk of transmission is low.[13] However, Blatchford et al. argue that it could be deemed paternalistic to decide whether notification is in the patients' best interest without consulting patients first.[14]

In September 2013, NHS Ayrshire and Arran's Health Protection Team received allegations that infection prevention and control procedures were being seriously breached in two local dental surgeries (both part of the same dental practice). The reported breaches involved re-use of gloves between patients, re-use of single-use matrix bands and incomplete processing of aspirators tips. An IMT was established, chaired by the consultant in public health to investigate, assess any risk to patients and recommend suitable control measures. In response to the resulting patient notification exercise, more serious allegations emerged, which led to a second notification exercise. This paper describes the public health management of the incident, and presents the challenges faced and lessons learnt from the investigation and the ensuing patient notification exercises.

Methods—exercise 1

Initial investigation to confirm or refute the allegations

An IMT was created to investigate the allegations and manage the incident. It was chaired by a consultant in public health and included NHS health protection specialists, a blood borne virus epidemiologist, consultant microbiologist, NHS dental manager and clinical lead for dentistry, infection control manager and nurse, NHS communications staff and specialists from Health Protection Scotland. The Head of Primary Care and/or Associate Medical Director for Primary Care often attended, particularly when issues around governance of the practices and patient care were discussed.

The dentist was asked to cooperate with the investigation and allow an inspection of the practice. This request was accompanied by information regarding the nature of the three allegations that had been made. The dentist agreed but delayed the practice inspections by a week. The health board had no powers to conduct an immediate, unannounced inspection. In the interim period, the health board had neither the power nor considered it appropriate to enforce temporary closure on unsubstantiated allegations. However, the dentist agreed to close on a voluntary basis.

Two simultaneous inspection visits, by two separate teams experienced in infection prevention and control standards, were undertaken. Information on infection control practices was obtained directly from interviewing all dental staff. An infection prevention and control inspection was undertaken in line with current requirements for dental practices.

The inspection teams established that most practice staff had not undergone any infection prevention and control training. When asked about practices surrounding the three allegations, staff denied that these breaches were occurring and were consistent in their responses. However, basic

knowledge and practices regarding hand washing and other important aspects of infection prevention and control were deemed unacceptable by the inspection team.

At this point in the investigation, the IMT was faced with inconsistent information regarding infection prevention and control practices. Contrary to the allegations, all practice staff were denying that any of the reported breaches had occurred. In an attempt to resolve this problem, the IMT requested from the practice invoices for gloves and matrix bands purchased by the practice for the past 12 months. Neither of the practice had space to store goods, so they ordered goods only as and when required. Thus, the invoices combined with information on the number of patients treated could help ascertain whether the quantity of gloves or matrix bands ordered by the practice was sufficient to maintain good hygiene standards. Initial reluctance by the dentist was addressed and invoices were provided. Analysis of the invoices suggested that the quantity of gloves ordered by the practice fell far short of what would have been needed to comply with infection control standards. The IMT had significant concerns about the authenticity of invoices provided for matrix bands and endodontic equipment.

Risk assessment of blood borne virus (BBV) transmission

The risk of BBV transmission associated with the alleged infection prevention and control failures was calculated using a modification of the method of Rutala and Weber.[15] The prevalence of BBV infection in the practice population was determined by a record linkage exercise using information derived from the databases of known BBV (hepatitis C virus [HCV], hepatitis B virus [HBV] and HIV) positive patients diagnosed in Scotland (held by Health Protection Scotland, NHS National Services Scotland) and the database of general dental service claims in NHS Scotland (held by the Dental Practitioners Service, NHS National Service Scotland). Records of all patients registered with the practice were linked to records held on the Health Protection Scotland (HPS) databases (HCV, HBV and HIV diagnosis database) using Community Health Index (CHI) number where available or a probabilistic linkage of forename initial, soundex code of surname, date of birth and gender. Prevalence of infection derived from the linkage was adjusted to account for prevalence of undiagnosed BBV infection in Scotland (50% for chronic HCV and HBV, and 25% for HIV).

The risk assessment calculation was made taking into consideration the fact that some attempt was made to clean the equipment and that the single-use items had been autoclaved. The risk of transmission was estimated to lie between the risk associated with mucocutaneous and percutaneous exposure.[16]

Method of determining whether to notify patients

The IMT unanimously agreed that the available evidence did not refute the allegations made. Although there remained a small degree of uncertainty, the IMT decided to proceed on the basis that the allegations were most likely to be true.

The potential risk of HIV transmission was estimated to be negligible and the potential risk of HBV transmission was considered to be very low. The potential risk of HCV transmission was estimated as higher than for HIV and hepatitis B, though still considered to be very low.

The IMT considered at length whether to notify patients, based on a number of factors such as the estimated risk of BBV infection from the alleged breaches, the anxiety that could ensue for some patients, the potential impact on future uptake of dental health care, the impact on the dental profession and health board costs associated with a large notification exercise. The decision to proceed to notification was primarily based on the need for transparency. In other words, the IMT agreed that patients had a right to know that the quality of their care had been sub-standard over a period of time.

Method of selecting patients to be notified

A specific time period for the notification could not be identified, as there was no indication of how long the infection control breaches had been going on. It was agreed that, as the IMT was not recommending active testing, it was not necessary to identify previous patients of the practice. All currently registered patients (NHS and private) were included in the notification (Fig. 1).

Notification method

All current practice patients, 5100 adults and children, were written to explaining that infection control breaches were alleged to have occurred at the practices. The letter was carefully worded to reassure patients that their BBV risk was very low. Testing was not recommended but was available on request. A helpline was set up to provide information and advice to any concerned patients. The helpline was staffed by health protection nurses and public health specialists. A press statement was released to ensure adequate, timely and accurate media coverage.

Methods—exercise 2

An unexpected result of the first notification exercise was that new and more serious allegations of infection control breaches emerged. The source of the new accusations, who was unaware of the detail of original allegations, was interviewed by a member of the NHS dental management team. They provided intelligence that confirmed the previous allegations but described more widespread and serious infection prevention and control breaches. These new allegations included re-use of single-use endodontic files, single-use stainless steel burs, single-use 3 in 1 tips and single-use impression trays following sterilisation. It was also alleged that amalgam carriers, aspirator tips and single-use ultrasonic scaler tips were surface wiped and not sterilised.

Risk assessment of BBV transmission

In light of this new intelligence, the IMT reviewed their risk assessment and concluded that the risk of infection was not insignificant for a small number of individuals who had

Fig. 1 – Sequence of events flowchart. BBV = blood borne virus; NHS A&A = NHS Ayrshire and Arran; PNE = patient notification exercise.

received treatment immediately after a BBV positive patient. It was not possible to identify all BBV positive patients due to the proportion likely to be undiagnosed. In addition, identification of patients treated following known BBV infected patients was not possible, due to incomplete patient records.

Method of deciding whether to notify

Ideally, the IMT would have offered BBV testing only to patients in whom risk of transmission was significant. However, it was not possible to identify these patients. The IMT went through a similar decision making process as in the first exercise, but this time the emphasis was on whether to offer testing to patients, as this small cohort had a significant risk. The IMT was extremely concerned that the practice was still with-holding information required to inform the risk assessment, and that there was potential that further breaches could come to light. The IMT decided that, due to the level of uncertainty, and on the basis that some patients had a significant level of risk, another notification exercise was required. Testing for BBVs was to be offered to all patients as a precaution. The purpose was to provide reassurance to the majority of patients who may be concerned at this stage, and to detect any cases.

Notification method

The same 5100 current patients who were contacted in the first exercise were written to again (NHS and private patients). The letter informed patients of the new allegations of infection prevention and control breaches and offered BBV testing as a precautionary measure. A patient helpline was set up to provide advice and to set up testing appointments.

Testing methodology

Community clinics were organised to allow patients to access testing easily, locally and promptly. Paediatric clinics were provided at the paediatric unit of the local hospital. Patients tested for blood borne viruses were provided with written information about the viruses being tested for, and were asked about their own risk factors, and being given information about the BBVs being tested for.

All patients were offered testing for HBV surface antigen, HCV antibody and HIV Antigen/Antibody Combo using the Abbott ARCHITECT i2000SR. The ARCHITECT i2000SR system is a fully automated chemiluminescent microparticle immunoassay for the qualitative detection of antibody to HCV, the qualitative detection of hepatitis B surface antigen and for the simultaneous qualitative detection of HIV p24 antigen and antibodies to human immunodeficiency virus type 1 and/or type 2 (HIV-1/HIV-2) in human serum and plasma.

Patients who tested negative for BBVs were notified by letter. Patients who tested positive were sent a letter asking them to phone the Public Health Department to discuss their results. Positive results were given by a Health Protection Nurse Specialist and appropriate onward referral was made for assessment and treatment. A system was put in place to double-check that letters sent to patients had the correct result.

Results—exercise 1

Of the 5100 contacted, no patients requested testing. There were some media interested in the situation, resulting in coverage in local press.

Results—exercise 2

During the second patient notification exercise (PNE), 2600 patients phoned the helpline, primarily to make a BBV testing appointment. Although all patients were offered a blood test for HIV, HBV and HCV, a small number of patients declined HIV testing for reasons of personal choice. In total, 2250 patients were tested. No new cases of HIV or hepatitis B were identified. Less than five new cases of hepatitis C were identified. Based on a number of factors including other risk factors, virus sequencing and records of payment for treatment held by Practitioner Services indicating temporal relationship between patient attendance, the IMT concluded that there was no definitive evidence of BBV acquisition from the dental practice among the patients tested.

Discussion

This paper reports a health board's response to repeated infection prevention and control failures in a primary dental care setting.[17] It highlights the challenges involved in the public health investigations in this setting. Although the circumstances of this incident were unusual in that the notification exercise was repeated, many of the challenges and lessons learnt will apply to other incidents involving infection control breaches within dentistry. The patient notification exercise associated with this investigation is one of the largest published in the UK to date, and provides further reassurance that the risk of BBV transmission associated with infection control failures in dentistry is low. However, as only half of the practice population were tested, transmission within the practice cannot be ruled out entirely.

It was unfortunate that this incident resulted in two notification exercises. On reflection, it is important to consider whether more could have been done during the preliminary investigations to uncover all potential breaches in the practices, avoiding a further notification exercise. The investigation was thorough and sought information to corroborate or refute the allegations, both directly from the dental staff and from practice inspections and invoices for the items implicated. The investigation was severely hindered, first by the inability to undertake an unannounced inspection and second, by the dishonesty of key practice staff and subsequent forgery of invoices. The initial practice inspection was delayed by a week, potentially allowing any evidence of breaches to be removed and for staff to be coached in answering questions regarding the breaches. It was frustrating for IMT members that the health board had no authority to undertake an unannounced inspection of the dental premises, which may have provided a more accurate assessment of any breaches. The IMT had hoped that the dentist would fully cooperate

with the investigation and were initially unprepared for the extent to which the dentist misled the investigation. The IMT wrote to the Chief Dental Officer for Scotland raising their concerns about the national dental inspection regime, under which these practices had passed both recent announced inspections. Since this incident, the new dental regulations for Scotland[18] now give NHS boards the right to undertake unannounced inspections of dental practices providing NHS General Dental Services, where concerns about patient safety are raised during a previous routine inspection by the NHS board; or information comes to light that necessitates further investigation by the NHS board. Had these regulations been in place at the time this incident began, it is entirely possible that a second notification exercise could have been avoided. The IMT was aware of the risks involved in invoking a patient notification exercise based on allegations that were denied by the practice involved, and had to take decisions based on the balance of available evidence and using a precautionary approach.

One of the main decisions IMTs are faced with when managing such infection prevention and control breaches is whether to notify patients. This decision is never taken lightly as there are some risks involved in notifying patients when care has been sub-standard. When deciding, it is important to consider the purpose of the notification exercise. Is it to inform patients that standards of care have been sub-standard and provide information, or is it case detection? If the aim is only to inform patients of the problem, a patient's right to know has to be weighed against other factors including potential harm to patients and reputational damage to dentistry and to the NHS. If the aim is to detect infection acquired as a consequence of an infection control breach, an assessment is required of whether testing is indicated. No UK incident to date has found evidence of BBV transmission in the dental setting, with the caveat that less than half of all patients have been tested in previous exercises, so transmission cannot be ruled out. In this instance the IMT acknowledged that, while the allegations indicated that the dentist was not adhering to infection prevention and control standards, the likelihood of BBV transmission associated with the alleged breaches were considered to be very low. In fact the re-use of matrix bands following sterilisation, although not acceptable in Scotland, is practiced in England. The decision to proceed with the initial patient notification exercise was primarily influenced by the health board's commitment to transparency and candour. Transparency is an important ethical concept but sometimes comes at a price that may be too high. In this instance there was a strong possibility that information about the breaches would become public knowledge once the General Dental Council trial was concluded. The health board was able to ensure that the information got out to patients in a responsible and carefully managed way.

Patients notified as part of both exercises may have suffered some anxiety upon receiving their letter and waiting for test results[14] and may also be reluctant to return for dental health care at this practice or indeed any other practice. While the health board sought to manage public anxiety related to this incident through the creation of advice sheets, a telephone helpline and the issuing of a pro-active press statement, media coverage of the incident cannot be controlled. Headlines such as; 'Dentist who sparked HIV scare for 6000 patients infected and four with hepatitis C by using dirty equipment…'[19] can only heighten public fear, and it is perhaps not surprising that the incident has prompted a mass litigation case.[20]

In terms of whether to notify patients, the IMT has to be able to justify why the decision was made. Given that the decision to notify is a crucial part of management of such incidents, health protection teams would benefit from a decision making tool to help assess the need for patient notification and testing where risk to patients is low. This would allow a robust assessment of all the relevant factors including potential risks, based on what is known from the existing evidence about the probability of a transmission event, and harms involved in notifying patients (or not notifying patients). To date, the probability of transmission events occurring in such instances has not been well quantified, which makes it difficult to decide when (and if) testing is justified.

Conclusions and recommendations

This paper describes the challenging public health investigation of two primary care dental practices following allegations of infection control failures, which led to two patient notification exercises, with the latter offering BBV testing to over 5000 patients. Lessons can certainly be learnt from this in relation to the consideration of warning signs that may require further investigation and suggest more serious breaches, which in this case included poor cooperation with the health board, answers during investigative interviews appearing to be coached and documents provided by the practice appearing to be falsified. The dentist's attempts to mislead the public health investigation were later confirmed at a General Dental Council (GDC) hearing in 2016, which resulted in the dentist (owner of the practice) and practice manager being removed from the dental register. This incident highlights the need for a nationally developed decision making tool to support health protection teams when deciding whether to proceed to a notification exercise. This should include consideration of potential costs, benefits and risks of conducting such exercises, and be supported by a proper assessment of the likelihood of BBV transmission associated with dental decontamination incidents, as the risk has never been well defined. This would help to ensure that future notification exercises do more good than harm to our populations.

Author statements

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Ethical approval

Not required (this paper is a description of management of a public health incident and does not involve research activities).

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Competing interests

None declared.

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Appendix 3: Participant information sheet for stakeholder consultation

Participation Information Sheet for Qualitative Interviews of Dental Incident Management Team Members Study

We are inviting you to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Discuss it with friends and relatives, if you wish. You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get now or in the future. Ask us if there is anything that is not clear or if you would like more information.

Why is this study being done?

This study is contributing towards the attainment of a University of Glasgow PhD. The PhD aims are four fold:

- to present the arguments for and against patient notification following a breach in dental cross infection control
- the collation and analysis of outcomes of historic dental patient notification exercises (PNEs) from both the published and unpublished literature
- to review and assess current guidance related to the management of dental PNEs
- to identify priorities for future research in this field

The qualitative results of this study will be used to highlight and explore the negative consequences created and benefits accrued as a result of notification exercises. Results will also aid in guiding the decision on which aspects of dental PNEs should be researched and presented as part of the PhD.

Why have I been invited to take part in this study?

You have been invited to take part in this study as you have been part of an incident management team that managed an incident resulting from a blood borne virus infected dental healthcare worker and/or breach(es) in dental cross infection control.

Can I be identified from the responses that I would provide for this study?

You work for a public health department as part of the NHS. We understand you may be concerned about being asked to discuss a topic which could outline the actions of yourselves or your board/trust in relation to one of these incidents. One of our research team members, Dr Kirsty Roy, has personal experience of managing these types of incidents and understands that we must be rigorous and thorough when it comes to the confidentitality of the boards/trusts/those who take part in this study. Confidentiality of participating IMT members/boards/trusts will be assured by taking the following steps:

1. No names will be mentioned in any quoted data.

2. Names of locations, boards, trusts and/or other colleagues will be removed or altered.

3. Specific/identifying/unique features of incidents will be removed from any quoted data.

4. You will be emailed any content derived from responses you (and only you) gave during interview, before submission for publication. You may check that you are happy with the response data we plan to use in publications. You may request the removal of any/all of your response data any time before submission to publication. Requests will always be honoured.

Do I have to take part?

Participation is entirely voluntary. You do not have to take part if you do not wish.

What will happen to me if I decide to take part?

You will meet one to one with the chief investigator of the study (Lorna Hopps) in a private office space either within Glasgow Dental School or your place of work (your choice) for approximately an hour and a half. You will be given a consent form to read through. The chief investigator will be present to answer any questions you may have. If you are still happy to participate you will sign and date the consent form.You will then be interviewed for approximately one hour whilst being recorded via an audio device. Questions will relate to:

- your opinions on what evidence related to historic dental PNEs you would like to be collated, analysed and presented to you as an IMT member

- your opinion on the sources, quantity and quality of guidance available to you as an IMT member

- your experiences of being part of an incident management team which managed a dental incident related to a BBV infected dental healthcare worker and/or breach(es) in dental cross infection control.

You will be emailed your anonymised response data that we plan to publish so that you may read it over and request for any sections/all of it to be removed before publication. Requests will always be honored.

How will the answers I give be stored?

The sessions will be recorded. Audio recording devices will be kept in a locked drawer within Glasgow University Dental School until transcribed. Following transcription audio files will be deleted. Hard copies of interview notes will be kept in a locked drawer within Glasgow Dental School and only refer to the participant using their unique ID number. Electronic forms of interview notes and/or transcriptions of the audio recordings will be kept on a password locked, University of Glasgow laptop. Mention of participants within notes and/or transcribed audio recordings will only be via use of a ID number which will feature on your consent form. Consent forms will be kept in a locked drawer separate from any interview

notes/transcriptions or audio recordings. Following analysis anonymous transcription documents will be stored on the Glasgow Dental Hospital's secure, backed-up server.

How will the answers I give be used?

Your answers will be presented anonymously when published or presented. As well participants' personal data, names of others/specific locations or health boards/trusts will also be omitted to avoid identification of the individal/health board or trust. Your answers are used not to reflect individual views but to contribute to a braoder perspective. By signing the consent form, you consent for the anonymised answers you give to be used in the following ways:

- Publication in a scientific journal paper
- Publication in a University of Glasgow PhD Thesis
- Presentation at a scientific conference
- Presented in the form of a direct quotation
- May be used in further research and shared anonymously with other researchers

Who is conducting this study?

A University of Glasgow research team led by a Dental Public Health PhD student, Lorna Hopps BDS.

Who is funding this study?

Health Protection Scotland have funded a University of Glasgow PhD research studentship which this study is part of.

I want to discuss this study with someone, who should I contact?

Please email me (Lorna Hopps – Chief Investigator) at [redacted] or call me on [redacted] should you have any further questions about the study.

You can also contact my educational supervisors. Proffessor Jeremy Bagg can be contacted on [redacted] or via email to [redacted]. Dr Kirsty Roy can be contacted on [redacted] or via email to [redacted].

Can I withdraw from the study or prevent use of my responses at anytime?

- You can cancel our meeting and withdraw from the study
- You can stop the interview at any time
- You will be able to review any data to be published when it is emailed to you following the interview. At this stage you can have sections/all of it removed should you wish.
- You can withdraw use of your data at any time before submission for any publications by emailing me at [redacted] or calling me on [redacted]

What are the possible benefits of taking part?

By taking part you will have contributed to the design and content of a PhD which could aid incident management teams across the UK. You will also be partaking in the sharing of knowledge with other IMT members.

What are the possible disadvantages of taking part?

Taking part may involve travel to Glasgow Dental Hospital (if you choose to have your interview conducted there) which carries with it a time commitment and travel costs. The interview will take approximately an hour to complete which involves use of your time.

What if something goes wrong?

If you wish to make a complaint in regards to your experience of this study please call the NHS complaints telephone number on: 0141 201 4500 or email: complaints@ggc.scot.nhs.uk. Further information on the NHS complaints procedure can be found at the following website: http://www.nhsggc.org.uk/get-in-touch-get-involved/complaints/

Who else will have access to the answers/data I provide other than the research team?

Collected information may be looked at by representatives of the study sponsor, NHS GG&C, to make sure the study is being conducted correctly

Which ethics committee has reviewed this study?

The University of Glasgow's College of Medical, Veterinary and Life Sciences ethics committee. Local NHS research and development offices have also reviewed this study.

Thank you for reading this information sheet

Appendix 4: Stakeholder consultation interview questioning route

Interview Questioning Route

As you may know, my research is focused on dental patient notification exercises. In this context I'm referring to patients notified following either the diagnosis of a dental healthcare worker with a blood borne virus or identification of poor dental infection control practices.

My PhD method is that of a comprehensive scoping review to establish what the benefits and negatives associated with dental patient notification exercises, what guidance currently exists in this area and what are the priorities for further research in this field.

A comprehensive scoping review involves three important stages:

1. Review and collation of the literature without necessarily assessing it for quality

2. Mapping of any relevant guidance

3. Stakeholder consultation

This interview is forming part of the stakeholder consultation aspect of this scoping review. This interview has the following purposes;

- To find out what you believe to be the positive and negative consequences of dental patient notification exercises
- To find out what you believe to be the most influential factors behind the decision to notify
- To ask you about any relevant literature, guidance or materials that you know of which may contribute to my PhD research
- To ask you where you feel gaps in this area lie and where future research in this area should be focused.

So, to start things off I just want to encourage you not to have any concerns about talking about the details of incidents that have happened. All identifiable information will be removed and anything that is to be published in relation to this interview will be reviewed by yourself and can be removed if you are unhappy with it. Nothing will be published without you seeing it and assessing it first.

Background:

So, to start the questioning off could you tell me your job title and how long you've been in your current position?

How many dental patient notification exercises have you been involved in managing?

If you were searching the literature for dental patient notification exercises are there any keywords that come to mind that you would use?

I was wondering if you had had a chance to look over the preliminary findings I sent you before this interview? If not I can provide this again just now for you to read before further discussion.

What did you think in general about these preliminary findings?

Key Questions:

General Problems and Benefits created

What benefits do you feel dental patient notification exercises bring?

Optional Prompts:

- Summarise points made. Would you say there were any other benefits you can think of?
- What about benefits for the patients?
- What about benefits for the health boards/trusts?

What do you feel are the negative aspects to notification?

Optional Prompts:

- Summarise points made. Would you say there were any other negative aspects you can think of?
- What about negatives for the patients?
- What about the negatives for the health boards/trusts?

What do you feel the impact on the dental practice is?

Optional Prompts:

- Good?
- Bad?

Health Board/Trust Environment

Do these notification exercises have an impact on other work being done by the health board/trusts at that time?

How do you feel whilst managing these incidents?

How do your staff feel about managing these incidents?

Optional Probe for this section:

- If respondents mention stress or anxiety probe further to gain an understanding of severity/effect this anxiety had on staff members eg. how long the anxiety lasted, concentration, affecting home life, sleeping, eating, performance, confidence?

Decision Making

If presented with a dental decontamination incident that had created a 'negligible risk' (eg. less than 1 in 100,000 of blood borne virus transmission), what are the main 'facts of the case' or concepts that would influence your decision to proceed to notification?

If you had decided not to proceed to notification what would be your main concerns, if any?

Guidance

How do you feel about the guidance documents to which you have access which would inform your discussions/decisions for dental incidents?

Optional prompts:

- Do you have a set way of managing these situations when they arise?

- What guidance/protocol, if any, do you turn to in these situations?

I'm now going to focus on how my research may be able to help you and other IMT members.

How could my PhD research assist you?

One of the aims of my PhD is to gather information on the outcomes of previous dental patient notification exercises. I would like to know what kind of information from these earlier exercises would help you determine the need for patient notification.

Activity 1

You have been notified of a dental decontamination failure and your local risk assessment has concluded that the risk of blood borne virus transmission in this incident is minimal. You therefore decide to consider the other facts/concepts that may influence your decision to proceed to patient notification.

To aid you in your decision you may want to consider the outcomes of previous dental notification exercises undertaken in the UK over the last ten years. In reference to the list below, what are the three most important pieces of information that would inform your decision making process on the need for a patient notification exercise in a 'minimal risk' incident?

(Please take as long as you need)

-the percentage of those deemed 'at risk' who were **successfully notified**
-the number of **new positive diagnoses** that were found
-how much did the **letter** alleviate notified patients' stress
-how much did contact with a dedicated **helpline** alleviate notified patients' stress
-the number of those who **called the helpline**
-the number of those that **requested/received counselling**
-the number of those successfully notified who **took up testing**
-the monetary **cost** of undertaking the exercise
-the degree of **psychological distress** caused to patients
-the effect the notification exercise had on **patients' uptake of future dental services/care**
-the effect the notification exercise had on **patients' levels of general dental anxiety**
-degree of **stress caused to staff** managing the incident
-degree of **disruption caused** to the normal health board/trust workload during management of the exercise
-**legal ramifications** of exercise
-what were notified **patients' opinions on when they should be notified** of these types of incidents
- how often is the **'patient's right to know regardless of risk' the main** driver for undertaking a patient notification exercise

Optional: Why do you feel these three things are the most important?

Is there something else you can think of that you would wish to know that is not outlined above?

In regards to the public health management of a dental decontamination incident, in which one area do you feel research should be conducted as a priority?

Can you think of any particular <u>type</u> of study that you would like to see conducted in this field?

Optional prompt:

- Using the list above?

<u>Closing Questions and Statement</u>

Of all the things we have discussed today which do you feel is the most important?

Do you feel there was anything that we didn't cover that should be covered?

Do you have any recommendations for the following?

- **papers to assess**
- **organisations to contact**
- **websites to search**
- **people to discuss my research with**

Optional question:

- Would you be willing to email me should you come across any literature of relevance or other sources you feel may be useful to the research?

I was wondering if you had had a chance to look over the PhD outline I sent you before this interview? If not I can provide this again just now for you to read before further discussion.

What do you think in general about my PhD research?

Optional prompts:

- title
- research questions
- aims
- content
- methodology

Do you have any recommendations for how I could improve this study or interview?

Are there any questions for me before we end the interview?

<u>Thank you</u>

Appendix 5: Stakeholder consultation consent form

Centre:

Participant Identification Number for this study:

CONSENT FORM

Title of Project: Qualitative Interviews of UK Dental Incident Management Team Members

Name of Researcher: Lorna Hopps

Please initial box

1. I confirm that I have read the participation information sheet dated 01/02/17 (version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I agree to my name and number of years within my post being seen/heard by the research team involved in this study and I understand that my name, job title and number of years within my post may be looked at/heard by representatives of the study's sponsor, NHS GG&C, for audit purposes. ☐

4. I understand that relevant data collected during the study, may be looked at by individuals from University of Glasgow Dental Hospital and ethics approval committees (where it is relevant to this study). I give permission for these individuals to have access to the data I provide. ☐

5. I understand that the anonymous data collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

6. I agree to publication of my anonymous responses within a University of Glasgow Dental PhD thesis ☐

7. I agree to publication of my anonymous responses within scientific journal papers ☐

8. I agree to presentation of my anonymous responses at scientific conferences ☐

9. I agree to presentation of my anonymous responses in the form of direct quotations ☐

10. I agree to a one-to-one interview lasting approximately an hour and a half with the chief investigator (Lorna Hopps) that will take place within a private office space in Glasgow Dental Hospital or a private office space within my place of work. ☐

11. I agree to the interview being recorded using an audio recording device ☐

12. I agree to the audio recording device used to record my interview being kept within a locked drawer within Glasgow Dental School until transcribed. Once transcribed, audio recordings will be deleted. ☐

13. I agree to electronic forms of interview notes and/or transcriptions of the audio recordings will be kept on a password locked, University of Glasgow laptop within encrypted drives during analysis of responses. The transcription documents will be backed up on a secure, encrypted Glasgow Dental Hospital server. ☐

14. I agree to hard copies of interview notes being kept in a locked drawer within Glasgow Dental School. This drawer will be separate to the consent forms. ☐

15. I agree to my notes and/or transcribed audio recordings being assigned an anonymous ID number which will be linked to the participant consent forms which will be kept in a separate locked drawer during analysis and storage following the study. ☐

15. I agree to take part in the above study ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Please note – You are being asked to sign two of these identical documents, one for you to keep and one for the research team, thank you.

Appendix 6: Thematic analysis process conducted on example stakeholder transcript extracts

1. Extract	2. Distillation of concept/idea	3. Interpretation in context of CFIR framework	4. CFIR thematic allocations	5. Changes to themes with explanations	6. Final thematic code applied
"so the most important thing is early diagnosis and the fact that we have a treatment that is effective and em less side effects and so people can actually either get some, with Hep C, get treated or with HIV reduce viral load and also transmission as well"	Notifying and testing patients will facilitate diagnosis of blood borne viruses and allow patients to access effective, modern treatments earlier.	The stakeholder is aware of the patients' needs and that conducting a notification exercise with testing may meet those needs, however, it could also simply be described as a benefit or relative advantage over not conducting notification.	Outer Setting (A) – Patient needs and resources Intervention Characteristics (C) – Relative advantage	Relative advantage was developed into the themes perceived benefits and negatives with the concept of 'meeting patient's needs' being incorporated into the benefits theme. Once all applicable codes were incorporated into the 'benefits' theme. This theme was broken down with all codes being allocated to one of five codes which included code B1.	Benefits - B1 (Diagnoses made resulting in earlier treatment and reduction of onwards transmission)
"with everything we do, because we have limited resources there's always an opportunity cost so especially with big incidents like the one in (location), [...] a number of public health professionals, [...] when they were dealing with this exercise, they couldn't do, they couldn't spend the time on doing other things possibly even you know even preventative..."	Within the NHS there is an awareness of finite resources. It is important to consider that dedicating staff time to one project will deprive another project of time and attention. The effect of this may be more significant if the incident is large and the 'other project' is considered important.	The stakeholder is clearly describing opportunity costs which would fit into the CFIR cost theme, however, he/she also discusses a consideration of available resources and relates this idea of back to his/her own board/trust experiences and an awareness that notification was not compatible with their ongoing projects and	Intervention Characteristics (H) – Cost Inner Setting (E2) – Available Resources Inner Setting (D2) - Compatibility	It was recognised that stakeholders would often discuss and consider the resource and opportunity costs of a notification exercise in the context of what was available/ongoing within their boards/trusts therefore the themes of '*cost*', '*available resources*' and '*compatibility*' were incorporated into one overarching theme of cost which included staff time, opportunity costs and direct monetary output. Once there was a move away from themes being based on the CFIR structure of different settings/contexts and their	Negatives - N2 (Resources used, time, staff, money. Workload/logistics. Opportunity costs.)

1. Extract	2. Distillation of concept/idea	3. Interpretation in context of CFIR framework	4. CFIR thematic allocations	5. Changes to themes with explanations	6. Final thematic code applied
		regular objectives.		influential impact. Cost was assigned to the final broad theme of *'negatives'*.	
"Their views would be more towards going public rather than not going public because politicians, being politicians and you know increasingly politicians becoming very...what's the word I'm looking for? They're very populist. They want to be popular with the public therefore they take the views, that, if in doubt tell them and that's the way things are moving and societies moving so think that has significant influence because it's very difficult for you, we can give them medical advice but unfortunately we as professionals don't run the NHS, it's run by politicians and senior managers and they will take the view, is that if	The opinions of government very much influence the decision making process because the incident management team are answerable to them. If examined by the government, the decision to notify is not based on medical information or a specific level of risk – it is based on public opinion and the public desire transparency.	The stakeholder is describing outer setting influences; courses of action dictated by the government and public opinion. He/she touches on patient needs ie. the public's need for transparency but there is more a focus on the decision being guided by governmental input and their policies. There is also a feeling of slight tension in regards to the fact that the decision is coming from a standpoint where perceived public opinion is being prioritised at the expense of a medical based risk assessment.	Outer setting (B) – Cosmopolitanism Outer setting (D) – External policy and incentives Intervention characteristics (A) – Intervention source	It was felt that a new theme was need which focused on the influence of outside organisations and which would incorporate the CFIR themes of cosmopolitanism and intervention source. The concept of an overarching theme was devised which would focus on what the stakeholder felt they should do based on external forces and influences. This theme was called *'standards'*. The CFIR themes of *'peer pressure'* and *'external policy and incentives'* remained virtually unchanged throughout the thematic analysis process and were allocated to this overarching 'standards' theme. The theme *'influence of outside organisations, experts, government and higher management'* was created and placed within the *'standards'* theme set. External policy and incentives was renamed *'guidance, law and policy'* and was eventually	Standards – S3 (Influence of outside organisations, experts, government, higher management, guidance, law and policy)

1. Extract	2. Distillation of concept/idea	3. Interpretation in context of CFIR framework	4. CFIR thematic allocations	5. Changes to themes with explanations	6. Final thematic code applied
there is a risk you need to let people know and I think that has significantly influenced a lot of the decision making process."				incorporated into the *'influence of outside organisations, experts, government and higher management*' theme as it was recognised that all policies and guidance being accessed by the incident management teams came from outside organisations.	
"Em, well, your dental, the dental. You're either gonna be dependent on records directly from the dental practice or from practitioner services [...] So, inevitably there's, there's gonna be record flaws, the data might not be right, person might have moved, person might have died, person might have changed dentists em, so all those issues come into the data and accuracy [...] and whether you can contact them."	Incident management team members must rely on data from external sources which may be inaccurate or incomplete. This makes notification of all at risk patients difficult.	This could be considered an issue of poor access to complete and correct information during the notification process which would be assigned to the CFIR theme; *'access to knowledge and information'* however, on a higher level this also represents a difficulty or inability to notify patients which is the purpose of patient notification exercise hence it could also be considered under the CFIR themes of *'complexity'* and *'self-*	Intervention characteristics (F) – Complexity Inner setting (E3) – Access to knowledge and information Inner setting (B) – Self-efficacy	Complexity was drawn out as broad theme in itself with the overall idea behind this theme being the concept of whether certain factors such as knowledge of access to data and knowledge of population characteristics would indicate that it would be more or less difficult to achieve the aims of a notification exercise. Because this concept was one of estimation and perception the theme was renamed as *'perceived complexity'*. The theme of perceived complexity incorporated the CFIR themes of *'complexity'*, *'access to knowledge and information', 'self-efficacy'*.	Perceived complexity - C1 (Predicted efficacy of notification exercise (are we going to be able to contact patients, get them to take up testing, will we find any diagnoses) also includes availability of and access to data. Profile of local area/population (ages/language barriers, mental capacity)

1. Extract	2. Distillation of concept/idea	3. Interpretation in context of CFIR framework	4. CFIR thematic allocations	5. Changes to themes with explanations	6. Final thematic code applied
		efficacy'		The theme of '*evidence strength and quality'* was also considered to be under the '*Perceived complexity'* thematic heading but only in relation to evidence of efficacy of logistical steps in the notification process e.g. testing uptake, not evidence of transmissions or diagnoses found which were included in the *'transmission risk'* theme structure.	
"Em and just I think and if I'm being honest I think that, some of the trouble historically as well is that those that are kind of involved in risk assessment are those that have been involved in regulation as well, I think that biases people as well, if I'm being honest, you know, if you were responsible for inspecting the practice and then there's a problem, there is a tendency to want to do nothing."	A decision maker may be disinclined to recommend notification because of their role within the organisation and their connection to the incident in question.	This extract is clearly related to the CFIR theme of 'Characteristics of Individuals' with the individuals being the incident management team, but crosses some thematic boundaries within that theme. In this extract the stakeholder is outlining that the decision maker's belief regarding notification is that it indicates a significant issue and that if instigated would	Characteristics of Individuals (A) – Knowledge and Beliefs about the Intervention Characteristics of Individuals (D) – Individual Identification with Organisation Characteristics of Individuals (E) – Other Personal attributes	It was felt that it was not beneficial to have as many sub-themes for 'Characteristics of Individuals' as are presented in the CFIR framework. All extracts which were deemed to link to one or more of the 'Characteristics of Individuals' sub-themes were assigned to a theme, now labelled 'Characteristics of IMT'. This theme was then broken down into two themes one of which focused on personal opinion of the decision maker in relation to notification and personal experiences/training of the decision maker.	Characteristics of IMT – IMT 1 (Personal experiences/training)

1. Extract	2. Distillation of concept/idea	3. Interpretation in context of CFIR framework	4. CFIR thematic allocations	5. Changes to themes with explanations	6. Final thematic code applied
		call into the question the actions of those who led to its occurrence this would relate to the theme of *'knowledge and beliefs about the intervention'*. However, it also eludes to the motivation of the decision maker and how the decision maker sees themselves within the organisation.		In the end, the two sub-themes were merged to facilitate thematic analysis as it was noted from the data that personal opinions about notification were always fuelled by personal experience and that the two were always linked.	
"I think in our situation because we could never pin down what the risk was because people weren't being honest we could never reassure ourselves that it definitely hadn't happened. Em, so we kind of had to."	If you cannot ascertain exactly what types of breaches have occurred then an assumption should be made that patients are at significant risk and notification/testing is necessary.	In terms of the influences shown here regarding implementation of a patient notification exercise, many aspects can be considered. This extract refers to the credibility of evidence behind decision to implement notification and the confidence that it will have the desired outcomes of notifying and testing	Too many themes deemed applicable, extract kept separate to be reanalysed following further development of themes	Extracts which dealt with the concept that transmission risk to patients would influence decision making were challenging to place using the CFIR framework as it could be considered from many different viewpoints, none of which would allow deeper exploration of the theme or give enough focus to this important influential factor. It was clear that rather than dividing all the aspects to transmission risk and spreading them across multiple non-cohesive	Transmission risk – T3 (Incident details, nature of breaches, length of time patients at risk, types of procedures performed. Structure of practice/clinic/integrity of practice creates suspicion of further more serious breaches).

1. Extract	2. Distillation of concept/idea	3. Interpretation in context of CFIR framework	4. CFIR thematic allocations	5. Changes to themes with explanations	6. Final thematic code applied
		patients who are truly at significant risk *('Evidence strength and quality'*) It also represents a moral or ethical imperative to err on the side of caution when it comes to consideration of patient safety ('*Culture'*). It also represents a *'Complexity'* in achieving the goals of the intervention and an inability to gain the necessary '*Access to knowledge and information'*.		CFIR sub themes it would be prudent to create a new theme – *'Transmission risk'*. This theme would incorporate all the factors that contribute towards the perceived transmission risk. Once all applicable codes were incorporated into the 'transmission risk' theme. This theme was broken down with all codes being allocated to one of six codes which became four after condensing ideas and merging concepts, for example, '*structure of practice/clinic/integrity of practice creates suspicion of further more serious breaches' and 'type of pathogen involved'* were included under the theme '*Incident details*'.	

Appendix 7: Interpretation of the Consolidated Framework for Implementation Research (CFIR) framework based on the context of a dental patient notification exercise decision making process

CFIR framework codes	Descriptions from CFIR framework	Chief investigator's description/interpretation
Intervention Characteristics		
Intervention source	Perception of key stakeholders about whether the intervention is externally or internally developed	Was the plan to notify/not notify created by the board/trust or an outside organisation?
Evidence strength/quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have the desired outcomes	How much quality evidence is there to suggest that what the board/trust does will work and meet its intended aims?
Relative advantage	Stakeholders perception of the advantage of implementing the intervention versus an alternative solution	Advantages of one plan compared to other courses of action.
Adaptability	The degree to which an intervention can be adapted, tailored, refined or reinvented to meet local needs	The degree to which the notification process can be adapted to meet local needs.
Trialability	The ability to test the intervention on a small scale in the organisation and to be able to reverse course (undo implementation) if warranted	Can the intervention be tested on a small scale and reverse/cancel if needed?
Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality and intricacy and number of steps required to implement.	Perceived difficulty of conducting notification ie: duration, scope, radicalness, disruptiveness, centrality and intricacy and number of steps required to implement.
Design Quality and Packaging	Perceived excellence in how the intervention is bundled, presented and assembled	How is the intervention bundled and presented?
Cost	Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs.	Costs associated with the intervention including investment, supply, and opportunity costs.
Outer Setting		
Patients' needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately	Are patients' needs and the ability to fulfil them, well known by the

	known and prioritized by the organization.	board/trust.
Cosmopolitanism	The degree to which an organization is networked with other external organizations	How well is the board/trust networked with other appropriate organisations?
Peer pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge.	Pressure to notify or not notify based on what other organisations/boards/trusts have done in the past.
External Policies and Incentives	A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.	External guidance and/or policies
Inner Setting		
Structural Characteristics	The social architecture, age, maturity, and size of an organization.	The board/trust's size, experience and social architecture.
Networks and Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.	The nature and quality of formal and informal communications within a board or trust
Culture	Norms, values, and basic assumptions of a given organization.	Norms, values and basic assumptions of a board/trust.
Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.	The board/trust's capacity for change, how receptive they are to change. How will change be rewarded/acknowledged.
Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.	The degree to which decision makers desire change.
Compatibility	The degree of tangible fit between	How does the intervention fit with

	meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.	decision makers existing values, work systems.
Relative priority	Individuals' shared perception of the importance of the implementation within the organization	Decision makers perception of how important the intervention is.
Organisational Incentives and Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect.	Board/trust based incentives and rewards for following a particular course of action in relation to notification
Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals.	How clearly are the goals of the intervention communicated to staff, acted upon and fed back
Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.	A positive working environment that can handle the intetrvention and have time to reflect on it.
Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention	Clear commitment by board/trust staff members to the decision and the course of action.
Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.	Commitment, involvement and accountability from leaders/managers
Available resources	The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time.	Money, training, education, physical space and time that can be dedicated to the implementation
Access to knowledge and information	Ease of access to digestible information and knowledge about	Ease of access to information re: notification/non-notification and

	the intervention and how to incorporate it into work tasks.	how to do it.
Characteristics of Individuals		
Knowledge and Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	Individuals' attitudes towards notification/non-notification; facts, truths, principles.
Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.	Individual belief in own capabilities to execute a course of action to achieve goals.
Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
Individual Identification with Organisation	A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization.	How do the decision makers perceive their own board/trust, their relationship with the board/trust and their commitment to it.
Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.	Personality traits of decision makers; intellectual ability, motivation, values etc.
The CFIR framework theme 'Process', and its associated sub-themes, was not included in the analysis of this study's data.		

Appendix 8: Notification following BBV transmission risk incidents (NFBI) framework

Transmission Risk	
T1	Prevalence of BBVs in local/practice population incld. levels of immunisation
T2	Profile/Characteristics of HCW such as: health status/infectivity/type of pathogen
T3	Incident details, nature of breaches, length of time patients at risk, types of procedures performed. Structure of practice/clinic/integrity of practice creates suspicion of further more serious breaches.
T4	Evidence of transmissions having already occurred. Index/source patients identified via cross matching. Transmission risk estimation based on scientific evidence, outcomes of historic investigations
Characteristics of IMT	
IMT 1	Personal experiences/training
Standards	
S1	Ethical concepts, norms/values in medical profession/public health
S2	Guided by peers, influenced by what others have done in similar circumstances
S3	Influence of outside organisations, experts, government, higher management. Guidance, Law, Policy
S4	Public Opinion
Benefits	
B1	Diagnoses made resulting in earlier treatment and reduction of onwards transmission
B2	Reassurance of patients and staff managing incidents
B3	Puts a spotlight on infection control for the general dental community and specific improvements needed
B4	Trust built/maintaining/engendering trust, taking complaints seriously
B5	Gathering further evidence to make estimation of dental transmission risk more accurate
Negatives	
N1	Anxiety/distress caused to patients, staff
N2	Resources used, time, staff, money. Workload/logistics. Opportunity costs.
N3	Legal exposure/vulnerability
N4	Reputational consequences to board/trust/managing organisation
N5	Reputational consequences to field of dentistry which could result in less uptake in treatment
N6	Reputational consequences to dentist/practice directly involved
Perceived Complexity	
C1	Predicted efficacy of notification exercise (are we going to be able to contact pts, get them to take up testing, will we find any diagnoses) also includes availability of and access to data. Profile of local area/population (ages, languages barriers, mental capacity)

C2	Gaps in knowledge/experience
C3	Profile of dental HCW/practice investigated. Levels of co-operation.
C4	Public/media awareness of incident

Appendix 9: NFBI framework intercoder reliability and agreement exercise

An intercoder reliability and agreement testing phase was employed to evaluate the suitability of the NFBI framework which resulted from thematic analysis of the stakeholder consultation transcripts (Chapter 3).

Inter-coder reliability is based on the concept that two individuals will assign the same thematic code from a framework to the same piece of data, in isolation. Inter-coder agreement is achieved through two individuals being able to agree on the application of the same code following discussion and debate (Campbell et al 2013).

Two rounds of coding were conducted. The CI had already established the 'units of meaning' that made up a given transcript and codes were applied to these units in each case without conferring. Meetings were held to discuss the resulting percentage of matching codes and whether the framework needed to be altered or simplified to increase inter-coder reliability.

A suitable level of inter-coder reliability is decided upon by the coders and relates to the intended purpose of the framework. As a rough guide Campbell et al (2013) outlined that most would consider a reliability percentage of 70-100% to be suitable.

Once a suitable level of inter-coder reliability has been achieved, a discussion concerning any code disagreements can be undertaken to establish an associated level of inter-coder agreement.

Two rounds of inter-coder reliability testing were conducted followed by one inter-coder agreement discussion.

Round 1 of inter-coder reliability rating

Having coded and thematically analysed the study's 11 interview transcripts, the CI possessed an initial draft of the NFBI framework. The themes for the NFBI framework were presented to a further two coders (KR and JB) in a spreadsheet format. Each code was accompanied by a description and two corresponding, example, transcript segments.

In each round of coding, two transcripts (an approximate 10% sample of all data) were separated into sections to be coded in isolation without conferring.

The NFBI framework comprises 'code families', with secondary codes relating to the overall primary codes. This meant that inter-coder reliability could be calculated for both primary code assignment and entire code (primary and secondary) application.

Overall inter-coder reliability was calculated by dividing the number of times coders agreed by the number of segments available to code (Campbell et al 2013).

Results from the first round of the NFBI framework inter-coder reliability exercise

Coders comparedA	Percentage agreement for primary code	Percentage agreement for Primary and Secondary code
JB and LH	59/98 (60%)	43/98 (44%)
KR and LH	61/98 (62%)	51/98 (52%)
JB and KR	64/98 (65%)	42/98 (43%)
	Mean = 62%	Mean = 46%

Round 2 of inter-coder reliability rating

Following this initial coding exercise, a meeting was held to restructure the framework through collapsing, combining and redefining themes (Campbell et al 2013). The CI then selected a further two transcripts and each coder coded the segments using the newly altered framework. Results are shown in the table below. The mean percentage agreement results between the first and second rounds of coding went up by 15% for application of both the 'correct' primary and secondary code.

Results from the second round of the NFBI framework inter-coder reliability exercise

Coders compared	Percentage agreement for primary code	Percentage agreement for Primary and Secondary code
JB and LH	108/155 (70%)	96/155 (62%)
KR and LH	114/155 (74%)	99/155 (64%)
JB and KR	105/155 (68%)	90/155 (58%)
	Mean = 71%	Mean = 61%

A level of inter-coder agreement was established (87%, 134/155) through meeting to discuss coding discrepancies and ascertaining whether a single code could be agreed upon for each segment.

Appendix 10: Outline of search strategy conducted as part of scoping review study literature review

Search within Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

1. (dental OR dentist* OR “oral surger*” OR “dental practice*” OR orthodonti*).mp

2. (“look back*” OR “large-scale adverse event*” OR LSAE OR LSAEs OR LBE OR LBEs OR lookback* OR (notif* adj2 patient*) OR (“medical error* adj2 disclos*) OR (“dental error*” adj2 disclos*).mp

3. 1 AND 2

4. (inadequate* OR poor* OR breach* OR improper* OR deficien* OR fail* OR inappropriate* OR unclean* OR unsteril* OR “not steril*”).mp

5. (decontamin* OR (infection* adj2 control*) OR clean* OR sterili#ation OR sterili*).mp

6. 1 AND 4 AND 5

7. (transmission* OR infection* OR infected OR spread OR contracted).mp

8. (BBV* OR HIV OR HCV OR HBV OR hepatitis OR “human immunodeficiency” OR AIDS OR “acquired immunodeficiency” OR “hep B” OR “hep C” OR “blood borne”).mp

9. 1 AND 7 AND 8

10. 3 OR 6 OR 9

11. Limit 10 to 1990-Current

12. Limit 11 to English Language

[mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

Appendix 11: Full text articles excluded with reasons in main literature search

Author	Year	Title	Reason for exclusion
Tumim LW	2006	Achieving Balance	Focuses on guidance and when to proceed to notification. Mainly discusses restrictions on infected HCWs (UK and worldwide)
Cavender JW	1992	AIDS in the healthcare setting: the congressional response to the Kimberley Bergalis case	Only 1 paragraph on the Acer case. The document focuses on regulations that were proposed following the incident.
Hancocks S	2008	A body of evidence	Outlines that the decision to notify should be evidence based. Discusses and calls for guidance. Does not, therefore, quite meet criteria of outlining pros and cons of notification
McIntyre I	2007	The caring face	Does not discuss any specific cases. Very briefly touches on privacy of HCW during notification
Miller C	1991	CDC updates guidelines	Numerical data related to Acer case out of date. Focuses on working conditions for infected HCWs. Mentions 1 incident involving a dental student but no details and no references.
Mauth T	1995	Charter Implications of compelling dentists to reveal their HIV status	Not relevant as entire article focuses on infected dentists revealing their status pre-procedure
Turkel S	2011	Current strategies for managing providers infected with bloodborne pathogens	A summary of American Guidance regarding the working conditions of infected HCWs
Cooper H	1993	Department of Health Guidelines for HCWs with HIV/AIDS infection	Focuses on the conditions and the career of the infected HCW
Oda G	2011	Development of a standardised process for conducting large-scale epidemiologic lookback investigations following improper reprocessing of reusable medical equipment	Only has two sentences on a specific incidents. Data provided is not new.
Anonymous	1991	Epidemiologic notes and reports update: transmission of HIV infection during an invasive dental procedure	Duplicate
Anonymous	1993	From the Centres for Disease Control and Prevention. Update: investigations of persons treated by HIV-infected Health-care workers - United States	Duplicate
Anonymous	1991	From the Centres for Disease Control: Current Trends	Duplicate

Mahboobi N	2010	Hepatitis B virus infection in dentistry: a forgotten topic	Only one sentence on a specific incident.
Nodzenski TJ	1993	HIV-infected health care professionals and informed consent	Mostly discusses whether infected HCWs should disclose their status before performing procedures. Very small section on Acer case.
Anonymous	1993	Infected dental student sued by patients	No new numerical data. Only 1 paragraph on a specific incident
Robert LM	1995	Investigations of patients of health care workers infected with HIV. The Centres for Disease Control and Prevention Database	Data merged together for 64 infected HCWs across all specialities, not enough detail given on specific dental cases
Danila RN	1994	Look-back investigation follow up	Discusses an infected physician not a dentist
Bell DM	1993	Preventing HIV transmission to patients during invasive procedures	Only 2 sentences on Acer case. Discusses pre:1990 dental transmissions
Grace M	1993	Private and confidential	Only 1 and a half sentences on Acer case. Article focuses on HCW's point of view
Unknown	1991	Recommendations for Preventing transmission of human immunodeficiency virus, hepatitis B virus to patients during exposure-prone invasive procedures	Provides guidance that incidents should be considered on a case-by-case basis but no pros or cons outlined. Only 1 paragraph on two specific incidents.
Samaranayake LP	1993	Revised guidelines for HIV-infected health care workers	Mentions 2 incidents but is not the focus of the article and no specifics. Discusses risk of HIV transmission, this may be a factor in the decision-making process but is not a pro or con of notification
Allos BM	2007	Transmission of Hepatitis B in the health care setting: The elephant in the room...or the mouse?	Mostly discusses the general theory of Hepatitis B acquired through healthcare. Mentions a specific incident but not enough detail or length.
Anonymous	1991	Transmission of HIV-1 infection during an invasive dental procedure--United States	Discusses Acer case but too briefly and numerical data is out of date
CDC	1992	Update investigations of patients who have been treated by HIV-infected health-care workers	Duplicate
Anonymous	1992	Update: transmission of HIV infection during invasive dental procedures	Duplicate
Tindall B	1992	Healthcare Workers	Covers a varied range of AIDS topics but only mentions Acer case briefly.
CDC	1991	Update: transmission of HIV	Duplicate

		infection during an invasive dental procedure - Florida	
Anonymous	1996	Jury says dentist did not infect patient with HIV	Incident discovery was pre-1990
Singh D	2001	Health care workers with AIDS: The Patient's Right to Know	Mentions 2 incidents but mostly focuses on debate over disclosure of HCW's BBV status before treatment
Schemo DJ	1992	Files of HIV infected dentist to be transferred	Mainstream news article

Appendix 12: Articles excluded from main literature search as related to Acer case and published pre-May 1993.

Anonymous	1991	Update: transmission of HIV infection during an invasive dental procedure: United States
Anonymous	1992	Update: transmission of HIV infection during invasive dental procedures
Anonymous	1991	Update: Transmission of HIV infection during invasive dental procedures - California
Anonymous	1991	Update: transmission of HIV infection during an invasive dental procedure - Florida
Anonymous	1991	Update: transmission of HIV infection during an invasive dental procedure - Florida
Anonymous	1992	From the Centers for Disease Control. Investigations of patients who have been treated by HIV-infected health-care workers
Coukos PS	1991	The Bergalis case: assessing the impact of documented provider to patient HIV transmission on the public health process
Ciesielski C	1992	Transmission of Human Immunodeficiency Virus in a Dental Practice
Palca J	1992	AIDS. CDC closes the case of the Florida Dentist
Centres for Disease Control	1990	Possible Transmission of Human Immunodeficiency Virus to a Patient during an Invasive Dental Procedure
Ou CY	1992	Molecular Epidemiology of HIV transmission in a dental practice
Breuer J	1992	HIV and hepatitis B virus infection in health-care workers: A risk to patients?
Hardie J	1991	A critique of HIV transmission during dental treatment
Smith K	1991	A victim of AIDS - or medical negligence
Kerr DL	1991	HIV transmission and Invasive Dental Procedures
Anonymous	1991	Facts About AIDS for the Dental Team
Anonymous	1991	Dental AIDS case

Appendix 13: Full text articles excluded from ‘references of references’ search with reasons

Author	Year	Title	Reason for Exclusion
Palca J	1992	The Case of the Florida Dentist	Acer case pre May 1993
Washington DC General Accounting Office	1992	CDC's investigation of HIV transmission by a dentist	Acer case pre May 1993
Smith T	1992	The continuing case of the Florida dentist	Acer case pre May 1993
Lewis DL	1994	The dental AIDS cases -- murder or unsolvable mystery?	Not a significant amount of information
Debry R	1993	Dental HIV transmission	Acer case pre May 1993
Anonymous	1991	Florida Office linked to other HIV patients	Acer case pre May 1993
Bell D	1991	Human Immunodeficiency Virus transmission in health care settings: risk and risk reduction	A focus on occupationally acquired HIV and seroprevalence of HIV in HCWs. Discusses Acer case but pre May 1993.
Gooch B	1993	Lack of evidence for patient-to-patient transmission of HIV in a dental practice	Acer case pre May 1993
Weber DJ	1991	Management of the Health-care worker Infected with Human-Immunodeficiency-Virus - lessons from Nosocomial Transmission of Hepatitis-B virus	Acer case pre May 1993
Breo DL	1990	Meet Kimberly Bergalis--the patient in the 'dental AIDS case'	Acer case pre May 1993
Holmes EC	1993	Sequence Data as Evidence	Acer case pre May 1993
Breo DL	1990	The 'slippery slope': handling HIV-infected health workers	Acer case pre May 1993
Unknown	1991	Special Investigation: Florida Dental Case. Unreported findings shed new light on HIV dental case	Acer case pre May 1993
McCarthy G	2002	Transmission of HIV in the dental clinic and elsewhere	No significant data on incidents. Mentions incident Acer case very briefly.
Goodman	1991	Transmission of Infectious-Diseases in	All dental incidents mentioned

RA		Outpatient Health-care settings	are pre 1990 apart from Acer case but data is pre May 1993
Perz JF	2010	US outbreak investigations highlight the need for safe injection practices and basic infection control	Nothing dental related.
Tulsa Health Department	2013	http://www.tulsa-health.org/news/tulsa-health-department-oklahoma-state-department-health-and-oklahoma-board-dentistry#.UmQS4lOwWgl	Duplicate
Burton J	1992	AIDS. Reaction to HIV positive dental personnel.	Summary of article already identified, no new information

Appendix 14: Dental incident data extraction forms

Form 1: Collection of data related to an infection control incident with notification

DENTAL INFECTION CONTROL INCIDENT WITH NOTIFICATION	
Location	
Year[a]	
Nature of infection control breach(es)/Incident	
How did the infection control breach(es) come to light?[b]	
Length of time patients deemed to be at risk[c]	
Was a lookback conducted for HIV? If so, were any postives found?[d]	
Was a lookback conducted for HBV? If so, were any positives found?[d]	
Was a lookback conducted for HCV? If so, were any positives found?[d]	
Index case(s)?[e]	
Potential source case(s)?[f]	
Risk of transmission calculated for HIV?[g]	
Risk of transmission calculated for HBV e antigen positive?[g]	
Risk of transmission calculated for HBV e antigen negative?[g]	
Risk of transmission calculated for HCV?[g]	
Overall risk of transmission calculated?[g]	
Patients notified Y/N	
Patients recommended testing Y/N	
Number of patients deemed to be 'at risk'	
Attempted to notify[h]	
Number successfully notified[j]	
Number of helpline calls received[k]	
Number tested for HIV	
Number tested for HBV	
Number tested for HCV	
Diagnoses found	
New diagnoses out of total diagnoses[l]	
New diagnoses with risk factors/ out of total new diagnoses[m]	
All relevant diagnoses serologically tested/compared[n]	
Percentage prevalence in tested persons	

Percentage prevalence in area	
Transmission proven?°	
If transmission was proven, what evidence exists to support this?	
Cost of exercise	
Cost per new diagnosis	
Could this be considered a limited notification? If so, why?ₚ	
How was the incident and risk described in the notification letter?ᵣ	

a – The year investigation of the incident began, the year the incident came to light, the year that it was brought to the attention of the board/trust.

b – Was a complaint received? If so, by who, a patient? a dentist? a nurse? Were infection control failings picked up during a routine inspection?

c – A period of time decided upon by the board or trust. The period of time, over which, patients were deemed to be at risk, regardless of availability of patient records.

d – Was the practice list/list of patients at risk compared with BBV national databases to establish if there were any potential source cases, transmissions or a higher prevalence of BBVs within that practice population than expected?

e – Was there an initial index case or cases which brought the incident to light? Or an index case or cases found as part of the lookback(s)? If so, what was their diagnosis?

f – Is there a patient or patients within the practice population who have an established/older BBV infection that could be a source of infection to other patients?

g – Was a risk of transmission calculated for each virus eg. 1 in 100,000 etc.

h – Although there may be a large number of patients at risk, it is often not possible to obtain contact information for all patients. How many patients had contact information and therefore could actually be sent a letter and/or called?

j –How many letters were sent back (returned to sender, no longer at this address). How many calls went unanswered? Were any patients not sent a letter but got in contact because they had been notified via the media? These would also count as having been successfully notified.

k – This is the number of total calls received regardless of whether the same patient or patients called multiple times. It may also be useful to track the volume of calls by day and how long it takes for number of calls to taper off.

l – How many of the diagnoses were new to the patients regardless of whether they were told that they have an acute infection or have evidence of past infection. Please specify the types of infection.

m – How many new diagnoses had alternative risk factors which could explain their infection?

n – 'Relevant diagnoses' would be considered to be infections that were diagnosed after dental treatment and in patients who had no alternative risk factors.

o – Remembering that this conclusion will be drawn following the highly likely scenario that not all at risk patients will have been tested. If the answer is yes, please specify what infection and how many patients were involved.

p – Limited notification refers to those notification exercises which are altered in some way to either reduce workload or cater to specific contexts or risks. Examples of limited notifications would be; notifying patients via the media and not sending out letters at all, only notifying dental patients who had had specific dental procedures, only notifying a certain number of patients treated after an infected potential source patient etc.

r – Was the risk described as low, negligible, extremely low etc. Was the letter's purpose purely to notify patients without recommending testing or even actively discouraging it?

Form 2: Collection of data related to a BBV-infected HCW with notification

INFECTED HCW WITH NOTIFICATION	
Location	
Year[a]	
Dental HCW infected with[b]	
How was the dental HCW's infection discovered by the board/trust?[c]	
Length of time patients deemed to be at risk[d]	
Was a lookback conducted for HIV? If so, were any postives found?[e]	
Was a lookback conducted for HBV? If so, were any positives found?[e]	
Was a lookback conducted for HCV? If so, were any positives found?[e]	
Index case(s)?[f]	
Risk of transmission calculated for HIV?[g]	
Risk of transmission calculated for HBV e antigen positive?[g]	
Risk of transmission calculated for HBV e antigen negative?[g]	
Risk of transmission calculated for HCV?[g]	
Overall risk of transmission calculated?[g]	
Patients notified Y/N	
Patients recommended testing Y/N	
Number of patients deemed to be 'at risk'	
Attempted to notify[h]	
Number successfully notified[j]	
Number of helpline calls received[k]	
Number tested for HIV	
Number tested for HBV	
Number tested for HCV	
Diagnoses found	
New diagnoses out of total diagnoses[l]	
New diagnoses with risk factors out of total new diagnoses[m]	
All relevant diagnoses serologically tested/compared[n]	
Percentage prevalence in tested persons	
Percentage prevalence in area	

Transmission proven?°	
If transmission was proven, what evidence exists to support this?	
Cost of exercise	
Cost per new diagnosis	
Could this be considered a limited notification? If so, why?ρ	
How was the incident and the risk described in the notification letter?ᵣ	

a – The year investigation of the incident began, the year the incident came to light, the year that it was brought to the attention of the board/trust.

b – If dental HCW infected with multiple infections please specify all.

c – Did the dental HCW report their infection after a long period of knowing they were infected or after just learning of their diagnosis. Was the board/trust contacted by occupational health or the HCW's doctor? Etc.

d – A period of time decided upon by the board or trust. The period of time, over which, patients were deemed to be at risk, regardless of availability of patient records.

e – Was the practice list/list of patients at risk compared with BBV national databases to establish if there were any potential transmissions?

f – Was there an initial index case or cases which brought the incident to light? Or an index case or cases found as part of the lookback(s)? If so, what was their diagnosis?

g – Was a risk of transmission calculated for each virus eg. 1 in 100,000 etc.

h – Although there may be a large number of patients at risk, it is often not possible to obtain contact information for all patients. How many patients had contact information and therefore could actually be sent a letter and/or called?

j –How many letters were sent back (returned to sender, no longer at this address). How many calls went unanswered? Were any patients not sent a letter but got in contact because they had been notified via the media? These would also count as having been successfully notified.

k – This is the number of total calls received regardless of whether the same patient or patients called multiple times. It may also be useful to track the volume of calls by day and how long it takes for number of calls to taper off.

l – How many of the diagnoses were new to the patients regardless of whether they were told that they have an acute infection or have evidence of past infection. Please specify the types of infection.

m – How many new diagnoses had alternative risk factors which could explain their infection?

n – 'Relevant diagnoses' would be considered to be infections that were diagnosed after dental treatment and in patients who had no alternative risk factors.

o – Remembering that this conclusion will be drawn following the highly likely scenario that not all at risk patients will have been tested. If the answer is yes, please specify what infection and how many patients were involved.

p – Limited notification refers to those notification exercises which are altered in some way to either reduce workload or cater to specific contexts or risks. Examples of limited notifications would be; notifying patients via the media and not sending out letters at all, only notifying dental patients who had had specific dental procedures etc.

r – Was the risk described as low, negligible, extremely low etc. Was the letter's purpose purely to notify patients without recommending testing or even actively discouraging it?

Form 3: Collection of data related to an infection control incident and BBV-infected HCW with notification

DENTAL INFECTION CONTROL INCIDENT AND INFECTED HCW WITH NOTIFICATION	
Location	
Year[a]	
Dental HCW infected with?[b]	
How was the dental HCW's infection discovered by the board/trust?[c]	
Nature of Infection Control Breach(es)/Incident	
How did the infection control breach(es) come to light?[d]	
Length of time patients deemed to be at risk[e]	
Was a lookback conducted for HIV? If so, were any positives found?[f]	
Was a lookback conducted for HBV? If so, were any positives found?[f]	
Was a lookback conducted for HCV? If so, were any positives found?[f]	
Index case(s)?[g]	
Potential patient source case(s) other than the HCW?[h]	
Risk of transmission calculated for HIV?[i]	
Risk of transmission calculated for HBV e antigen positive?[i]	
Risk of transmission calculated for HBV e antigen negative?[i]	
Risk of transmission calculated for HCV?[i]	
Overall risk of transmission calculated?[i]	
Patients notified Y/N	
Patients recommended testing Y/N	
Number of patients deemed to be 'at risk'	
Attempted to notify[j]	
Number successfully notified[l]	
Number of helpline calls received[m]	
Number tested for HIV	
Number tested for HBV	
Number tested for HCV	
Diagnoses found	
New diagnoses out of total diagnoses[n]	

New diagnoses with risk factors out of total new diagnoses[o]	
All relevant diagnoses serologically tested/compared[p]	
Percentage prevalence in tested persons	
Percentage prevalence in area	
Transmission proven?[r]	
If transmission was proven, what evidence exists to support this?	
Cost of exercise	
Cost per new diagnosis	
Could this be considered a limited notification, if so, why?[s]	
How was the incident and risk described in the notification letter?[t]	

a – The year investigation of the incident began, the year the incident came to light, the year that it was brought to the attention of the board/trust.

b – If dental HCW infected with multiple infections please specify all.

c – Did the dental HCW report their infection after a long period of knowing they were infected or after just learning of their diagnosis. Was the board/trust contacted by occupational health or the HCW's doctor? Etc.

d – Was a complaint received? If so, by who, a patient? a dentist? a nurse? Were infection control failings picked up during a routine inspection?

e – A period of time decided upon by the board or trust. The period of time, over which, patients were deemed to be at risk, regardless of availability of patient records.

f – Was the practice list/list of patients at risk compared with BBV national databases to establish if there were any potential source cases besides the HCW, transmissions or a higher prevalence of BBVs within that practice population than expected?

g – Was there an initial index case or cases which brought the incident to light? Or an index case or cases found as part of the lookback(s)? If so, what was their diagnosis?

h – Is there a patient or patients within the practice population who have an established/older BBV infection that could be a source of infection to other patients?

i – Was a risk of transmission calculated for each virus eg. 1 in 100,000 etc.

j – Although there may be a large number of patients at risk, it is often not possible to obtain contact information for all patients. How many patients had contact information and therefore could actually be sent a letter and/or called?

l –How many letters were sent back (returned to sender, no longer at this address). How many calls went unanswered? Were any patients not sent a letter but got in contact because they had been notified via the media? These would also count as having been successfully notified.

m – This is the number of total calls received regardless of whether the same patient or patients called multiple times. It may also be useful to track the volume of calls by day and how long it takes for number of calls to taper off.

n – How many of the diagnoses were new to the patients regardless of whether they were told that they have an acute infection or have evidence of past infection. Please specify the types of infection.

o – How many new diagnoses had alternative risk factors which could explain their infection?

p – 'Relevant diagnoses' would be considered to be infections that were diagnosed after dental treatment and in patients who had no alternative risk factors.

r – Remembering that this conclusion will be drawn following the highly likely scenario that not all at risk patients will have been tested. If the answer is yes, please specify what infection and how many patients were involved.

s – Limited notification refers to those notification exercises which are altered in some way to either reduce workload or cater to specific contexts or risks. Examples of limited notifications would be; notifying patients via the media and not sending out letters at all, only notifying dental patients who had had specific dental procedures, only notifying a certain number of patients treated after an infected potential source patient etc.

t – Was the risk described as low, negligible, extremely low etc. Was the letter's purpose purely to notify patients without recommending testing or even actively discouraging it?

Form 4: Collection of data related to a BBV-infected HCW or infection control incident without patient notification

NO NOTIFICATION CONDUCTED	
Location	
Year[a]	
Infection Control Breach(es)/Nature of Incident/Dental HCW's infection[b]	.
How was the HCW's infection discovered by the board/trust?[c]	
How did the infection control breach(es) come to light?[d]	
Length of time patients deemed to be at risk[e]	
Was a lookback conducted for HIV? If so, were any positives found?[f]	
Was a lookback conducted for HBV? If so, were any positives found?[f]	
Was a lookback conducted for HCV? If so, were any positives found?[f]	
Index case(s)?[g]	
Potential source case(s) (other than HCW if applicable)[h]	
Number of Patients deemed to be 'at risk'	
Risk of transmission calculated for HIV?$_i$	
Risk of transmission calculated for HBV e antigen positive?$_i$	
Risk of transmission calculated for HBV e antigen negative?$_i$	
Risk of transmission calculated for HCV?$_i$	
Overall calculated risk of BBV transmission?$_i$	

Percentage prevalence in area	
Reason(s) given for non-notification	

a – The year investigation of the incident began, the year the incident came to light, the year that it was brought to the attention of the board/trust.

b – If dental HCW infected with multiple infections please specify all.

c – Did the dental HCW report their infection after a long period of knowing they were infected or after just learning of their diagnosis. Was the board/trust contacted by occupational health or the HCW's doctor? Etc.

d – Was a complaint received? If so, by who, a patient? a dentist? a nurse? Were infection control failings picked up during a routine inspection?

e – A period of time decided upon by the board or trust. The period of time, over which, patients were deemed to be at risk, regardless of availability of patient records.

f – Was the practice list/list of patients at risk compared with BBV national databases to establish if there were any potential source cases besides the HCW, transmissions or a higher prevalence of BBVs within that practice population than expected?

g – Was there an initial index case or cases which brought the incident to light? Or an index case or cases found as part of the lookback(s)? If so, what was their diagnosis?

h – Is there a patient or patients within the practice population who have an established/older BBV infection that could be a source of infection to other patients?

i – Was a risk of transmission calculated for each virus eg. 1 in 100,000 etc.

Appendix 15: Information on 68 dental incidents for which sufficient data were available to conduct further analysis

Year[a]	Type of incident	Dental HCW infection	Location	Nature of suggested breaches	Information Sources
1990	IH	HIV	USA	N/A	Witte 1993; Scully and Porter 1993; O'Brien and Goedert 1996; Anonymous 1995[a]; Anonymous 1995[b]; Scully and Greenspan 2006; Horowitz 1994[a]; Runnells 1993; Horowitz 1994[b]; Horowitz 1994[c] Hardie 1993; Robinson and Challacombe 1993; Ciesielski et al 1994; Barr 1996; Brown 1996;
1990	IH	HIV	USA	N/A	Comer et al 1992; Sampson 1991; Comer et al 1991; Samaranayake 1991; Cowley et al 1991; Scully and Porter 1993
1991	IH	HIV	USA	N/A	Jaffe et al 1994; Anonymous 1995[a]; Anonymous 1995[b]
1991	IH	HIV	USA	N/A	Longfield et al 1994; Jacob 1992; Anonymous 1991
1991	LN	HIV	USA	- Suspicions re: use of washer disinfector	Arnow et al 1993
1991	IH	HIV	USA	N/A	Heuer 1992; Closen 1996; Anonymous 1997[a]
1991	LN/IH	HIV	USA	N/A	Byers 1993
1991	IH	HIV	USA	N/A	Lutz 1991; Cowley et al 1991; Jacob 1992

1991	IH	HIV	USA	N/A	Lutz 1991; Jakush 1991; Jacob 1992; Anonymous 1995[c]; Anonymous 1995[d]; Anonymous 1997[b]
1991	IH	HIV	USA	N/A	Cottone et al 1992
1991	IH	HIV	USA	N/A	Scully and Porter 1993; Mishu and Schaffner 1993; Dickinson et al 1993
1992	IH	HIV and HBVe+	USA	N/A	Taylor 1992
1992	IH	2 HIV infected dentists	USA	N/A	Scully and Greenspan 2006
1993	NN	HBV	Canada	N/A	Christianson et al 1993
1993	NN	3 HIV dentists	USA	N/A	York and Arthur 1993
1995	IH	HBV	UK	N/A	Blatchford et al 2000; Unpublished report
1995	IH	HIV	UK	N/A	Monteith et al 1995
1998	IH	HIV	UK	N/A	Gaudoin et al 2000
1998	LN	N/A	USA	- Dentist "used dirty drill bits”	Anonymous 1998
2000	IH	HIV	UK	N/A	Irwin and Millership 2002

2000	NN	N/A	UK	- HCV index patient presented with no RFs other than dental tx.	Roy et al. 2005; Unpublished report
2001	DI	N/A	UK	- Use of unsterilised dental equipment on patients	Roy et al 2005; Unpublished report
2002	DI	N/A	USA	- “We can only speculate about the mechanism of transmission; cross-contamination from an environmental surface is one possibility”	Redd et al 2007; Cleveland et al 2016; Merchant 2014
2004	DI	N/A	UK	- Failure to sterilise dental instruments appropriately	Unpublished report
2004	DI	N/A	UK	- Dentist not qualified and therefore serious concerns re: infection control practices	Unpublished report
2005	DI+IH	HCV	UK	- Failure to “consistently wear gloves" - Failure to "employ a tray system for sterilising instruments" - Failure to "appropriately store instruments after sterilisation"	Mason et al 2008
2005	NN	N/A	UK	- Main issue concerned zoning of instruments - Wore gloves but did not wash hands in between patients - Reuse of plastic disposable impression trays	Unpublished report

2006	NN	N/A	UK	- Re-use of LA cartridges - Poor decontamination records - Inappropriate decontamination room - Lack of weekly autoclave safety checks - Reservoir tank in autoclave never drained, only topped up	Unpublished report
2006	IH	HIV	Ireland	N/A	Fitzgerald et al 2010
2007	NN	N/A	UK	- Never autoclaving dental hand pieces - "Using cold disinfectant solution for sterilisation of all other instruments since the breakdown of the autoclave some time previously" - "Presence of dried blood on hand-mirror heads, on filling materials and on the dental chair"	Millership et al 2007; Unpublished report
2007	NN	N/A	UK	- Re-used single use items between patients such as "surgical blades, suture needles, latex gloves and anaesthetic cartridges" - "Dental handpieces [...] sometimes sprayed with disinfectant rather than autoclaved" - Poorly maintained autoclave and lack of autoclave records - Surgical blades immersed in chemical disinfectant prior to use	Millership et al 2007; Unpublished report

2007	NN	N/A	UK	- Dental burrs were heavily contaminated with bone debris - No manual cleaning of dental burs - No autoclave records	Millership et al 2007; Unpublished report
2007	LN	N/A	UK	- Dentist practising during suspension. - Infection control could not be verified	Unpublished report
2007	NN	HBV	UK	N/A	Unpublished report
2008	DI	N/A	UK	- Serious failures in infection control practice - Inadequate decontamination of blood contaminated equipment	Close et al 2013; Dr Bicuspid Staff 2009
2008	LN	N/A	UK	- Instruments[...] cleaned in line with national guidance only at the end of each treatment session rather than between each patient	Conrad et al 2011
2008	IH	HIV and HCV	UK	N/A	Unpublished report
2008	NN	HCV	Australia	N/A	Condon 2008
2009	NN	HCV	UK	N/A	Unpublished report

2009	DI	N/A	USA	- No barriers between operating areas, - All operations in close proximity - Hand pieces not sterilised between uses - Leaving sterilised instruments unwrapped - Patients bringing their used anaesthetic cartridges from station to station	Radcliffe et al 2013; Cleveland et al 2016; Merchant 2014; Domino 2010[a]; Dr Bicuspid Staff 2010[a]; CDC outbreak table[1]
2010	DI	N/A	USA	- Failure to properly clean dental instruments. - Sink and strong soap for manual cleaning. - Improper wrapping of instruments for sterilising technique. - Poor knowledge of staff of decontamination guidance - No records of training.	Merchant 2014; Dr Bicuspid Staff 2010[b]; 2010[c]; 2010[c]; Domino 2010[b]; Department of Veterans Affairs Office of Inspector General 2011[a]; 2012[a]; 2012[b]
2010	NN	N/A	UK	- Hand pieces surface wiped with alcohol wipes instead of going through full decontamination process	Unpublished report
2011	DI	N/A	USA	- Not changing gloves - Not sterilising instruments properly - Allegations of not cleaning/ sterilising instruments at all.	Merchant 2014; Dr Bicuspid Staff 2011[a]; 2012[a]; 2011[b]; 2011[c]; 2011[d]; 2011[e]; 2011[f]; 2011[g]; 2010[e]; 2011[h]; 2011[i]; 2011[j]; 2011[k]; 2011[l]; 2011[m]; 2011[n]; 2011[o]; 2011[p]; 2011[q]; Department of Veterans Affairs Office of Inspector General 2011[b]
2011	NN	HBV	UK	N/A	Unpublished report

2012	DI	N/A	Hong Kong	- Failed sterilisation of instruments - Some of the instruments had not undergone thermal disinfection during washing steps	Cheng et al 2013
2012	DI	N/A	UK	- Endodontic hand pieces not being decontaminated/ sterilised appropriately, - Sterilisation and decontamination not being performed in line with guidance - Staff were advised not to change gloves as frequently as is recommended - Endodontic instruments being re-used for the same patient at subsequent appointments	Unpublished report
2012	DI	N/A	UK	- Poor decontamination processes - Dental nurses not trained in decontamination - Low numbers of instruments/ drills - Restriction of use of gloves - Inadequate cleaning equipment - Illegal practice of dentistry by owner	Unpublished report
2012	DI	N/A	USA	- Re-use needles and syringes	Merchant 2014; Dr Bicuspid Staff 2012[b]; 2012[c]

2013	DI	N/A	USA	- Breaches in standard infection control practices - Inappropriate management and administration of controlled drugs very likely - Re-use of contaminated vials - Use of older, rusted instruments that could not be sterilised properly. - Delegation of IV sedation to non-certified dental assistants. - Lack of autoclave monitoring and maintenance. - Dental offices had no infection control plans. - No biological monitoring of autoclave for last 6 years. - Sterilization room unorganised and unclean. - Soaking of instruments in cold disinfection which is changed every 28 days.	Oklahoma State Department of Health 2013; Cleveland et al 2016; Weaver 2014; Merchant 2014; Molinari and Nelson 2014; Hanley 2013; Unpublished report; Dr Bicuspid Staff 2013[a]; 2013[b]; 2013[c]; 2013[d]; 2013[e]; 2013[f]; 2013[g]; 2013[h]; 2013[i]; 2013[j]; 2013[k]; 2013[l]; 2013[m]; 2013[n]; 2013[o]; 2013[p]; Domino 2013[a]; 2013[b]; Bradley 2015; Tulsa Health Department 2013[a]; 2013[b]
2013	LN	N/A	UK	- Re-use of gloves between patients - Re-use of matrix bands - Aspirator tips through ultrasonic bath but not autoclave	Henderson et al 2017; Unpublished report
2013	NN	HCV	UK	N/A	Unpublished report
2013	NN	HIV	UK	N/A	Unpublished report
2013	IH	HIV	UK	N/A	Unpublished report

2013	NN	HIV	UK	N/A	Aitken et al 2015
2013	LN	N/A	USA	- Drugs possibly contaminated with infectious material	CDC HAI outbreak table[2]; Unpublished report; Arkansas Health Department online update[3]; Arkansas State Dental Association online update[4]
2014	DI	N/A	UK	- Re-use of endodontic files, burs, 3 in 1 tips, impression trays, gloves between patients, matrix bands. - Incomplete processing of aspirator tips" amalgam carriers, aspirator tips - Ultrasonic scaler tips surface wiped not sterilised. - Poor training of staff in decontamination	Henderson et al 2017; Unpublished report
2014	LN	N/A	UK	- Re-use of PPE between patients - Re-use of instruments both unclean and unsterilised between patients - Not hand washing between patients - Failure to maintain clean and dirty areas	Unpublished report
2014	NN	N/A	UK	- Heavy contamination discovered within internal lumens of endodontic ultrasonic tips	Unpublished report
2014	LN	N/A	USA	- Insufficient time for cold sterilisation - Lack of proper scrubbing before disinfection.	Merchant 2014; Goszkowski 2014

				- No monitoring of steriliser. - Instruments sitting in a shallow basin, above fluid level of disinfectant. - Only 1 hand piece. - No knowledge of autoclave.	
2014	DI	N/A	Australia	- Poor infection control	New South Wales Government 2016
2014	NN	N/A	UK	- 3 in 1 tips not adequately decontaminated - Limiting use of disinfecting spray - No disinfection of water lines - Cats in surgery - No dates on sterilised instruments	Aitken et al 2015
2014	NN	HIV	UK	- Suspicions re use of WD	Unpublished report
2015	NN	N/A	UK	- Not always sterilising hand pieces between every patient - Reuse of matrix bands - Not disinfecting dental impressions before sending them to the lab. - Poor autoclave records.	Unpublished report

2015	NN	N/A	UK	- Re-use of potentially inadequately decontaminated etch tips, composite capsules, acrylic burs and endodontic hand pieces	Unpublished report
2015	NN	HBV	UK	N/A	Unpublished report
2016	DI	N/A	USA	- Cleaning (spray used) and re-use of burs - Not always washing hands	Department of Veterans Affairs Office of Inspector General 2017
2017	NN	N/A	UK	- No working autoclave	Unpublished report
NM	NN	N/A	UK	- Lack of appropriate infection control procedures	Unpublished report
DI – Decontamination incident, IH – Infected healthcare worker LN – Limited notification, NN – No notification, NM – Not mentioned					

Appendix 16: Numerical risk estimations presented in the literature regarding healthcare related BBV transmission

Risk	Numerical estimation of chance of occurrence	Breakdown of calculation	Source	Year	Cited in
"Probability of HIV transmission from a dentist to patient during a dental procedure in which the patient bleeds"	1 in 2,631,579 to 1 in 263, 158	Based on assumption that dentist has 0.4% chance of self-injury during procedure, 32% of contacting patients wound following injury and chance of HIV infection between 0.03%-0.3%	CDC	1991	(Anon 1995[d]; Chiodo and Tolle 1992)
"Probability of sporadic transmission from an infected surgeon to a patient during an invasive procedure"	2.4 in 1 million to 24 in 1 million	NM	CDC	1991	(Ciesielski et al 1991; Weller 1999; Chamberland and Bell 1992; Iheukwumere 1997)
"Risk of HIV transmission from infected surgeons"	1 in 1 million operations to 10 in 1 million operations	NM	Rhame	1990	(Ciesielski et al 1991; Weller 1999; Chamberland and Bell 1992; Closen 1996)
"Risk of HIV transmission from infected surgeons"	0.5 in 1 million hours of surgery to 38.5 in 1 million hours of surgery	NM	Lowenfels and Wormser	1991	(Ciesielski 1991; Weller 1999; Closen 1996)
"Risk of HIV transmission from an infected surgeon to patients"	Less than 1 in 1 million procedures.	NM	Schulman et al.	1994	(Mishu and Schaffner 1993)
"Incident of HIV transmission"	1 per 83,000 hours of surgery	NM	Lowenfels and Wormser	1991	(Chamberland and Bell 1992)

"The probability that an infected surgeon performing 500 surgeries in 1 year will transmit the virus"	0.2 in 100 to 2.8 in 100 depending on surgical specialty	NM	CDC	1996	(Closen 1996)
Risk of transmission of any BBV due to infection control failure.	0.000093 (nearly 1 in 10,000) for every 1000 patient seen	Risk of patient having HBV was assumed to be 1 in 1000, for HIV 1 in 1000 and HCV 1 in 2000. Transmission risk following instrument being used on infected individual, inadequately cleaned and then immediately used on patient was assumed to be the same as percutaneous risks (HBV close to 0% for HBVeAg-, 30% for HBeAg+, HIV 0.3% and HCV 3%).	Millership et al.	2007	(Millership et al 2007)
"Risk of catching HIV from a dentist"	1 in 200,000 to 1 in 2,000,000	NM	Bayer	1997	(Shaw 2008)

Appendix 17: Theories regarding the ‘Acer case’ transmissions and supporting evidence

Theory 1: Acer incurred sharps injury during procedure resulting in contact of his and the patient's blood, either directly through bleeding onto exposed patient tissues or indirectly via use of the now contaminated instrument	
For	Against
- Dentists commonly incur sharps injuries (Ciesielski et al 1994) - Acer could have been more prone to injury through fatigue caused by infection (Horowitz 1994[b]) - Needles were recapped (Ciesielski et al 1991) - Acer reported occasionally getting stuck with the needle when recapping (Barr 1996; Horowitz 1994[c]) - Infected patients all treated following Acer's progression to AIDS when his blood would have been more infectious (Ciesielski et al 1991) - Postulated by CDC as most likely cause of infections (Witte 1993) - GAO reviewed entire investigation and supported CDC conclusions (Ciesielski et al 1994)	- Not all patients had invasive procedures conducted (Shields 1993) - Acer reported no sharps injuries to the CDC (Shields 1995; Ciesielski et al 1991; Ciesielski et al 1994; Barr 1996) - HIV is not easily transmitted, it is unlikely that as many as 6 patients became infected this way (Robinson and Challacombe 1993) - No patients recalled being treated without gloves (Ciesielski et al 1991; Horowitz 1994[c]) - No patients recalled the dentist sustaining a sharps injury during their procedure (Ciesielski et al 1991; Barr 1996) - Staff did not recall the dentist incurring any sharps injuries (Ciesielski et al 1994)

Theory 2: Patient to patient transmission occurred through use of inadequately cleaned/sterilised instruments	
For	Against
- Infection control poor with disposable items being reused after submersion in germicide (Ciesielski et al 1991). - Infection control described as "woefully inadequate". Did not autoclave all instruments after every patient. Used alcohol to disinfect equipment (Barr 1996; Runnells 1993)	- Administration of LA only procedure common to all infected patients (Shields 1993) - Patterns/procedures performed do not support theory. (Ciesielski et al 1994) - Volumes of blood that would be needed to cause transmission would not be found on contaminated instruments (Hardie 1993) - HIV is fragile. (Hardie 1993) - Patient sequences more similar to dentist than each other (Hardie 1993) - 43 days where 5 HIV infected patients shared treatment days with 78 non-infected patients and no transmissions occurred (Hardie 1993).

Theory 3: Acer deliberately exposed patients to his blood, potentially through injection of local anaesthetic contaminated with his blood or semen.	
For	Against
- Horowitz's paper compares Acer attributes with those of serial killers and people who had been charged with intentionally exposing people to HIV. He concludes that 9 out of 11 characteristics matched (Horowitz 1994[a]; Horowitz 1994[b]; Horowitz 1994[c]) - Unprofessional/unethical behaviour. Gave false name and false profession when receiving HIV treatment and ignored medical advice to stop working (Horowitz 1994[a]; Shields 1995; Runnells 1993; Horowitz 1994[c]) - Unprofessional/unethical behaviour. Ignored friend who urged him to be tested in 1985 but reported to CDC that he was shocked to have been found to be HIV positive in 1986. (Horowitz 1994[c]) - Proven to have lied to investigators on multiple occasions eg. about having had no sexual contacts since learning of his AIDS diagnosis (Barr 1996) - Jaffe himself reported that Acer was deceptive, self-interested and not co-operative (Horowitz 1994[b]) - Acquaintance supported murder theory (Breo 1993; Anon 1995[c]; Ciesielski et al 1994). "he said something to the effect that, well, our society does not want to address the issue because they perceive it to be a homosexual problem, and when it begins to affect younger people and grandparents [...] then maybe society will do something." (Runnells 1993; Horowitz 1994[c]) - As white or colourless, semen would not be as noticeable in a syringe of lidocaine (Pepper 1994) - No other reports of transmission of HIV occurring through dental treatment (Pepper 1994) - Administration of LA only procedure common to all infected patients (Shields 1993) - The provision of an initial blood sample may align with serial killer profile (Horowitz 1994[b]). - Staff may not have been present for LA administration. Common to hide needle/for patients to look away during LA administration (Horowitz 1994[b]) - Very mixed accounts of his personality traits. Some say he was quiet and kind others say he drank heavily, was selfish, aggressive and knowingly placed others at risk of HIV via unprotected sex. (Barr 1996) - Patient reports of Acer being cold and unsociable; One of the infected patients stated that "Acer showed no remorse and expressed no apology after inflicting her with pain". (Horowitz 1994[c])	- Acquaintance who originally supported murder theory changed story in sworn deposition (Breo 1993; Anon 1995[c]; Ciesielski et al 1994) - Dentist initially co-operated by permitting interview and allowing sample of blood to be taken (Robinson and Challacombe 1993) - Patients all awake during procedures. Procedures observed by staff. Neither staff nor patients noticed anything unusual (Robinson and Challacombe 1993; Ciesielski et al 1994) - Intentionally infecting patients would have drawn attention to his practice and his infection. Something he was trying to keep secret. (Runnells 1993) - Investigators stated that friends and family said Acer was a "very kind" and "gentle" man and that he couldn't have done it. (Horowitz 1994[c])

- Another infected patient stated; “I was terrified...I tried to crack jokes to try and break the ice for myself, and he didn’t even react....He came in and worked on my teeth and left.” (Horowitz 1994[c])	

Theory 4: Instruments contaminated with dentist’s blood following performance of procedures on himself	
For	Against
May have used LA cartridges when conducting electrocautery on own oral lesions at home (Horowitz 1994[b]; Barr 1996)	Dentist only received treatment on one occasion (Ciesielski et al 1994) Staff not aware of dentist ever treating himself (Ciesielski et al 1994; Robinson and Challacombe 1993)

Theory 5: Patients contracted their infections via other routes outside of dental treatment	
For	Against
Administration of LA only procedure common to all infected patients (Shields 1993) Patient A had sexual contacts even though she initially denied this (Brown 1996; Anon 1995[c]; Ciesielski et al 1994) Patient A originally claimed she was a virgin, but court ordered examination revealed hymen was consistent with sex and she tested positive for HPV18. (Barr 1996) Patient B had extramarital affair, sexual contact not tested (Brown 1996; Ciesielski et al 1994; Barr 1996) Patient B had indicated on two forms that she had had a blood transfusion and had indeed had several invasive surgeries (Anon 1995[c]; Ciesielski et al 1994; Barr 1996) Patient C had multiple sexual contacts (14 since 1978) one homosexual contact and HIV infected prostitutes. 5 sexual contacts of Pt C could not be traced (Brown 1996; Ciesielski et al 1994; Barr 1996) Patient G had history of IVDU and sex with prostitutes (Ciesielski et al 1994). Patient G’s friend states that he visited a local crack house 3-4 times a week in mid 1980s and had traded crack for sex as well as having unprotected sex with a prostitute who later died of AIDS (Barr 1996). Patient I had multiple sexual partners and when her infection was first discovered, she initially mentioned that the source may be her boyfriend but 6m after case went public she stated boyfriend had tested negative when she tested positive and that he had been found to positive later (Barr 1996). 1 sexual contact could not be traced out of 6	CDC reported that sequences of Patient I closer to the dentist and the other patients than local controls: Within Patient I = 3.2% (0.3-5%) Dentist + Patient I = 4.3% (2.8-7.8%) Patient I + Patients A, B, C, E and G = 4.9% (2.1-8.1%) Patient I + 34 controls = 12.0% (6.8-17.9%) A, B, C, E + G sequences significantly closer to Patient I than 28 local controls (p=<0.0001) (Witte 1993) Both Patient A’s sexual contacts did not have HIV (Brown 1996; Anon 1995[c]; Ciesielski et al 1994) Later established that Patient A was negative for HPV (Barr 1996) Patient B’s affair was early and sexual contact showed no signs of HIV/AIDS 15 years later (Brown 1996). Since 1970s Patient B’s only sexual partner was husband who was negative (Anon 1995[c]; Ciesielski et al 1994) No hospital record of Patient B receiving transfusion (Anon 1995[c]; Ciesielski et al 1994; Barr 1996) Patient C denies homosexual contact and claims never paid for sex. (Ciesielski et al 1994) Patient C’s suspected homosexual contact was negative for HIV (Barr 1996) Patient G reported no IVDU or sex with prostitutes since late 1970s. Negative for HIV in 1986. Two sexual contacts since 1986 both negative for HIV. (Ciesielski et al 1994) Contact who could not be traced had had one sexual

(Ciesielski et al 1994) Not all sexual partners of Patient I tested, 5 out of 6 (Witte 1993) Patient E had multiple sexual contacts. 2 out of 10 were dead (not in relation to HIV but status unknown). 1 out of remaining 8 positive. (Ciesielski et al 1994) KB reported conducing 'blood sisters' pact with childhood friend. Blood to blood contact following needle prick on fingers. Friend never officially reported to be HIV negative. (Runnells 1993) Had 5 boyfriends (Runnells 1993) Debry analysed genetic sequence data and determined that results were inconclusive. Evidence did not suggest that dentist was or was not source of infection. (Crandall 1995) CDC's choice of controls may have been inappropriate as some 90 miles away. (Robinson and Challacombe 1993) Hardie claims that control groups used by CDC did not reflect sequences of the infected patients due to differences in length of time of infection and use of therapy (Hardie 1993) Before case went public, one of Ciesielski's colleagues stated that results of strain comparison were scientifically inclusive. (Barr 1996) Were controls inappropriate? Sequence data was changed many times. Could there have been contamination of blood samples (Barr 1996) Patient A, Kimberely Bergalis had unusually short incubation period of 2 years (Robinson and Challacombe 1993; Shields 1995) Patients had financial incentives to not share risk factors (Hardie 1993; Barr 1996) Dr Resnick called sequencing into question, claiming similar strains could be found within the community (Ciesielski et al 1994) Prevalence of HIV infected patients is similar to community at large (Barr 1996) KB had shared razors with dorm room mates and had cut foot on broken glass of dance floor. (Barr 1996)	contact with Patient I and protection was used. (Ciesielski et al 1994) Positive contact of Patient E tested positive in Dec 1990 after acute retroviral syndrome in 1989 and had had negative results in Oct 1988 and Dec 1988. Patient E tested positive in Oct 1988. Contact also had different strain of virus than Patient E CDC reported that KBs friend with who she conducted 'blood sisters' act was "well". Investigators "checked on her health" but later excluded as viral strains of patients and Acer matched (Runnells 1993) KB claimed to be a virgin and CDC could not find evidence to refute this (86) CDC say they tested "a number of those" with whom she had had "non-intercourse intimacies" (Barr 1996) Acer and patients showed sequencing similarity of 96% compared with controls which were 89%. Similarity between Acer and patients reflects sequence similarity within infected persons (95-100%) and those between mother and child (94-98%). (Myers 1994) Average distance between Acer and patients ranged from 3.4-4.9% whereas difference between Acer and local controls ranged from 5.8-16% (Dickenson et al 1993) Crandall re-examined DeBry et al. and Ou et al.'s genetic sequence data and supported their findings that dentist was source of infection. (Crandall 1995) In 1994, all sequence data reanalysed by Hillis and Heulsenbeck, they strongly supported the theory that Acer infected patients A, B and E, with doubt only cast on Patient G. (Ciesielski et al 1994) "analysis showed a similarity between the sequences from the patient (KB) and the dentist that were comparable to what had been observed for cases that had been epidemiologically linked" (Barr 1996) "Using this DNA technology, it was possible for the CDC sequencing group eventually to match the viruses in the bodies of Acer, Kimberley and the four other infected patients to an accuracy of 99.94%." (Runnells 1993) Viruses of dentist and patients A, B and C were as closely related as sequences found within an HIV infected person or those were patients are epidemiologically linked. The V3 sequences from the dentist and patients A, B and C were not related to pt D, 7/8 control patients and the 21 north American isolates. In a more stable area of the viral sequence. The dentist and patients A, B and C had an average difference of 1.8% whereas the average difference

	amongst the 8 local controls was 4.8%. The dentist and patients A, B and C shared a unique pattern of amino acids that was absent in the other sequences analysed. (Runnells 1993) "All 6 patients had no other RFs for infection and all had viral strains that closely matched that of the dentist" (Robert and Bell 1994; Ciesielski et al 1994) Evidence surrounding potential, alternative patient risk factors presented by investigators hired as part of private litigation (Ciesielski et al 1994) Dr Resnick cast doubt on sequencing conclusions but had been paid over $57,000 to conduct additional sequencing and to provide consultant testimony for the dentist's insurance company (Ciesielski et al 1994; Runnells 1993) These risk factors were discounted following discovery that the viral strains of the patient and dentist matched. (Barr 1996)

Limitations of 'Acer case' investigation
- Only one short interview with Acer (Horowitz 1994[a]; Ciesielski et al 1991; Barr 1996) and no dentist present (Horowitz 1994[c]) - Limited inspection of practice as practice had closed (Longfield et al 1994; Barr 1996; Horowitz 1994[c]) - DNA method new therefore potential errors (Iheukwumere 1997; Hardie 1993) - No consensus on which statistical method to use (Brown 1996) - Patient records incomplete, no complete list of patients (Longfield et al 1994; Ciesielski et al 1991; Barr 1996) - Samples for sequencing were labelled creating bias (Hardie 1993; Barr 1996) - Looked at variable regions but examining stable regions could have been a prudent first step as, if different, links could be excluded. (Hardie 1993) - Did CDC use best region of genome? (Barr 1996) - Acer blood sample examined only on one occasion by CDC (Barr 1996) - By the time Acer's interview was conducted his health and memory had greatly deteriorated (Barr 1996)

Appendix 18: Guidance documents cited by authors of incident management papers and how they influenced decision-making and PNE processes (UK and Ireland)

Guidance or policy referred to	How is it presented/described in the article?	Specific Incident Context	Reference	Year guidance published	Year used
Management of Public Health Incidents, Guidance on the Roles and Responsibilities of NHS led incident management teams	A document which outlines the "Generic organisational arrangements for managing [...] incidents"	Dental Infection Control Breach Incident in Scotland	Henderson et al 2017	Updated 2013	2013
AIDS/HIV infected health care workers: Guidance on the management of infected health care workers and patient notification	Guidance indicates that "all patients who have undergone an [...] EPP [...] as far as practicable should be notified"	HIV infected dentist in London	Gaudoin et al 2000	1998	~1999
The Prevention of Transmission of Blood borne disease in the Health-Care setting Department of Health and Children (Ireland)	Guidance stipulated that a local expert group be assembled to ascertain if a PNE was required	HIV infected dentist in Ireland	Fitzgerald et al 2010	2005	2006
Association for Professionals in Infection Control and Epidemiology (APIC) recommendations	Guidance outlined the purposes of notification	HBV infected dentist in UK	Blatchford et al 2000	1991	1995
Department of Health	Guidance obliges health authorities to inform all patients who may have been at risk of infection by health care workers who are *subsequently* diagnosed HIV-positive	HBV infected dentist in UK	Blatchford et al 2000	1993	1995
Wilson and Junger criteria	Suggested for use in aiding the decision of whether to notify patients	BBV infected HCWs	Blatchford et al 2000	1968	1995
Rutala and Weber	Modified version of framework used to calculate risk of transmission	Dental Infection Control Breach in Scotland	Henderson et al 2017	2007	2013

Appendix 19: 102 websites searched for guidance documents as part of the policy mapping exercise

ADA, Centre for Evidence Based Dentistry	http://ebd.ada.org/en
Agency for Healthcare Research and Quality	https://www.ahrq.gov/
Alberta Health and Wellness	http://www.health.alberta.ca/
Australian Government/Departme nt of Health	http://www.health.gov.au/
Austrian Institute of Technology	https://www.ait.ac.at/en/
Bandolier Knowledge	http://www.bandolier.org.uk/knowledge.html
BBC World	http://www.bbc.co.uk/news/world
Belgian Health Care Knowledge Centre (KCE)	https://kce.fgov.be/en
Blue Cross and Blue Shield association	https://www.bcbs.com/
California Technology Assessment Forum	https://icer-review.org/programs/ctaf/
Canada.ca	https://www.canada.ca/en.html
Catalan Agency for Health Information, Assessment and Quality (CAHIAQ)	http://www.aatrm.net
CDC	https://www.cdc.gov/
CDR Weekly Archived Content	http://webarchive.nationalarchives.gov.uk/+/http://www.hpa.org.uk/cdr/archives/back_issues_list.htm
Centre for Clinical Effectiveness - Monash Health	http://www.monashhealth.org/page/CCE
Centres for Medicare and Medicaid services	https://www.cms.gov/
CIHI (Canadian Institute for Health Information)	https://www.cihi.ca/en
Consortium of European Social Science Data Archives	https://www.cessda.eu/
Danish Health Authority	https://www.sst.dk/en
DIMDI German Institute of Medical Documentation and Information	https://www.dimdi.de/static/en/
ECRI Institute	http://www.ecri.org.uk/
European Centres for Disease Control	http://ecdc.europa.eu/en/Pages/home.aspx

Euroscan International Network	https://www.euroscan.org/
Eurosurveillance 1995-2017	http://www.eurosurveillance.org/
Faculty of Dentistry University of Toronto	https://www.dentistry.utoronto.ca/
Faculty of General Dental Practice	https://www.fgdp.org.uk/
French National Authority for Health	https://www.has-sante.fr/portail/jcms/r_1455134/en/about-has
GDC	https://www.gdc-uk.org/
GOV.uk*	https://www.gov.uk/
Health and Safety Executive	http://www.hse.gov.uk/
Health Council of the Netherlands	https://www.gezondheidsraad.nl/en/home
Health Facilities Scotland	http://www.hfs.scot.nhs.uk/
Health information and quality authority (Ireland)	https://www.hiqa.ie/
Health Protection Scotland/HAI Compendium	http://www.hps.scot.nhs.uk/
Health Quality Council of Alberta	http://www.hqca.ca/
Health Quality Ontario	http://www.hqontario.ca/
Health Systems Evidence	https://www.healthsystemsevidence.org/?lang=en
Healthcare Improvement Scotland	http://www.healthcareimprovementscotland.org/
Healthcare Inspectorate Wales	http://hiw.org.uk/splash?orig=/
HealthScotland	http://www.healthscotland.scot/
Information Commissioners Office	https://ico.org.uk/
Information Services Division Scotland	http://www.isdscotland.org
Institut national d'excellence en sante at en services sociaux	https://www.inesss.qc.ca/en.html
Institute for Clinical and Economic Review	https://icer-review.org/
Institute for Clinical Evaluative Sciences	https://www.ices.on.ca/
Institute for Healthcare Improvement	http://www.ihi.org/Pages/default.aspx

Institute of Health Carlos 3	http://www.eng.isciii.es/ISCIII/es/contenidos/fd-el-instituto/quienes-somos.shtml
Institute of Health Economics	https://www.ihe.ca/
International Network of Agencies for Health Technology Assessment	http://www.inahta.org/
Ireland - Health Service Executive	http://www.hse.ie/eng/
Joanna Briggs Institute	http://joannabriggs.org/
Latin American and Caribbean Health Sciences (LILACS)	http://metodologia.lilacs.bvsalud.org/php/level.php?lang=en&component=19&item=2
Legislation.gov.uk	http://www.legislation.gov.uk/
Ludwig Boltzman Institute for HTA (Austria)	https://hta.lbg.ac.at/page/homepage/en
Manitoba Centre for Health Policy	http://umanitoba.ca/faculties/health_sciences/medicine/units/chs/departmental_units/mchp/
McGill University Health Centre	https://muhc.ca/
McMaster University (CHEPA) (canada)	http://www.chepa.org/
National Clinical Assessment Service	http://www.ncas.nhs.uk/
National Guideline Clearinghouse	https://www.guideline.gov/
National Health Care Institute Netherlands	https://english.zorginstituutnederland.nl/
National Institute for Health and Care Excellence	https://www.nice.org.uk/
New Brunswick Office of the Chief Medical Officer Of Health Division	http://www2.gnb.ca/content/gnb/en/departments/ocmoh.html
Newfoundland and Labrador Centre for Applied Health Research	http://www.nlcahr.mun.ca/
NHS England	https://www.england.nhs.uk/
NHS improvement: News and Alerts	https://improvement.nhs.uk/news-alerts/
NHS National Institute for Health Research	https://www.nihr.ac.uk/
NHS Scotland	http://www.scot.nhs.uk/
NHS Wales	http://www.wales.nhs.uk/
Norwegian Knowledge Centre for Health	https://www.fhi.no/sys/ks/

Services	
Office for National Statistics	https://www.ons.gov.uk/
OpenGrey	http://www.opengrey.eu/
OSHA	https://www.osha.gov/
Ottawa Hospital Research Institute	http://www.ohri.ca/home.asp
Pan-Canadian HTA Collaborative	https://www.cadth.ca/resources/hta-database-canadian-search-interface
Practitioner Health Programme	http://php.nhs.uk/
Public Concern at Work	http://www.pcaw.org.uk/
Public Health Agency Northern Ireland	http://www.publichealth.hscni.net/
Public Health Wales	http://www.publichealthwales.wales.nhs.uk/
Queensland Government Health	https://www.health.qld.gov.au/home
Robert Koch Institute	https://www.rki.de/EN/Home/homepage_node.html
Royal Australasian College of Surgeons	https://www.surgeons.org/
Royal college of Surgeons	https://www.rcseng.ac.uk/
Sahlgrensha Univ. Hospital (Sweden)	https://www2.sahlgrenska.se/en/sahlgrenska-university-hospital/in-english/
Scottish Dental Clinical Effectiveness Programme	http://www.sdcep.org.uk/
Scottish Intercollegiate Guidelines Network	http://www.sign.ac.uk/
Statistics Canada	https://www.statcan.gc.ca/eng/start
Statistics.Gov.Scot	http://statistics.gov.scot/
SWEDISH AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT AND ASSESSMENT OF SOCIAL SERVICES	http://www.sbu.se/en/
The National Reporting and Learning System	https://report.nrls.nhs.uk/nrlsreporting/
The Northern Ireland Adverse Incident Centre	https://www.health-ni.gov.uk/topics/safety-and-quality-standards/northern-ireland-adverse-incident-centre-niaic
The Scottish Public Health Observatory	https://scotpho.nhsnss.scot.nhs.uk/scotpho/homeAction.do
THETA (Canada)	http://theta.utoronto.ca/home
TRIP Database	https://www.tripdatabase.com/
UK Data Service	https://www.ukdataservice.ac.uk/
UN Data	http://data.un.org/Browse.aspx?d
UNAIDS	http://www.unaids.org/en

University of Aberdeen HERU	https://www.abdn.ac.uk/heru/
University of British Columbia Centre for Health Services and Policy Research	http://chspr.ubc.ca/
Viral Hepatitis Prevention Board	http://www.vhpb.org/
Washington State Health Care Authority	https://www.hca.wa.gov/
Welsh Government	http://gov.wales/?lang=en
World Health Organisation	http://apps.who.int/ghodata/

Appendix 20: Toolkits which can be used to assess the impact of a healthcare incident

Name of Toolkit/Process / Grading system.	Guidance Document in which it features.	What does the toolkit measure?	What recommendations are made based on grade/level etc?
Public Health England Incident Levels	Communicable Disease Outbreak Management Operational guidance (PHE 2014[c])	Grades an incident from 1-5 based on predicted public health impact *Resources required* *Public/Media Interest* *Size of Geographic Area* *Numbers of persons affected* *Incident Severity*	- Number and type of departments that should be involved in management - Role of Lead person - Role of person who signs off on press releases/statements - Activation of other specific processes or plans
NCC MERP Index for Categorising Medication Errors	Respectful Management of Serious Clinical Adverse Events (Conway et al 2011) **AND** Learning from adverse events through reporting and review: A national framework for Scotland (Healthcare Improvement Scotland 2018)	Grades an error from A-I based on whether it reached the patient and the degree of harm caused	Not specified

NHS Scotland Risk Assessment Matrix **(adapted from AS/NZS 4360:2004 'Making it Work')**	Learning from adverse events through reporting and review: A national framework for Scotland (Healthcare Improvement Scotland 2018) **AND** The Risk Management of HAI: A Methodology for NHS Scotland (Scottish Government 2008)	Assigns level of **RISK** from low to v.high based on: Impact/Consequences of incident *Patient Experience* *Objectives/Project* *Injury (physical or psychological) to patients, visitors or staff* *Complaints/claims* *Service/Business interruption* *Staffing/competence Financial* *Inspection/Audit* *Adverse publicity/reputation* **AND** Likelihood of occurrence	Not Specified
Categorisation of adverse events/Guide to levels of review	Learning from adverse events through reporting and review: A national framework for Scotland (Healthcare Improvement Scotland 2018)	Assigns a category of adverse event from 1-3 based on: - Financial Loss - Negative publicity - Degree of harm caused	- Suggested minimum level of review - Composition of review team - How to report findings/share lessons learned - Timescales for completion of stages
Healthcare associated infection (HAI) incident/outbreak risk matrix (Adapted from the Watt	The Risk Management of HAI: A Methodology for NHS Scotland (Scottish Government 2008)	Assigns level of **RISK** from low (green) to high (red) based on:	- Type of team required - Type of plan requiring

report 2002)		- Level of patient harm - Public health implications - Nature of infection episode - Disruption of services - Public anxiety and concern	implementation - Who to establish communications with
Classification of public health incidents and suggested level of response	Management of Public Health Incidents, Guidance on the Roles and Responsibilities of NHS led Incident Management Teams (HPS and Scot Gov 2017)	Grades an incident from 0-5 based on: - Numbers involved - Effect on services - Actual or potential public health impact	- Type of management team - Role of lead - Types of staff involved - Who to report to - Reporting/ assessment tools - Post-incident reporting
Dynamic Risk Assessment Model	Northern Ireland Infectious Disease Incident / Outbreak Plan (Public Health Agency 2018)	Assigns a level of **RISK** based on 5 criteria. A grade of 0-4 is given for each criterion: - Severity and prognosis of known cases - Confidence in hypothesis - Potential for the organism to spread given the circumstances	Not specified

		- Feasibility and predicted success of intervention - Context (Media, local concern, historical issues, professional knowledge, guidance available, concurrent events etc.)	
Information table for rapid risk assessment to support risk-ranking algorithm (option 2: separate algorithms for probability and impact)	Operational guidance on rapid risk assessment methodology (ECDC 2011)	Assigns a level of **RISK** from very low to very high based on: - Probability of infection *Possibility of further human exposure* *Susceptibility of population* *Infectivity of disease* **AND** - Impact *Likelihood of causing severe disease* *Number of people affected* *Availability of effective treatments/control measures* *Contextual factors*	Not specified
Escalation/Risk Assessment Criteria (adapted from Health Protection Scotland Watt Risk	The Communicable Disease Outbreak Plan for Wales ('The Wales Outbreak Plan') (Public Health Wales 2014)	Assigns description of incident from minor-major based on: - Patient harm/interventions	- Type of incident - Team to be assembled

Matrix)		required - Disruption of services - Likelihood of further transmissions - Public anxiety	- Use of specific plans/processes
Risk Analysis Matrix	Australian Guidelines for the Prevention and Control of Infection in Healthcare (Australian Government – NHMRC 2010)	Assigns level of **RISK** from low to extreme based on: - Likelihood - Consequences - Context	- Routine or specific procedures
HSC Regional Impact Table and Risk Matrix	Procedure for the Reporting and Follow-Up of Serious Adverse Incidents (Health and Social Care Board 2016)	Assigns level of **RISK** from low to extreme based on: - Impact *Patient harm/interventions required* *Degree of deviation from professional standards/guidelines* *Reputational effects* *Financial consequences* *Resource demands* *Environmental effects*	Not specified

		AND - Likelihood *How often does/might this occur?*	
Risk Assessment Tool	HSE Integrated Risk Management Policy Incorporating an overview of the Risk Management process (Health Service Executive 2017)	Assigns level of **RISK** from low to high based on: - Impact *Harm to a person* *Service user experience* *Compliance* *Objectives* *Business continuity* *Adverse publicity/reputation* *Finance* *Environment* **AND** - Likelihood *Actual Frequency* *Probability*	"This rating will assist both in the evaluation of risk and the prioritisation of the management of risks"

Severity Assessment Code Matrix	The NSW Health Incident Management Policy (NSW Government 2014)	Assigns level of **RISK** from low to extreme based on: - Consequences *Harm and interventions required (patients, staff, visitors)* *Disruption to services* *Financial consequences* *Environmental effects* **AND** - Probability *How often does/might this occur?*	- How to report - Who to report to - Type of investigation required
NIPCM Healthcare Infection Incident Assessment Tool (HIIAT)	Chapter 3 - Healthcare Infection Incidents, Outbreaks and Data Exceedance (NSS 2019[a]) **AND** Literature Review: Healthcare infection incidents and outbreaks in Scotland (HPS and NSS 2017)	Assigns an incident a colour of green, orange or red based on 4 criteria: - Severity of Illness - Impact on services - Risk of transmission - Public Anxiety	- Forms requiring completion - Who to report to - Timescales for reporting - Necessity for preparation of press statements - Frequency of HIIAT review - Support from HPS

Appendix 21: Guidance given by different organisations on when to notify patient(s) following a healthcare incident

Organisation	Year	Advice
Healthcare Improvement Scotland (Sco)	2015	**Single patient incident:** Notify those who have suffered moderate or severe harm based on NPSA definitions. **Further notes:** There may be exceptional circumstances where it is not appropriate to inform a patient, or the family or carer of an adverse event. For example, because of the distress it would cause to the patient.
Agency for Healthcare Research Quality (USA)	2016	**Single patient incident:** Notify patient if it is deemed to be a CANDOR event: an event that causes unexpected harm (psychological, emotional or physical). **Further notes:** Potential patient harm (unsafe conditions, near misses, no harm events) are not CANDOR events
Health Quality Council of Alberta (Ca)	2006	**Single patient incident:** When a patient experiences harm while receiving healthcare, full and complete disclosure must occur. When an adverse event occurs and there is no apparent harm to the patient but the potential for harm remains disclosure is good to promote an open, transparent and trusting relationship. It also allows the patient and family to knowingly monitor his/her condition. **Further notes:** Times when disclosure may not be appropriate (when a patient's condition provides a rationale not to disclose). However if in doubt best to err on the side of open disclosure.
Royal College of Surgeons (Eng)	2015	**Single patient incident:** any unintended or unexpected incident that occurred in respect of a patient's care that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in the patient's death, severe harm, moderate harm, or prolonged psychological harm. **Further notes:** The words 'could result in' in the definition of a notifiable safety incident suggest that the unintended incident is likely to manifest harm in the future, even if no harm is immediately evident at present.
National Patient Safety Agency (Eng)	2009	**Single patient incident:** notify a patient when an incident has led to moderate harm, severe harm or death **Further notes:** Problems if you discuss 'no harm' incidents with patients. - added stress to patients - potential loss of confidence in the standard of care - negative effects on staff confidence and morale; - decreased public confidence in the NHS. - Impractical - adding to staff workload - potentially interrupting their ability to provide patient care. However, the NRLS believes that where an incident led to moderate

		harm, severe harm or death, the benefits outweigh these problems.
Australian Commission on Safety and Quality in Health Care (Aus)	2014	**Single patient incident:** Disclosure always advised. Indications for a higher-level response (more comprehensive open disclosure process) - 1. Death or major permanent loss of function - 2. Permanent or considerable lessening of body function - 3. Significant escalation of care / change in clinical management - 4. Major psychological or emotional distress - 5. At the request of the patient Indications for a lower level response (less comprehensive open disclosure process) - 1. Near miss / no-harm incident - 2. No permanent injury - 3. No increased level of care required - 4. No, or minor, psychological or emotional distress. A lower-level response should only be initiated if the risk of further harm (from not conducting higher-level open disclosure) is unlikely. If harm unclear continue investigation until ascertained. **Multiple patient incident:** Large-scale disclosure, disclosing multiple adverse events or large-scale harm (or potential harm) to multiple individuals or the general public is out of scope of the Framework. Relevant health service organisations are advised to have procedures in place to expedite decision-making in the event of multiple or large-scale incidents, and assess each situation promptly with legal counsel and public relations departments. **Further notes:** Near misses and no harm incidents - Will the distress or psychological harm of disclosing the information outweigh the benefit that could feasibly be achieved by disclosure? - Will disclosure reduce the risk of future incidents? - Will disclosure maintain patient, family and carer trust in the service?
CQC (Eng)	2014	**Single patient incident:** For a health service body e.g. NHS trust, patients should be notified when both harm has occurred or when it could occur. 'Harm' refers to death, severe harm, moderate harm and psychological harm. Moderate harm is defined as harm that requires a moderate increase in treatment or significant, but not permanent, harm. 'Moderate increase in treatment' means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care). For 'Any other registered person' who is 'not a health service body' patients should be notified when harm has occurred. 'Harm' refers to death, impairment of sensory or motor function, altered structure of body, prolonged pain, prolonged psychological harm, shortened life

		expectancy. requires treatment by a health care professional in order to prevent the death of the service user, or any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned. **Further notes:** Ethical duty (professional duty) exists when low threshold for notification - any harm or distress to patients. When the Scottish duty of candour comes into force it will be very similar to the English regulations. Only differences are that the medical practitioner making decision about harm must not be involved in the incident and that patients can decide if they wish to know further information
The College of Physicians and Surgeons Ontario (Ca)	2003	**Single patient incident:** an unintended outcome arising during the course of treatment, which may be reasonably expected to negatively affect a patient's health and/or quality of life. This includes outcomes that occur as a result of individual or systemic acts or omissions. This also includes adverse events that result in unintended harm related to the care and/or services provided to the patient rather than to the patient's underlying medical condition. This policy applies to all physicians who become aware, while treating a patient, that the patient has sustained harm in the course of receiving health care. **Further notes:** The patient should receive knowledge of a close call if there is still an ongoing similar safety risk for the patient, or if the patient is aware of the close call and an explanation will allay concern and promote trust.
Health Service Executive and State Claims Agency (Ire)	2013	**Single Patient Incident:** Service users should be informed of the occurrence of an adverse event that has resulted in or is expected to result in harm to the patient. **Multiple Patient Incident:** There may be times when a single event will require notification to a large number of people. Large-scale disclosures need to be well thought out with some degree of rationale as to who needs to be targeted. A risk assessment will assist in identifying which service users have been potentially exposed to a safety incident/ adverse event and who are therefore at risk and require disclosure. Where the likelihood of exposure is high, the need to contact all affected service users is straightforward. When the likelihood of harm decreases the probability of harm in conjunction with weighing up ethical obligations is required. It is vital that this decision is made with the necessary input from all of the relevant parties and with consideration of a number of perspectives, including medical, ethical, legal, risk management and communications aspects to determine a structured, informed and targeted approach. **Further notes:** The need to disclose when there is no harm, but the potential for harm exists is influenced by the potential likelihood of severe consequences in the future. If it is unknown if harm has occurred it is recommended that disclosure takes place. If, after

		consideration of the near miss event, it is determined that there is a risk of potential for future harm from the event then this should be discussed with the service user. Consider if there is a reason to defer disclosure at this time/can disclosure cause additional harm? Healthcare providers and services should consider what the reasonable person would want to know about the near miss event under the circumstances. When a clinician makes a decision, based on his/her clinical judgement, not to disclose to the service user that an adverse event has occurred, the rationale for this decision must be clearly documented in the service user's healthcare record and this decision may need to be reviewed by the clinician at a later date, depending on the circumstances involved.
GMC (UK)	2015	**Single patient incident:** Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. **Further notes:** This guidance also applies in situations where a patient may yet suffer harm or distress as a result of something going wrong with their care. A 'near miss' is an adverse incident that had the potential to result in harm but did not do so* *This does not include adverse incidents that may result in harm but have not yet done so – the patient must be told about these events and they must be reported in line with this guidance.
VHA (USA)	2018	**Single patient incident:** Disclosure is required for the following: - Adverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage (or that are reasonably expected to result in death or serious and/or permanent disability) - Adverse events that have had, or are reasonably expected to have, an effect on the patient that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of a diuretic (a medication that dramatically increases urine output), disclosure is required because a perceptible effect has, or is anticipated to occur. - Adverse events that precipitate a change in the patient's care. For example, a medication error that necessitates extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or a surgical procedure that necessitates further (corrective) surgery. - Adverse events with a clinically-significant risk of serious future health consequences to patients, even if the likelihood of that risk is

		small. For example, a known, accidental exposure of a patient to "ionizing radiation," "a toxin," "an organism," or "infectious entity" associated with a rare, but recognized serious short-term or long-term effect (e.g., blood borne pathogen infection or increased incidence of cancer). In some cases, however, no definite exposure of this type can be determined. Only an increased risk of exposure is known or thought to exist. In such cases, disclosure needs to be decided with careful deliberation considering the best interests of the patient, and weighing the risks and benefits of disclosure relative to the probability of serious future health consequences. If, after disclosure in such cases, it is later determined through the look-back process or subsequent investigation that harm did not occur, or that the risk of harm is actually negligible, disclosure of the new risk information must be made to the patient. Caution must be exercised in differentiating "clinically significant" risk of harm from harm that is only "plausible" or "hypothetical." **Multiple patient disclosure:** The SME Review Panel is a panel convened to conduct fact-finding, including, as needed, site visits, literature reviews, and risk assessment regarding events that have the potential for a large-scale disclosure. They will conclude that either (a) There is a negligible risk of harm, considering both the probability of harm and the severity of potential harm; therefore no disclosure is required and the issue should be closed (b) There is a clinically-significant risk of harm, considering both the probability of harm and the severity of potential harm; therefore disclosure is required and there is no need to convene a CRB (c) There is an indeterminate risk of harm, considering both the probability of harm and the severity of potential harm; therefore a CRB should be convened to consider whether disclosure is ethically warranted based on factors other than risk alone. The CRB (clinical review board) uses a transparent and systematic process to consider whether disclosure is ethically warranted in light of the indeterminate risk. There is a presumptive obligation to disclose adverse events that cause harm or potential harms to patients. However, in the case of an adverse event that has the potential to affect dozens or even thousands of patients, a public health response also requires a determination of the probability and severity of harm resulting from the adverse event, as well as a weighing of additional factors, including, but not limited to: salient ethical principles; risk of harm to patients and potentially-affected third parties; benefit and burden of disclosure to patients, including medical, psychological, social, or economic; impact on the institution's perceived integrity and its capacity to provide care and treatment for all patients; as well as applicable policy and relevant precedent. - 1. DO WE HAVE ALL THE IMPORTANT FACTS RELEVANT TO THE DECISION? - 2. HAVE WE INVOLVED EVERYONE WHO SHOULD BE PART OF THIS

		DECISION? - 3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES? - 4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY LIKELY HARMS? - 5. DOES THIS DECISION ESTABLISH A GOOD MODEL FOR FUTURE DECISION-MAKING? - 6. HOW WOULD THIS DECISION LOOK TO SOMEONE OUTSIDE THE ORGANIZATION? **Further notes:** VHA believes that there is an unwavering ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future.
Canadian Patient Safety Institute (Ca)	2011	**Single patient incident:** Flowchart shows that one should always disclose a harmful incident, generally disclose no harm incidents and near miss means generally need not disclose unless it is felt patient would benefit from knowing ie: there is an ongoing safety risk. **Multiple patient incident:** Guidance seldom addresses the distinct challenges of large-scale disclosure Which patients are 'at risk' and require disclosure As likelihood of harm decreases a complex weighing of clinical probabilities and ethical obligations may be required. Ultimately criteria for contacting patients should be conducted with risk assessment in mind Need access to evidence based risk assessment literature Anticipate challenges by having experts available to make decisions. **Further notes:** The need to disclose when there is no immediate harm but the potential for harm exists is influenced by the future likelihood of important clinical consequences and the urgency is determined by the ability to prevent, identify or mitigate future harm through clinical testing or treatment. When uncertain about whether harm has occurred. It is recommended that disclosure take place, however, further consultation may be required before proceeding. Consider consulting with clinical experts and as appropriate an ethics committee or similar experts for advice or sometimes legal council about the risk of future harm and the need to disclose.
NSW Government (Aus)	2014	**Single Patient Disclosure:** Open disclosure is required whenever a patient has been harmed, whether that harm is a result of an unplanned or unintended event or circumstance, or is an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement or cure. A disclosure discussion must occur whenever a patient has been harmed, whether that harm is a result of an unplanned or unintended event or circumstance, or is an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement

		or cure. Flowchart indicates - Always disclose a harmful incident, Generally disclose a no harm incident, Generally no need to disclose a near miss incident unless ongoing patient safety risk. **Multiple patient incident**: To guide decisions about open disclosure, expert advice may be required to assist with the determination of the level of risk. Appears to be mandatory when patient has been harmed or will be harmed but open disclosure always encouraged. **Further notes:** Open disclosure begins with the recognition that a patient has been harmed or will potentially be harmed by an ongoing safety risk as a result of receiving or not receiving treatment or care. In the case of a near miss disclosure is discretionary, based on whether it is felt the patient would benefit from knowing, for example, if there is a residual safety risk.
Health and Disability Commission (NZ)	2009	**Single patient incident:** A consumer should be informed about any adverse event, ie, when the consumer has suffered any unintended harm while receiving health care or disability services An error that affected the consumer's care but does not appear to have caused harm may also need to be disclosed to the consumer.
Canadian Medical Protection Association (Ca)	2017	**Single patient incident:** Patient should be notified when the clinical outcome is not as anticipated and whatever the reasons for harm, physicians are obligated to communicate directly with their patients. **Further notes:** Sometimes an incident has the potential for harm, that is, harm might manifest in the future. For example, a patient exposed to poorly sterilized equipment might subsequently acquire a viral infection. The infection would take time to declare itself and serial monitoring would be required. No harm incidents require disclosure. The patient should be informed about a near miss if there is a similar, ongoing safety risk for that patient, or if the patient is aware of the near miss and an explanation will allay concern and promote trust. In 'near misses' the event did not reach the patient because of timely intervention or good fortune. In general, a near miss need not be disclosed, although there are exceptions.
Nova Scotia Health (Ca)	2005	**Single patient disclosure:** At minimum the facts of the event and its impact on the client and on the care must be disclosed when an adverse event occurs during the process of providing health care and results in client injury, death or negatively impacts health (real or perceived). **Multiple patient incident:** Processes for disclosure become more complex in certain situations, for example where large numbers of individuals are involved. A comprehensive decision-making framework aims to assist in the step-by-step process of bringing the relevant stakeholders together, clarifying the issue, gathering and

		examining the relevant information, identifying possible response options, considering the burdens and benefits of each and to whom, selecting a response and implementing a comprehensive strategy, and evaluating the outcomes. The Department of Health and health care agencies shall participate in collaborative communication planning when informing the public about adverse events which (1) involve multiple clients; (2) are perceived as a public health hazard; or (3) have the potential to undermine public confidence in the health care system.
Danish Society for Patient Safety (Den)	2008	**Single patient incident:** Notify when patients have been harmed or are exposed to a serious risk of harm in their encounter with the health care services. **Further notes:** As a general rule, an apology should be offered to patients sustaining harm or having been exposed to unnecessary risk. However, it should be emphasised once again that not two patients are the same, and the same is true of the nature of events causing harm. It is not possible to make an exhaustive inventory of scenarios, dividing them into 'requiring an apology' or 'not requiring an apology'. It is always a question of an individual assessment, and that assessment must pay special attention to the patient's experience of what happened. As a general rule, patients should not be informed about near misses, defined as events that are prevented from happening due to timely intervention.
Clinical Excellence Commission (Aus)	2014	**Single Patient incident:** Open disclosure is required whenever a patient has been harmed, whether that harm is a result of an unplanned or unintended event or circumstance, or an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement or cure. Whenever a harmful incident occurs, the patient and/or their support person(s) must be informed. Flowchart indicates - Always disclose a harmful incident, Generally disclose a no harm incident, Generally no need to disclose a near miss incident unless ongoing patient safety risk. **Multiple patient incident:** When there is potential for a number of people to be harmed by a common patient safety incident or series of incidents, each situation should be assessed promptly with legal counsel and public relations departments. Proactive disclosure is recommended. This may include a public announcement (e.g. a press conference) and description of what has occurred using various media; an apology for distress that the announcement may cause, details of the investigation underway and what would happen if it is identified that a person has been affected, and details of a dedicated toll-free contact number staffed by clinical members of the team and an email address **Further notes:** A disclosure discussion is also generally required when

		a no harm incident has been identified, and may be required for 'near miss' incidents if there is an ongoing safety risk to the patient and the patient would benefit from knowing. Even though no harm is immediately apparent, an ongoing patient safety risk may be present and the patient and/or their support person(s) may be aware that some sort of mistake or incident has occurred. For a near miss incident, disclosure is discretionary, based on whether it is felt the patient would benefit from knowing, for example, if there is an ongoing safety risk to the patient. Advice may be required from the senior treating clinician and/or open disclosure advisor to assist with the determination of risk.
Scottish Government (Sco)	2018	**Single patient incident:** Organisations (as responsible persons) must activate the duty of candour procedure as soon as reasonably practicable after becoming aware that: • an unintended or unexpected incident occurred in the provision of the health, care or social work service provided by the organisation as the responsible person; • in the reasonable opinion of a registered health professional not involved in the incident: (a) that incident appears to have resulted in or could result in any of the outcomes mentioned below; and (b) that outcome relates directly to the incident rather than to the natural course of the person's illness or underlying condition. The relevant outcomes are as follows: A. The death of the person. B. Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions (including removal of the wrong limb or organ or brain damage) ("severe harm"). C. Harm which is not severe harm but which results in one or more of the following criterion: • an increase in the person's treatment; • changes to the structure of the person's body; • the shortening of the life expectancy of the person; • an impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days; • the person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days. D. The person requires treatment by a registered health professional in order to prevent: • the death of the person; • any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned in paragraph B or C. **Further notes:** If an event is unlikely to result in harm organisational duty of candour does not need to be activated. It is important to note that where the duty of candour procedure start date is later than one month after the date on which the incident occurred, an explanation of the reason for this has to be provided to the relevant person.

Sco – Scotland

Eng – England

Ire – Ireland

Aus – Australia

Den – Denmark

Ca – Canada

NZ – New Zealand

USA – United States of America

UK – United Kingdom

Appendix 22. Questionnaire development – the ‘Think Aloud’ interview study

Introduction

Questionnaires are used to gather standardised information from a sample of participants who represent a wider population (Rattray and Jones 2007). The science and importance of good questionnaire design is the focus of a multitude of textbooks and papers (Rattray and Jones 2007; Bradburn et al 2004; Tsang et al 2017; Dillman 2007). If questionnaire design is done without adequate feedback or reflection, it can result in a poorly worded and structured survey with a high degree of response error (Boynton and Greenhalgh 2004).

Researchers may choose to utilise a validated, pre-existing questionnaire to capture data. A validated tool has been tested for validity and reliability (Rattray and Jones 2007). Researchers have accessed, for example, whether the questionnaire gathers data that truly reflect and contribute to the entity being measured and whether the survey exhibits test-retest reliability. Use of a validated questionnaire saves time and reassures the researcher that they are using a tried and tested survey tool (Tsang et al 2017). However, if no validated tool, which measures your factor of interest, exists, a new questionnaire must be developed. Adapting a pre-existing questionnaire for an alternative but connected use and still considering it validated, is not recommended. Altering a validated questionnaire in any way, such as re-ordering questions, can result in unexpected influences upon respondent answers and invalidate the tool (Juniper 2009; Dowrick et al 2015).

Whether your questionnaire is new or has been extracted from the existing literature, it should be piloted and tested to establish if it is fit for use on your specific, target population (Boynton and Greenhalgh 2004). A traditional piloting phase was not executed as part of this doctoral work but is, however, recommended in the main questionnaire study proposal (Appendix 23). The 'think aloud' interview process described here, was used to aid development of the questionnaire and is not designed to replace a piloting phase but rather to complement it.

What is a 'think aloud' or cognitive interview study?

A 'think aloud' interview study or cognitive interviewing process involves asking a small sample of individuals to assess a newly designed tool or survey. Participants take part in an interview where they complete the instrument and voice their thoughts aloud. Their comments are then used to improve the content and design of the tool (Willis 2005[f]).

The focus in a 'think aloud' interview is primarily on the participants' interpretation of how questions should be read and answered, not the specific content of the answers themselves (Willis 2005[f]). The researcher is looking for feedback on factors such as readability, complexity and length (Willis 2005[f]). In

his key, methodological text, Willis (2005[f]) stated that we use cognitive interviewing to study how "targeted audiences understand, mentally process and respond to the materials we present". Only a small sample size is required and multiple interviews with multiple rounds should result in a final instrument draft where many barriers to understanding and completion have been removed (Willis 2005[f]; van Oort et al 2011; McCorry et al 2013).

Roots of the 'think aloud' methodology lie in psychological research, specifically the concept of introspection (van Someren et al 1994). Discussion surrounding introspection began in the 1930s and was based on the idea that cognitive processes can be observed in the same way that physical aspects of our environment are (van Someren et al 1994). The origin of cognitive interviewing as a technique truly lies, however, in the early 80s with the development of the CASM approach: Cognitive Aspects of Survey Methodology (Willis 2005[a]). In 1984, Jabine et al outlined four key elements that underpin the concept of CASM.

1: Question intent, what does the respondent believe the question to be asking, meaning of terms, what do specific words and phrases in the question mean?

2: Recall of information, what kinds of information are asked about, retrieval strategy, for example does the respondent count each event by recalling them or estimation strategy.

3: Motivation, are they devoting sufficient effort to answering the question. Sensitivity/social desirability, does the respondent want to answer, do they want to make themselves appear a certain way?

4. Can the respondent match their internally generated answer to the response options provided in the question?

The four elements of the CASM approach (Jabine et al 1984)

Aims

i. To obtain feedback on the design of a novel questionnaire

ii. To alter the questionnaire based on participants' comments thus resulting in a survey tool which is easy to understand, inoffensive and straightforward to complete.

Methods

Selection and recruitment of study participants

An ideal pilot sample for this study would have been those who had recently been involved in a dental PNE. A suitable incident, however, had not recently or was not currently, being managed at the time of this doctoral study. Seeking out

those who had been involved in a historic exercise was considered but with the last relevant incident having occurred three years previously, respondent recall would most likely have been poor.

Recruiting members of the public was considered, and although they would have aptly reflected the profile of future respondents it was postulated that communication with the general public regarding PNEs may create feelings of concern about the safety of their own dental healthcare provision.

It was decided that a 'think aloud' study or cognitive interview technique would be used to develop the questionnaire with a traditional pilot phase being recommended as part of the main questionnaire study proposal (Appendix 23).

A convenience sample was selected from those working within Glasgow Dental School. It was, however, stipulated that participants must not have a clinical background to avoid obtaining only healthcare professionals' input and hopefully mirror the responses of those from a typical, general public background.

A poster was placed in all Glasgow Dental School staff areas to publicise the study and invite recruits. Those who were interested in taking part were invited to email the chief investigator (LG). Interested parties were emailed a detailed participant information sheet and advised that should they still be interested, following its perusal, they should email the CI once more.

Two rounds of interviews were conducted involving a total of eight participants, four in each round.

Interview process

Interviews took place within a private office space of Glasgow Dental School. Participants were asked to read and complete a ten-item consent form and to initial each point if they were satisfied with its content. The form was signed and dated by the participant and then co-signed and dated by the researcher taking consent. Participants were asked if they had any questions or concerns. A copy of the form was given to the participant for their personal records. Following consent, audio recording was commenced. Participants were then asked to select both an age range and highest level of education from a list of pre-assembled options and speak their selections aloud.

The structure of the 'think aloud' interviews was carefully constructed based on examples in the literature and key 'think aloud' or cognitive interview methodology publications (Willis G 2005; Boeije and Willis 2013; McCorry et al 2013; van Oort et al 2011).

Participants were asked to read and complete the questionnaire whilst voicing their thoughts aloud. Throughout the interview, interaction with the participant

was limited in order to reflect a self-administered questionnaire environment. If the participant fell silent for a long period of time they were prompted to speak by asking them what they were thinking (Willis 2005[i]; McCorry et al 2013; van Oort et al 2011).

The pre-questionnaire interview guide

Before the participant began assessing and commenting on the questionnaire, a four-part, pre-questionnaire interview guide was followed that introduced the participant to the concept of 'thinking aloud'. Part A was read to the participant by the CI and detailed the purpose and process of the 'Think Aloud' interview. It was modelled on an example script published by McCorry et al in 2013.

It is considered good practice to incorporate a 'think aloud' participant training phase into the interview process (Willis 2005[d]). Part B of the guide prompted the interviewer to administer a 'warm up' questionnaire. This comprised a short series of questions on the weather and how the participant travelled to the interview. A similar short, introductory, questionnaire was included in van Oort et al's 2011 'Think Aloud' study. This training exercise allows participants to practise the skill of thinking aloud and tests their ability to identify mistakes or questionnaire difficulties.

Part C involved providing the participant with a scenario letter. Participants were asked to imagine that they had received this letter in the post. The letter was modelled on those sent to patients involved in a Scottish dental incident and provided a context for the questionnaire.

Part D involved the delivery of a short statement which encouraged the participant to not hold back with any of their comments or concerns as the the chief investigator was keen to receive constructive criticism in order to improve the questionnaire.

Data analysis

Each of the first four interviews were transcribed verbatim and, as the literature recommends, a report was compiled which mainly consisted of the questionnaire, annotated with participants' comments (Willis 2005[b]). Each questionnaire item was presented alongside participants' comments pertaining to that question. The report also included the demographic features of the participants, notes regarding how well participants were able to express their thoughts aloud and a final section which outlined any general comments participants made (Willis 2005[b]; Boeije and Willis 2013). The CI, alongside research team member (AR) used their personal judgement to decide which comments would be used to influence the re-design of the questionnaire.

Interviewing and questionnaire re-design: an iterative process

'Think Aloud' interviews should ideally be conducted in multiple rounds. This facilitates design alterations throughout the study with accompanying feedback, bringing the researcher ever closer to the production of a highly effective questionnaire (Boeije and Willis 2013; Willis 2005[g]).

Following the first round of 'Think Aloud' interviews, contact with a UK public health consultant resulted in the acquisition of data surrounding a further, unpublished, study which had assessed psychological impact following a dental incident (unpublished report 2007). First interview round findings, along with the design features of this newly discovered study, influenced the creation of a second questionnaire draft (unpublished report 2007). A second round of interviews was conducted with four more participants and the new questionnaire version.

Audio recordings were once again transcribed verbatim and a similar 'report of findings', that had been created following the first round of interviews, was produced.

Ethical approval

NHS research ethics committee approval was not required for the 'think aloud' interview study as it involved the recruitment and participation of NHS staff only. Ethical approval was, however, sought from Glasgow University MVLS College as well as NHS Greater Glasgow and Clyde Research and Development.

As previously outlined, the study involved multiple rounds of interviews. A number of documents, including the questionnaire and recruitment poster, were altered following the first round thus a substantial amendment to the original, ethical approval was submitted and approved before initiation of the study's second phase.

Data management

Consent forms were stored in a locked cabinet within Glasgow Dental School. Ethical approval requires that data related to the study be stored in a secure location for ten years. A data manager for the study was selected (AR) and knowledge regarding access to the data will be passed to another research colleague should AR leave his post.

Each participant was allocated a unique identification number which was linked to their consent forms and used in subsequent transcriptions.

Results

Participant demographics

In total, this study had eight participants, four in the first round of interviews and four in the second. Six participants were male and two female. Three participants were 40-49, two were 30-39, one was 20-29, one 50-59 and one 60-69. One participant's highest level of education was a University degree with all other participants (7/8) possessing the highest level of education listed - a postgraduate degree.

Comments on structure

In the first round, three out of four participants explained that they felt the questionnaire was too long but those involved in round two, following alterations, found it to be of suitable length.

In round two, participants commented that overall flow of the questionnaire was adequate but two participants felt that answer options were too close together which resulted in confusion as to which answer coincided with which arrow directing you to the appropriate follow-up section.

One participant highlighted the need for consistency in the scales that were presented and commented that all scale options should be presented in the same manner throughout the questionnaire (e.g. all high to low or all poor to good etc.)

In round two of the interviews one participant gave excellent advice concerning the structure of the open text questions. Some questions provided space for open text answers via a series of underlined rows. One participant explained that an open box, without lines, would accommodate inclusion of more text and not constrain any style of handwriting.

Comments on subject and content of questions

There were some aspects of the questionnaire that prompted differing opinions. In response to a question which focused on the reasons behind why patients may call an incident helpline, some participants felt that an open text response gave the participant freedom in their answer and felt that pre-determined response options may put ideas into the respondent's head creating directed answers.

8. Why did you attempt to contact the helpline?
(Please tick all that apply)

I was anxious ☐

I wanted more information ☐

I wanted to complain about the incident ☐

I wanted to complain about the content of the letter ☐

I wanted to be sure that I definitely had had contact with this practice ☐

I wanted to know more about Hepatitis B, Hepatitis C and/or HIV ☐

I wanted to know about Hepatitis B, Hepatitis C and/or HIV testing ☐

I can't remember ☐

Other ☐ Please state……

'Reason for calling helpline' question (PINE Questionnaire V1.0)

An open text response was therefore used in the second round of interviews but was found to discourage detailed answers.

6. Why did you attempt to contact the helpline?

……

……

……

'Reason for calling helpline' question (PINE Questionnaire V2.0)

In the end a balance was struck by keeping the open text response but altering the wording of the question to encourage the provision of a more detailed answer.

8. What information did you want from the helpline staff?
(Please write your answer in the box below)

'Reason for calling helpline' question (PINE Questionnaire V3.0)

Participants questioned the inclusion of a 'general comments' question as they felt it was not needed and would not yield useful results. One participant commented that some patients may write questions in such a box, forgetting that the questionnaire was anonymous and expect a response from the board/trust.

One participant reported that they felt asking someone why they did not get tested may not yield a response, as it was perhaps a more sensitive question.

Comments on missing questions

One participant made it clear that two extra questions needed to be added to the questionnaire. Firstly, a question regarding how the patient first heard about the incident, as it cannot be assumed that it was via the letter from the health board/trust. This answer could then be compared with levels of anxiety and other factors.

Secondly the question asking about whether patients were tested needed to be extended to ascertain for which viruses they had been tested. Some incidents encourage patients to be tested for all BBVs but patients may not choose to be tested for all three.

Comments on the 'symptoms of anxiety' question

In the first round of interviews the 'Impact of Events Scale' (Horowitz et al 1979; Weiss 2007; Sundin and Horowitz 2002) was used to assess levels of anxiety following notification and how they affected daily functioning. Most participants had to re-read the question's introduction a couple of times as they found the language used confusing. Multiple respondents found the tool's questions to be repetitive and in a strange order with similar ideas not being presented together. Participants felt that patients may become frustrated or lose interest in completing the instrument. One participant felt that perhaps some of the tool's questions were quite vague and that a number of patients may have reservations about, or be uncomfortable with, expressing the feelings included in them.

In round two, hardly any difficulty was experienced by participants in interpreting and completing the 'assessment of anxiety question' which was now designed around the 'Hospital Anxiety and Depression' scale (Zigmond and Snaith 1983). One participant did feel, however, that the question should be moved to an earlier point in the questionnaire where the other, incident related, anxiety questions featured. They also felt that the sub questions (a-e) should be arranged to be read from left to right as this reflected a more natural reading style.

Comments on the 'opinions regarding risk and notification' question

This question undoubtedly caused the most issues, with all participants struggling to make sense of its structure and language both in the first and second rounds of interviewing. Many participants had to re-read the question multiple times.

The design used in the first round of interviews resembled several rows of statements with tick boxes. Each row featured a description of the risk and a question as to whether that risk would merit patient notification. Risks were presented as a range of figures (eg. 1 in 10,000 – 1 in 100,000) alongside a 'Calman's' description of the risk (eg. the same as the risk of dying within 1 year in an accident at work) (1996). A final option of 'patients should never be told' was provided.

It was hoped that the design would encourage the patient to tick 'yes' to all the risks they felt merited notification and 'no' to all the ones where they felt it was not required. In doing so, an answer would be provided for every row.

Participants felt that a 'don't know' option was needed and many did not grasp that ticking all of the risk options would be equivalent to selecting an option of 'patients must always be told'.

One respondent explained that the 'Calman' (1996) descriptors did not clarify the nature of the risks but rather served as a distraction, making the participant think about cigarette smoking or having an accident at work. They also found the numerical representation of the risks confusing and commented that they would prefer use of descriptive words such as high, medium and low.

Some respondents questioned the validity of asking patients, who had already been informed and involved in an incident, about triggers for notification. They explained that such patients may be too close to the situation to make an impartial decision.

18. Please tell us when you think patients should be told about these types of incidents by answering all of the following yes/no questions.

Patients should be notified when the chances of getting an infection (such as Hepatitis B, Hepatitis C and/or HIV) as a result of any incident are…

a. between 1 in 100 and 1 in 1000 (the same as the risk of dying within 1 year from smoking 10 cigarettes a day)

Yes ☐ No ☐

b. between 1 in 1000 and 1 in 10,000 (the same as the risk of dying within 1 year in a road accident)

Yes ☐ No ☐

c. between 1 in 10,000 and 1 in 100,000 (the same as the risk of dying within 1 year in an accident at work)

Yes ☐ No ☐

d.between 1 in 100,000 and 1 in 1 million (the same as the risk of dying within 1 year in a train accident)

Yes ☐ No ☐

e. less than 1 in 1 million (the same as the risk of dying within 1 year from being struck by lightning)

Yes ☐ No ☐

f. Patients should never be told

Yes ☐ No ☐

'Risk and notification' question (PINE questionnaire V1.0)

Following alteration of this question, second round participants still raised issues. They explained that the question was visually overwhelming and its structure complicated.

The design of the question had been changed to include a column structure with only one answer now being required. Respondents explained, however, that the many tick boxes (one for each row) strongly suggested that multiple answers were to be provided.

17. When do you think patients should be told about incidents involving infection control errors/infected health care workers?

(please circle one answer)

a. Patients should never be told → Please skip to question 19

b. Patients should always be told → Please skip to question 19

c. Patients don't always need to be told, it depends on the level of risk involved

18. Please select only one of the following rows for your answer.

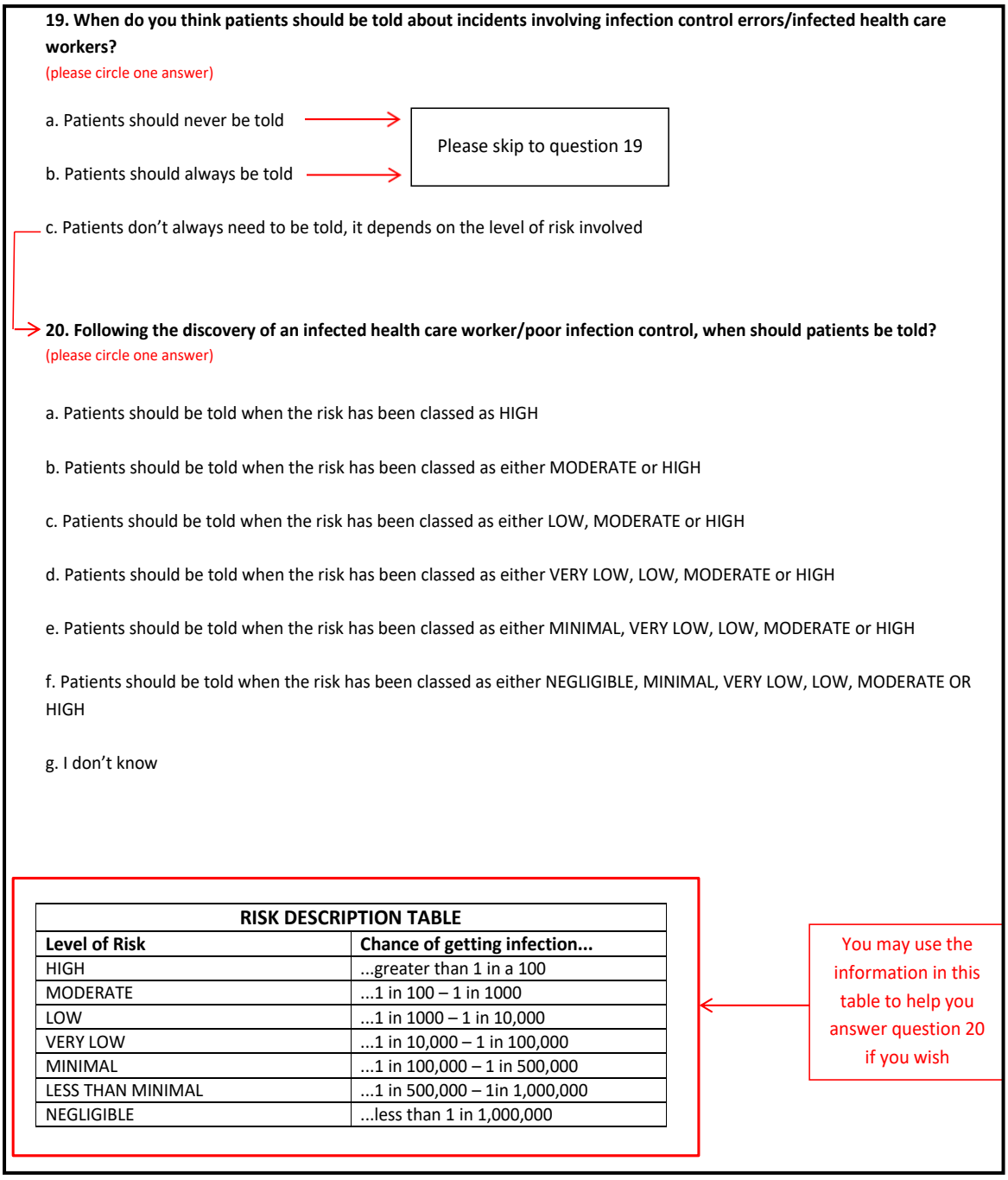
Following the discovery of an infected health care worker/poor infection control, when should patients be told?

(please tick only one row for your answer)

	LOW RISK → HIGH RISK											
A. When the risk is classed as...											**HIGH** (Higher than a 1 in 100 chance of infection)	☐
B. When the risk is classed as either...									**MODERATE** (a 1 in 100 chance of infection)	**OR**	**HIGH** (Higher than a 1 in 100 chance of infection)	☐
C. When the risk is classed as either...					**LOW** (a 1 in 1000 chance of infection)	**OR**	**MODERATE** (a 1 in 100 chance of infection)	**OR**	**HIGH** (Higher than a 1 in 100 chance of infection)	☐		
D. When the risk is classed as either...			**VERY LOW** (a 1 in 10,000 chance of infection)	**OR**	**LOW** (a 1 in 1000 chance of infection)	**OR**	**MODERATE** (a 1 in 100 chance of infection)	**OR**	**HIGH** (Higher than a 1 in 100 chance of infection)	☐		
E. When the risk is classed as either...		**MINIMAL** (a 1 in 100,000 chance of infection)	**OR**	**VERY LOW** (a 1 in 10,000 chance of infection)	**OR**	**LOW** (a 1 in 1000 chance of infection)	**OR**	**MODERATE** (a 1 in 100 chance of infection)	**OR**	**HIGH** (Higher than a 1 in 100 chance of infection)	☐	
F. When the risk is classed as either...	**LESS THAN MINIMAL** (a 1 in 500,000 chance of infection)	**OR**	**MINIMAL** (a 1 in 100,000 chance of infection)	**OR**	**VERY LOW** (a 1 in 10,000 chance of infection)	**OR**	**LOW** (a 1 in 1000 chance of infection)	**OR**	**MODERATE** (a 1 in 100 chance of infection)	**OR**	**HIGH** (Higher than a 1 in 100 chance of infection)	☐

'Risk and notification' question (PINE questionnaire V2.0)

The final draft of this question can be seen to incorporate the positively received elements of the two previous drafts and eliminates features that received negative feedback. Calman's risk descriptors (1996) have been removed and detailed information regarding risk quantification is available but has been separated from the responses. All risks are now described in words HIGH, LOW etc. and patients have to select only one option. Options have also been stripped of any visual complications.



19. When do you think patients should be told about incidents involving infection control errors/infected health care workers?

(please circle one answer)

a. Patients should never be told → Please skip to question 19

b. Patients should always be told → Please skip to question 19

c. Patients don't always need to be told, it depends on the level of risk involved

20. Following the discovery of an infected health care worker/poor infection control, when should patients be told?

(please circle one answer)

a. Patients should be told when the risk has been classed as HIGH

b. Patients should be told when the risk has been classed as either MODERATE or HIGH

c. Patients should be told when the risk has been classed as either LOW, MODERATE or HIGH

d. Patients should be told when the risk has been classed as either VERY LOW, LOW, MODERATE or HIGH

e. Patients should be told when the risk has been classed as either MINIMAL, VERY LOW, LOW, MODERATE or HIGH

f. Patients should be told when the risk has been classed as either NEGLIGIBLE, MINIMAL, VERY LOW, LOW, MODERATE OR HIGH

g. I don't know

RISK DESCRIPTION TABLE	
Level of Risk	**Chance of getting infection...**
HIGH	...greater than 1 in a 100
MODERATE	...1 in 100 – 1 in 1000
LOW	...1 in 1000 – 1 in 10,000
VERY LOW	...1 in 10,000 – 1 in 100,000
MINIMAL	...1 in 100,000 – 1 in 500,000
LESS THAN MINIMAL	...1 in 500,000 – 1in 1,000,000
NEGLIGIBLE	...less than 1 in 1,000,000

You may use the information in this table to help you answer question 20 if you wish

'Risk and notification' question (PINE questionnaire V3.0)

Comments on terminology

Following both rounds of interviews, multiple participants commented that, generally, they found the language appropriate for a lay audience. Small issues surrounding terminology were occasionally raised, all of which were easily addressed.

Participants had suggestions for alternative terms that were not critical to their understanding of the questionnaire but rather, represented a preference in language. For example when asked 'how do you feel about the incident now?', participants preferred the term 'today' in place of the word 'now'. Use of the word nervous instead of anxious, was also preferred when considering feelings towards dental treatment.

One participant highlighted that one could not ask someone to rank something on a scale of 1-5 if the answers did not represent a scale with continuous increasing or decreasing increments. An example of such a scale would be one in which there is was a middle option of 'don't know/can't remember'; this scale cannot be considered a ranking.

Multiple participants wanted to make sure that the appropriate, ethically responsible, terminology had been used in the question concerning gender identity.

Discussion

This study is the first to describe the development of a questionnaire which assesses anxiety following large-scale notification. The questionnaire's design is inspired by experts in the field, questionnaire design literature, similar studies in the field and eight 'think aloud' interview respondents (Tsang et al 2017; Rattray and Jones 2007; Bradburn et al 2004; Boynton and Greenhalgh 2004); unpublished report 2007; Pashley et al 1991; Blatchford et al 2000; Monteith et al 1995).

Main findings

Both phases of this study revealed a plethora of issues with a questionnaire that was initially but incorrectly deemed to be highly appropriate following creation of the first draft which demonstrates the utility of the 'Think Aloud' process.

The technique of thinking aloud was difficult for participants to master. Even in this group of highly educated individuals, many participants struggled to make the distinction between discussing the content of their answer and discussing issues of question interpretation. The warm-up questionnaire gave the participant a much-needed opportunity to practise the skill but often the most effective means of explanation involved the researcher demonstrating the skill

themselves. For future studies this author would recommend some form of demonstration of 'thinking aloud' by the researcher with an unrelated sample questionnaire.

Strengths and weaknesses

The 'think aloud' process was deemed to be a very useful exercise resulting in a high-quality final questionnaire draft. In contrast to piloting, where written responses are interpreted, interviews allow for an in-depth discussion. This is especially important where sensitive subjects need to be explored and complex concepts, such as risk perception, are to be assessed. Assessment of written responses alone, in a piloting phase, would not have facilitated such detailed and enlightening conversation. Those who design questionnaires are often blind to their faults and having multiple, lengthy conversations with respondents was very productive.

Further strengths of this study include the decision to execute two rounds of interviews meaning that two drafts of the questionnaire were assessed. This author would highly recommend multiple rounds of interviews when refining the design of a questionnaire through 'think aloud' interviewing.

A wide age range of participants were involved. Of nine age categories, ranging from 16-19 to 90+, five were represented. On reflection, however, participation of those with an age below 19 or higher than 69, would have been unlikely, as participants were selected from a working environment.

A convenience sample from within Glasgow Dental Hospital saved time, facilitated a smooth ethical approval process and allowed multiple rounds of interviews with multiple alterations of the questionnaire (Willis 2005[f]).

This author feels that, although it cannot replace a piloting process, the 'Think Aloud' interview approach is an under used technique that can highly benefit the development and design of questionnaires. It is a process which is especially beneficial when an entirely new questionnaire is being created and/or in circumstances where the chief investigator is new to the process of survey design.

The 'Think Aloud' interview process involves a great deal of time as interviews can last anywhere from 15 minutes to two hours depending on the length of the questionnaire (Willis 2005[g]). If you choose to transcribe all interviews verbatim this also increases the time commitment considerably (Willis 2005[b]). This author would advise that researchers simply take notes on a copy of the questionnaire during the interview as an alternative to word-for-word transcription.

There can be issues with participants straying from the subject matter (Willis 2005[d]) or withholding negative comments as they wish to avoid offending the

researcher who they will presume designed the questionnaire. This author would advise that the interview is led by someone who did not design the questionnaire and that this is stated upon its commencement. A limitation specific to this study included the narrow range of educational backgrounds, with all but one out of eight participants having postgraduate degrees. Willis' 2005 cognitive interviewing textbook does however emphasise that this is an issue of many 'Think Aloud' studies.

In comparison to piloting your questionnaire on a large, representative sample, there are a number of results that a 'think aloud' interview process cannot produce e.g. data to facilitate sample size calculations. Piloting is a valuable and necessary process for which the 'think aloud' interviewing process does not negate the need.

Appendix 23. Psychological impact of notification exercises (PINE) questionnaire study proposal

Introduction

Three publications provided data on the psychological impact of dental, large-scale notification. Two presented limited information on comments given by notified patients who called a designated, incident helpline. Both were connected to an HIV-infected dental HCW and took place in the 1990s (Pashley et al 1991; Monteith et al 1995). The third study possessed significantly more detail and was associated with an HBV-infected dentist in Glasgow (Blatchford et al 2000).

All three studies possessed limitations in their approach and findings. The first study was associated with a US dental student who was diagnosed with HIV in 1990 (Pashley et al 1991). The incident resulted in the college receiving calls from all 153 patients who were notified as part of the associated PNE (Pashley et al 1991).

Those who answered calls attempted to capture information about the caller using a pre-defined checklist (Pashley et al 1991). Aspects to be recorded on the checklist included: how the caller had heard about the incident, the caller's demeanour and their profile eg. were they a patient, reporter, dental professional? (Pashley et al 1991). A number of issues with the content and structure of the checklist can be identified. When considering the patient's demeanour, the check list prompts the user to tick all that apply from a list of options: calm, anxious, angry, hysterical and threatening (Pashley et al 1991). These options are not only limiting but do not allow assessment of strength of emotion e.g. a little anxious to very anxious.

The idea of ticking a topic if it was raised is flawed as an assumption is made that if a matter is not raised by the caller, they have no opinion on it (Pashley et al 1991). Another limitation was the concept that the demeanour of the patient was interpreted by the person who took the call and not reported by the patient themselves (Pashley et al 1991). This obviously creates room for misinterpretation and is made worse by the fact that the caller is not face-to-face with the data gatherer, which would allow a visual assessment of emotion (Pashley et al 1991).

The team reported that "fourteen percent of callers were judged to be angry at the beginning of the call but seemed to become more calm as they were told of the testing plan" (Pashley et al 1991). This implies that those gathering data could record changes in callers' emotions which is not evident on the checklist (Pashley et al 1991). In conclusion it is clear that the results presented (58% calm, 28% anxious and 14% angry) may not be reliable (Pashley et al 1991).

A very short article describes the second study which was conducted following the death of a London dentist with AIDS (Monteith et al 1995). This study similarly gathered data from patients who called the incident helpline. Of 130 callers, 74% reported feeling anxious when they received the notification letter (Monteith et al 1995). Again, no indication is given of the degree of anxiety experienced. Ninety-six per cent thought that contact by letter was the best method of notification and "a similar proportion" felt that they had a right to be told (Monteith et al 1995). This study may be subject to non-response bias as data were gathered on those who called the helpline, not all involved in notification. Therefore those who did not call were automatically excluded from the study (Monteith et al 1995).

In 2000, Blatchford and his team sent questionnaires to those who had been notified of treatment by an HBV-infected, UK dentist. 528 questionnaires were sent out with 291 returned, a 55% response rate (Blatchford et al 2000). The structure of the questionnaire mainly focused on asking respondents how they felt following each stage of the notification process: after receiving the letter, contacting the helpline and getting HBV test results (Blatchford et al 2000). The scale for each of these questions ranged from 'Completely reassured' to 'Very Anxious' with a 'Can't remember option' (Blatchford et al 2000). This scale is unconventional with options that are not mutually exclusive as after reading the letter you may have been 'Slightly reassured' by its content but also still 'Very anxious' (Blatchford et al 2000).

The questionnaire's content was good as it included an assessment of whether notification was effective, whether enough information was provided and whether communications successfully alleviated anxiety (Blatchford et al 2000). A similar, newer study could explore further subjects such as effect of anxiety on daily activities and effect of notification on desire to seek out future dental treatment. Blatchford et al's questionnaire does ask patients to provide an answer to whether patients should be notified following discovery of an infected HCW but does not provide a context of risk level (2000).

An additional study was identified midway through the questionnaire design process. A British public health team distributed questionnaires to those attending for BBV testing following the practice of dentistry by an unregistered individual where infection control quality could not be verified (unpublished report 2007). 165 responses were received and results indicated high levels of anxiety with 45% indicating that they felt they might be infected before receiving test results (unpublished report 2007). The researchers went on to state that 17 individuals of the 45% felt that it was 'likely' they were infected (unpublished report 2007). Over three quarters of respondents reported experiencing somatic symptoms such as headaches or shaking (unpublished report 2007). Bias may exist in this case as those who took part could be

considered different, in certain respects, to the notified patients as they were 1) attending for testing and 2) volunteering to take part.

Rationale for study

Blatchford et al's questionnaire was very detailed and represented a huge step forward in the evaluation of distress caused to notified dental patients (2000). Further anxiety elements, however, need to be explored along with a more up-to-date representation of public opinion. Responses following an infection control incident rather than an infected HCW should be assessed and more detailed questions, relating to whether patients feel notification should be connected to the level of risk posed by the incident, should be included.

Aims

The purpose of this cross-sectional questionnaire study was to assess the significance and extent of the psychological impact of being notified as part of a PNE.

Methods

The proposal outlined below represents a series of recommendations. Many study design aspects will depend on the circumstances under which the research team wish to execute the research.

Questionnaire design

The questionnaire pack would include a cover letter, a participant information sheet, the questionnaire itself and a free post envelope.

The questionnaire was designed in line with feedback received from participants of the 'think aloud' interview study (Appendix 22), guidance from Dr Alastair Ross (AR), a behavioural sciences lecturer based at the University of Glasgow and the aforementioned studies conducted by Blatchford et al (2000) and the UK IMT in 2007 (unpublished report). D. Dillman's 2007 book; 'Mail and Internet Surveys – The Tailored Design Method', also proved to be highly useful.

The primary outcome measure would be percentages of respondents reporting different levels of psychological distress following involvement in a dental PNE.

Wherever possible, validated tools and question styles were used within the questionnaire. It is suggested that The Hospital Anxiety and Depression Scale[17]

[17] Please note that in reference to the Hospital Anxiety and Depression Scale "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

be used to gauge levels of distress caused to patients following notification (Zigmond and Snaith 1983). When asking about anxiety specifically related to current or future dental treatment, the Modified Dental Anxiety Scale could be used (Humphris et al 1995) and when inquiring about frequency of dental attendance the question structure from the latest Adult Dental Health Survey is useful (The Health and Social Care Information Centre 2009). In designing the question which asked about when patients feel they should be notified, Calman's risk ratings (1996) were used to form the basis of response options and when asking about gender, the question was modelled on the structure advised in the 'Do Ask Do Tell' guide produced by The Stonewall Organisation (2016).

Sampling

Distribution of the questionnaire would follow a UK based incident related to either the discovery of a BBV infected dental HCW and/or inadequate dental cross infection control.

The study would commence as soon as confirmation had been received from the involved health board/trust that all anticipated testing was complete, so as not to interfere with the main PNE process. It is advised that the study should not proceed if the questionnaire is going to be received more than a year after the patient was originally notified of the incident. In Blatchford et al's study, questionnaires were received seven months after the incident and response rate was still adequate (55%) (2000).

The associated PNE would need to involve the intention to notify at least 500 patients so that the resulting sample size, selected from this pool of notified patients, would be large enough to create sufficient statistical power in relation to the primary outcome of this study.

Potential participants would come from the health board/trust's list of exposed patients who had been notified as part of a recent dental PNE. This list would be screened for eligibility, a random sample would be drawn and letters would be sent. All of this would be done by health board/trust staff.

The population would be defined as all patients deemed to be put 'at risk' by the incident, who are over 16 and had not been given a new BBV diagnosis as part of the PNE.

To calculate the appropriate sample size for this study several different factors must be considered:

- The population size (this will not be known until the incident has occurred and its corresponding exercise completed)
- The expected response rate

- The amount of response data that will be manageable to input and analyse
- The cost of printing and postage

Sample size would be calculated more accurately, once the population size was known, but as a rough guide please see the table below (Dillman 2007).

The figures outlined assume the highest level of variance (50/50 split) for each binomial question between the two groups of responders (those with high anxiety/desire to seek testing versus those with low anxiety/did not desire testing). This is based on four previous UK PNEs where the mean percentage of uptake of testing was 50% with a range of 33-73% (Close et al 2013; Mason et al 2008; Conrad et al 2011; Roy et al 2005).

Example sample size calculations for PINE study (Dillman 2007)

Population Size	Sample required	Sample required factoring in a 40% response rate
600	**234**	**585**
800	**260**	**650**
1000	**278**	**695**
2000	**322**	**805**
4000	**351**	**878**
6000	**361**	**903**
8000	**367**	**918**
10,000	**370**	**925**
95% confidence level, sampling error of +/- 5% and 50/50 split in responses		

A response rate of 40% is estimated based on Blatchford et al's response rate of 55% (2000). A predicted response rate 15% lower than Blatchford et al's was chosen because their questionnaire (2000) was shorter, less complex and conducted over 20 years ago when postal response rates were higher (Dillman 2007).

Ethical considerations

As this questionnaire involves participation of NHS patients, ethical approval should be sought from the NHS Research Ethics Committee. Local R&D ethical approval should be sought from the Scottish health board or English trust managing the incident.

Patients would be made aware that participation was voluntary and that choosing to participate would not affect their standard care in any way. Patients would be informed that once their questionnaires had been returned they would not be able to request the removal or alteration of any responses as they would be anonymous and could not be linked to individuals.

Data analysis

Responses to the proposed questionnaire would be categorical, Likert or open text. Data would be double entered into a statistical package using anonymised identifiers assigned to each questionnaire and featured on the hard copies of the questionnaires received. Quality assurance would be achieved through the use of range checks, histograms and frequency tabulations.

Descriptive statistics would be presented as means (standard deviations), medians (Q1, Q3), or percentages, with 95% confidence intervals, as appropriate for the type of data. Categorical questionnaire responses would be cross-tabulated to explore associations between two variables and chi-squared tests or Fisher's exact tests would be used to test hypotheses. To test differences between groups when the outcome variable is ordinal (eg from a Likert scale), non-parametric tests would be used (eg Mann-Whitney U test or Kruskal-Wallis test). All measures of effect would be accompanied by 95% confidence intervals.

Appendix 24: Psychological Impact of Notification Exercises (PINE) Study Questionnaire

PINE Study - Questionnaire

PLEASE READ BEFORE STARTING QUESTIONNAIRE:

CONSENT: By completing and returning this questionnaire you consent to the following.
Please tick the boxes next to the statements below if you agree to them:

- Use of your anonymous responses in a research study ☐
- Publication of your anonymous responses in scientific journal articles ☐
- Publication of your anonymous responses in a University of Glasgow thesis ☐
- Presentation of your anonymous responses at scientific conferences ☐
- Presentation of your anonymous reponses in the form of a direct quotation ☐
- I understand that once I have posted my questionnaire I will be unable to request the removal of my responses/data from the study as all responses are anonymous and cannot be traced or linked to an individual. ☐

START:

1. Did you receive a letter from us telling you about poor infection control practices at ..... dental practice/that a dentist you received treatment from has been diagnosed with .....?
(Please circle one answer)

a. Yes

b. No → please do not complete any more of this questionnaire. Please contact ..... Health Board on .....

2. How did you <u>first</u> hear about the incident?
(Please circle one answer)

a. The letter that was sent to me by ..... health board/trust
b. A friend/family member told me about it
c. A member of staff at the dental practice in question told me about it
d. From the media (newspaper, news programme on television etc.)
e. Another way? If so, please specify .....

3. How worried did you feel immediately after learning about the incident?
(Please circle one answer)

1	2	3	4	5
Not at all worried	A little bit worried	Not sure/can't remember	Quite worried	Very worried

[18] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

4. If being told about this incident caused you <u>any</u> worry please answer this question.

Thinking back to when you first learnt about this incident.

How did you feel during the week that followed?
(please tick one box for each statement, a-g)

a. I felt tense or 'wound up'	
Most of the time	☐
A lot of the time	☐
From time to time, occasionally	☐
Not at all	☐

b. I would get a sort of frightened feeling, as if something awful was about to happen	
Very definitely and quite badly	☐
Yes, but not too badly	☐
A little, but it didn't worry me	☐
Not at all	☐

c. Worrying thoughts would go through my mind	
A great deal of the time	☐
A lot of the time	☐
From time to time, but not too often	☐
Only occasionally	☐

d. I could sit at ease and feel relaxed	
Definitely	☐
Usually	☐
Not often	☐
Not at all	☐

e. I would get a sort of frightened feeling like 'butterflies' in the stomach.	
Not at all	☐
Occasionally	☐
Quite often	☐
Very often	☐

f. I felt restless as if I had to be on the move	
Very much indeed	☐
Quite a lot	☐
Not very much	☐
Not at all	☐

g. I would get sudden feelings of panic	
Very often indeed	☐
Quite often	☐
Not very often	☐
Not at all	☐

5. How do you feel about the incident today?
(Please circle one answer)

1	2	3	4	5
Not at all worried	A little bit worried	Not sure/can't remember	Quite worried	Very worried

[19] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

6. If your answers to questions 2 and 3 are different (ie. your feelings have changed) is there a reason for this?
(Please write your answer in the box below)

7. Did you attempt to contact the helpline provided in the letter that told you about the incident?
(Please circle one answer)

a. Yes

b. No → please skip to question 10

8. What information did you want from the helpline staff?
(Please write your answer in the box below)

9. Thinking about your answer to question 6, how helpful were the helpline staff, in meeting your needs?
(Please circle one answer for each statement)

1	2	3	4	5
Not at all helpful	A little bit helpful	Not sure/can't remember	Quite helpful	Very helpful

10. If you did not contact the helpline, why not?
(Please write your answer in the box below)

[20] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

11. Did you get tested after being told about the incident?
(Please circle one answer)

a. Yes

b. No → please skip to question 13

12. Which virus(es) did you get tested for?
(Please tick all that apply)

Hepatitis B ☐

Hepatitis C ☐

HIV (Human Immunodeficiency Virus) ☐

I don't know/can't remember ☐

13. If you did not get tested, why not?
(Please write your answer in the box below)

14. On a scale of 1-5, how anxious about dental treatment were you, before being told about this incident?
(Please circle one answer)

1	2	3	4	5
Not anxious	Slightly anxious	Fairly anxious	Very anxious	Extremely anxious

15. On a scale of 1-5, how anxious about dental treatment are you now, after learning about this incident?
(Please circle one answer)

1	2	3	4	5
Not anxious	Slightly anxious	Fairly anxious	Very anxious	Extremely anxious

[21] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

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16. On average, how often did you attend the dentist before this incident?
(Please circle one answer)

1	2	3	4	5
I never attended	At least once every 2 years	At least once a year	At least every 6 months	At least every 3 months

17. Please look at your answer to question 13, how often do you/will you attend the dentist now, after learning about this incident?
(Please circle one answer)

1	2	3
Less Often	About the same	More Often

18.After being told about the incident did you consider avoiding treatment from any of the following?
(Please tick all that apply)

I would avoid the particular dentist involved ☐

I would avoid the dental practice involved ☐

I would avoid all dental practices/services ☐

I would avoid health care services in general (eg. Doctor, Hospital) ☐

[22] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

19. When do you think patients should be told about incidents involving infection control errors/infected health care workers?
(please circle one answer)

a. Patients should never be told → Please skip to question 19

b. Patients should always be told → Please skip to question 19

c. Patients don't always need to be told, it depends on the level of risk involved

20. Following the discovery of an infected health care worker/poor infection control, when should patients be told?
(please circle one answer)

a. Patients should be told when the risk has been classed as HIGH

b. Patients should be told when the risk has been classed as either MODERATE or HIGH

c. Patients should be told when the risk has been classed as either LOW, MODERATE or HIGH

d. Patients should be told when the risk has been classed as either VERY LOW, LOW, MODERATE or HIGH

e. Patients should be told when the risk has been classed as either MINIMAL, VERY LOW, LOW, MODERATE or HIGH

f. Patients should be told when the risk has been classed as either NEGLIGIBLE, MINIMAL, VERY LOW, LOW, MODERATE OR HIGH

RISK DESCRIPTION TABLE	
Level of Risk	**Chance of getting infection**
HIGH	higher than 1 in a 100
MODERATE	1 in 100 – 1 in 1000
LOW	1 in 1000 – 1 in 10,000
VERY LOW	1 in 10,000 – 1 in 100,000
MINIMAL	1 in 100,000 – 1 in 500,000
LESS THAN MINIMAL	1 in 500,000 – 1in 1,000,000
NEGLIGIBLE	less than 1 in 1,000,000

You may use the information in this table to help you answer question 20 if you wish

[23] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).

21. Please could you tell us the date you filled in this questionnaire _____

22. What age are you? _____

21. What is your gender?
(please circle one option)

a. Male
b. Female
c. Non-binary/third gender
d. Prefer to self describe _____
d. Prefer not say

Thank you so much for taking the time to complete this questionnaire, please post this back to us using the freepost envelope enclosed.

END

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[24] Please note that before using this questionnaire permissions must be sought in relation to question 4 which utilises part of the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983). "a license agreement must be completed beforehand and a user fee is required to all users (commercial, healthcare organizations and academic users)" (www.gl-assessment.co.uk).