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THE REGULATION OF ADVANCED NURSING PRACTICE

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AUTHORS DECLARATION

Printed name

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

Introduction

The typical picture that is conjured up when one thinks of a nurse is that of a matronly figure, in a uniform and cap, sitting at the patient's bedside administering care. Associated with this is the traditional view held by the public, in which nurses are beholden to doctors and dependent on them for instruction, and perform a generally subservient role. However, those who have had the misfortune to require treatment more recently will testify to a far different situation, in which nurses perform a more professional and clinically autonomous role, as well as having a caring and compassionate function. In fact, the picture that exists in most clinical environments is one in which nurses are recognised as knowledgeable and capable clinicians, and independent practitioners in their own right, rather than obedient medical handmaidens.

The delivery of modern healthcare has also changed beyond recognition. Indeed, rather than the traditional picture in which healthcare was provided in a hospital-centric monolithic system into which those needing specialist care were referred, the situation that now exists is one in which interventions once the domain of hospital practitioners are provided in a more diverse and liberated community-based system. Within this structure, the role of healthcare professionals has similarly been transformed, with the balance of 'power' having shifted away from doctors and towards non-medical clinicians. This has, in turn, resulted in non-medical practitioners, most notably nurses, having more authority, autonomy and responsibility for clinical decision-making, rendering them more equal in the clinical hierarchy and more evenly aligned as professionals.

Occurring over decades, the effect of this change has been insidious. However, its magnitude soon becomes evident when one considers that a significant proportion of traditional medical activities are now performed by non-doctors, with doctors focused on more specialised interventions. Indeed, in the majority of cases, these activities are now performed by nurses, who have expanded their practice in order to accommodate the additional responsibilities that these activities afford. This has resulted in the role of nurses changing, and, in some cases, to the creation of new clinical roles, with the result being that, in some

cases, nurses are considered as performing the role of medical substitute. Colloquially referred to as 'advanced nursing practice', and its agents as 'advanced nurses', this new breed of nurse has developed such that it constitutes a significant part of the modern workforce, and signifies the dawn of a new era for clinical nursing practice.

On the face of it, this new breed of nurse seems to have been well accepted, with challenges from cynics having been overcome, and critics having otherwise been silenced. However, this assumption may be erroneous, since the reality is that critics of 'advanced nursing practice' are still very much alive, and the jury is out regarding its public perception. The extent to which such change is supported by effective public consultation and informed professional agreement is also something of a moot point, with many patients unclear when it comes to the discipline of their treating clinician, and many medical professionals suspicious regarding the motives and competence of nursing colleagues.

Some patients are, of course, completely unconcerned regarding who treats them, as long as they have been suitably educated and are competent, irrespective of their discipline. They are, however, concerned about the ability of those who attend upon them, and assume a level of competence on the part of their clinicians each time they consent to treatment. Underpinning this is the expectation that healthcare practitioners will have undergone the requisite training commensurate with their roles and been assessed as competent, and the associated risks will have been managed.

On the face of it, this would appear to be a legitimate expectation. However, the reality is that unanswered questions remain surrounding the preparation of advanced nurses and, in particular, the standards surrounding their education and training. Many of these questions derive from the fact that educational programmes associated with advanced nursing practice are not standardised, and do not benefit from the quality assurance mechanisms that statutory regulation affords. This means that those educational institutions wishing to offer programmes leading to advanced nursing practice qualifications may do so, with few, if any, constraints placed upon them. In so doing, they are also able to select their own content and quality, and determine the preferred means by

which they recognise and accredit clinical competence. Given the variance that this inherently attracts, this has implications for the quality of care that patients can expect to receive, and, ultimately, their safety.

Accepting that safety is a priority in healthcare, and that high quality education plays a central role in ensuring this, the lack of standardisation is concerning. So, too, is the fact that patients seem to be largely unaware of the changes that have taken place, and the ways in which these may affect them. When considered alongside the climate of public expectation that exists, and the value that is currently placed on openness and transparency, this does not bode well for patients, who are unlikely to take kindly to being potentially misled regarding the education, preparation and, ultimately, the competence of those treating them. Further, in the event that patients suffer harm as a result of clinical error or mishap at the hands of an advanced nurse, that may ultimately become an allegation of clinical negligence, it stands to reason that they will be unwilling to accept excuses for related failures, and instead call these nurses to account.

With all indications pointing to the further devolution of clinical tasks, and the creation of more clinical roles, it seems fitting that a review of the nursing profession's regulatory processes should take place, in order to ensure their ability to respond to current and future challenges. In fact, given the criticisms that have beset the Nursing and Midwifery Council (NMC) in recent years, with reports citing serious weaknesses in its operational management and governance, significant failures in its performance of statutory duties, and difficulties in retaining stakeholder confidence, a review has never been timelier. When added to the fact that the current system is based on traditional nurses and traditional nursing care, with little, if any, provision made for those practising beyond conventional boundaries, failure to act is not an option.

Against this backdrop, this thesis will seek to explore the processes by which nurses are currently regulated, and the extent to which they suffice in relation to advanced nursing practice. Given that the purpose of regulation is to protect the public and ensure their safety and well-being, it will question the extent to which the current system satisfies this requirement, and consider whether an

alternative approach, such as that which is provided by another professional regulator, may be more appropriate. In so doing, it will acknowledge the current political imperative that militates against any new form of statutory regulation except in compelling cases, but will assert that, in the case of advanced nursing practice, the risks are such that a convincing case can be made.

With no 'ceiling' having been imposed on the scope of permissible nursing practice, and certification of death and termination of pregnancy the only legally prohibited restrictions, both of which are likely to be lifted in the years to come, it will be submitted that this unsatisfactory, and potentially indefensible, situation cannot be allowed to continue. Indeed, it will be averred that it is only a matter of time before the risks that are associated with advanced practice materialise, and a patient suffers harm at the hands of an 'advanced nurse'. Accepting this submission, it will be asserted that action is not only warranted, but is overdue, if the public is to be protected from those practitioners who are ill-prepared, and those who are unwilling to account for their practice.

Seeking to contextualise the significance of these issues, this thesis will focus on four new roles that now populate the clinical arena. In so doing, it will submit that a compelling case for the statutory regulation of advanced nursing practice can be made, and will suggest a number of options regarding how this regulatory solution can be achieved. Included among the options presented will be those relating to midwifery, recognising the challenges that midwives have successfully and consistently overcome en route to being recognised as established professionals, and those relating to medicine, on the basis that most, if not all, advanced nursing practice derives from medicine.

In addressing these issues and considering options for regulatory change, this thesis will also point to consequential problems that could potentially arise as a result of the failure to regulate advanced nursing practice. Central among these problems are those associated with the state's failure to 'protect' through legal means the advanced nursing practice title, meaning that any nurse able to demonstrate training and learning beyond initial registration could hold

themselves out as being 'advanced'. In practice, this could result in patients mistaking advanced nurses for doctors, and lead to the situation whereby they could believe that a doctor was treating them when they were, in fact, being treated by a nurse. This situation could also result in advanced nurses potentially being able to escape liability for their actions, rather than accepting responsibility for their actions, by reverting to others - most notably doctors - to 'cover' for them when things go wrong.

In concluding, this thesis will submit that a compelling case has been made for the statutory regulation of advanced nurses and advanced nursing practice, and assert that action is not only warranted but is overdue. It will also submit that an appropriate and proportionate regulatory solution for advanced nursing practice can be found in one of the options presented, and assert that this would provide the necessary regulatory safeguards. In so doing, it will acknowledge the current political imperative that militates against the statutory regulation of new clinical groups on the basis of cost and complexity, but will contend that statutory regulation presents the only acceptable and proportionate regulatory response for this group. It will further contend that issues surrounding cost should not be allowed to stand in the way of public protection, and submit that the need to ensure public protection should always prevail. Finally, it will be averred that, if left unchanged and unchallenged, failure to address the unacceptable situation that is currently in place will serve only to reduce public confidence in the regulatory process and the healthcare professions, jeopardise the integrity of the therapeutic relationship, and compromise patient safety and practitioner credibility.

1. Setting the scene: The regulation of healthcare

The delivery of healthcare in the UK is the envy of the world, with the National Health Service (NHS) viewed as the epitome of social conscience and the embodiment of clinical quality. Central to this is the quality of care that patients can expect to receive, and the level of confidence they have in healthcare practitioners, with professional regulation providing the assurance that those into whom they entrust their care are competent, capable and of good character. Underpinning this is the belief that regulation will protect patients from those practitioners who fail to meet the required standards, and confidence that practitioner competence will be assured through regulatory processes such as revalidation and remediation and, if necessary, removal from the Register when these measures fail.

1.1 Professional regulation

In this context, the term 'professional regulation' is used to describe the measures that are in place to ensure that healthcare professionals acquire and maintain clinical competence, and are fit to practise¹. Within the UK, this system is largely one of state-sanctioned self-regulation, with those professionals who wish to use 'protected' titles, such as 'Registered Nurse' or 'Registered Medical Practitioner', required to be registered with their respective regulatory bodies in order to do so. This means that it is an offence for those who are not registered practitioners to hold themselves out as such².

In order to become registered, healthcare professionals are required to meet the standards of education, conduct and practice that have been set by the relevant regulatory bodies. In order to remain registered, they are required, as a

¹ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(i). London: HMSO. 2001

² The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 s44(1)

minimum, to maintain those standards of conduct and competence that are associated with initial registration³, and to demonstrate ongoing fitness to practise⁴. The regulators, in turn, have a responsibility to police these standards, supported by state-supported disciplinary procedures, and to take legal action against those individuals who practise unlawfully, or who falsely represent themselves⁵.

For their part, the public are known to be reassured by the existence of regulation and the maintenance of professional Registers⁶. In fact, professional Registers are recognised as being the vehicles to which the public refer when seeking to validate practitioner credentials, identify any sanctions that have been imposed on practitioners' practice, and obtain information regarding their qualifications, speciality and training⁷. Interestingly, this reassurance does not extend to information whose quality has not been verified⁸, thus reinforcing the level of confidence the public has in statutory regulation.

At the moment, the system of professional regulation that exists in the UK comprises thirty-one health professions, consisting of approximately 1.4 million professionals, all of whom are regulated in law by nine regulatory bodies⁹. Although differences exist between the various regulatory bodies in terms of their size and governance, their structures and functions are broadly similar, in that they all aim to protect the public from unsafe practitioners or poor-quality care. To fulfil these functions, and ensure the requisite level of protection, all have a similar suite of duties they are required to discharge. Included among these duties is the responsibility to set standards for education and training,

³ Nursing and Midwifery Council. The PREP Handbook. London: NMC. 2011

⁴ Council for Healthcare Regulatory Excellence. An approach to assuring continuing fitness to practise based on right-touch regulation principles. London: CHRE. 2012

⁵ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

⁶ Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

⁷ Council for Healthcare Regulatory Excellence. Health professional regulators' registers: Maximising their contribution to public protection and patient safety. London: CHRE. 2010

⁸ Council for Healthcare Regulatory Excellence. Health professional regulators' registers: Maximising their contribution to public protection and patient safety. London: CHRE. 2010

⁹ Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

maintain a Register of those who are appropriately qualified to practise, set standards for good practice for registered practitioners, investigate and adjudicate fitness to practise cases and, where relevant, prosecute those practitioners who are found to have fallen short of these standards¹⁰.

As a consequence of the differences - however subtle - that exist between the various regulatory bodies, multiple legal frameworks have emerged, each of which has been amended by Parliament in a range of ways, and at different times, over the years. This has resulted in a complex legal landscape, leading to a number of idiosyncrasies and inconsistencies in the powers, duties and responsibilities of each of the regulators. This, in turn, has led to variation in how the various professions are regulated, and to a disparate array of Registers, lists and information being held by individual regulatory bodies. In some cases, this has also led to concern that the main purpose for this information being gathered is for the benefit and advancement of the professions, rather than enhanced public protection¹¹.

Acknowledging the difficulties that are posed by this complexity, most notably significant delays necessitated by the cumbersome and often onerous steps that require to be followed each time changes need to be made to rules or regulations, a tripartite review of the regulation of healthcare professionals led by the UK Law Commissions is currently underway¹². Aimed at establishing a single Act of Parliament that would encompass all those regulators affected by the current system, and intended to be simple, transparent, modern and consistent, it is envisaged that the proposed system of statutory regulation would replace all existing statutes and orders, and impose consistency across the regulators where this is necessary in the public interest. Other than this, the regulators would be given greater autonomy in the exercise of their statutory responsibilities, thus allowing them to adopt their own approach to regulation in light of their individual circumstances and resources. In practice, this

¹⁰ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

¹¹ Council for Healthcare Regulatory Excellence. Health professional regulators' registers: Maximising the contribution to public protection and patient safety. London: CHRE. 2010 ¹² Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

consistency, aligned with the appropriate level of discretion, would afford the public an equivalent level of protection from all healthcare professionals, irrespective of their clinical discipline, with similar standards and sanctions able to be applied by all the regulators.

1.1.1. Statutory regulation

Historically based on the medical profession, it was originally perceived that unqualified people would be unable to understand or evaluate clinical expertise, and that responsibility for determining clinical standards and monitoring the actions of practitioners should be left to the professions¹³. However, in recent years there has been a notable shift away from this emphasis on self-regulation, with market forces, increased consumerism and the introduction of a range of regulatory tools, such as clinical governance and service regulation, undermining its legitimacy^{14,15,16}. Changes in social and political attitudes following high-profile regulatory failures^{17,18,19} and a series of investigations into a number of individual practitioners^{20,21,22} have also challenged the public's faith in self-regulation, leading to a less deferential and more demanding attitude towards

¹³ Waring J, Dixon-Woods M, Yeung K. Modernising medical regulation: Where are we now? Journal of Health Organisation and Management 2010;24(6):540-555

¹⁴ Halligan A, Donaldson L. Implementing clinical governance: turning vision into reality. British Medical Journal 2001;322(7299) 1413-1417

¹⁵ Johnson J. Independence is key to better regulation. British Medical Journal 2006;333(7575):966-967

¹⁶ Irvine D (Sir). Professionalism and professional regulation. In Carter Y, Jackson N: Medical education and training: From theory to delivery. Oxford: Oxford University Press. 2008;1-17

¹⁷ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(i). London: HMSO. 2001

¹⁸ The Royal Liverpool Children's Inquiry Report (2000-01) No 0012-II. London: HMSO. 2001

¹⁹ Independent Inquiry relating to deaths and injuries on the children's ward at Grantham and Kesteven General Hospital (The Clothier Report). London: HMSO. 1994

²⁰ Independent Review Group on the Retention of Organs at Post-Mortem. Report on Stage 3 (The McLean Report). Edinburgh: Scottish Executive. 2003

²¹ The Shipman Inquiry Fifth Report: Safeguarding patients, lessons from the past - proposals for the future. Cm6394. London: HMSO. 2004

²² Ritchie QC. An Inquiry into quality and practice within the NHS arising From the actions of Rodney Ledward (2000), Report of the Clifford Ayling Inquiry (2004) Cm6298, Report of the Richard Neale Inquiry (2004) Cm 6315, and Kerr/Haslam Inquiry (2005) Cm6640

those in positions of clinical authority^{23,24}. This, in turn, has led to uncertainty and lack of confidence in the ability of the professions to self-regulate, and to calls for more transparency and accountability^{25,26,27}, thus paving the way for the state to take a more prominent role.

Seeking to restore the public's confidence in the professions, and instil a sense of pride among practitioners, the Government's response has been to introduce a range of mechanisms aimed at addressing the perceived lack of independence of the regulators from those whom they regulate. Originally contained within the White Paper 'Trust, Assurance and Safety'28, the aim was that these measures would increase individual and corporate accountability, and bring together the healthcare professions under one cohesive regulatory structure in the interests of patient safety. Included among these measures were the revalidation of practitioners, mechanisms to enable concerns to be tackled locally rather than resulting in immediate referrals to regulators, and a more standardised approach to dealing with concerns at a national level. included was a proposed method of 'distributed regulation' for new and emerging clinical roles²⁹, with the aim being that professionals would remain with their original regulatory body, while incorporating the practice associated with another profession. Collectively, it was intended that these measures would provide a structured approach to the way in which those performing new roles would be regulated, and provide a level of consistency across the regulators.

²³ Dyer C. Courts too deferential to doctors, say judge. British Medical Journal. 2001;322(7279):129

²⁴ Rosen R, Dewar S. On being a doctor: Redefining medical professionalism for better patient care. London: King's Fund. 2004

²⁵ Bartle I, Vass P. Self-regulation within the regulatory state: towards a new regulatory paradigm? Public Administration 2007;85(4):885-905

²⁶ Chantler C. The purpose and limits to professional self-regulation. The Journal of the American Medical Association 2009;302(18):2032-2033

²⁷ Shaw K, Cassel CK, Black C, Levinson W. Shared medical regulation in a time of increasing calls for accountability and transparency: Comparison of recertification in the United States, Canada and the United Kingdom. The Journal of the American Medical Association 2009;302(18):2008-2014

²⁸ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

²⁹ Department of Health. The regulation of non-medical healthcare professionals: a review by the Department of Health (The Foster Report). London: HMSO. 2006

Although mainly focused on improving the regulation of doctors, it was envisaged that the proposed reforms would resonate with the wider body of healthcare professionals, and enhance their overall accountability. However, despite receiving considerable support, only some of these proposals were able to be taken forward, with a change in Government in 2010 directing that any new policy initiatives should focus on reducing the costs of statutory regulation, rather than extending it³⁰. Accordingly, rather than progressing with plans to extend statutory regulation to those groups from whom the public had already been judged as requiring greater protection, these plans were put on hold, meaning that alternative means of providing protection have had to be found.

As things stand, the current direction of policy is enshrined in the Command Paper 'Enabling Excellence'31. This policy dictates that all of the healthcare regulators must reduce regulation where it is safe to do so, thus enabling them to free up resources so that they can be applied to areas of high risk and/or poor compliance. With the current approach to statutory regulation focused on embedding the principles of better regulation, as endorsed by Hampton³² and reinforced by the 'Better Regulation Taskforce', the emphasis is now on balancing the costs of regulation with the benefits it confers. Included within these principles is proportionality, consistent with the need to reduce the regulatory burden, intervene only where necessary and ensure that remedies are appropriate to the risks posed, and accountability, consistent with the need for regulators to justify decisions and be subject to public scrutiny³⁴. Also inherent in these principles is an acknowledgement that risks can never be completely eradicated, even when statutory regulation is in place, and acceptance of the fact that responsibility for managing and determining the severity of these risks should increasingly lie with those best placed to deal with them. In practice,

³⁰ Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

³¹ Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

³² Hampton, P. Reducing administrative burdens: effective inspection and enforcement. (The Hampton Review Final Report). Norwich: HMSO. 2005

³³ British Regulation Task Force. Regulation - Less is more. Reducing burdens, improving outcomes. London: Better Regulation Task Force. 2005

³⁴ Better Regulation Task Force. Better routes to redress. London: Better Regulation Task Force. 2004

this means that responsibility should fall to those working at a local level, rather than being dealt with by those operating at a more strategic level³⁵.

When applied to the healthcare context, this approach acknowledges that clinical practice is founded on an inexact science that is underpinned by risk and uncertainty^{36,37}, and accepts that mistakes can, and will, inevitably happen^{38,39}. Also recognised is the belief that those individuals who are most closely involved in the delivery of healthcare are best equipped to manage the risks posed, and acceptance of the fact that local evidence-based solutions can usually be found. With the policy imperative reinforcing this premise, and stipulating that a balance needs to be found between national regulation and local governance and scrutiny, this has paved the way for a more balanced approach to healthcare regulation in the form of 'right-touch' regulation.

1.1.2. 'Right touch' regulation

Encapsulating the notion that any system of regulation should be proportionate, accountable, consistent, transparent and targeted⁴⁰, the concept of 'right-touch' regulation is premised on the principle that only the minimum regulatory force that is required to achieve the desired result should be permitted. Applied literally, this approach seeks to ensure that an acceptable compromise is achieved between over-regulation, which is seen by many as interfering with personal conduct and individual freedom and as giving a false sense of security, and under-regulation, which is viewed by some as an abdication of public

³⁵ Better Regulation Commission. Risk, responsibility and regulation. Whose risk is it anyway? London: Better Regulation Commission. 2006

³⁶ Daniels S. The pragmatic management of error and the antecedents of disputes over the quality of medical care. In Dingwall R, Fenn P (Eds) Quality and regulation in healthcare: international experiences. London: Routledge. 1992

³⁷ Higgs J, Jones MA. Clinical decision making and multiple problem spaces. In Higgs J, Jones MA, Loftus S, Christensen N. Clinical reasoning in the health professions. 3rd Edition. London: Butterworth-Heinemann. 2008

³⁸ McCall Smith A, Merry A. Errors, medicine and the law. Cambridge: Cambridge University Press. 2001

 ³⁹ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010
 ⁴⁰ Better Regulation Commission. Risk, responsibility and regulation. Whose risk is it anyway?
 London: Better Regulation Commission. 2006

responsibility⁴¹. Closely aligned with Hampton's principles⁴² and the notion of shared responsibility⁴³, the basis of 'right-touch' regulation lies in a proper evaluation of risk, and achieving the correct balance between providing the necessary levels of protection while preserving reasonable levels of risk. Inherent in this approach is the recognition that risks should be quantified and prioritised, such that those associated with the highest cost, most serious consequences or the greatest public interest are addressed first, with every effort taken to minimise or remove any unintended or unwanted 'side-effects'.

Working on the basis that regulation exists to protect people rather than control how they live their lives, and that there is usually more than one way to solve a problem, the 'right-touch' approach acknowledges that statutory regulation does not always present the best solution, and the risks posed by individual failings can often be better dealt with by timely local action and effective leadership. Implicit in this analysis is recognition of the need for individuals, teams and employers to accept accountability for their actions, and for a wider outcomes-focused perspective to prevail. Also implicit is acknowledgement that patients and the public, as the intended beneficiaries of regulatory activity, will benefit from a more simple and insightful approach to regulation, and find this an easier and less confusing process through which to navigate. In practice, this means that a thorough risk-based assessment of problems should be undertaken at an early stage to ascertain the most appropriate level of intervention, and, therefore, the best regulatory solution. Under this model, statutory regulation would be reserved for those situations where new risks to patient safety present, and where risks to public protection have been created.

If one accepts this premise, this suggests that alternative forms of regulation, such as employer-led models, may afford the requisite degree of oversight in the majority of cases. This would signal a clear move away from state-enforced regulation, which is perceived by some as representing an over-reliance on the Government to manage all risks at the expense of eroding personal

⁴¹ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010

⁴² Hampton, P. Reducing administrative burdens: effective inspection and enforcement. (The Hampton Review Final Report). Norwich: HMSO. 2005

⁴³ British Regulation Task Force. Regulation - Less is more. Reducing burdens, improving outcomes. London: Better Regulation Task Force. 2005

responsibility, in favour of a more local and targeted response. Signifying an important change in emphasis, it is possible that this approach might garner support, particularly in the current economic climate, given its aim of imposing the least cost and complexity consistent with securing public safety and confidence. On the other hand, in the event that this approach is seen as providing a light and potentially disproportionately 'soft' approach to regulation, it is possible that it could be perceived as the state having abdicated its overriding duty to protect the public, in the interest of saving costs.

Significantly, the introduction of 'right-touch' regulation has had the most pronounced impact on those new groups seeking statutory regulation. This is particularly evident in the case of aspirant groups such as Practitioner Psychologists who had already satisfied the necessary formalities for statutory regulation, and awaited only final legislative approval for its implementation⁴⁴. Indeed, with 'Enabling Excellence' stipulating that no new groups will be statutorily regulated unless a compelling case can be made on the basis of a risk to public safety⁴⁵, plans for these groups have had to be put on hold, leaving these practitioners with a high hurdle to climb and little likelihood of success, other than in exceptional circumstances. As such, they are required to look to alternative methods of accreditation, such as Assured Voluntary Registers (AVRs), in order to provide the necessary safeguards, with the expectation being that these will be sufficient to manage the risks posed in the majority of cases⁴⁶.

Also affected by this revised approach to regulation, are those healthcare professionals who are engaged in new and emerging roles, such as Physician Assistants and Emergency Care Practitioners. Indeed, a number of these groups had also submitted applications for statutory regulation, and hoped they would be received favourably, with statutory regulation possibly being granted to them under the previous regimen. However, with *Enabling Excellence* stipulating that alternative regulatory systems, such as AVRs, must first be attempted, and their adequacy assessed before any alternative regimens will be considered, these

⁴⁴ Department of Health. Extending professional and occupational regulation: The report of the Working Group on extending professional regulation. Leeds: DH. 2009

⁴⁵ Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

⁴⁶ Health and Social Care Act 2012 c7 s228 and s229

groups have a high hurdle to climb. Indeed, in order for statutory regulation to be considered by policy-makers and warrant further consideration, these groups are required to present convincing risk-based evidence that the current regulatory solutions, including AVRs, do not suffice. Of particular significance to nurses, given that many have advanced their practice such that it now constitutes a new clinical role, this begs the question of whether the current regulatory framework that underpins the nursing profession is sufficient to manage the risks posed.

1.2. The regulation of nursing practice

The nursing profession is among the oldest established and longest regulated professions in the UK, having benefited from statutory professional self-regulation since 1919⁴⁷. Currently regulated by the Nursing and Midwifery Council (NMC)⁴⁸, it has undergone numerous reforms and restructuring over the years, most notably those resulting in the establishment of its predecessor body, the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC)^{49,50,51}. However, despite benefiting from a range of well-developed statutory processes, the nursing profession's ability to self-regulate effectively has been consistently called into question, leading some commentators^{52,53} to express doubt regarding its ability to fulfil its statutory obligations and manage its regulatory affairs. Interestingly, this doubt is particularly evident in the NMC's perceived inability to protect the public from unsafe practice, and its inability to keep up to date with, and respond effectively to, changes in the healthcare environment. Included within these changes are developments in professional education, the emergence of new clinical roles, and changed public

⁴⁷ Davies C, Beach A. Interpreting professional self-regulation. A history of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting. London: Routledge. 2000

⁴⁸ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

⁴⁹ Nurses, Midwives and Health Visitors Act 1979

⁵⁰ Nurses, Midwives and Health Visitors Act 1992

⁵¹ Nurses, Midwives and Health Visitors Act 1997

⁵² House of Commons Health Committee. Annual accountability hearing with the Nursing and Midwifery Council. Seventh Report of Session 2010-2012. HC 1428. London: HMSO. 2011

⁵³ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

expectations regarding the role and accountability of healthcare professionals; all of which have created perennial problems.

With a remit to define and maintain standards of education and training, and a mandate to monitor standards of conduct and performance, the paramount duty of the nursing regulator is, and has always been, to protect the public through ensuring the fitness to practise of its practitioners⁵⁴. Implicit in this duty is the expectation that individuals will be held accountable for their actions, and that fair, proportionate and timely action will be taken in the event of concerns being raised. In practice, this places a duty on the NMC to establish the bar for fitness to practise, enforce professional standards, and identify and respond timeously to any related issues. This, in turn, is intended to ensure and enhance the integrity and public perception of the profession, and maintain stakeholder confidence. However, with the NMC plagued by criticism surrounding its governance and culture, and concerns regarding the integrity of those in positions of trust, the current situation is one in which confidence in its ability is low, and concern is high.

As things stand, questions abound regarding the status of the NMC and its credibility as an effective regulator. As such, its future is in doubt. Underpinning this uncertainty are successive high-level reports ^{55,56,57,58} which reinforce weaknesses in its governance, leadership and operational management, and raise doubts regarding its ability to maintain standards and secure registrant and public confidence. Sitting alongside these concerns are unresolved difficulties in dealing with fitness to practise cases and poor financial management and stewardship, both of which were inherited from the UKCC as a

⁵⁴ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

⁵⁵ Council for Healthcare Regulatory Excellence. Special report to the Minister of State for Health Services on the Nursing and Midwifery Council. London: CHRE. 2008

⁵⁶ Council for Healthcare Regulatory Excellence. Fitness to practise audit report. Audit of health professional regulatory bodies' initial decisions. London: CHRE. 2011

⁵⁷ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

⁵⁸ Council for Healthcare Regulatory Excellence. Audit of the Nursing and Midwifery Council's initial stages fitness to practise process. London: CHRE. 2012

consequence of poor decision-making, and have resulted in key stakeholders questioning its competence⁵⁹.

At the same time, lack of clarity surrounding the NMC's statutory purpose and lack of a consistent strategic direction have led to confusion regarding the parameters of its role, and the scope of its regulatory 'reach'. Notable in this confusion are issues surrounding the 'protection' of title and function, in particular the extent to which those individuals acting in assistant roles, such as Health Care Assistants (HCAs), should be regulated by the NMC, and disagreement surrounding what the extent of their practice should be^{60,61,62,63}. Inherent in this uncertainty is the question of whether traditional nursing tasks should be delegated to unqualified people to perform, or whether these activities should only be carried out by those nurses who are registered and, therefore, regulated. Underpinning this discord is the inference that those individuals who are regulated are more accountable, and, as such, will practice to a higher standard^{64,65}. Also inherent in this uncertainty is the associated question of whether the assumption of advanced practice by nurses is to blame for the current nursing 'crisis', and whether nursing has lost its way by allegedly abdicating its 'caring' function in favour of a more technical and diagnostic function^{66,67,68,69}.

⁵⁹ Royal College of Nursing. RCN members 'losing confidence' in NMC. 2 July 2012 http://www.rcn.org.uk/newsevents/news/article/uk/rcn_members_losing_confidence_in_nmc (Last accessed 18.10.12)

⁶⁰ Storey L. Regulation of healthcare assistants: an ongoing debate. British Journal of Healthcare Assistants 2007;1(1):15-17

⁶¹ Snow T. The case for healthcare assistant regulation becomes overpowering. Nursing Standard 2011;25(49):12-13

⁶² House of Commons Health Committee. Education, training and workforce planning. First report of session 2012-2013 Volume 1. London: HMSO. 2012

⁶³ Lintern S. Lack of HCA regulation 'unacceptable' says Willis. Nursing Times 2012;108(39):3

⁶⁴ Frankel MS. Professional codes: Why, how, and with what impact? Journal of Business Ethics 1989;8(2-3):109-115

⁶⁵ Savage J, Moore L. Interpreting accountability: an ethnographic study of practice nurses, accountability and multidisciplinary team decision making in the context of clinical governance. RCN research reports. London: Royal College of Nursing 2004

⁶⁶ Jecker N, Self D. Separating care and cure: An analysis of historical and contemporary images of nursing and medicine. Journal of Medicine and Philosophy 1991;16(3):285-306

⁶⁷ Baumann A, Deber R, Silverman B, Mallette C. Who cares? Who cures? The ongoing debate in the provision of health care. Journal of Advanced Nursing 1998;28(5):1040-1045

⁶⁸ Rushforth H, Glasper EA. Implications of nursing role expansion for professional practice. British Journal of Nursing 1999;8(22):1507-1513

Having actively engaged with the debate surrounding HCAs in recent years, the NMC has been a strong advocate for their statutory regulation, arguing in favour of their place as regulated practitioners rather than unregistered assistants in the healthcare team⁷⁰. In fact, such has been the NMC's level of interest in this campaign that this is perceived to be responsible, at least in part, for 'distracting' the NMC away from its statutory obligations, and for contributing to its failure to discharge its duties satisfactorily⁷¹. Currently in abeyance, it seems that this 'distraction' may have been temporarily removed. However, given the strength of public and political feeling surrounding this issue, and the frequency with which it features in high level inquires⁷², it is likely to be only a matter of time before it resurfaces, bringing with it far-reaching implications for the NMC.

With attention having focused so heavily on the NMC's regulatory credibility and competence, it is easy to see how concerns have arisen regarding the quality of patient care, and the direction that the nursing profession has chosen to take. Indeed, with the professions and the healthcare system both coming under scrutiny following events at Mid-Staffordshire NHS Foundation Trust⁷³ and Winterbourne View Hospital⁷⁴, amid allegations of failures at both organisational and individual levels, these concerns have been heightened. Further, with *The Francis Inquiry*⁷⁵ expected to publish its findings in relation to events at Mid-Staffordshire in the foreseeable future, and all indications suggesting that it will paint the main healthcare professions in a negative light, it is almost certain that these issues will feature prominently. Central among the criticisms that are

69 UK Parliament. Has the nursing profession lost its status? Lords debate on frontline nursing care examines the issues. House of Lords 1 Dec 2011

http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/1112010001.htm#1112014200 0932 (Last accessed 17.10.12)

⁷⁰ Santry C. NMC 'single minded' about HCA regulation. Nursing Times 19 January 2010

⁷¹ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Interim report. London: CHRE. 2012

⁷² The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

⁷³ The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

⁷⁴ Department of Health. Department of Health Review: Winterbourne View Hospital. Interim Report. London: DH. 2012

⁷⁵ The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

most anticipated, and those that are most likely to affect the nursing profession, are issues surrounding the role of HCAs, and the future direction that the nursing profession is likely to take. In the meantime, patients will continue to put their trust in nurses at all levels, and expect to be cared for with dignity and respect when they are at their most vulnerable⁷⁶, with the NMC, in turn, expected to ensure that appropriate standards are not only in place, but enforced.

1.3. The evolution of professional nursing practice

Far removed from the days when nurses were restricted to bedside duties and consigned to the realms of obedient handmaiden, the current situation in nursing is one in which it is commonplace to see experienced nurses managing complete episodes of care, and practising autonomously at an advanced level. This has emerged as a result of numerous initiatives over the years with those receiving support from the UKCC, the NMC, the Department of Health (DH) and the Scottish Government, the most significant and enduring. Featuring centrally among these initiatives are the Calman Reports^{77,78} and the European Working Time Directive⁷⁹, all of which have resulted in changes to the working patterns of doctors and the reduced availability of medical staff. This, in turn, has led political leaders and workforce planners to look to non-medical practitioners, most notably nurses, to bridge the gaps in care that doctors are no longer able Subsequently subsumed under the auspices of a 'higher level of practice', and encompassing innovations at the nursing/medical interface, these initiatives triggered a sequence of events that brought an end to nursing's subservience, and created a more modern and dynamic profession.

⁷⁶ Health Service Ombudsman. Care and compassion? Report of the Health Service Ombudsman on ten investigations into NHS care of older people. London: HMSO. 2011

⁷⁷ NHS Management Executive. Junior Doctors: the new deal. London: HMSO. 1991

⁷⁸ Department of Health. Hospital doctors: Training for the future. The report of the working group on specialist medical training (The Calman Report). London: HMSO. 1993

⁷⁹ The Working Time Regulations 1998. Statutory Instrument 1998 No 1833 amended by Statutory Instrument 2003/1684. The Working Time (Amendment) Regulations 2003 No 1684

1.3.1. The expanded nursing role

First mooted in the 1950s, the concept of the 'extended nursing role' began to appear in a series of statements issued jointly by the Royal College of Nursing (RCN) and the British Medical Association (BMA)^{80,81,82}, and guidance issued by the Chief Nursing and Chief Medical Officers⁸³. At the time, the prevailing model of care was a disease-orientated medical approach, in which nurses had responsibility for carrying out tasks that were labelled as being either basic or technical. Seeking to clarify those duties that lay within the nursing domain and the parameters against which extended roles could be assumed, the purpose of these directives was to permit nurses to perform tasks that technically fell outside their remit, and enable them to expand the confines of their practice. Included within this extended remit were activities such as venepuncture, intravenous cannulation, recording electrocardiograms (ECGs), defibrillation, infiltrating local anaesthetic, wound suturing, applying Plaster of Paris and administering intravenous drugs; all of which were traditionally medical interventions. Prior to this time, those nurses who wished to extend their practice could do so, but only unofficially, albeit often with the endorsement of senior doctors who turned a blind eye to the associated lack of legal authority.

However, although ground-breaking, these directives were not without their limits. In fact, in stipulating that 'extended roles' were only suitable for registered nurses who had completed three years of training, and been assessed as competent in the performance of selected tasks, the situation soon emerged whereby certificates, rather than competence, provided the key to progress. Accordingly, although credited with bringing an end to unauthorised practices, the fact that these directives focused on the assessment of individual tasks, rather than the development of competence, meant that they were of limited impact in that they restricted rather than expanded the parameters of practice. Indeed, the reality is that they bred an unhelpful 'certificate culture' in which practices were determined, and, to a large extent, dominated, by the possession

⁸⁰ Royal College of Nursing. The duties and position of the nurse. London: RCN. 1961

⁸¹ Royal College of Nursing. The duties and position of the nurse. London: RCN. 1970

⁸² Royal College of Nursing. The duties and position of the nurse. London: RCN. 1978

⁸³ Department of Health and Social Security. HC(77)22. The extending role of the clinical nurse - legal implications and training requirements. London: DHSS. 1977

of certificates, rather than the acquisition of skill⁸⁴. Further, with many employers requiring regular recertification, and many organisations requiring additional training, examination and certification for each task each time a nurse changed employer or health authority, their validity could not be relied upon. When added to the fact that the system was premised on the assumed competence of the person issuing the certificate, and with no guarantee of the assessed nurse's competence beyond the date of issue, their legitimacy left a lot to be desired.

Nevertheless, galvanised by the autonomy afforded by these initiatives, the RCN sought to establish a new regime for determining the competence of those extending their roles⁸⁵. This culminated in new guidance issued by the UK Chief Nursing Officers⁸⁶, which directed that all nurses should act in accordance with the *Code of Professional Conduct*⁸⁷ and *The Scope of Professional Practice*⁸⁸; both of which were issued simultaneously by the UKCC. Premised on the twinned concepts of accountability and responsibility, and founded on the principles of beneficence and non-maleficence, which lie at the heart of the therapeutic relationship⁸⁹, these seminal documents signified the cornerstone of professional nursing practice from this point onwards, and attracted something of a biblical force.

1.3.2. The Scope of Professional Practice

Introduced primarily to give structure to extended nursing roles, *The Scope of Professional Practice* (hereinafter referred to as *Scope*) is widely acknowledged

⁸⁴ Hunt G, Wainwright P. Expanding the role of the nurse: The scope of professional practice. London: Blackwell Scientific Publications. 1994

 $^{^{85}}$ Royal College of Nursing. Boundaries of nursing: a policy statement. London: RCN. 1988

⁸⁶ Department of Health. PL/CNO (92) 4. The extended role of the nurse/scope of professional practice. London: DH. 1992

⁸⁷ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. Code of Professional Conduct. London: UKCC. 1992

⁸⁸ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. The Scope of Professional Practice. London: UKCC. 1992

⁸⁹ Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 5th Edition. New York, Oxford: Oxford University Press. 2001

as the driving force behind autonomous nursing practice^{90,91,92,93,94}. Renowned for espousing the importance of individual accountability for practice, and for ensuring that all actions taken were in the best interests of patients, it is also credited with reinforcing, and building upon, the principles enshrined in the *Code of Professional Conduct* (hereinafter referred to as the *Code*). Notable among these principles were the imperative for nurses to act at all times in such a manner as to promote and safeguard the interests of individual patients, and to ensure that no actions or omissions are detrimental to their interests, condition or safety.

Significantly, *Scope* also emphasised the principles that underpin adjustments to practice, rather than the performance of individual tasks, and reinforced the experience, education and skills required to perform them. As such, it placed the onus on the development of competence rather than the acquisition of certificates, and on ability rather than qualification, thus releasing nurses from the restrictions imposed by earlier guidance, and the subordinate role to medicine in which they had been cast. This meant that, in practice, nurses were free to perform a wider range of activities than was previously the case, including those derived from medicine.

With an end having been brought to 'extended roles', which were perceived as being medically-dominated and orientated towards the convenience of others, and favour instead given to 'expanded roles', which enabled practitioners to realise their full potential, the situation soon emerged whereby nurses could effectively expand their practice in any area they wished as long as they were confident and competent to do so, and there were no statutory

⁹⁰ Hunt G, Wainwright P. Expanding the role of the nurse: The scope of professional practice. London: Blackwell Scientific Publications. 1994

⁹¹ Sbaih L. To do or not to do: use the scope of professional practice in accident and emergency work. Accident & Emergency Nursing 1995;3(1):7-13

⁹² Jones S, Davies K. The extended role of the nurse: the United Kingdom perspective. International Journal of Nursing Practice 1999;5(4):184-188

⁹³ Rowe JA. Accountability: a fundamental component of nursing practice. British Journal of Nursing 2000;9(9):549-552

⁹⁴ Walsh M. Nursing frontiers: accountability and the boundaries of care. Oxford: Butterworth-Heinemann 2000

restrictions^{95,96,97,98}. Known colloquially as the 'scope of their practice', *Scope* mandated that nurses could undertake expanded activities, but only if they were in the best interests of patients, and decreed that they would be held personally accountable for their personal and professional development. In addition, by asserting that responsibility for maintaining and improving knowledge, acknowledging any limitations in competence, and declining any duties or responsibilities unless able to perform them in a safe and skilful manner, lay with nurses themselves, rather than with their employers, *Scope* introduced a much-needed sense of autonomy and a climate of reflective self-analysis.

With the tension between extended and expanded roles thus resolved, nurses found themselves arbiters of their own competence and free to take on roles that had hitherto only been permitted at the discretion of others. Indeed, such was the success of Scope that, that within a few years of its publication, a plethora of new roles started to emerge with most focusing on expanded rather than extended practice⁹⁹. However, although indicative of the profession having matured, Scope also raised concerns, for in failing to stipulate ways in which expansions to practice were to be monitored, it created the situation whereby patients could assert that they were not protected from poor practitioners, and practitioners could allege that they were not protected from poor teaching, leaving both vulnerable to exploitation. Not only this, but in saying nothing about the way and the extent to which nurses could achieve authority over their practice, and in seeming to gloss over the fact that they could choose whether and how to adjust their practice, Scope created the situation whereby nurses could find themselves coerced into performing certain roles due to medical offloading or organisational pressures, rather than willingly accepting them.

 $^{^{95}}$ Greenhalgh and Co. The interface between junior doctors and nurses. Macclesfield: Greenhalgh and Co. 1994

⁹⁶ Dowling S, Barrett S, West R. With nurse practitioners who needs house officers? British Medical Journal 1995;311:309-313

⁹⁷ Mitchinson S, Goodlad S. Changes in the roles and responsibilities of nurses. Professional Nurse 1996;11(11):734-736

⁹⁸ Tye C, Ross F. Blurring boundaries: professional perspectives of the ENP role in a major A&E department. Journal of Advanced Nursing 2000;31(5):1089-1096

⁹⁹ Wilson-Barnett J, Bariball KL, Reynolds H, Jowett S, Ryrie I. Recognising advanced nursing practice: evidence from two observational studies. International Journal of Nursing Studies 2000;37(5):389-400

With the regulatory infrastructure arguably not ready for its implementation and some within the profession struggling to come to terms with its implications, it is possible that *Scope* was a concept before its time. It is equally possible that observations made by commentators such as Walsh¹⁰⁰, that in publishing *Scope* it was as if the UKCC had let the genie out of the bottle without really knowing what to do with it and has spent the years since trying to push it back in, may have been correct. Nevertheless, despite reservations that it presented something of a double-edged sword, *Scope* has continued to exert its influence over the nursing domain. Indeed, such has been its impact that it is credited with the growth of the Nurse Practitioner movement in the UK, and many of the early specialist nursing developments¹⁰¹.

Underpinning this influence is the belief that in encouraging nurses to expand their practice and view inter-professional boundaries as a platform for new ways of working, *Scope* seemed to be pushing nurses towards acquiring more diagnostic and clinical management skills, and adopting a more medical model. When considered alongside the fact that the changes taking place within the NHS at the time (including the internal market¹⁰² and the drive to provide more care in the community¹⁰³) necessitated alternative ways of working, it is easy to see how this conclusion was arrived at. In fact, it is reasonable to conclude that the entire nurse-led movement may be attributed to *Scope*, for in facilitating the development of complementary roles in which specialist nurses provided expert advice in partnership with other professions, the creation of niche roles whereby nurses with a special interest carved out new services in an innovative way, and the formation of substitute roles whereby nurses took on more technical activities in place of doctors, it enhanced their decision-making skills and provided a legitimate platform from which they could practice^{104,105}.

 $^{^{100}}$ Walsh M. Nursing frontiers: accountability and the boundaries of care. Oxford: Butterworth-Heinemann 2000

¹⁰¹ Finlay T. The Scope of Professional Practice: A literature review to determine the document's impact on nurses' role. Journal of Research in Nursing 2000;5(2):115-125

¹⁰² Department of Health. Working for Patients. Cmd555. London: HMSO. 1989

¹⁰³ Department of Health. Caring for people: community care in the next decade and beyond. Cmd849. London: HMSO. 1989

¹⁰⁴ Scholes J, Furlong S, Vaughan B. New roles in practice: charting three typologies of role innovation. Nursing in Critical Care 1999;4(6):268-275

¹⁰⁵ Scholes J, Vaughan B. Cross-boundary working: implications for the multi-professional team. Journal of Clinical Nursing 2002;11:399-408

1.3.3. The Clinical Nurse Specialist

Widely considered to be one of the first advanced nursing roles, the Clinical Nurse Specialist (CNS) first appeared in the UK in the mid-1970s as a means of addressing specific needs that were not being met by existing staff. Exemplified by Ruth Martin, a senior neurosurgical nursing sister who wished to develop her career along clinical rather than managerial lines, the first UK-based CNS role is said to have encapsulated the medical aspects of neurosurgery such as lumbar punctures and ventricular taps while at the same time remaining orientated towards nursing care¹⁰⁶. Received positively by both patients and clinicians, such was the success of this role that many UK hospitals and community facilities followed suit, implementing CNS roles in a wide range of specialities including oncology, rheumatology and diabetology, partly as a means of retaining expert nurses with specialist skills at the bedside, and partly as a means of offering nurses an alternative avenue for advancement beyond those of education and management¹⁰⁷.

With the early reforms of the 1980s^{108,109} increasing their profile, CNS numbers started to grow, albeit with little evaluation of their impact. So, too, did the number of posts implemented following the publication of *Scope* increase, many of which were in response to medical staff shortages arising from the government's 'New Deal' for doctors¹¹⁰, and many of which were due to changes in the preparation of medical specialists arising from the Calman Report¹¹¹. However, despite having increased in number, with the necessary clarification from the UKCC regarding specialist and higher level practice lacking, and with no consensus regarding how nursing practice should develop, CNSs found

¹⁰⁶ Castledine G. Generalist and specialist nurses - complementary or conflicting roles? New nursing roles: deciding the future for Scotland. Conference paper 17 November 2003 http://www.scotland.gov.uk/Publications/2004/04/19201/35586 (Last accessed 30.06.2011)

¹⁰⁷ Wilson-Barnett J, Beech S. Evaluating the clinical nurse specialist: a review. International Journal of Nursing 1994;31(6):561-571

¹⁰⁸ Department of Health. Working for patients. London: HMSO. 1989

¹⁰⁹ Department of Health. Caring for people: community care in the next decade and beyond. Cmd849. London: HMSO. 1989

¹¹⁰ NHS Management Executive. Junior doctors: the new deal. London: NHSME. 1992

¹¹¹ Department of Health. Hospital doctors: Training for the future. The report of the working group on specialist medical training (The Calman Report). London: HMSO. 1993

themselves without the requisite authority, meaning that they still had to look to doctors for guidance and instruction.

Recognised as being capable practitioners, and supported by the International Council of Nurses (ICN)¹¹², which saw them as practising beyond the level of general nurses and having expertise in a branch of nursing, CNSs were soon able to expand the depth of their knowledge and improve their autonomy, while at the same time reducing medical staff workload 113. However, although credited with pioneering advanced practice, they also received mixed acclaim, because in being implemented in a piecemeal, ad-hoc and often unstructured fashion in the absence of national guidance, their impact was not always recognised and their unique characteristics could not always be identified. In fact, with lingering uncertainty regarding the specialist and generalist aspects of their role, and growing confusion surrounding the parameters of their practice, the only criteria that could be reliably ascribed to them focused on physical aspects such as working across institutional and community boundaries, teaching, consulting and advising, and conducting research in their specialisation¹¹⁴. Nevertheless, despite this, they managed to develop their own identity and, working alongside and under the 'control' of hospital consultants, became recognised for carrying an independent caseload of patients with already detected and diagnosed problems from within a specific client or disease group¹¹⁵.

Although not fully evaluated in the early days, the positive reaction that CNSs received from patients was such that they quickly became accepted as an integral part of the clinical team. Much of this acceptance derived from the improved availability and access to clinicians, the enhanced continuity of care provided by CNSs, and the favourable response from medical staff who were

112 International Council of Nurses. Guidelines on specialisation in nursing. Geneva: ICN. 1992

¹¹³ Wilson-Barnett J, Beech S. Evaluating the Clinical Nurse Specialist. A review. International Journal of Nursing Studies 1994;31(6):561-571

¹¹⁴ Castledine G. Generalist and specialist nurses - complementary or conflicting roles? New nursing roles: deciding the future for Scotland. Conference paper 17 November 2003 http://www.scotland.gov.uk/Publications/2004/04/19201/35586 (Last accessed 30.06.2011)

Jones ML. Role development and effective practice in specialist and advanced practice roles in acute hospital settings: a systematic review and meta-synthesis. Journal of Advanced Nursing 2005;49(2):191-209

convinced of their value. No doubt motivated by this, and encouraged by the growing need for 'medical' cover in an increasingly technical and complex environment, this resulted in many subsequent CNSs expanding their remit to include diagnostic testing, medical assessments, patient monitoring, minor treatments and the development of protocols and guidelines. With their practice essentially focused on being available to patients at the right time and place, being able to discuss treatment plans and interpret medical findings, and being positioned so as to maintain the clinical continuity that is arguably not provided by junior doctors who come and go as their rotations end, CNSs complemented and facilitated the skills of other team members and helped to bridge the gaps in care. Thus differentiated from other nurses by virtue of their advanced knowledge and expertise, and recognised for their specialist skills, they became an established resource and an integral part of the nursing armoury.

1.3.4. Nurse Practitioners

Imported into the UK some years later and first introduced into primary care and Accident and Emergency (A&E) arenas as a means of responding to shortages in medical staff and the need to do more with less, the Nurse Practitioner (NP) role also initially struggled to gain recognition. Originally undertaken by nurses such as Barbara Stilwell, one of the first NPs to be recognised in the UK, and premised on blending aspects of medicine and nursing, these roles were considered unique in being able to merge clinical diagnosis with nursing care ¹¹⁶. With a remit that enabled nurses to be based solely within the clinical arena, and to examine, investigate, diagnose, treat and refer or admit patients with undifferentiated and undiagnosed healthcare problems independently, these roles typically attracted those interested in expanding their practice, and those seeking an advanced level of autonomy.

¹¹⁶ Barton TD, Thorne R, Hoptroff M. The nurse practitioner: redefining occupational boundaries. International Journal of Nursing Studies 1999;36(1):57-63

As with CNSs, NPs were recognised by the ICN¹¹⁷ which acknowledged them as having acquired the expert knowledge base, complex-decision-making skills and the clinical competencies necessary for expanded practice. Also recognised by the RCN¹¹⁸ as having the ability to make professionally autonomous decisions for which they were accountable, receive unscreened patients, diagnose their healthcare needs, order necessary tests and investigations, and manage complete episodes of care through to admission or discharge, NPs prided themselves on having unique skills which set them apart from conventional nurses. More closely aligned with the medical model, and arguably more focused on the adoption of medical tasks rather than on representing a higher level of 'nursing', the uniqueness of NP roles lay in their ability to balance the nursing role with elements of medical substitution, and retain a high level of problem-solving. In fact, such was their success in retaining this balance that NPs became viewed as the first point of contact for unscheduled care, and are now considered to be a feasible and less expensive alternative to doctors¹¹⁹.

However, although successful in improving statistics such as waiting times, so that patients with less serious conditions could be seen more quickly, and recognised as enhancing patient choice¹²⁰, the advent of NPs has not been completely uncontroversial. Indeed, the extension of NP skills into the medical domain is notable for having blurred the boundaries at the nursing/medical interface, and for giving rise to confusion surrounding whether NPs are in fact advanced nurses or medical substitutes^{121,122,123,124}. Characterised by core

¹¹⁷ International Council of Nurses. ICN announces its position on advanced nursing roles. International Nursing Review 2002:49;199-206

¹¹⁸ Royal College of Nursing. Nurse practitioners - an RCN guide to the nurse practitioner role, competencies and programme accreditation. London: RCN. 2002

¹¹⁹ Venning P, Durie A, Roland M, Roberts C, Leese B. Randomised controlled trial comparing cost effectiveness of general practitioners and nurse practitioners in primary care. British Medical Journal 2000;320(7241):1048-1053

¹²⁰ Chang E, Daly J, Hawkins A, McGirr J, Fielding K, Hemmings L, O'Donoghue A, Dennis M. An evaluation of the nurse practitioner role in a major emergency department. Journal of Advanced Nursing 1999;30(1):260-268

¹²¹ Richardson G, Maynard A, Cullum N, Kindig D. Skill mix changes: substitution or service development? Health Policy 1998;45:119-132

¹²² Walsh M, Crumbie A, Reveley S. Nurse practitioners: clinical skills and professional issues. Edinburgh: Butterworth-Heinemann. 1999

Woods LP. The enigma of advanced nursing practice. Wiltshire: Mark Allen Publishing Ltd. 2000

clinical competencies including history taking, physical examination, diagnostic reasoning (based on the interpretation of findings including laboratory results, X-rays, and invasive and non-invasive procedures), prescribing of medications, and dealing with uncertainty and the risks that are inherent in clinical decision-making¹²⁵, it is true that the NP remit resembles that of junior doctors. In fact, with responsibility for managing an independent caseload a key component of their work, and much of their time occupied by a medical task field, it is easy to see how the public might confuse NPs with doctors. However, with nursing rather than medicine the essence of their role, and holism rather than fragmentation the foundation of their work, NPs reject criticisms made by commentators such as Castledine¹²⁶ that they are at risk of losing their professional identity.

Armed with an enhanced clinical portfolio, similar to that of junior doctors, NPs have continued in their quest to be recognised as autonomous practitioners. However, with varying levels of clinical confidence resulting in variable degrees of 'independent' working, and skill retention featuring as a major issue, particularly in those forced to split their time between conventional nursing and NP roles, the extent to which they have been accepted as clinical equals is questionable. Despite this, it is interesting to note that studies 127,128,129,130 report no major differences between NPs and doctors in terms of clinical outcomes, and equal or greater levels of satisfaction among those patients who

12

patients with minor illnesses in a general practice: multicentre randomised controlled trial. British Medical Journal 2000;320:1038-1043

¹²⁴ Brook S, Crouch R. Doctors and nurses in emergency care: where are the boundaries now? Trauma 2004;6(3):211-216

¹²⁵ Read S, Roberts-Davis M. Preparing Nurse Practitioners for the 21st Century. Realising specialist and advanced nursing practice: establishing the parameters of and identifying the competencies for Nurse Practitioner roles and evaluating programmes of preparation. University of Sheffield. 1998

¹²⁶ Castledine G. Generalist and specialist nurses - complementary or conflicting roles? New nursing roles: deciding the future for Scotland. Conference paper 17 November 2003 http://www.scotland.gov.uk/Publications/2004/04/19201/35586 (Last accessed 04.08.2011) 127 Scum C, Humphreys A, Wheeler D, Cochrane M, Skoda S, Clement S. Nurse management of patients with minor illnesses in a general practice: multicentre randomised controlled trial

¹²⁸ Horrocks S, Anderson E, Salisbury C. Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. British Medical Journal 2002;324:819-823 ¹²⁹ Sakr M, Kendall R, Angus J, Saunders A, Nicholl J, Wardrope J. Emergency nurse practitioners: a three part study in clinical and cost effectiveness. Emergency Medicine Journal

a three part study in clinical and cost effectiveness. Emergency Medicine Journal 2003;20(2):158-163

¹³⁰ Laurant M, Reeves D, Hermens R, Braspenning J, Grol R, Sibbald B. Substitution of doctors by nurses in primary care. The Cochrane Database of Systematic Reviews. 2004;2:CD001271

are seen by NPs when compared with doctors. In fact, such has been the growth in the NP role and the level of acceptance that NPs have received, that they are now recognised as an integral part of the workforce in most Emergency Departments (EDs) and Primary Care Centres, and many other areas including orthopaedics, neonatology, urology and paediatrics^{131,132,133}. Indeed, such has been their success that they are considered by some¹³⁴ to be the precursor to the most advanced of all clinical nursing roles; that of the Consultant Nurse.

1.4. Advanced nursing practice

Typically associated with a 'higher level of practice' and, therefore, an assumed higher level of risk, 'advanced nursing practice' is accepted as the umbrella term that denotes the array of non-traditional nursing roles and practices that now populate the clinical arena¹³⁵. Included within this is the range of 'expanded' activities that are undertaken by experienced nurses such as Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs) and, more recently, Consultant Nurses (CNs), and the practices of those undertaking more modern Comprising the requisite experience, expertise and clinical clinical roles. judgement necessary for autonomous professional practice, and the pioneering of new roles in response to changing needs¹³⁶, it is credited with enabling the skills of practitioners to be recognised, and acknowledging their role in improving the quality of patient care. However, although now used in everyday parlance and assumed to be reasonably straightforward, deeper analysis shows that it is a relative, flawed and somewhat ambiguous term given that it only makes sense when applied as a benchmark to some other aspect of practice.

131 Touche Ross Management Consultants. Evaluation of nurse practitioner pilot projects. London: South Thames Regional Health Authority. 1994

¹³² Coopers and Lybrand. Nurse practitioner evaluation project. Uxbridge: Coopers and Lybrand. 1996

¹³³ Fotheringham D, Dickie S, Cooper M. The evolution of the role of the Emergency Nurse Practitioner in Scotland: a longitudinal study. Journal of Clinical Nursing 2011;20:2958-2967

¹³⁴ National Leadership and Innovation Agency for Healthcare. Framework for advanced nursing, midwifery and allied health professional practice in Wales. Llanharan: NLIAH. 2011

¹³⁵ Department of Health. Advanced level nursing: a position statement. Leeds: DH. 2010

¹³⁶ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. The future of professional practice: the Council's standards for education and practice following registration. London: UKCC. 1994

Historically associated with perceived differences in the practice of those accepting post-registration roles, this ambiguity originally centred on whether 'advanced' and 'specialist' nursing practice were of equivalent status, or whether a hierarchical relationship existed between the two¹³⁷. Resolved, in part, by the UKCC's Post Registration and Education Project (PREP)¹³⁸ which distinguished them on the basis of depth and breadth, 'advanced nursing practice' emerged as the highest and most complex level of practice beyond initial registration. In practice, this distinction associated 'advanced nursing practice' with the acquisition of horizontal expertise that spanned a range of domains, in contrast to 'specialist nursing practice' which was characterised as the acquisition of vertical expertise within a single domain, and the highest level of judgement and discretion in clinical decision-making. However, despite this clarification going some way to assist, with early definitions lacking any degree of specificity and the inference still persisting that advanced practice was superior in the hierarchical chain 139,140,141, ambiguity prevailed, meaning that standards could not always be guaranteed and variance was commonplace.

As a consequence of this ambiguity, the UKCC looked to introduce a 'higher level of practice' aimed at encompassing all roles and titles and providing a stable and more generalised platform from which to proceed. Focused on eliciting explicit standards that would embrace all existing and future roles, this sought to identify ways in which the breadth, depth and complexity of higher level

¹³⁷ Read S, Roberts-Davis M. Preparing Nurse Practitioners for the 21st Century. Realising specialist and advanced nursing practice: establishing the parameters of and identifying the competencies for Nurse Practitioner roles and evaluating programmes of preparation. University of Sheffield. 1998

¹³⁸ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. The future of professional practice: the Council's standards for education and practice following registration. London: UKCC. 1994

¹³⁹ Castledine G. The role and criteria of an advanced nurse practitioner. British Journal of Nursing 1996;5(5):288-289

 ¹⁴⁰ Castledine G, McGee P, Brown R. A survey of specialist and advanced nursing practice in England. Birmingham: The Nursing Research Unit, University of Central Birmingham. 1996
 141 Read S, Roberts-Davis M. Preparing Nurse Practitioners for the 21st Century. Realising specialist and advanced nursing practice: establishing the parameters of and identifying the competencies for Nurse Practitioner roles and evaluating programmes of preparation. University of Sheffield. 1998

¹⁴² United Kingdom Central Council for Nursing, Midwifery and Health Visiting. A higher level of practice: consultation document. London: UKCC. 1998

practice could be differentiated, and provide a mechanism by which users and employers could verify the validity of practitioners claiming to practise at this level. Focused also on looking at how such practice could be regulated, it sought to identify specific outcomes and competencies against which practitioners could be assessed, and around which a robust system could be developed. From this platform emerged the concept of 'higher level practice', which the UKCC saw as providing the basis for a post-registration regulatory framework.

Depicting that higher level standards should be generic, applicable across all healthcare settings, concerned with the level of practice rather than speciality or role, assessed by a system founded on the attainment of clinical competence, and based on a framework that allowed practitioners to rely on educational qualifications as part of their portfolio of evidence, this approach was significant in enabling a clear structure to form. However, with a change of government in 1997 setting a new strategic direction, and developments such as the Consultant Nurse role overtaking and bringing an end to planned initiatives, this project was halted in its tracks. Accordingly, rather than reaching fruition, the 'higher level of practice' project found itself consigned to history, albeit with its recommendations¹⁴⁴ referred to the newly constituted NMC¹⁴⁵.

With attempts to formalise advanced nursing practice thus derailed, the ICN's global definition of advanced practice¹⁴⁶, published in 2002, heralded a welcome turning point. Reinforcing the need for an expert knowledge base, complex decision-making skills, advanced clinical competencies and the possession of a Masters degree as essential prerequisites, the aim was that this definition would facilitate a common understanding and guide the development of advanced roles. Achieving some success, this led to the NMC and Skills for Health

¹⁴³ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. A higher level of practice. Report on the consultation on the UKCC's proposals for a revised regulatory framework for post-registration clinical practice. London: UKCC. 1999

¹⁴⁴ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. Report of the Higher Level of Practice pilot and project. London: UKCC. 2002

¹⁴⁵ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

¹⁴⁶ International Council of Nurses. Definition and characteristics of the role. 2002 http://66.219.50.180/inp%20apn%20network/practice%20issues/role%20definitions.asp (Last accessed 04.08.2011)

describing advanced nurse practitioners as highly experienced and educated members of the team with the ability to diagnose and treat or refer to an appropriate specialist if needed¹⁴⁷, and as experienced professionals with highly developed knowledge and skills with the ability to make high-level clinical decisions and have their own caseload¹⁴⁸, respectively. Receiving further endorsement by the DH in its consultation on a proposed framework for post-registration nursing in 2004¹⁴⁹, the *Framework for Developing Nursing Roles*¹⁵⁰ produced by the Scottish Executive in 2005, the *Advanced Practice Toolkit*¹⁵¹ devised by the Scottish Government in 2008, and the DH advanced practice position statement in 2010¹⁵², it seems that a consensus has finally been reached.

1.5. The evolution of new clinical roles

With new and more innovative ways of working sitting at the heart of healthcare modernisation, *The NHS Plan*¹⁵³ will undoubtedly be remembered as one of the most influential and liberating documents in healthcare policy. Synonymous with role redesign and service re-engineering, it will forever be acknowledged as the milestone that formally expanded nursing horizons, and introduced incentives for senior and experienced nurses who craved greater autonomy and professional influence to remain in clinical practice. Incorporating the Chief Nursing Officer's 'ten key roles for nurses' which legitimised their authority

2005

¹⁴⁷ Nursing and Midwifery Council. Implementation of a framework for the standard of post-registration nursing. Agendum 27.1. C/05/160. December 2005

¹⁴⁸ Skills for Health. Career framework for health. 2007 http://www.aanpe.org/AdvancedNursing%20Practice/tabid/721/Default.aspx (Last accessed 09.09.2011)

Department of Health. Post-registration development: a framework for planning,
 commissioning and delivering learning beyond registration for nurses and midwives. The report of a task group convened and chaired by the Chief Nursing Officer. London: DH 2004
 Scottish Executive. Framework for developing nursing roles. Edinburgh: Scottish Executive

¹⁵¹ The Scottish Government. Supporting the development of advanced nursing practice - a toolkit approach. Chief Nursing Officer Directorate. Edinburgh: The Scottish Government. 2008 http://tinyurl.com/3mw6add (Last accessed 05.09.2011)

¹⁵² Department of Health. Advanced level nursing: a position statement. Leeds: DH. 2010

¹⁵³ Department of Health. The NHS Plan: A plan for investment, a plan for reform. London: HMSO. 2000

¹⁵⁴ Department of Health. PL CNO (2002)5. Implementing the NHS Plan - ten key roles for nurses. London: HMSO. 2002

and empowered nurses to undertake a wider range of clinical tasks, and renowned for reinforcing personal accountability, it will also be remembered as paving the way for structured and sustainable change, and for signalling an end to reactive responsiveness.

Of particular significance to those tasked with enhancing clinical outcomes while adhering to financial constraints, *The NHS Plan*¹⁵⁵, and the related Scottish Health Plan¹⁵⁶, is also notable for offering hospital Trusts (Health Boards in Scotland) the freedom to determine local staffing structures and the flexibility to introduce alternative ways of working. However, with the result being an array of new, unregulated and, in some cases, self-styled and self-appointed titles, many of which have persisted beyond the initial pilot phase and, in some cases, have become accepted as commonplace despite being poorly understood, difficulties have arisen regarding variances in their practice with some performing interventions beyond their intended remit. Viewed with suspicion by some, and associated with the potential to mislead patients regarding their variable education and preparation and, ultimately, their competence, this unsatisfactory situation has prevailed, with attempts by the profession to standardise new and existing roles having thus far fallen short.

Nevertheless, poised to capitalise on this 'freedom' and welcoming of new roles, nurses have seized the opportunities afforded by this initiative and forged ahead seeking to maximise their clinical contribution and achieve their full potential. Resulting in an enhanced clinical portfolio, including the prescribing of medicines and the requesting and interpretation of diagnostic tests and investigations, the impact of these new roles is significant. However, with unresolved variability in their standards of education and training, a proliferation of titles that convey little meaning, unclear lines of accountability, and the not uncommon tendency of patients to misidentify them as doctors given their tendency to adopt a more medical model of consultation, the risks

 $^{^{\}rm 155}$ Department of Health. The NHS Plan: A plan for investment, a plan for reform. London: HMSO. 2000

¹⁵⁶ Scottish Executive. Our National Health: A plan for action, a plan for change. Edinburgh: Scottish Executive. 2006

associated with their practice are considerable. This leaves those responsible for regulating advanced nursing practice with much to address.

1.5.1. Non-medical prescribing

Widely considered to be one of the most significant developments in nursing's evolution, the lifting of historical constraints on non-medical prescribing has transformed the face of clinical nursing practice. Due in large part to the 'Cumberlege Report' and the far-reaching 'Crown Reports' which conferred rights, on prescribing and subsequent nurses limited legislation 160,161,162,163 which 'opened up' the entire British National Formulary (BNF)¹⁶⁴ to suitably qualified nurses, the advent of non-medical prescribing has enabled nurses to benefit from a more autonomous and clinically fulfilling role. More importantly, however, it has enabled patients to benefit from a reduction in inter-professional handovers, improved clinical journeys and more efficient hospital discharges. Also associated with an improved safety profile, due to prevention of the technically illegal and inherently risk-laden practice in which the name, dose and strength of prescription-only medicines were noted by nurses on prescription charts only to be signed and, therefore, 'prescribed' by doctors at a later stage, patients have also benefited from more timely drug administration and more efficient prescribing practices.

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¹⁵⁷ Department of Health and Social Security. Neighbourhood nursing: a focus for care (The Cumberlege Report). London: DH. 1986

¹⁵⁸ Department of Health. Report of the advisory group on nurse prescribing (1st Crown Report). London: DH. December 1989

¹⁵⁹ Department of Health. Review of prescribing, supply and administration of medicines (2nd Crown Report). London: DH. 1999

¹⁶⁰ The Medicinal Products: Prescription by Nurses etc. Act 1992 Ch 28

¹⁶¹ The Prescription Only Medicines (Human Use) Amendment Order 2000. Statutory Instrument No 1917

¹⁶² The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment (no.2) Regulations 2000. Statutory Instrument No 1918

¹⁶³ The Medicines (Pharmacy and General Sale Exemption) Amendment Order 2000. Statutory Instrument No 1919

¹⁶⁴ British National Formulary. BMA and Royal Pharmaceutical Society of Great Britain http://bnf.org/bnf/index.htm (Last accessed 12.09.2011)

With positive evaluations 165,166,167,168 dispelling deep-seated concerns that prescribing rates would rise uncontrollably, amid fears that patients would be subjected to unnecessary and potentially harmful medications, and outcomes showing similar prescribing rates between medical and non-medical clinicians when comparing like with like, opponents of non-medical prescribing have Indeed, with studies 169,170 showing that non-medical largely been silenced. prescribers receive greater training in the art of prescribing than their medical counterparts, albeit associated with a less intense grounding in pharmacology, and undergo more practical and theoretical assessments, these concerns would seem to have been addressed. However, despite this, and irrespective of the fact that the anticipated rise in pharmacy costs has not materialised, anxiety surrounding a wider roll-out of the programme has persisted, meaning that, at least for the time being, non-medical prescribing will be available to the select few rather than the majority, thus effectively consigning it to the advanced nursing ranks.

1.5.2. Access to diagnostic tests and investigations

Also significant in developing advanced practice has been the removal of historic barriers that have until relatively recently prevented non-doctors from directly accessing diagnostic services¹⁷¹. Originally perceived as falling within the medical domain, and requiring a level of intelligence and analysis beyond that

¹⁶⁵ Department of Health. Nurse prescribing, final report. A cost benefit study. London: HMSO. 1991.

¹⁶⁶ Latter S, Maben J, Myall M, Courtenay M, Young A, Dunn N. An evaluation of extended formulary independent nurse prescribing. Executive summary of final report. Policy Research Programme, Department of Health and University of Southampton. 2005

¹⁶⁷ Watterson A. An evaluation of the extension of nurse prescribing in Scotland. Edinburgh: Scottish Government. 2009

¹⁶⁸ Latter S, Blenkinsopp A, Smith A, Chapman S, Tinelli M, Gerard K, Little P, Celino N, Granby T, Nicholls P, Dorer G. Evaluation of nurse and pharmacist independent prescribing. Department of Health Policy Research Programme Project, University of Southampton and Keele University. 2010

¹⁶⁹ Latter S, Maben J, Myall M, Courtenay M, Young A, Dunn N. An evaluation of extended formulary independent nurse prescribing. Executive summary of final report. Policy Research Programme, Department of Health and University of Southampton. 2005

¹⁷⁰ Heaton A, Webb DJ, Maxwell SRJ. Undergraduate preparation for prescribing: the views of 2413 UK medical students and recent graduates. British Journal of Clinical Pharmacology 2008;66(1):128-134

¹⁷¹ Ball J. Maxi nurses. Advanced and specialist nursing roles. London: RCN. 2005

associated with nurses, access to clinically-led diagnostic and laboratory facilities has now been extended to nurses and other non-medical professionals in an attempt to increase capacity and improve efficiency. Initially resisted on the basis of concerns surrounding the risk of excessive or inappropriate testing, and fears that patients would be exposed to unnecessary and potentially harmful investigations, it seems that the increased use of multi-disciplinary protocols and guidelines may have reassured defenders of the old regimen. With fears thus allayed, and access to telemedical and decision-support systems enabling a wider range of diagnostic interventions to be performed, including in remote locations, liberation of this key interface has effectively transformed the delivery of care.

1.5.2.1. Pathology tests

Recognised as a conduit to timely and effective care and the linchpin of many clinical encounters, the initiation of nurse-requested pathology tests also features highly among the most significant interventions to have improved the experience of patients. In fact, it is notable for enabling many unnecessary hospital admissions to be avoided and many clinical decisions to be expedited¹⁷². Supported by government-led directives^{173,174} and championed by local clinical leads, these changes have resulted in pathologists becoming enablers of efficient person-centred care rather than being perceived by some as protective guardians of the laboratory¹⁷⁵. Resulting in opening of the pathology floodgates, and a more inclusive approach to healthcare, this has not only improved access to the myriad of investigations that underpin the 70% to 80% of healthcare decisions that affect the diagnosis and treatment of one in seven patients¹⁷⁶, but also contributed to their monitoring and management. With nurses able to initiate diagnostic tests and investigations at as early a stage as possible in the

 172 Department of Health and Royal College of Nursing. Freedom to practise: dispelling the myths. London: HMSO. 2003

¹⁷³ Department of Health. Modernising pathology services. London: DH. 2004

¹⁷⁴ Department of Health. Modernising pathology: Building a service responsive to patients. London: DH. 2005

NHS Modernisation Agency stakeholder workshop - improving flow and capacity. July 2004

¹⁷⁶ Department of Health. Report of the review of NHS pathology services in England. London: DH. 2006

clinical journey, and expedite clinical decision-making at a time when 24 hour care is not only required but expected¹⁷⁷, these developments have widened access to pathology services such that it has become one of the most significant initiatives to impact upon autonomous nursing practice.

1.5.2.2. Radiology tests and investigations

Changes in nurse-initiated and nurse-interpreted radiology tests have also been instrumental in developing the clinical infrastructure, albeit at a somewhat slower pace, with resistance from those perceived by some as being 'guardians' of the X-ray' having taken longer to overcome 178. Traditionally the domain of radiologists, who are invariably medically qualified, and radiographers, who process and normally approve requests for investigations, this reluctance to change is acknowledged as having presented one of the biggest challenges to advanced nursing practice, with embedded resistance to new initiatives preventing nurses and other non-medical clinicians from practising to their full capacity. Now acknowledged as being poorly substantiated and having lacked a robust evidence base, these concerns are recognised as having been largely founded on professional protectionism rather than experience. So, too, are concerns that existed surrounding the presumed inability of non-medical clinicians to select appropriate tests, identify abnormalities and accurately interpret findings, although it is likely that limited resource availability and concerns surrounding the potential exposure of patients to unnecessary and potentially harmful examinations that may not affect their treatment may have also played a part.

With concerns surrounding safety able to be defeated on the basis that all radiology requests need to be accompanied by detailed clinical information outlining their indication and justifying their use¹⁷⁹, supported by the fact that all investigations are reviewed by highly qualified radiologists who provide

¹⁷⁷ NHS Improvement. Equality for all: Delivering safe care - seven days a week. Leicester: NHS Improvement. 2012

NHS Modernisation Agency stakeholder workshop - improving flow and capacity. July 2004
 The Royal College of Radiologists. Making the best use of a Department of Clinical Radiology:
 Guidelines for doctors. London: The Royal College of Radiologists. 2012

written, albeit retrospective, reports summarising their findings, it would seem that these risks have been addressed. Indeed, arguments opposing nurse-initiated radiology also seem to have been addressed on the basis that many doctors who request investigations are similarly inexperienced in their interpretation and, thus, limited in their diagnostic ability, particularly early on in their careers. However, an argument that may carry more weight is that relating to the belief that many nurses request tests on the basis of strict protocols, either in the interests of expedience or due to so-called 'defensive practice', resulting in patients being subjected to a battery of tests that may not always be clinically indicated. Linked with the suggestion that advanced nurses are, in fact, advanced technicians rather than autonomous professionals given their performance of technically advanced and repetitive skills in the perceived absence of diagnostic expertise, this argument is likely to be short-lived on the basis that it lacks substance.

With a convincing body of evidence^{180,181,182,183,184,185} having begun to emerge which shows nurses to be capable of identifying appropriate radiology investigations and accurately requesting and interpreting them, it seems that deep-seated resistance to nurse-initiated radiology may have been overcome. Largely based in the emergency arena and focused mainly on triage and the Emergency Nurse Practitioner (ENP) role, these studies highlight the potential benefits that may be afforded by this initiative, and point to positive patient feedback and satisfaction surveys as indicators of success. Also supported by robust regulations^{186,187} which are aimed at minimising the potential for harm,

¹⁸⁰ Macleod AJ, Freeland P. Should nurses be allowed to request X-rays in Accident and Emergency Departments? Archives of Emergency Medicine 1992;9:19-22

¹⁸¹ Lindley-Jones M, Finlayson BJ. Triage nurse requested X-rays - are they worthwhile? Journal of Accident and Emergency Medicine 2000;17:103-107

¹⁸² Lindley-Jones M, Finlayson BJ. Triage nurse requested X-rays - results of a national survey. Journal of Accident and Emergency Medicine 2000;17:108-110

¹⁸³ Allerston J, Justham D. Nurse Practitioners and the Ottawa ankle rules: comparisons with medical staff in requesting X-rays for ankle injured patients. Accident and Emergency Nursing 2000;8(2):110-115

¹⁸⁴ Benger JR. Can nurses working in remote units accurately request and interpret radiographs? Emergency Medicine Journal 2002;19:68-70

¹⁸⁵ Hopkins M. A comparative analysis of ENPs and SHOs in the application of the Ottawa ankle rules. International Emergency Nursing 2010;18:188-195

¹⁸⁶ Department of Health. Ionising Radiation Regulations. London: DH. 1999

¹⁸⁷ Department of Health. The Ionising Radiations (Medical Exposure) Regulations. London: DH. 2000

nurse-requested radiology has gradually become an established part of advanced nursing practice and is now a regular feature in most clinical areas.

1.6. The regulation of advanced nursing practice

There is little doubt that the changes in healthcare delivery that have shifted the balance of 'power' away from medicine and towards nursing 188 are here to stay. There is similarly little doubt that advanced practice will remain a central part of modern nursing practice, with nurses continuing to assume responsibility for tasks that are increasingly complex and complicated. Associated with these developments are the risks to patient safety that could potentially be posed by nurses taking on roles for which they lack the necessary competence, or as a consequence of the necessary safeguards not being in place 189. With the onus on the NMC, as the professional regulator, to recognise the risks to public protection and ensure that they are appropriately assessed, quantified and managed, this raises the question of whether the current regulatory system that is in place is sufficient to provide the necessary safeguards, or whether additional regulatory intervention is required.

At present, the regulation of nursing practice is overseen by the NMC. Enshrined in legislation contained within the Nursing and Midwifery Order 2001¹⁹⁰, this regulatory framework requires the NMC to verify and accredit educational courses and curricula, and maintain an up-to-date Register of those nurses who are practising. The registration entries of these nurses are, in turn, amended to reflect the acquisition of requisite competencies, with the Register denoting details of the principal training and education that has been undertaken by registrants. The Order also requires the NMC to ensure that nurses adhere to professional standards and rules, many of which are contained in the

¹⁸⁸ Department of Health. Shifting the balance of power within the NHS: securing delivery. London: HMSO. 2001

 $^{^{189}}$ Council for Healthcare and Regulatory Excellence. Advanced practice: policy summary. London: CHRE. 2009

¹⁹⁰ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

professional 'code'¹⁹¹, and to take action where patients' interests have not been protected as a consequence of non-compliance. Central among these obligations are the duty to provide a high standard of practice and care at all times, act with integrity and uphold the reputation of the profession, accept personal accountability for actions and omissions in practice, and be able to justify decisions. Also central is the duty of nurses to practise only where they are competent to do so, and always to ensure that their actions do not jeopardise patient care, or otherwise put patient safety at risk.

Although founded on traditional nurses and traditional nursing practice, it has generally been assumed that the regulatory mechanisms that are in place will suffice in providing the necessary safeguards to protect patients from those advanced nurses who have expanded their practice beyond traditional boundaries. Indeed, this is a position that has been adopted by the Professional Standards Authority (PSA), on the basis that much of what is called advanced practice represents career development over time, rather than a fundamental break with traditional professional practice¹⁹². Also supporting this position is the premise that the risks associated with advanced practice are the same as those associated with other types of practice, and, as such, are adequately captured by existing standards of proficiency and ethical duties¹⁹³.

However, acknowledging the pressures that the NMC is currently facing and struggling to overcome in the discharge of its statutory duties in the traditional context, it is possible that this assumption may, in fact, be erroneous. Indeed, with momentum having grown to support the view that the current regulatory processes are insufficient to manage the risks posed to patients from the wider body of nurses and their associated practices 194,195,196, this is a presumption that

¹⁹¹ Nursing and Midwifery Council. NMC. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

¹⁹² Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

¹⁹³ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

¹⁹⁴ Royal College of Nursing. Policy statement: RCN's position on advanced nursing practice. London: RCN. 2009

¹⁹⁵ The Prime Minister's Commission on the Future of Nursing and Midwifery in England. Front Line Care: the future of nursing and midwifery in England. Report of the Prime Minister's Commission on the Future of Nursing and Midwifery in England 2010. London: COI. 2010

can arguably be rebutted. With concerns also having arisen that the regulatory framework has not kept pace with educational and clinical change, particularly in not enabling levels of nursing practice to be differentiated, this does not bode well for advanced nursing practice, nor does it bode well for patient safety. When added to the fact that the current system does not provide a mechanism, such as a 'protected' title, by which to identify those practitioners who have acquired the relevant additional qualifications to render them 'advanced', and prevent those who do not hold the necessary credentials from holding themselves out as such, it seems clear that an additional form of intervention may be needed.

1.6.1. Accountability for practice

Denoting the ability to make and act upon decisions independently, and the responsibility to determine appropriate courses of action without prior authorisation, clinical autonomy is acknowledged as the essence of advanced nursing practice¹⁹⁷. It is also recognised as the discriminator that sets 'advanced nursing' apart from traditional nursing activities^{198,199,200}. Sitting alongside this is accountability, which is widely accepted as representing the essence of professional practice²⁰¹; namely, the requirement for practitioners to justify and take responsibility for their actions and omissions, including when outcomes are less favourable or where blame is to be apportioned. With accountability for practice no longer able to be passed on as the responsibility of doctors, and now forming the basis of their professional code²⁰², this compels nurses to

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¹⁹⁶ Dean E. Patients' deaths spark call for advanced practitioner regulation. Nursing Standard 2010;24(41):5

¹⁹⁷ Skar R. The meaning of autonomy in nursing practice. Journal of Clinical Nursing 2010:19:2662-2663

¹⁹⁸ McParland J, Scott PA, Arndt M, Dassen T, Gasull M, Lemonidou C, Valimaki M, Leino-Kilpi H. Autonomy and clinical practice 1: identifying areas of concern. British Journal of Nursing 2000;9:507-513

¹⁹⁹ MacDonald C. Nursing autonomy as relational. Nursing Ethics 2002;9:194-201

²⁰⁰ Skar R. The meaning of autonomy in nursing practice. Journal of Clinical Nursing 2010;19(15-16):2226-2234

²⁰¹ Walsh M. Nursing frontiers: accountability and the boundaries of care. Oxford: Butterworth-Heinemann 2000

²⁰² Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

acknowledge any limitations in their practice, act only when it is safe and in patients' best interests to do so, and be able to justify any, and all, decisions taken.

On the face of it, one could be forgiven for thinking that the practical application of this apparently straightforward concept would be uncomplicated. However, as events at Bristol Royal Infirmary have shown, this is an erroneous assumption, with findings from the related Inquiry chaired by Sir Ian Kennedy²⁰³ revealing systemic problems regarding organisational culture, and lack of clarity about where responsibility for decision-making lay. Of particular concern, were findings which revealed a culture in which confused accountability between clinicians and managers, lack of supervision and support for junior doctors when undertaking new procedures, inadequate standards for evaluating performance, and failure to put patients at the centre of care prevailed - to the detriment of patients. Admittedly, many of the problems that took place at Bristol Royal Infirmary were attributed to local working practices and individual decision-However, with The Kennedy Report making almost two hundred making. recommendations, at the heart of which lay the imperative for increased DH implementing a accountability, and the number of associated recommendations²⁰⁴, the implications for the wider healthcare team are evident.

Of heightened significance in the advanced nursing practice context, issues arising from *The Kennedy Report* have particular resonance, especially when considering the development of new roles and practices. Indeed, with those practitioners adopting such roles requiring additional support, supervision and monitoring, particularly in the early stages²⁰⁵, these findings are particularly pertinent and render it all the more pressing for regulatory processes to be robust, so that those whose competence levels have not been maintained can be

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²⁰³ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(i). London: HMSO. 2001

²⁰⁴ Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Cm 5363. London: DH. 2002

²⁰⁵ Scottish Executive. Framework for developing nursing roles. Edinburgh: Scottish Executive. 2005

supported, and, where appropriate, dealt with swiftly and effectively. In practice, this suggests that further work is needed to strengthen the regulation, education and training of advanced nurses, increase their opportunities for shared learning, and extend enhanced accountability and supervision arrangements to groups other than doctors, so that patients and the public can be reliably protected.

As things stand, responsibility for ensuring accountability for nursing practice, at all levels, resides in the NMC²⁰⁶. Contained within the professional 'code' and requiring nurses to be personally accountable for their practice and always to be able to justify their decisions, this duty applies to all nurses, irrespective of status, role or qualification. However, no additional regulatory requirements or imperatives have been put in place for those who have expanded the confines of their practice. This has left some commentators²⁰⁷ concerned that the current regulatory mechanisms are lacking to the extent that advanced nurses may be able to escape liability for their actions, for example by asserting team liability on the basis that they were not the sole contributors to the events in question, or by citing ignorance of the law²⁰⁸.

Denoting an unsatisfactory and, arguably, unacceptable state of affairs, it is submitted that this situation cannot be allowed to continue. As such, it is incumbent on those leading the nursing profession to ensure that those taking on new and advanced roles receive appropriate education, training, support and supervision, are clear surrounding the parameters of their practice, and are held suitably accountable for their actions and decisions taken in the performance of their duties. To be effective and consistent, it is asserted that change of the magnitude required requires intervention in the form of statutory regulation, and that less robust forms of regulation will not suffice.

²⁰⁶ Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

²⁰⁷ Dean E. Patients' deaths spark call for advanced practitioner regulation. Nursing Standard 2010;24(41):5

²⁰⁸ McGowan B, Long A. Am I covered to do this? The legal implications of expanding practice. Paediatric Nursing 2003;15(8):24-27

1.6.2. Learning beyond registration

To date, more than 670,000 nurses and midwives are registered with the NMC²⁰⁹. All are required to undertake continuing professional development (CPD) as a condition of ongoing registration, and to declare that associated requirements have been satisfied each time registration is renewed. However, although clearly referred to in statute²¹⁰ with CPD standards set out in related guidance²¹¹, no such provision has been made in relation to post-registration education, resulting in poorly standardised programmes with widespread variation in their content, scope, duration and quality.

Significant changes in the context in which post-registration learning takes place have also complicated matters. With professionally accredited awards perceived as having been devalued as a consequence of the general shift towards academic learning²¹², and the recognition given to 'accreditation of prior (and experiential) learning' (APL) having arguably been diluted, professional experience and on-the-job learning now seem to be less significant than they once were. Exacerbated by the demise of the 'National Boards', which performed a central role in assuring the standard of education and training necessary for admission to the Register²¹³, this has resulted in post-registration education suffering from the absence of an accreditation system that, despite its limitations, assured the transferability of qualifications by providing employers and practitioners with a common currency of nationally recognised courses and awards. Leading to a vacuum that has only been partially filled by the transfer of powers to the NMC²¹⁴ (and prior to this the UKCC²¹⁵), and with the role of the professional bodies in bridging this gap having yet to be properly established,

²⁰⁹ Nursing and Midwifery Council. Annual Fitness to Practise Report 2011-2012. London: HMSO. 2012

²¹⁰ Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

²¹¹ Nursing and Midwifery Council. The PREP Handbook. London: NMC. 2011

²¹² Department of Health. Post-registration development: A framework for planning, commissioning and delivering learning beyond registration for nurses and midwives. The report of a task group convened and chaired by the Chief Nursing Officer. London: DH. 2004

²¹³ JM Consulting Ltd. The regulation of nurses, midwives and health visitors: Report on a review of the Nurses, Midwives and Health Visitors Act 1997. Bristol: JM Consulting Ltd. 1998

²¹⁴ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

²¹⁵ Nurses, Midwives and Health Visitors Act 1992

this has left those nurses who wish to advance their practice doing so in a myriad of ways, with few controls and little, if any, standardisation.

Encompassing all forms of activity following initial qualification, postregistration learning is best described as falling into four main categories: ad hoc training in the form of study days that deliver mandatory updates such as those required for health and safety purposes; continuing professional development that is intended to update and refresh professional knowledge and skills, and maintain competence in current spheres of practice; formalised education and training associated with additional knowledge, skills and competencies to enable progression to more specialist or advanced activities; and generic programmes linked to activities such as research, leadership and management development²¹⁶. Intrinsically linked to the transition from student to accountable practitioner, and from 'knowledgeable doer' to accomplished clinician, learning from each of these categories is mutually inclusive, and acknowledges that learning can, and does, take place in the absence of formal training and, for the most part, goes hand in hand with education. However, with inconsistent terminology having left the meaning of important concepts to be inferred and imprecise definitions having left threshold standards yet to be determined, the development of post-registration learning has been hampered, leading to inequitable standards and unacceptable variations in care. This, in turn, has resulted in programmes of varying scope and duration, complicated by the temptation of organisations to compete in the labour market by pioneering new roles and developing new courses in the hope of attracting the most able recruits.

Suggested as a possible solution, the notion of a shared framework for interprofessional learning²¹⁷ seems to have attracted interest²¹⁸. Premised on the belief that healthcare professionals should learn together if they are to work

²¹⁶ Department of Health. Post-registration development: A framework for planning, commissioning and delivering learning beyond registration for nurses and midwives. The report of a task group convened and chaired by the Chief Nursing Officer. London: DH. 2004

²¹⁷ Department of Health. Developing a framework for health professional learning beyond registration. Leeds: DH. 2003

²¹⁸ Humphris D, Macleod Clark J. Shaping a vision for a 'New Generation' workforce. University of Southampton: Future Health Worker Project. 2002

together²¹⁹, the aim was that this approach would provide a more collaborative type of learning, and enable inter-professional divisions to be set aside^{220,221}. Influenced by a range of factors, including the Inquiries into the deaths of Victoria Climbié²²² and 'Baby P'²²³, *The NHS Plan*²²⁴, the clinical governance agenda²²⁵ and recommendations from the Bristol Royal Infirmary Inquiry²²⁶, these findings highlighted the need for consistency in developing knowledge, skills and attitudes, and for a broadened notion of competence to be developed.

Centred around linking CPD and post-registration learning to clinical outcomes, agreeing minimum levels of proficiency, accrediting academic and work-based learning, incorporating processes for re-registration and revalidation, and developing a framework in which credits could be transferred across the range of disciplines²²⁷, it was hoped that this approach would enable practitioners and employers to pursue career development in a more flexible way. However, with momentum lacking, and sceptics unconvinced regarding the benefits of placing so much emphasis on common studies, plans to advance this initiative, including proposals to position education for senior nurses alongside that offered to doctors²²⁸, were put on hold. Thus, despite support existing for shared interprofessional education, the result has been even greater diversity, with service planners and workforce commissioners continuing to implement a variety of initiatives based on local service needs.

²¹⁹ Department of Health. Working together - learning together: A framework for lifelong learning for the NHS. London: DH. 2001

²²⁰ McCallin A. Interdisciplinary practice - a matter of teamwork: an integrated literature review. Journal of Clinical Nursing 2001;10(4):419-28

²²¹ Barr H. New NHS, new collaboration, new agenda for education. Journal of Interprofessional Care 2002;14(1):81-86

²²² Laming H. The Victoria Climbié Inquiry. Report of an inquiry. London: HMSO. 2003

²²³ Haringey Local Safeguarding Children Board. Serious Case Review 'Child A'. 2008

Department of Health. The NHS Plan: A plan for investment, a plan for reform. London: HMSO. 2000

²²⁵ Department of Health. A first class service: quality in the new NHS. London: HMSO. 1998

²²⁶ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(i). London: HMSO. 2001

²²⁷ Department of Health. Learning for delivery: making connections between post qualification learning/continuing professional development and service planning. Leeds: DH. 2004

²²⁸ Glen S. Healthcare reforms: implications for the education and training of acute and critical care nurses. Postgraduate Medical Journal 2004;80:706-710

The extent to which this diversity in education and training has adversely affected the credibility of advanced nurses is something of a moot point. So, too, is the extent to which the associated plethora of new clinical roles and titles reflects the implied level of diversity. However, given that the calibre of practitioners is dependent on the quality of their education, and with assumptions invariably made on the basis of titular 'awards', this inevitably raises concerns surrounding the extent to which standards have been achieved, and expectations have been satisfied.

This issue also raises concerns regarding the extent to which patients are aware of, and can understand, the differences in the skill set and competencies of those treating them. With opinions ranging from those who view the creation of new roles as the domain of employers, to those who favour an overall framework within which job titles that would enable uniformity of experience, qualifications, competence and responsibility should sit, this has prompted discussion as to whether the acquisition of skills should assume priority over the titles of those performing them²²⁹. Nevertheless, with many practitioners reluctant to relinquish their titles, and new roles having yet to be fully established, it seems that a health service based on the talents of practitioners²³⁰ rather than their titles, may still be a long way off.

Given that the NHS is increasingly reliant on advanced nurses to meet the needs of patients, particularly those arising from gaps in the medical workforce, their future does not seem to be in doubt. However, what does seem to be in doubt is the quality of their training, with the lack of regulatory control over their adoption of associated titles questioning its validity. Accepting that the aim of healthcare regulation is to protect the public, including through the provision of appropriate education and prevention of the use of unauthorised titles, and acknowledging that the public is known to be reassured when treated by healthcare professionals with recognised titles²³¹, this makes arguments in

²²⁹ Department of Health. Liberating the talents: Helping Primary Care Trusts and nurses to deliver the NHS Plan. London: HMSO. 2002

²³⁰ Department of Health. A health service of all the talents: developing the NHS workforce. London: DH. 2000

²³¹ Council for Healthcare Regulatory Excellence. Protecting the public from unregistered practitioners: Tacking misuse of protected title. London: CHRE. 2010

favour of regulating post-registration practice and recognising and 'protecting' associated titles convincing.

1.6.2.1. Levels of practice

The idea that it is possible to distinguish different levels of post-registration practice has pervaded the professional literature for decades. So, too, has the assumption that where practitioners take on new roles and assume responsibility for tasks more demanding and complicated than their initial qualification, risks to patients increase. With debates focusing on whether such developments represent genuine advancement or a natural part of career development²³², the question that needs to be asked is whether, when areas of practice develop which pose different risks to patients and require new and distinct standards of proficiency to be safely performed, professional bodies recognise them and regulatory processes capture them²³³.

Intrinsic to this issue is the way in which post-registration qualifications are recorded, with those seeking to differentiate practitioners developed beyond initial registration looking to professional Registers for assistance²³⁴. Expecting to see the entries of those authorised to practise at an advanced level modified in some way to reflect the attainment of relevant post-registration qualifications, this would seem to be a logical assumption. However, given that threshold standards exist for initial registration only^{235,236}, and with parallel standards for post-registration practice aspirational rather than a statutory requirement, this assistance has not always been forthcoming, leaving formal registration limited to baseline awards with no associated mechanism by which to recognise post-registration achievements.

²³² Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

²³³ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

²³⁴ Council for Healthcare Regulatory Excellence. Health professional regulators' registers. Maximising their contribution to public protection and patient safety. London: CHRE. 2010

²³⁵ Nursing and Midwifery Council. Standards to support learning and assessment in practice. London: NMC. 2008

²³⁶ Nursing and Midwifery Council. Standards for pre-registration nursing education. London: NMC. 2010

Arguing against the need for such differentiation are those who consider the recognition of advanced practice not to be a regulatory matter, instead considering it to be a reflection of career development and, as such, falling within the scope of existing regulation^{237,238}. Considering it more appropriate for advanced practice to be governed by mechanisms other than statutory regulation, such as employer-led codes, this position holds that other provisions that render practitioners accountable for their practice, whatever its level or context, suffice, with any additional regulatory intervention perceived as being disproportionate and unnecessary. However, with variance existing in the strength of governance arrangements, and significant differences emerging in the way post-registration practice is monitored and utilised across the professions, it is possible that arguments in favour of an identifiable structure that clearly delineates the different standards and awards are more likely to prevail.

1.6.2.2. Recognising post-registration qualifications

Frequently described as complex, variable and unpredictable, the concept of post-registration practice does not easily lend itself to standardisation. Neither does its preparation, with programmes required to deliver competence, confidence and fitness for practice and purpose across the clinical spectrum. Nevertheless, given that one of the primary aims of regulation is to assure the quality of education through the approval of relevant qualifications, with the integrity of professional Registers as authoritative sources of information held on practitioners at stake, the need for a cohesive system that consistently recognises post-registration awards is clear.

Faced with a number of difficulties when seeking to differentiate levels of practice, and enable accredited educational programmes and competence to be identified and verified, regulators, such as the NMC, have a number of options

²³⁷ Council for Healthcare Regulatory Excellence. Advanced practice: policy summary. London: CHRE. 2009

²³⁸ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

available to them. First, they could specify threshold standards for a higher level of practice and the associated practical, experiential and cognitive outcomes that are required in relation to the relevant professional qualifications. With practitioners achieving these standards having the relevant awards recorded against their registration entries, such as by annotation, albeit on a voluntary basis given the absence of a statutory requirement to do so, it is possible that this approach could control the use of specialist titles and provide clarity and consistency.

Secondly, regulators could control entry to those types of practice perceived to be associated with a higher level of risk, and require further qualifications to be attained before practitioners would be permitted to take on the related responsibilities. With the registration entries of those satisfying the relevant requirements similarly modified to signify the completion of accredited post-registration learning and attainment of the relevant qualifications, this could limit advanced levels of practice to those who are appropriately qualified, and allow post-nominal qualifications to be externally verified.

Alternatively, regulators could record the required information by annotating Registers to reflect all forms of additional learning, including that which is not associated with a higher level of competence and, therefore, not associated with restrictions on practice. This would apply in situations such as those where higher educational qualifications have been undertaken as a means of personal development. On the other hand, regulators could adopt an entirely different stance by tying appointments to particular posts to specific qualifications²³⁹, thus limiting the extent to which these qualifications would be able to be utilised. However, given that the PSA's preferred position is to restrict the annotation of Registers to exceptional circumstances only²⁴⁰, described as those situations where this would be considered necessary to protect the public and when accompanied by a critical mass of registrants in order to constitute a proportionate regulatory response, these options may not be feasible.

²³⁹ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

²⁴⁰ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

Accordingly, the professions, including nursing, have found themselves having to look elsewhere in order to find an acceptable alternative solution.

1.6.2.2.1. The position within nursing

Unique in its approach, nursing has in the past benefited from the 'National Boards' - professional bodies established by statute²⁴¹ to assist with regulating and accrediting post-registration qualifications. However, with most of their remit having been transferred to Higher Education Institutions (HEIs), who retain individual accountability for the quality of their education and the standard of awards made in their name rather than externally being held to account, following the introduction of the NMC²⁴², concern has grown surrounding the degree of external scrutiny that is in place. This has led some commentators²⁴³ to question whether there is a place for additional oversight such as that provided by the professional (medical) Royal Colleges.

With a precedent for this additional degree of oversight having already been established in the relationship between the General Medical Council (GMC) and the various 'medical' Royal Colleges, support has grown for nursing to replicate this model. This support is premised on the assertion that the external scrutiny that this model could afford would control standards and access to post-registration qualifications, and provide a more integrated platform from which nursing could proceed. However, given that, in nursing, tensions frequently exist in the relationship between regulators and professional bodies, particularly in relation to the relationship between the NMC and the RCN, it is possible that this approach may not be feasible.

Seeking to address some of the difficulties associated with recognised postregistration qualifications, nursing has, in the past, sought to differentiate postregistration qualifications by classifying them as either 'registerable' or

²⁴² The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

²⁴¹ Nurses, Midwives and Health Visitors Act 1979

²⁴³ Department of Health. The national education and competence framework for advanced critical care practitioners. London: DH. 2008

'recordable'. However, although straightforward in principle, the practical application of this approach has been to create further difficulties, with the lack of clarification regarding mandatory 'recording' requirements further muddying the waters. Putting aside additional complications arising from the fact that, within nursing, specialist practice is already subject to a form of quasi-regulation in that the Specialist Practitioner Qualification (SPQ), which enables practice as a specialist community public health nurse, is voluntarily recordable on the Register^{244,245}, the issue that really needs to be addressed is how advanced level competence and related qualifications can best be recognised. Indeed, with the PSA²⁴⁶ confirming that nationally agreed and recognised standards are required for advanced level practice in order to support the provision of adequate governance arrangements, and looking to revalidation to provide an opportunity for regulatory bodies to identify high risk areas and focus their efforts where the risks are highest, intervention is clearly needed.

1.6.2.2.2. National Boards

Forming an integral part of the regulation that underpinned the creation of the UKCC in 1983²⁴⁷, the National Boards for Nursing, Midwifery and Health Visiting for Scotland²⁴⁸, England²⁴⁹, Northern Ireland²⁵⁰ and Wales²⁵¹ originally represented the statutory framework for nursing education. Implemented following the Briggs report on nursing²⁵², and tasked with a quality assurance function that included defining and monitoring the quality of courses and

²⁴⁴ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Article 5(2)(a)

²⁴⁵ Nursing and Midwifery Council. Standards of proficiency for specialist community public health nurses. London: NMC. 2004

²⁴⁶ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

²⁴⁷ Nurses, Midwives and Health Visitors Act 1979

²⁴⁸ The National Board for Nurses, Midwives and Health Visitors for Scotland Order 1993. Statutory Instrument 1993 No 637

²⁴⁹ The National Board for Nurses, Midwives and Health Visitors for England (Constitution and Administration) Order 1993. Statutory Instrument 1993 No 629

²⁵⁰ The National Board for Nurses, Midwives and Health Visitors for Northern Ireland (Constitution and Administration) Amendment Order (Northern Ireland) 1997. Statutory Instrument 1997 No 441

²⁵¹ The National Board for Nurses, Midwives and Health Visitors for Wales (Constitution and Administration) Order 1993. Statutory Instrument 1993 No 614

²⁵² Report of the Committee on Nursing (The Briggs Report). Cmnd 5115. London: HMSO. 1972

maintaining the training records of students undertaking them, their remit was both comprehensive and extensive. Incorporated within this remit was oversight of pre-registration programmes, recognition of post-registration qualifications, approval of training courses, provision of advice and guidance to local supervising authorities (LSAs) for midwives, holding or arranging examinations to satisfy registration criteria or enable the attainment of additional qualifications, and improving training methods within their respective jurisdictions.

Required to discharge their functions in accordance with rules pertinent to the constituent professions, and accountable to the Government from whom they derived much of their funding, the National Boards also played a central role in regulating educational quality and ensuring fitness to practice. However, although they were answerable to the UKCC whose requirements they had to satisfy, their success was largely reliant upon collaboration with the UKCC, rather than formal monitoring and accountability arrangements. As such, much was left to chance with the UKCC having little influence over the way in which the National Boards worked, unless they were failing in their duty to ensure that educational standards were being met.

Sitting structurally alongside the UKCC, which operated through a number of professional committees, the National Boards formed a key part of the regulatory infrastructure for approximately ten years. However, with changes in their structure and membership introduced in 1992²⁵³ creating difficulties in strategic decision-making, their integrity and impartiality were called into question. Exacerbating this situation was the fact that the National Boards themselves provided the majority of members to the UKCC, to whom they were accountable for significant aspects of their work, meaning that, in effect, they were responsible for monitoring themselves. As a result, their days were numbered, resulting in their impact and reign coming to an end in 2002, when the UKCC ceased to exist and its functions were transferred to the NMC²⁵⁴.

Responsible for overseeing the two categories of nursing award, namely registerable and recordable qualifications, with the former denoting primary

²⁵³ Nurses, Midwives and Health Visitors Act 1992

²⁵⁴ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253

registration associated with licensure to practice and the latter depicting secondary awards associated with programmes of training consolidated by appropriate experience, the National Boards met with reasonable success during their tenure. However, despite enabling reciprocal recognition of awards across the four countries, and a degree of commonality between the respective courses, the fact that there was no way of guaranteeing that the same standards had been consistently applied in the various jurisdictions meant that recordable qualifications became less valuable than initially intended. When added to the fact that nurses could choose whether or not to register recordable qualifications, given the absence of a statutory requirement to do so, this meant that their validity could not be relied upon. Also questioning the validity of these qualifications was the fact that, once recorded, they became a permanent entry on the Register, with no associated requirement for nurses periodically to demonstrate updated knowledge and competence. As such, the NMC had no power to remove from the Register those nurses who were deemed unfit to practise, other than by reinforcing sanctions arising from formal Fitness to Practise proceedings, such as the imposition of conditions on practice, suspension or erasure.

Unable to provide a universally acceptable framework to ensure the quality of transferable education, the National Boards also came under criticism for excessive bureaucracy associated with course approval processes and, in particular, the 'certificate-collecting' mentality that had reached its peak at the time of their demise²⁵⁵. Indeed, with the English National Board (ENB) alone having approved more than 400 separately titled post-registration courses²⁵⁶ at the time of its demise, with many offered in only a handful of academic institutions, criticism abounded that, despite indicating a level of achievement and enhanced knowledge in a particular speciality, these courses said nothing about the quality of practitioners and their ability to practise at a higher level. Admittedly, education is now more concerned with outcome standards rather than curricular inputs, and more aligned with ensuring fitness to practise than

²⁵⁵ JM Consulting Ltd. The regulation of nurses, midwives and health visitors: Report on a review of the Nurses, Midwives and Health Visitors Act 1997. Bristol: JM Consulting Ltd. 1998

²⁵⁶ Department of Health. Post-registration development: A framework for planning, commissioning and delivering learning beyond registration for nurses and midwives. The report of a task group convened and chaired by the Chief Nursing Officer. London: DH. 2004

course content. However, with remnants of the National Boards still evident, given that many nurses still practising acquired their post-registration qualifications under this regime, these weaknesses have yet to be fully eradicated.

With the advent of the NMC signalling the abolition of the National Boards and the transfer of responsibility for quality assurance back to the Council, a milestone was marked in nursing's history. With new bodies established in each country to take over the remaining statutory functions²⁵⁷, most notably *NHS Education for Scotland* (NES)²⁵⁸ in Scotland, this presented an opportunity to revisit course approval and accreditation processes, and provide the much-sought assurance that consistent standards would be set. However, despite being tasked with a remit that included the oversight of post-registration courses and qualifications, these bodies failed to implement an overarching structure of regulation that would enable transparency and national transferability, and instead favoured a more flexible approach in response to local service needs.

At the moment, only a limited number of post-registration qualifications require to be registered with the NMC. With few changes having been made to differentiate those having attained post-registration awards from those having achieved initial registration only, with the notable exception of independent nurse prescribing which is subject to specific legislation²⁵⁹, this means that practice has continued to advance but without reciprocal regulatory intervention. Given that regulatory intervention in the form of additional forms of statutory regulation will only be permitted in the event that public protection concerns or risks to patient safety cannot be met by existing safeguards²⁶⁰, it is possible that change may be more likely to come from professional bodies rather than from statutory regulation.

²⁵⁷ The Nursing and Midwifery (Transfer of Staff and Property etc.) Order 2002. Statutory Instrument 2002 No 923

²⁵⁸ The NHS Education for Scotland Order 2002. Statutory Instrument 2002 No 103

²⁵⁹ The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006. Statutory Instrument 2006 No 915

²⁶⁰ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. 2011

1.6.2.2.3. Professional bodies

Making the distinction between the roles of professional and regulatory bodies can sometimes be difficult, with perceived overlap in their status, function and authority sometimes making them easy to conflate²⁶¹. Existing primarily to protect the public by guaranteeing professional titles that reflect technical and ethical competence, regulatory bodies are responsible for agreeing minimum standards and CPD requirements, holding a single Register of practitioners who meet standards of training and practice, developing and promoting core curricula, accrediting courses as a means of regulating qualifications and training, and holding healthcare professionals accountable for their actions. With professional bodies, on the other hand, existing to protect the interests of individual professions, their role is largely an advisory one with most having a remit to set standards and issue guidance to members. However, with some also having a remit to represent and support members' interests, and others still providing a professional indemnity function, such as the RCN²⁶², the result can often be a confused picture that is sometimes described in terms of tension and disharmony.

Given that regulators have a remit to set the baseline and the standard below which practice must not fall, and professional bodies have a responsibility to raise the bar and encourage practitioners to achieve excellence in practice, their roles are clearly complementary. In some cases, they function independently of each other, balancing public and professional interests, with both maintaining effective relationships with HEIs in the interests of developing and maintaining standards. In others, they work alongside each other with responsibility for designing, accrediting, monitoring and reviewing educational programmes resting with one body, and the other having more of a quality assurance function, including assuring the processes by which awards are made.

However, given that the approaches taken by regulators to assure the quality of such activities vary in their scope and intensity, and the approaches taken by

²⁶¹ The UK Inter-Professional Group. Professional regulation: A position statement by the UK Inter-Professional Group. London: UKIPG. 2002

²⁶² Royal College of Nursing. Royal Charter. London: RCN. Amended 08 March 2012

professional bodies sometimes stray into regulatory territory, this can potentially muddy the waters leading to confusion, conflict and damage to professional credibility and reputation. This is a situation that was recently highlighted in the PSA's strategic review of the NMC²⁶³, with the NMC's relationship with the RCN singled out for particular attention. With the NMC having effectively been given a final opportunity to rectify its regulatory and governance processes, or risk having an external solution imposed upon it such as a merger with another healthcare regulator, it seems timely to revisit the approach that the NMC has taken to the regulation of advanced nursing practice, and consider the extent to which this affords the public the level of protection that it has the right to expect.

1.6.3. Do current regulatory processes suffice?

Acknowledged by the PSA as potentially posing a risk to the public in the event of training not adequately preparing practitioners to take on responsibilities not traditionally associated with their roles, advanced practice refers to a level of practice that is undertaken by those who have developed their skills to a high level, have a higher level of responsibility than their peers, and require less supervision²⁶⁴. Assumed to signify higher qualifications and experience, and thought to inspire greater levels of public confidence, it is widely associated with continuous professional development, education to Masters level or beyond, regular appraisal, robust clinical supervision and periodic revalidation checks to ensure continued fitness to practise. However, given that it is underpinned by non-standardised education and training, and with the profession failing to 'protect' through legal means the advanced nursing practice title, this situation has resulted in potentially inequitable standards of education, leading to questions being asked surrounding the adequacy of existing safeguards.

London: CHRE. 2009

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²⁶³ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

²⁶⁴ Council for Healthcare and Regulatory Excellence. Advanced practice: policy summary.

Seeking to address this imbalance and differentiate learning associated with, and beyond, initial registration, and the skills and experience required to apply them safely, the approach taken by nursing thus far has been to allocate tasks and competencies to first and post-registration status based on an assessment of the risk posed to patients. Associated with a presumed level of autonomy and authority commensurate with practitioners' level of seniority, it has been assumed that those tasks requiring greater levels of training and supervision carry a higher level of risk, and thus warrant post-registration status. However, with low-level and relatively low-risk interventions such as venepuncture and intravenous cannulation that were once restricted to experienced nurses, now recognised as registration-level tasks, and activities such as the administration of intravenous drugs now featuring in undergraduate curricula, it seems that this approach may no longer be suitable.

It is clear that the parameters of the original advanced nursing roles and interprofessional practice boundaries as depicted by Read and Roberts-Davis²⁶⁵ and Read *et al*²⁶⁶ have now been exceeded. Indeed, with trials of workplace change having shown traditional healthcare roles to be overly restrictive, and high-volume, repetitive tasks with low-level interpretive requirements such as ECG recording, defibrillation, endotracheal intubation, screening endoscopies and coronary angiograms, and operations such as cystoscopies, transurethral resections, cataract removals and lens implants to be suitable for non-doctors²⁶⁷, it could arguably be concluded that these demarcations no longer apply. When added to the fact that the array of political imperatives that have emerged in recent years have encouraged and, in some cases, compelled nurses to advance their practice, this presents a convincing argument for statutory regulation. So, too, does the fact that the statutory restrictions which have limited the scope of nursing practice have now been lifted, with the exception of termination of

²⁶⁵ Read S, Roberts-Davis M. Preparing Nurse Practitioners for the 21st Century. Realising specialist and advanced nursing practice: establishing the parameters of and identifying the competencies for Nurse Practitioner roles and evaluating programmes of preparation. University of Sheffield. 1998

²⁶⁶ Read S, Lloyd Jones M, Collins K, McDonnell A, Jones R, Doyal L, Cameron A, Masterson A, Dowling S, Vaughan B, Furlong S, Scholes J. Exploring new roles in practice (ENRIP). University of Sheffield, University of Bristol and Kings Fund. 2001

²⁶⁷ Cameron PA, Thompson DR. Changing the healthcare workforce. International Journal of Nursing Practice 2005;11:1-4

pregnancy²⁶⁸, which is currently under review, and certification of death²⁶⁹. When considered alongside the fact that other restrictions, such as ultrasound examination and echocardiography derive only from locally imposed rules, the scope of permissible nursing practice is almost endless.

Underpinning these developments is the regulatory process that ensures the fitness to practise of practitioners and the safety of patients. Central to this is the assurance of appropriate preparation for practice, and it is here that many of the concerns regarding advanced nursing are most evident. Of particular concern is the disparate array of non-standardised training programmes and post-registration curricula that now permeate the educational arena. Ranging from days, weeks or months at one end to several years at the other, and with some resulting in the conferring of university degrees, the effect of differently preparing nurses to arguably different levels has been to create the potential for double standards within both clinical care and the profession. With no nominated body to oversee and ratify the quality, content and duration of these programmes, and with accreditation and revalidation processes lacking the necessary rigour, the result has been to prepare advanced nurses inadequately for the responsibilities that await them. When aligned with claims of inadequate supervision, this lack of standardisation exposes patients to potentially inexperienced clinicians who may attempt to perform roles for which they are inappropriately qualified, rendering them vulnerable to unnecessary and unjustifiable risk.

With responsibility for addressing this situation and arriving at an appropriate resolution lying with the NMC, attention needs to focus on determining the standards that should reasonably be expected of advanced nurses, and the way in which they should be regulated. With momentum also gathering for an informed debate on the subject, and growing unrest with the status quo manifesting itself in high level discussions between policy makers and regulators^{270,271,272,273,274}, the key issue to be addressed is the extent to which

²⁶⁸ Abortion Act 1967 Ch 87

²⁶⁹ Births and Deaths Registration Act 1953 Part II

²⁷⁰ Council for Healthcare and Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

existing regulatory measures suffice, and the nature of additional measures that may be required. Essentially focused on the reliability and validity of educational programmes, the adequacy of measures by which to hold advanced nurses accountable, and the consistency of sanctions in the event of impaired fitness to practise, arguments largely centre on reducing the plethora of nursing roles and titles that have emerged, identifying the preferred means of registering advanced practitioners, and finding appropriate ways of standardising the qualifications and competencies required for registration. However, with uncertainty lingering regarding the extent to which additional regulation would strengthen public protection, and dissent existing regarding the preferred means by which to register such practitioners, an early resolution does not seem likely to be forthcoming.

1.7. A new regulatory framework for advanced nursing practice?

It is clear that the delivery of healthcare has changed such that the balance of 'power' now lies less with medicine and more with nursing. Also changed is the workforce model, with new ways of working having opened the door to alternative care pathways, and the abrogation of clinical tasks from one discipline to another having paved the way for the talents of all healthcare professionals to be liberated²⁷⁵. Given this backdrop, the onus is on regulators to protect the public effectively and ensure the quality of practitioners when roles have expanded and alternative systems are in place. Of particular relevance to nurses, given that most new ways of working involve them in some

²⁷¹ Department of Health. Front line care: Report by the Prime Minister's Commission on the Future of Nursing and Midwifery in England. London: DH. 2010

²⁷² Santry C. Advanced nursing practice regulation needs 'measured debate' says NMC. 27 January 2010

http://www.nursingtimes.net/whats-new-in-nursing/management/advanced-nursing-practice-regulation-needs-measured-debate-says-nmc/5010863.article (Last accessed 02.06.2011)

²⁷³ Ford S. NMC welcomes mandate to regulate advanced nursing roles. 2 March 2010 http://www.nursingtimes.net/whats-new-in-nursing/pms-commission/nmc-welcomes-mandate-to-regulate-advanced-nursing-roles/5012125.article (Last accessed 15.05.2011)

²⁷⁴ Santry C. Government unconvinced by advanced nurse regulation. 22 February 2011 http://www.nursingtimes.net/nursing-practice/clinical-specialisms/public-health/government-unconvinced-by-advanced-nurse-regulation/5025942.article (Last accessed 03.09.2011)

²⁷⁵ Department of Health. Liberating the NHS: Developing the healthcare workforce. London: DH. 2010

way, and the fact that few changes have been made to the NMC's processes in recent years, despite the myriad of developments that have engulfed the profession, there is growing support for the view that the current system for regulating nurses is unfit for practice and is failing in its purpose^{276,277,278,279}.

With little provision having been made for those nurses choosing to advance their practice beyond conventional boundaries, the NMC has come under increasing pressure to take decisive and responsive action, and provide strategic direction and leadership. Responsible for ensuring that its regulatory processes reflect the reality of modern healthcare and take account of related developments, a central issue that needs to be addressed is the extent to which advanced nurses represent the face of modern nursing, and whether the associated regulatory processes have kept up to date with changes in their practice. With lack of action considered by some to be synonymous with failure to grasp the magnitude of the associated risks, and, therefore, failure to protect the public's interests, the NMC is in the unenviable position of being forced into taking action as a result of peer and political pressure, rather than doing so of its own volition. Included among the advocates for change, and providing the peer pressure, are those^{280,281,282} who perceive that the risks associated with advanced nursing practice have increased exponentially, given the absence of a regulatory ceiling on the scope of permissible advanced nursing practice.

Underpinning this situation is the question of whether advanced nurses are traditional nurses, albeit with an expanded remit to their practice, a distinct

 $^{^{276}}$ Council for Healthcare Regulatory Excellence. Special report to the Minister of State for Health

Services on the Nursing and Midwifery Council. London: CHRE. 2008

²⁷⁷ Council for Healthcare Regulatory Excellence. Fitness to practise audit report. Audit of health professional regulatory bodies' initial decisions. London: CHRE. 2011

²⁷⁸ Council for Healthcare Regulatory Excellence. Audit of the Nursing and Midwifery Council's initial stages fitness to practise process. London: CHRE. 2011

²⁷⁹ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

²⁸⁰ Castledine G. Nurse who took on responsibilities beyond her competence. British Journal of Nursing 2004;13(6):297

²⁸¹ Beesley J. Much care needed over advanced practitioner roles. Health Estate: Journal of the Institute of Healthcare Engineering and Estate Management. July 2005

²⁸² Shannon C. Doctors object to a wider role for surgical care practitioners. British Medical Journal 2005;330(7500):1103

breed of practitioner able to be differentiated from their more traditional colleagues by virtue of their enhanced knowledge base and educational underpinning, an elite group of super-nurses in a specialist subdivision of nursing, or a new breed of quasi-doctor. Working on the basis that advanced nurses are performing a more medical role that increasingly involves the more sophisticated and technical aspects of care, it seems reasonable to proceed on the basis that they are likely to be considered as a discrete and more specialised group of (nurse) practitioner. It also seems reasonable to proceed on the basis that nurses working at this level will be held accountable to a higher standard than that of their more traditional counterparts, presumably that of their medical peers given that most, if not all, aspects of their advanced roles derive However, given that there are currently no standardised from medicine. curricula and no formal mechanisms by which to distinguish those nurses professing to practise at an advanced level from those legitimately authorised to do so, and no clear mechanisms through which they will be held to account, the extent to which effective regulation can be said to be in place is questionable.

Also of concern are the parameters of permissible nursing practice, given that there are currently no professional restrictions on the range and scope of advanced nursing interventions, and any self-imposed limitations derive only from individual interpretations of the professional 'code'²⁸³, which dictates competence and confidence as the essential prerequisites. When considered alongside the fact that the few remaining statutory restrictions on nursing practice are likely to be lifted in the years to come, and the pressure on organisations to reduce and further refine the clinical workforce is set to continue, the enormity of the problem is apparent. Complicated by the fact that some nurses have taken on roles for which they have been inadequately prepared²⁸⁴, are practising beyond their scope or competence level²⁸⁵, are illequipped to deal with the consequences of their actions²⁸⁶, and have accepted

²⁸³ Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

²⁸⁴ Castledine G. Practice nurse who expanded her role without appropriate training. British Journal of Nursing 2005;14(21):1141

²⁸⁵ Bostock N, Lepper J. Nurses working beyond competence. GP Online. December 14, 2007 http://www.gponline.com/News/article/772906/Nurses-working-beyond-competence/ (Last accessed 06.09.2010)

²⁸⁶ Kent K. Warning: nurses at work. Daily Mail (London), Mail Online. November 14, 2006

responsibilities that lie outwith the bounds of their legitimate authority²⁸⁷, this casts doubts upon the adequacy of existing safeguards, and questions the extent to which patients are appropriately protected.

Assuming that the day will inevitably come when an increasingly questioning public will become aware of this situation, it is more than likely that they will seek answers regarding the competence and credibility of those practitioners attending upon them. It is also likely that they will seek assurance from regulators regarding the eligibility of nurses to practice in an advanced way. As such, it stands to reason that they will be unlikely to accept excuses for mistakes or substandard care from potentially incompetent practitioners and, instead, demand evidence of ability and accountability. With the current system unable to respond to such demands, and not holding advanced nurses formally accountable for their actions, this means that intervention is clearly warranted.

At the moment, any nurse who is able to demonstrate training and learning beyond initial registration, irrespective of its duration, content, level or quality, can, at least theoretically, hold themselves out as being 'advanced'. This creates the legitimate expectation that they possess a higher level of skill and competence. Potentially compromising the credibility of nursing and belittling the efforts of those who have satisfactorily completed acceptable levels of post-registration education, as defined by existing professional parameters, this situation is likely to lead to confusion and loss of confidence on the part of patients and the public, who will almost certainly expect a more expert level of care from those practitioners purporting to be 'advanced'.

Also problematic is the use of potentially misleading titles, many of which have been self-styled and self-appointed, leaving patients unclear of the skill set, competence and, in some cases, the discipline, of their treating clinicians. Linked with the possibility that consent obtained under such circumstances could potentially be invalidated, given that it may have been secured by someone

http://www.dailymail.co.uk/health/article-416299/Warning-Nurses-work.html (Last accessed 15.08.2008)

²⁸⁷ Snow T. Nurses urged to resist prescribing requests outside their competence. Nursing Standard 2008;22(20):10

unaware of and, therefore, unable to explain and disclose the relevant risks, this presents serious ethical and legal problems. When considered against the fact that the nursing profession has yet to 'protect' through legal means the 'Advanced Nurse' title with 'Registered Nurse' remaining the only legally protected nursing title²⁸⁸, there is currently no formal mechanism that would prevent those practitioners without the relevant qualifications from assigning themselves advanced nursing titles, such as CNS, NP, Advanced Nurse Practitioner or Consultant Nurse.

With the current system also rendering patients unable clearly to identify the level at which nurses are practising, and titles serving to mislead rather than clarify the situation, this leaves them potentially vulnerable to exploitation and substandard care. On this basis, it is submitted that a new regulatory framework for advanced nursing is not only warranted, but is overdue.

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²⁸⁸ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Article 6(2) and Article 44

Chapter 2

2. Modern advanced nursing practice: the emergence of new clinical roles

Although originally considered as denoting the acquisition of clinical tasks and the adoption of piecemeal extensions to practice^{289,290,291}, the concept of advanced nursing has evolved significantly over the years. Indeed, such has been the pace of change that it is now a far more encompassing concept, and one that is recognised as incorporating a wide range of functions once considered to be medical. Included within these developments is a range of 'hybrid' roles, such as those that were originally implemented to cover hospital care at night when junior doctors were scarce^{292,293}, and completely new roles that have been developed in response to clinical and service needs^{294,295,296}.

Although a number of hybrid roles have evolved, with each asserting to bridge a gap in care, usually in response to medical staff shortages, some have been of transient duration, having been implemented in response to local service needs. Others have been more enduring, and have retained a place in at least some clinical teams. Others still, most notably those who perform a quasi-medical role, have had a much higher profile, and are set to retain their place within the modern healthcare system.

²⁹⁶ Cooper S, Grant J. New and emerging roles in out of hospital emergency care: A review of the international literature. International Emergency Nursing 2009;17:90-98

²⁸⁹ Daly WM, Carnwell R. Nursing roles and levels of practice: a framework for differentiating between elementary, specialist and advancing nursing practice. Journal of Clinical Nursing 2003;12(2):158-167

²⁹⁰ Minchin A, Wensley M. The medical nurse practitioner's role in early stroke recognition. Nursing Times 2003;99:33-35

²⁹¹ Lockhart K. Presenting a framework for developing nursing roles in Scotland. Journal of Research in Nursing 2005:10(1):7-25

²⁹² Jones AM. Changes in Practice at the Nurse/Doctor Interface. Journal of Clinical Nursing 2003;12(1):124-131

²⁹³ Department of Health. The implementation and impact of Hospital at Night pilot projects. An evaluation report. Leeds: DH. 2005

²⁹⁴ Armitage A, Shepherd S. A new professional in the healthcare workforce: role, training, assessment and regulation. Clinical Medicine 2005;5(4):311-314

²⁹⁵ Martin S, Purkayastha S, Massey R, Paraskeva P, Tekkis P, Kneebone R, Darzi A. The Surgical Care Practitioner: A feasible alternative. Results of a prospective 4-year audit at St Mary's Hospital Trust, London. Annals of Royal College of Surgeons of England 2007;89(1):30-35

Although different, each of these roles is similar in that they are all bound by the expectation of a higher level of competence and skill. They are also similar in that those practising them perform an autonomous role that is considered to be associated with genuinely advanced practice. This is in contrast to those roles that are associated with expansions to nursing practice which, no matter how extensive, do not always constitute a new clinical role.

Associated with the expectation of higher level of competence is the assumption that the risks posed to patients are greater when these roles are performed by nurses, rather than doctors. Also binding these roles together are difficulties in identifying the skill set that renders their practitioners unique. This is particularly the case, given that there is currently no formal means by which the credentials of those nurses practising in an advanced way may be differentiated from those who wish to practise in a more traditional way.

Although a number of examples could have been presented to illustrate the problems that are associated with new clinical roles, four new roles have been singled out for particular attention. These roles have been selected on the basis that they are relatively well-established, and each is associated with a specific regulatory issue that needs to be addressed. Central to these issues are the lack of a 'protected' title, lack of accredited standards of education and proficiency, and lack of accountability for a higher level of practice. So, too, is the fact that it is possible for any nurse who has undertaken training following registration to purport to be advanced when they are, in fact, not suitably qualified, leaving patients at risk of being treated by those who have not been suitably trained, and potentially exposed to double standards in care.

Although not insurmountable, the NMC's failure to address these weaknesses thus far has meant that, in practice, patients and the public have no means of verifying the qualifications or credentials of those nurses who attend upon them. They also have no way of validating any associated claims of competence or expert knowledge that those caring for them may purport to have. As such, they are dependent upon the integrity of individual practitioners to undertake only those procedures they are competent to perform, be able to recognise the limits

of their competence and skill, and know when, how and from whom to seek help.

However, although problematic, precedent does exist that would enable these roles to be more clearly identified, and the associated standards to be more clearly defined. With midwives - considered by many informally to be the original advanced nurses - already recognised as a separate profession by the Nursing and Midwifery Council (NMC), it is possible that change of the required magnitude could be implemented within the current regulatory system. In fact, it is asserted that the changes that are required could be introduced with little effort on the part of the NMC, thus allowing it to deliver upon its core regulatory duties, and protect the public from nurses *at all levels*. Recognising the precedent that midwifery has set, and the regulatory issues that each of these new roles presents, it is hoped that those responsible for leading the NMC, and those who are in positions of influence, will be convinced by the arguments presented which assert that the time has come for nursing's regulatory framework to change.

2.1. The basis for change

Underpinning the creation of all new clinical roles are initiatives aimed at modernising medical careers and improving the conditions for doctors in training. Central among these initiatives are the Calman Reports^{297,298} and the European Working Time Directive (EWTD)²⁹⁹, both of which have contributed to the introduction of shift patterns for doctors, and to changes in the way in which their training is delivered. In practice, this has led to difficulties in recruiting sufficient numbers of doctors to fill medical staffing rotas, meaning that workforce planners have had to look beyond medicine to fill the gaps in care that doctors are no longer able to provide.

²⁹⁷ NHS Management Executive. Junior Doctors: the new deal. London: HMSO. 1991

²⁹⁸ Department of Health. Hospital doctors: Training for the future. The report of the working group on specialist medical training (The Calman Report). London: HMSO. 1993

²⁹⁹ The Working Time Regulations 1998. Statutory Instrument 1998 No 1833 amended by Statutory Instrument 2003/1684. The Working Time (Amendment) Regulations 2003 No 1684

Featuring centrally among the non-medical professionals to fill these gaps in care are nurses, who have seized upon the opportunities that these initiatives have afforded. In so doing, and in demonstrating their ability to practise safely outside of traditional boundaries, this has forced the public to view them in a more discerning light, and recognise them as intellectual and capable professionals rather than clinical assistants serving in ancillary roles. In fact, such has been the extent of the opportunities offered to nurses by the Calman Reports and the EWTD that, in some cases, this has led to them adopting completely new clinical roles and to new ways of working in healthcare.

Supported by the DH through its Changing Workforce Programme³⁰⁰, and underpinned by The NHS Plan³⁰¹, the creation of these new roles has opened the floodgates for expanded clinical nursing practice. This has, in turn, paved the way for nurses to exercise clinical judgement, make autonomous decisions and manage complete episodes of care, and, as such, has created a new generation of nurse capable of delivering "the right care in the right place at the right time" 302,303. Underpinning this new generation of nurse is the dispelling of the widely held belief that doctors are the sole practitioners with the legal 'right' to independently assess, diagnose and treat patients, and acknowledgement of the fact that other practitioners, most notably nurses, are 'legally entitled' to practice in this way³⁰⁴. Also dispelled is the mistaken belief that most procedures require a medical degree to be skilfully performed, as evidenced by the increasing number of non-medical healthcare professionals, including nurses, who now regularly perform a range of traditionally medical interventions.

Nevertheless, despite this 'evidence', critics, mainly medical, continue to question the credibility of non-medical practitioners such as nurses, and, in particular, their suitability and eligibility to perform advanced clinical roles.

³⁰⁰ Department of Health. Changing workforce programme: New ways of working in healthcare. London: HMSO. 2002

³⁰¹ Department of Health. The NHS Plan: A plan for investment, a plan for reform. London: HMSO. 2000

³⁰² Department of Health. Delivering the NHS Plan: next steps on investment, next steps on reform. London: HMSO. 2002. p36

³⁰³ Scottish Executive. Partnership for Care: Scotland's Health. White Paper. Edinburgh: Scottish Executive. 2003. p17

³⁰⁴ Department of Health and Royal College of Nursing. Freedom to practise: dispelling the myths. London: HMSO. 2003

Featuring centrally among these criticisms are concerns that point to lack of professional status, lack of educational preparation, and specialisation into 'technician status' rather than 'autonomous professional' - all of which are claimed to represent an inadequate foundation and poor substitute for medical intervention^{305,306,307,308}. Also central to these concerns is the belief that, while nurses and other non-medical professionals may become competent in performing certain interventions, this does not necessarily equip them with the ability to deal with the consequences of their actions, meaning that they will often still be reliant on doctors for guidance and instruction.

If one accepts this premise, this implies that nurses and other non-medical professionals who have chosen to perform these new roles would not be autonomous practitioners, but would instead be acting in a subservient role to doctors, albeit in a glorified form. This suggests that, although the nature and scope of their practice may have developed such that it is considered to be 'advanced', the associated increase in their accountability may not have transferred. If so, it follows that these nurses could potentially abdicate responsibility for their actions, thus belittling their status as autonomous practitioners, and leaving patients unsure of their credibility.

Sitting alongside this possibility is the belief held by some medical practitioners^{309,310}, that by expanding opportunities to non-medical professionals, pressure may be increased on the finite clinical resources that are available to junior doctors. Exacerbating this concern is the reduction in the number of training hours that doctors are now required to complete in order to be eligible for consultant posts, as necessitated by the introduction of the

³⁰⁵ Murray WJG. Nurses in surgery - opportunity or threat? A personal view. Journal of the Royal College of Surgeons of Edinburgh 1998;43:372-373

³⁰⁶ Newton P. Care practitioner plan 'poses safety threat'. BMA news 2005; Saturday November 12:1

³⁰⁷ Swarbrick E, Harnden S, Hodson R, Vance M, Bottrill P, Elliott D, Hayward M, Panting G. Non-medical endoscopists. A report of the working party of the British Society of Gastroenterology. British Society of Gastroenterology. London 2005

³⁰⁸ Pritchard L. BMA alarm over new non-medic role. BMA news 2006; Saturday February 11:1

³⁰⁹ Murray WJG. Nurses in surgery - opportunity or threat? A personal view. Journal of the Royal College of Surgeons of Edinburgh 1998;43:372-373

³¹⁰ Pritchard L. BMA alarm over new non-medic role. BMA news 2006; Saturday February 11:1

Modernising Medical Careers³¹¹ initiative. This is most notable in the case of trainee surgeons, who rely upon hands-on experience, exposure to individual teaching and supervision, and the development of manual dexterity and real-time decision-making skills, in order to learn their craft³¹². This has, in turn, led to anxiety among doctors that the quality of their training will be compromised, and to concerns that, in 'permitting' non-medical clinicians to take up the clinical gauntlet, this has granted them clinical authority through the back door without the necessary grounding in traditional medical education.

Despite this controversy, nursing leaders have forged ahead, intent on creating a clinical career structure able to deliver a workforce capable of working in a variety of roles in both hospital and community settings. In adopting Modernising Nursing Careers (MNC)³¹³ as their vehicle for change, the approach taken by these leaders has been to select a competency-based framework that values leadership potential as well as practical expertise, and educational ability as well as clinical acumen. With this approach also viewed as providing the basis for a more engaged profession to take the lead in managing local health services, the intention was that this would provide the basis for a more informed public to understand and appreciate the range of services that nurses can deliver.

Now firmly embedded in practice, and recognised as the basis for all clinical nursing developments, the effect of this framework has been to encourage nurses to maximise their skill set by progressing up, through and across specialties by climbing a ladder of responsibility through a so-called 'skills escalator'³¹⁴. In so doing, this has provided them with a robust platform from which to progress, and the confidence with which to take on more advanced responsibilities. Not only this, but by embedding competence rather than qualification as the currency for movement, and ability rather than certification

³¹¹ Department of Health. Modernising Medical Careers: The next steps. The future shape of foundation, specialist and general practice training programmes. London: HMSO. 2004

Mickute Z. Surgical training: what has changed? Annals of the Royal College of Surgeons of England (Supplement) 2009;91:56-59

³¹³ Department of Health. Modernising nursing careers: setting the direction. London: HMSO. 2006

³¹⁴ Department of Health. Working together, learning together - a framework for lifelong learning in the NHS. London: HMSO. 2001

as the route to advancement, MNC has created a future in which, at least theoretically, there is no ceiling on the scope of permissible nursing practice, and no limit on the range of interventions that nurses can perform.

2.2. The modern clinical team

With the balance of 'power'³¹⁵ thus shifted, such that it now lies less with medicine and more with nursing, there is little to stop those nurses who wish to develop their practice from doing so. However, while commendable in enabling nurses to practise to their full potential³¹⁶, the risks associated with these initiatives and the plethora of new advanced nursing roles that have emerged are concerning. Indeed, with anecdotal evidence suggesting that many of these roles have been implemented with no or inadequate preparation, little, if any, risk assessment, and no real understanding of the long term implications for clinicians or patients, this situation is alarming. When added to the fact that, in some cases, organisational pressures have overtaken training, outcomes have overtaken processes, posts have been established with little consideration given to the associated responsibilities, and little control has been exercised over the allocation of job titles, this means that confusion and uncertainty have prevailed.

In practice, the lack of control over the associated array of advanced nursing titles to have adorned the workplace is particularly problematic. Indeed, the reality is that many of the titles that have been adopted reflect local workforce solutions and use terminology that is aimed at attracting the most high calibre applicants, rather than following nationally recognised nomenclature. This has resulted in the clinical arena being flooded with a range of practitioners that are known by titles that do not clearly depict the roles they are performing, or the level of education or practice that underpins them^{317,318}.

³¹⁵ Department of Health. Shifting the balance of power within the NHS: securing delivery. London: HMSO. 2001

Department of Health. Liberating the talents: Helping Primary Care Trusts and nurses to deliver the NHS Plan. London: HMSO. 2002

³¹⁷ Warner J. A plethora of job titles just serves to confuse our patients. Nursing Times 2011;107(27):11

When one considers that those appointed to these posts comprise a spectrum of individuals ranging from the risk-averse to the reckless, and from the ignorant to the informed, the potential for harm is clear. Nevertheless, despite this, policy-makers have forged ahead, apparently working under the assumption that the public is welcoming of an enhanced relationship with non-medical clinicians, and doctors are accepting of this new regimen. In reality, however, it seems that this assumption may, in fact, be erroneous, given that many patients are unknowing participants³¹⁹, and many doctors are unwilling observers³²⁰ who object to what they perceive as destabilisation of their power base and undermining of their clinical authority.

As an inevitable product of healthcare modernisation and system redesign, these new ways of working are set to feature centrally in modern healthcare. So, too, are those new clinical roles which challenge inter-professional boundaries, particularly between nursing and medicine, and blur traditional role demarcations³²¹. However, given that there is no recognised regulatory framework for advanced nursing practice, and no regulatory requirement to follow standardised curricula or programmes of education when developing new roles, this has led to variation in the standards of preparation for advanced nurse practitioners, resulting in an array of titles that do not always reflect the experience or education of those adopting them. As a consequence, this has led to the situation being created in which patients are provided with variable levels of care, and in which some practitioners are ill-prepared for the roles that await them.

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³¹⁸ Royal College of Nursing. Advanced nurse practitioners: An RCN guide to advanced nursing practice, advanced nurse practitioners and programme accreditation. London: RCN. 2012 (Revised)

³¹⁹ Hall C. Nurse suspended after 'taking out man's appendix'. The Independent Friday 13 January 1995

³²⁰ Shannon C. Doctors object to a wider role for Surgical Care Practitioners. British Medical Journal 2005;330(7500):1103

³²¹ Hyde P, McBride A, Young R, Walshe K. Role redesign: new ways of working in the NHS. Personnel Review 2006;34(6):697-712

2.3. A proliferation of roles

Featuring among the more enduring advanced nursing roles to have emerged in recent years, those of Clinical Nurse Specialist, Nurse Practitioner and Consultant Nurse have been the most prominent. However, although acknowledged as signifying a higher level of practice, only the consultant roles have been developed in a structured way³²², with the others emerging in the absence of national guidance. More recently, initiatives aimed at maximising the contribution of nurses by combining their skills with those of other healthcare professionals, or by pushing the limits of their competence such that their roles are now more closely aligned with other professions, have also come to fruition, resulting in the emergence of completely new roles that do not fit comfortably within existing professional boundaries³²³. Filled by new or existing staff on completion of appropriate education and training, and focused on the assessment, diagnosis and treatment of patients with often unscheduled healthcare needs, these roles complicate the picture by adding a new and, as yet, uncharted clinical dimension.

Viewed as offering an alternative to the traditional healthcare professions, these new 'nursing' roles cover a variety of domains. Ranging from Physician Assistants³²⁴ on the one hand, to Surgical Care Practitioners³²⁵, who in some cases act as First Surgical Assistants on the other, and to Emergency Care Practitioners³²⁶ and Immediate Care Practitioners³²⁷ at the far end of the spectrum, their aim is to increase capacity by ensuring that patients receive timely care, in an appropriate location, from suitably qualified

³²² Department of Health. Health Service Circular 1999/217: Nurse, Midwife and Health Visitor Consultants: Establishing Posts and Making Appointments. London: HMSO. 1999

³²³ Department of Health. Changing workforce programme: New ways of working in healthcare. London: HMSO. 2002

³²⁴ Department of Health. The competence and curriculum framework for the Physician Assistant. London: HMSO. 2006

³²⁵ Department of Health. The curriculum framework for the Surgical Care Practitioner. London: HMSO. 2006

³²⁶ Department of Health. Taking healthcare to the patients; transforming NHS ambulance services. London: HMSO. 2005

³²⁷ British Medical Association. The future healthcare workforce. Health Policy and Economic Research Unit Discussion paper No 9. London: BMA. 2002:9

practitioners^{328,329}. However, with many roles having been implemented in the absence of a robust risk assessment, and with consensus having yet to be reached regarding where they sit in the portfolio of professions or on the 'continuum of care', their impact has not always been fully realised, and their potential has not always been fully achieved.

In practice, although the role that these practitioners can play in the healthcare team and their potential clinical contribution is not in doubt, issues surrounding their governance and regulation have caused particular problems. As has already been intimated, central among these problems is the lack of a 'protected' title and the absence of defined educational standards, both of which have had led to difficulties in terms of their identity. Included within these difficulties are the potential for patients to mistake these practitioners for doctors by virtue of their skill set and the role they perform. With the absence of the relevant regulatory safeguards meaning that anyone purporting to hold these roles could pass themselves off as such, with nothing in the way of regulatory sanctions able to be applied, this means that the extent to which patients are protected from these practitioners is doubtful.

With ambiguity surrounding the parameters of their practice, and multiple reporting arrangements complicating their governance, the place of these new practitioners within the healthcare team is often unclear³³⁰. Indeed, in some cases, it has not certain whether their roles are more associated with 'advanced nursing practice', or are more aligned with medicine^{331,332}. Complicating this situation is the fact that, while each of these roles brings a new clinical opportunity for nurses, each also presents a regulatory challenge, given that the

³²⁸ Department of Health. Delivering the NHS Plan: next steps on investment, next steps on reform. London: HMSO. 2002

³²⁹ Scottish Executive. Partnership for Care: Scotland's Health. White Paper. Edinburgh: Scottish Executive. 2003.

³³⁰ Lowe G, Plummer V, O'Brien AP, Boyd L. Time to clarify - the value of advanced practice nursing roles in health care. Journal of Advanced Nursing 2012;68(3):677-685

³³¹ Venning P, Durie A, Roland M, Roberts C, Leese B. Randomised controlled trial comparing cost effectiveness of general practitioners and nurse practitioners in primary care. British Medical Journal 2000;320(7241):1048-1053

Horrocks S, Anderson E, Salisbury C. Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. British Medical Journal 2002;324(7341):819-823

underpinning regulatory framework has not kept abreast of developments. This is particularly the position in the case of roles such as that of the Emergency Care Practitioner (ECP), considered by some³³³ to represent the original 'hybrid' role and to pose some of the most significant regulatory challenges.

In the early days, when 'new ways of working' were first conceived, the regulation of new clinical roles did not appear to be contentious. Indeed, when new clinical roles were first discussed, those conversations that involved regulation in any way tended to focus on by whom practitioners would be regulated, rather than if they would be regulated, with the assumption being that statutory regulation would, in some way, be afforded to them. retrospect, this assumption was naïve, in that it did not acknowledge the complexity of the regulatory issues that were involved, nor did it anticipate or make allowances for any changes in healthcare policy. As a result, the situation has emerged in which those practitioners who have chosen to perform new clinical roles have found themselves in an unenviable situation, with those regulatory frameworks that do exist having failed to develop in tandem with clinical developments, and current healthcare policy prohibiting the extension of statutory regulation to new groups except in compelling circumstances. practice, this means some new roles have been left with no form of statutory regulation, whereas others have been left to navigate their way through existing forms of regulation, in the hope that a solution for the advanced element to their practice can be found.

Typically originating from one clinical discipline, but incorporating additional training and education associated with another, those practitioners who undertake new clinical roles generally describe them as being rewarding, stimulating and challenging, and derive particular satisfaction from the high level of patient contact³³⁴. They also derive satisfaction from the increased autonomy and clinical 'freedom' that these roles afford, and from the sense of

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³³³ Mason S, Coleman P, O'Keefe C, Ratcliffe J, Nicholl J. The evolution of the emergency care practitioner role in England: experiences and impact. Emergency Medicine Journal 2006;23(6):435-439

³³⁴ Cooper S, O'Carroll J, Jenkin A, Badger B. Collaborative practices in unscheduled emergency care. The role and impact of the Emergency Care Practitioner (ECP). Plymouth: University of Plymouth. 2006

achievement they confer^{335,336}. However, with evidence^{337,338} also suggesting that, in some cases, these roles can be professionally isolating, given that practitioners 'belong' to neither one professional group nor the other, and pointing to confusion of identity and accountability as being commonplace, it is clear that regulatory intervention is needed.

Also signifying the need for intervention are issues associated with the lack of a 'protected' title. These issues are of particular significance, on the basis that, in the absence of a regulated title, patients and the public are not able to be reliably protected from those practitioners who have not undergone the requisite training, but who, nevertheless, wish to hold themselves out as practising at an advanced level. Issues associated with the absence of defined educational standards also signify the need for intervention, on the basis that the current system leaves patients at risk of receiving a lower standard of care from those who have completed non-standardised training regimens. In the case of some new roles, most notably the 'hybrid' roles, the regulatory issues are more widespread and relate to two regulatory masters, thus leading to potential difficulties when seeking to apply regulatory codes. In other cases, the issues centre on roles having no form of statutory regulation at all, leaving those practitioners who are caught by this 'weakness' potentially prevented from practising autonomously, and precluded from being able to prescribe medicines independently.

 $^{^{335}}$ Department of Health. Freedom for ambulance staff to deliver healthcare tailored to patients' needs. London: DH. 2004

³³⁶ Mason S, Coleman P, O'Keefe C, Ratcliffe J, Nicholl J. The evolution of the emergency care practitioner role in England: experiences and impact. Emergency Medicine Journal 2006;23(6):435-439

³³⁷ Service Development Organisation. The impact of changing workforce patterns in emergency and urgent out-of-hours care on patient experience, staff practice and health system performance. Final report for the National Institute for Health Research Service Delivery and Organisation programme. Southampton: SDO. 2010

³³⁸ Cooper S, O'Carroll J, Jenkin A, Badger B. Collaborative practices in unscheduled emergency care. The role and impact of the Emergency Care Practitioner (ECP). Plymouth: University of Plymouth 2006

Nevertheless, despite these regulatory problems, support for new clinical roles does not seem to be in question^{339,340}. Indeed, in some cases, momentum has grown for the number of practitioners performing these roles to increase³⁴¹, and for further roles to be created in response to clinical and service needs³⁴². However, if these roles are to proceed in a more structured and safety-focused way, it is clear that a more coordinated approach to their development, implementation and - most importantly in the current context - their regulation, is needed. This is particularly the case when one considers that patients and the public are known to have confidence in the process of statutory regulation, and are known to make reasonable inferences about the experience, education, qualifications and ability of clinicians from their job titles³⁴³. It is also pertinent when one considers that workforce planners and those making appointments to posts make similar inferences from job titles, and use nomenclature as a shorthand way of denoting competence³⁴⁴. As such, this suggests that anything less than a coordinated approach to their development, implementation, and, in particular, their regulation, would be unacceptable.

Denoting the range of activities that may legitimately be performed by those nurses that have adopted new roles, the emergent picture is thus one of a continuum on which the confines of practice are dictated by knowledge and skills, rather than clinical discipline. Underpinned by the notion of a 'skills escalator', this continuum signifies the range of activities that nurses may undertake, and their place on the clinical 'learning curve'. At the one extreme of the continuum are those nurses who choose to practise in the traditional way,

³³⁹ Bartley T. Advanced care nurse practitioners can safely provide sole resident cover for level three patients: impact on outcomes, cost and work patterns in a cardiac surgery programme. European Journal of Cardiothoracic Surgery: Oxford University Press 17 August 2012

³⁴⁰ Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clinical Medicine 2012;12(3):200-206

³⁴¹ Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clinical Medicine 2012;12(3):200-206

³⁴² The Scottish Government. Delivering for remote and rural healthcare: The final report of the remote and rural workstream. Edinburgh: The Scottish Government. 2008

³⁴³ Council for Healthcare Regulatory Excellence. Health professional regulators' registers: Maximising their contribution to public protection and patient safety. London: CHRE. 2010

³⁴⁴ Department of Health. The nature of advanced practice. Post-registration development: a framework for planning, commissioning and delivering learning beyond registration for nurses and midwives. The report of a task group convened and chaired by the Chief Nursing Officer - a consultation. London: DH. 2004

and who refrain from maximising their skills to their full potential, due to satisfaction with existing practices, feelings of confidence within their chosen sphere, or fear of stepping outside their 'comfort zone'. At the other extreme are those who believe that the absence of legal prohibition permits them to perform as wide a range of interventions as possible. Applied literally, this means that there is little to prevent those nurses who choose to practise in an advanced way from performing even the most technical of practices, assuming that they have been trained in their performance, assessed as competent, and obtained employer support.

Admittedly, it is difficult to envisage a situation in which nurses would choose to pursue a path that involved the most technical and risky of procedures. However, given that most modern-day advances could not have been predicted years ago, it is entirely possible that future pioneers may choose to do so, seeking acclaim as the first non-medical practitioners to break through the relevant proverbial 'barrier'. Indeed, it is important to acknowledge that, only a few years ago, the possibility of nurses being granted the full range of prescribing rights that is now available to them would have been almost inconceivable. So, too, would the possibility of nurses acting as first surgical assistants in theatre³⁴⁵, performing surgical procedures independently³⁴⁶, undertaking endoscopies³⁴⁷, operating as first contact practitioners in out-of-hospital settings³⁴⁸ and initiating thrombolysis³⁴⁹ - all of which now populate the modern clinical landscape. Accordingly, it would be unwise to assume that just because it may be prudent for nurses to refrain from pursuing the full array of

³⁴⁵ Royal College of Surgeons of England. Assistants in surgical practice: a discussion document. London: Royal College of Surgeons of England. 1999

³⁴⁶ Newey M, Clarke M, Green T, Kershaw C, Pathak P. Nurse-led management of carpal tunnel syndrome: An audit of outcomes and impact on waiting times. Annals of the Royal College of Surgeons of England 2006;88(4):399-401

³⁴⁷ Williams J, Russell I, Durai D, Cheung W-Y, Farrin A, Bloor K, Coulton S, Richardson G. What are the clinical outcome and cost-effectiveness of endoscopy undertaken by nurses when compared with doctors? A Multi-Institution Nurse Endoscopy Trial (MINuET). Health Technology Assessment 2006;10(40):

³⁴⁸ Horrocks S, Anderson A, Salisbury C. Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. British Medical Journal 2002;324(7341):819-823

³⁴⁹ Qasim A, Malpass K, O'Gorman DJ, Heber ME. Safety and efficacy of nurse initiated thrombolysis in patients with acute myocardial infarction. British Medical journal 2002;324(7349):1328-1331

opportunities that may be available to them that they will comply, and it may be wise to proceed on the basis that some of the more ambitious among their ranks may choose to do so. Given this situation, it seems reasonable to ask whether a ceiling should be placed on the extent of permissible procedures that may be performed by nurses, and to question the approach that is being taken by regulators in this regard.

Acknowledging these problems, it seems prudent to explore some of the more prominent clinical roles to have emerged in recent years, and to analyse the specific regulatory issues that each presents. Although it is accepted that a proliferation of new clinical roles now populate the clinical landscape, all of which involve advanced nurses, four roles have been selected for consideration on the basis that each signifies a particular regulatory issue that a new regulatory framework for advanced nursing practice would be expected to address. Given that some of these roles are also considered to be associated with the highest level of risk to patient safety, and are, therefore, arguably most in need of statutory regulation, this makes their analysis all the more meaningful.

2.3.1. Consultant Nurses

First announced in 1998³⁵⁰, the Consultant Nurse (CN) role entered the clinical arena amid a flurry of expectation, and a fanfare of publicity. Viewed as the pinnacle of the clinical nursing career, and the accolade to which professional nurses would aspire, the expectation was that the CN role would persuade the most experienced nurses to remain within the clinical arena, rather than pursuing more managerial and academic pursuits. Intrinsic to this was the belief that a formal structure such as this would enable nurses occupying these roles to draw upon advanced levels of knowledge and expertise, and enjoy a fulfilling and clinically autonomous role. With others also looking to them to make decisions where precedents did not exist, and to support colleagues in situations where protocols did not apply, the intention was that CNs would be able to

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³⁵⁰ Department of Health. HSC 1998/161. Nurse consultants. London: DH. 1998

practise to the limits of their competence, and be afforded professional 'standing' on a par with 'medical' consultants³⁵¹.

Colloquially referred to as 'super-nurses' due to their assumed ability to deal with the full array of nursing issues, and now embedded within the clinical infrastructure, those employed in CN roles enjoy an advanced level of decisionmaking and a wide scope of practice, with many performing technical interventions normally associated with doctors 353,354,355. Some also have 'protected time' afforded to the various aspects of their role similar to that of senior doctors (such expert clinical practice, professional as leadership/consultancy, education and professional development, and service development/research and evaluation), suggesting that, in some cases, equivalence of 'standing' has been achieved. However, with relaxation of the rules for making their appointments resulting in responsibility for their appointment falling to workforce planners, and less stringent monitoring resulting in less robust arrangements governance and monitoring arrangements³⁵⁶, the profile of the CN role has arguably diminished. Indeed, the situation that now exists in which some CNs are now perceived as having been appointed as a result of 'grade inflation' rather than 'earned autonomy', and are now viewed as skilled technicians rather than autonomous practitioners³⁵⁷.

³⁵¹ Department of Health. HSC 1999/217: Nurse, midwife and health visitor consultants: establishing posts and making appointments. London: DH. 1999

Westhead J. Super nurses to boost health service. 8 September 1998 http://news.bbc.co.uk/1/hi/health/166621.stm (Last accessed 06.08.12)

³⁵³ Fitzsimmons CL. Central venous catheter placement: extending the role of the nurse. Journal of the Royal College of Physicians of London 1997;31(5):533-535

³⁵⁴ Royal College of Physicians. Skillmix and the hospital doctor: new roles for the healthcare workforce. Report of a working party of the Royal College of Physicians. London: RCP. 2001

³⁵⁵ Haines C. The establishment of a nurse consultant role in paediatric intensive care: a reflective analysis. Nursing in Critical Care 2002;7(2):73-83

³⁵⁶ Department of Health. HSC 1999/217: Nurse, midwife and health visitor consultants: establishing posts and making appointments. London: DH. 1999

³⁵⁷ The Scottish Government. Consultant Nurses, Midwives and Allied Health Professionals (NMAHPs): Guidance for NHS Boards. Edinburgh: The Scottish Government. 2010

2.3.1.1. The issues in context: lack of clinical authority

Working to a robust job plan and with clearly defined role domains, one could be forgiven for thinking that CNs had set the benchmark for future advanced nursing roles. So, too, would the level of enthusiasm that initially greeted them, and the esteem in which they were held. However, with evaluations showing that less than half apportion their time as stipulated, managers and colleagues vary in their levels of support, and lack of clinical authority impedes their effectiveness, their sustainability is in doubt.

If one accepts that the primary aim of the CN role was to enable the most experienced nurses to remain in clinical practice, and to enable them to practise to the limit of their autonomy, the lack of clinical authority and uncertainty over their future is concerning. So, too, is the apparent dilution in the processes by which their appointments are now made, with weakened selection criteria arguably affecting the calibre of those appointed to these roles and, ultimately, the clinical contribution they are able to make. With their impact determined by their credibility as well as clinical outcomes, and their credibility determined by their reputation, this raises concern surrounding the lack of support that CNs receive from their colleagues and the related impact on their reputation.

Given that autonomy is known to be dependent on the triumvirate of responsibility, accountability and authority for practice, and all three are essential prerequisites^{361,362}, this calls into question the extent to which CNs are autonomous and casts doubt upon their validity. So, too, does the lack of

³⁵⁸ Guest DE, Peccei R, Rosenthal P, Redfern S, Wilson-Barnett J, Dewe P, Coster S, Evans A, Sudbury A. An evaluation of the impact of nurse, midwife and health visitor consultants. London: King's College. 2004

³⁵⁹ Humphreys A, Johnson S, Richardson J, Stenhouse E, Watkins M. A systematic review and meta-synthesis: evaluating the effectiveness of nurse, midwife/allied health professional consultants. Journal of Clinical Nursing 2007;16(10):1792-1808

³⁶⁰ Kennedy F, McDonnell A, Gerrish K, Howarth A, Pollard C, Redman J. Evaluation of the impact of nurse consultant roles in the United Kingdom: a mixed method systematic literature review. Journal of Advanced Nursing 2012;68(4):721-742

³⁶¹ Walsh M. Nursing frontiers: accountability and the boundaries of care. Oxford: Butterworth-Heinemann. 2000

³⁶² Eby MA. The challenges of being accountable. In Brechin A, Brown H, Eby MA (Eds) Critical practice in health and social care. The Open University. London: Sage Publications Ltd. 2000

clinical authority, which has been found to limit their effectiveness^{363,364}. With the lack of formal accountability also casting doubt upon their autonomy, and limited authority questioning their responsibility and credibility, it is clear that intervention is needed if their future is to be secure.

2.3.1.2. The need for formal recognition

When the new CN roles were first established³⁶⁵, it was envisaged that patients would benefit from improved clinical services, enhanced quality of care, strengthened leadership, and a new clinical career opportunity that would enable expert nurses to remain and develop their expertise within practice³⁶⁶. Much of this vision was founded on their role encapsulating an expert function, a leadership dimension, an education and development role, and a research and evaluation function³⁶⁷. It was also based on the understanding that stakeholder awareness and support for the CN role would be strong, and robust reporting systems would be embedded³⁶⁸. However, as research³⁶⁹ has shown, nurses and doctors often have competing expectations of the CN roles, and motivation behind their introduction is variable, meaning that the way in which these roles have been received is variable.

Given that the success of the CN role is known to be dependent upon structures that support role autonomy, and role autonomy is dependent upon advanced nurses having the authority to make clinical decisions independently, it is clear

³⁶³ Bryant-Lukosius D, Dicenso A. A framework for the introduction and evaluation of advanced practice nursing roles. Journal of Advanced Nursing 2004;48(5):530-540

³⁶⁴ Royal College of Nursing. Becoming and being a nurse consultant: towards greater effectiveness through a programme of support. London: RCN. 2012

³⁶⁵ Department of Health. Making a difference: Strengthening the nursing, midwifery and health visiting contribution to health care. London: DH. 1999

³⁶⁶ NHS Executive. Health Service Circular 1999/217: Nurse, midwife and health visitor consultants. Leeds: NHSE. 1999

³⁶⁷ Burns SM. Selecting advanced practice nurse outcome measures. In Kleinpell RM (Ed) Outcome Assessment in Advanced Practice Nursing. New York: Springer Publications. 2001:73-90

³⁶⁸ Bryant-Lukosius D, Dicenso A. A framework for the introduction and evaluation of advanced practice nursing roles. Journal of Advanced Nursing 2004;48(5):530-540

³⁶⁹ Guest DE, Peccei R, Rosenthal P, Redfern S, Wilson-Barnett J, Dewe P, Coster S, Evans A, Sudbury A. An evaluation of the impact of nurse, midwife and health visitor consultants. London: King's College. 2004

that clinical authority is essential if CNs are to work to their full capacity^{370,371,372}. However, as Redwood *et al*³⁷³ have shown, any clinical authority that CNs have may be derived from their credibility as individuals, rather than the nature of the post they are holding. This suggests that, if clinical authority is to be afforded, further work is needed to establish the CN role and provide its practitioners with the credibility they deserve.

Interestingly, this is not the first time that concerns in relation to nursing credibility and authority have been raised. Indeed, as far back as 1996 and 1999, commentators including Dowling³⁷⁴ and Levenson *et al*³⁷⁵ highlighted the need for regulatory approval when planning new nursing roles and establishing the credentialing process for 'expanded role' activities. Included within their proposals for this approval was the need for agreement, through policies and protocols, regarding the parameters of advanced nurses' practice, including the extent of their prescriptive and diagnostic authority^{376,377}, and the amount of exposure to nursing interventions they should have^{378,379}. However, as events since then have shown, this regulatory approval seems not to have been sought, leaving modern advanced nurses often still unclear of the scope of their authority, and the limits of their autonomy undefined.

Woods L. Implementing advanced practice: identifying the factors that facilitate and inhibit the process. Journal of Clinical Nursing 1998;7(3):265-273

³⁷¹ Irvine D, Sidani S, Porter H, O'Brien-Pallas L, Simpson B, McGillis Hall L, Graydon J, DiCenso A, Redelmeir D, Nagel L. Organizational factors influencing nurse practitioners' role implementation in acute care settings. Canadian Journal of Nursing Leadership 2000;13(3):28-35
³⁷² Cameron A, Masterson A. Managing the unmanageable? Nurse Executive Directors and new role developments in nursing. Journal of Advanced Nursing 2000;31(5):1081-1088

³⁷³ Redwood S, Carr E, Graham I. Perspectives on the Consultant Nurse role. University of Bournemouth: Institute of Health and Community Studies. 2005

³⁷⁴ Dowling S, Martin R, Skidmore P, Doyal L, Cameron A, Lloyd S. Nurses taking on junior doctors' work: a confusion of accountability. British Medical Journal 1996;312(7040):1211-1214 ³⁷⁵ Levenson R, Vaughan B. Developing new roles in practice: An evidence-based guide. Sheffield; School of Health and Related research (ScHARR). 1999

³⁷⁶ Knaus VL, Felten S, Burton S, Fobes P, Davis K. The use of nurse practitioners in the acute care setting. Journal of Nursing Administration 1997;27(2):20-27

³⁷⁷ Sidani S, Irvine D, Porter H, O'Brien-Pallas L, Simpson B, McGillis Hall L, Nagel L, Graydon J, DiCenso A, Redelmeir D. Practice patterns of acute care nurse practitioners. Canadian Journal of Nursing Leadership 2000;13(3):6-12

³⁷⁸ McFadden EA, Miller MA. Clinical nurse specialist practice: facilitators and barriers. Clinical Nurse Specialist 1994;8(1):27-33

³⁷⁹ Brooten D, Naylor MD. Nurses' effect on changing patient outcomes. Image: Journal of Nursing Scholarship 1995;27(2):95-99

Consultant Nurses also present an interesting situation in that, when they were first introduced, the expectation was that their creation would result in the formation of a new clinical role. Much of this expectation was based on the understanding that CNs would be performing clinically autonomous roles, and managing complete episodes of care. However, the reality is that, in many cases, this expectation has not materialised. Rather, CNs have tended to develop their practice in an inconsistent and increasingly disparate way, leading some to conclude that they highly experienced nurses who have expanded their practice, rather than advanced nurses who have developed their practice such that it constitutes a new clinical role. Although this distinction may seem to be insignificant in practice, it is submitted that this difference is important in that it forms the basis of a number of arguments that will be presented surrounding the regulation of those nurses who have chosen to practise in an advanced way.

2.3.2. Physician Assistants

Originally emerging in the USA in the 1960s, and since adopted in other countries in response to workforce needs, the Physician Assistant (PA) first appeared in the UK in 2003³⁸⁰ (and in Scotland in 2007³⁸¹), as a means of expanding workforce capacity. Although initially met with mixed acclaim, the expectation was that PAs would be able to work in a variety of settings under the guidance of experienced doctors, and relieve some of the pressure on doctors that had arisen due to a reduction in the number of medical staff. With their practice underpinned by a curriculum and competence framework³⁸² and a highly developed skill set, it was envisaged that PAs would be able to deliver holistic care to patients, and assess and manage their conditions as part of the wider clinical team.

Working to a medical model and typically performed by those looking to have a semi-autonomous role - such as life sciences graduates and nurses - the strength

³⁸⁰ Stewart A, Catanzaro R. Can Physician Assistants be effective in the UK? Clinical Medicine 2005;5:344-348

³⁸¹ Buchan J, O'May F, Ball J. New role, new country: introducing US physician assistants to Scotland. Human Resources for Health 2007;5-13

³⁸² Department of Health. The competence and curriculum framework for the Physician Assistant. London: HMSO. 2006

of the PA role lies in its practitioners having a medical base to their practice. Intrinsic to this model is a repertoire of skills that is greater in breadth and depth than that of traditional nurses, and broad generic competencies that are regularly assessed and appraised³⁸³. Featuring centrally among these skills are history-taking, clinical assessment, physical examination, and differential diagnosis and treatment, with those PAs who work in defined clinical areas, such as Emergency Departments (EDs) and Primary Care, also having additional skills relevant to their clinical speciality.

Also referred to as Medical Care Practitioners (MCPs)³⁸⁴, due in part to differing perceptions of the term 'physician' between the UK and the USA³⁸⁵, PAs have enjoyed increasing acceptance within the UK³⁸⁶. In fact, to date, more than 200 PAs are employed across the UK in 23 different locations, with the only real dissent about their role coming from a small number of doctors, who oppose the term MCP on the basis that it could potentially mislead patients into thinking that its practitioners are medically qualified^{387,388,389}. In all cases, PAs enjoy a degree of autonomy, albeit with restrictions on their practice, given that they are authorised to carry out clinical assessments, arrange tests and investigations, and formulate diagnoses, but are unable to supply or administer medicines unless they have been first prescribed by a doctor.

Effectively sitting somewhere between traditional nurses and doctors on the professional continuum, PA roles appeal to those practitioners who are eager to have a wide clinical impact, but are unwilling to accept the responsibility

³⁸³ Begg PAP, Ross NM, Parle JV. Physician Assistant Education in the United Kingdom: The first five years. The Journal of Physician Assistant Education 2008;19(3):47-50

³⁸⁴ Department of Health. The competence and curriculum framework for the medical care practitioner: Consultation outcome. London: HMSO. 2005

³⁸⁵ Child DL, Benett I, Walton I, Reeves D, Browne C, Heath I. The medical care practitioner: Newspeak and the duping of the public. British Journal of General Practice 2005;55(512):229-231 ³⁸⁶ Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clinical Medicine 2012;12(3):200-206

³⁸⁷ Armitage A, Shepherd S. A new professional in the healthcare workforce: role, training, assessment and regulation. Clinical Medicine 2005;5(4):311-314

³⁸⁸ British Medical Association. BMA response: Competence and curriculum framework for the Medical Care Practitioner. London: BMA. 10 February 2006

³⁸⁹ Royal College of Surgeons of England. The competence and curriculum framework for the Medical Care Practitioner: A response from the Royal College of Surgeons of England. London: RCS(Eng). 2006

associated with fully autonomous practice. Considered by some³⁹⁰ to practise at the level of Senior House Officer, equivalent to the modern FY2 doctor, and by others³⁹¹ as practising at a level between the FY2 and ST2 doctor, their competence is variable, depending upon experience, expertise and individual level of ability. Given that most of their practice is permitted under 'delegated medical authority', and all of their findings needing to be 'supervised' by a doctor, this means that the extent to which PAs are able to practise to their full potential is questionable.

With evaluations^{393,394,395} revealing high levels of patient satisfaction, and positive correlations between the work that can be done by doctors, Nurse Practitioners and PAs, the intended benefits that were hoped to be achieved by the PA role would seem to have been realised. Indeed, such has been their success that PAs are now recognised as making a positive and cost-effective contribution to many clinical teams³⁹⁶, and, in some cases, are appointed in place of doctors in areas where recruitment is difficult³⁹⁷. This is particularly the case in Emergency Departments (EDs), Medical Assessment Units (MAUs) and General Practitioner (GP) practices^{398,399,400}, where PAs play a central role in meeting access targets, reducing waiting times, and ensuring the timely assessment of patients.

³⁹⁰ Woodin J, McLeod H, McManus R, Jelphs K. Evaluation of US-trained Physician Assistants working in the NHS in England. University of Birmingham. 2005

³⁹¹ Farmer J, Currie M, West C, Hyman J, Arnott N. Evaluation of Physician Assistants to NHS Scotland. Final Report. UHI Millennium Institute, Inverness. January 2009

³⁹² General Medical Council. Good Medical Practice. London: GMC. 2009

³⁹³ Woodin J, McLeod H, McManus R, Jelphs K. Evaluation of US-trained Physician Assistants working in the NHS in England. University of Birmingham. 2005

³⁹⁴ Caldow J, Bond B. An evaluation of Physician Assistants in NHS Grampian. Aberdeen: University of Aberdeen Department of General Practice and Primary Care. June 2008

³⁹⁵ Farmer J, Currie M, West C, Hyman J, Arnott N. Evaluation of Physician Assistants to NHS Scotland. Final Report. UHI Millennium Institute, Inverness. January 2009

³⁹⁶ Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clinical Medicine 2012;12(3):200-206

³⁹⁷ Drennan V, Levenson R, Halter M, Tye C. Physician Assistants in English general practice: a qualitative study of employers' viewpoints. Journal of Health Service Research Policy 2011;16(2):75-78

³⁹⁸ Stewart A, Catanzaro R. Can physician assistants be effective in the UK. Clinical Medicine 2005;5:344-348

³⁹⁹ Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clinical Medicine 2012;12(3):200-206

⁴⁰⁰ Ostler J, Vassilas C, Parle J. Physician assistants: friends or foes to doctors? BMJ Careers 8 July 2012

Also lending support to the esteem in which PAs are held, is the popularity of the first PA postgraduate surgical course; an initiative that was introduced in 2009 as a means of supporting those newly qualified PAs for whom basic surgical training had not been provided as part of their undergraduate curriculum. With the number of applicants to this programme exceeding capacity, and candidates attracted from across the UK, the result of this initiative has been to see PAs take up posts in a wide range of surgical specialities, and increase their exposure in a number of areas. This, in turn, has raised the profile of this new profession, and highlighted the role that its practitioners could play in the modern clinical arena.

With their role favoured, and evaluations supportive, momentum has grown for the number of PAs to increase. Much of the impetus for this growth has come from surgical specialists who recognise the valuable contribution that PAs can make to the surgical team, particularly given their medical model of training, and the flexibility and stability that they can bring to a transient medical workforce^{401,402}. Indeed, such is the level of interest in PAs among surgeons, and the rapidity with which these posts have begun to appear in some specialities, that it is entirely feasible that they could be incorporated into surgical teams in the future.

However, given that there are no statutory standards of education and training to underpin PA practice, and no defined standards by which to determine their baseline level of competence, this means that the situation could exist in which different hospitals could have different interpretations of the level of competence that is required for equivalent PA posts. This, in turn, could lead to the possible situation in which some hospitals inadvertently accept a lower level of competence from its practitioners, and to some patients potentially receiving substandard care. Further, given that there are no statutory standards by which to determine the boundaries of PA competence, this means that the public is

Buchan J, Ball J, O'May F. Physician assistants in NHS Scotland: reviewing the issues. Report for the Scotlish Executive Health Department. Edinburgh: Queen Margaret University College.

2006

⁴⁰² Goudie S. The physician assistant. BMJ Careers 19 May 2010

currently provided with minimal levels of protection from those PAs who do not realise, or who are unaware of, the limits of their competence.

Workforce issues associated with emergency medicine across the UK have also led to momentum in the growth in numbers of PAs. Lending support to this drive are patient safety concerns arising from ED closures, overnight staffing problems due to shortages of middle and consultant grade doctors, external agency and locum costs, attrition rates among trainees, and lack of supervision among junior doctors⁴⁰³. Associated with these factors are a predicted 30% reduction in the junior doctor workforce and a shift towards training in the community and General Practice⁴⁰⁴, both of which illustrate the extent of the risks associated with medical staffing problems.

With PAs likely to form part of the multidisciplinary teams that will replace the reduced number of doctors, this means that more reliance will be placed on PAs to practice to their full capacity, and fulfil a wider clinical remit. Central to this wider remit is the need to ensure that patient safety remains paramount, and to acknowledge the potential adverse consequences, in terms of clinical quality, that could potentially result if high quality care is not maintained. Underpinning this is the expectation that regulatory processes will assure the quality of practitioners and the standard of their care, and ensure that competence will always be maintained.

However, given that PAs are not specifically statutorily regulated, and relyt upon Voluntary Registers for their governance, this means that there is currently no reliable mechanism for ensuring consistency of standards, and variations in practice cannot be negated. As a consequence, the 'protection' that would normally flow from statutory regulation would not be provided, meaning that the risks that are associated with PA practice would not be able to be completely eradicated. The absence of statutory regulation also means that the extent to which the PA role is able to be developed clinically is limited, thus restricting the extent to which PAs would be able to achieve their full potential.

⁴⁰³ Medical Education England. Interim report on staffing issues in Emergency Departments. London: Medical Education England. 2012

⁴⁰⁴ Shemilt S. A UK perspective. The physician assistant role: An evidence base to support statutory registration for physician assistants. Aberdeen: University of Aberdeen. 2012

Sitting at the heart of PA practice is acknowledgement of the fact that PAs are not legally permitted to prescribe medicines independently, or to order tests and investigations independently. Also recognised within this context is the detrimental effect that the inability to prescribe medicines can have on the scope of their practice, and on the quality of patients' care^{405,406}. Given that statutory regulation is a prerequisite for legislation, and legislation is a necessity if PAs are to be granted the authority to prescribe independently, this seems to be a problem that will only be resolved through statutory regulation. With statutory regulation also a prerequisite for PAs to be eligible to supply and administer medicines or short courses of treatment under Patient Group Directions (PGDs)⁴⁰⁷ - an alternative system that allows non-medical practitioners who do not have prescribing rights to administer specified medicines to a designated range of patients in certain circumstances - statutory regulation would seem to provide the only answer to this problem.

2.3.2.1. The issues in context: limited autonomy

There are few who would disagree that the inability to prescribe medicines independently is the single biggest hurdle facing PAs, and the factor that most limits their autonomy. In practice, this causes frustration and inconvenience for practitioners, and can lead to handovers in care that could otherwise be avoided. With handovers in care recognised as being one of the most common causes of failure in the NHS^{408,409,410}, and patient safety and well-being

⁴⁰⁵ Buchan J, O'May F, Ball J. New role, new country: introducing US physician assistants to Scotland. Human Resources for Health 2007;5-13

⁴⁰⁶ Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clinical Medicine 2012;12(3):200-206

⁴⁰⁷ National Prescribing Centre. Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions. Liverpool: NPC. 2009

⁴⁰⁸ Department of Health. An organisation with a memory, Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. London: HMSO. 2000

⁴⁰⁹ Institute of Medicine. To err is human: building a safer health system. Washington: National Academies Press. 2000

⁴¹⁰ Cronenwett L, Sherwood G, Pohl J, Barnsteiner J, Moore S, Taylor Sullivan D, Ward D, Warren J. Quality and safety education for advanced nursing practice. Nursing Outlook 2009;57(6):338-348

acknowledged as being the primary purpose of professional practice⁴¹¹, this is a situation that needs to be addressed.

Also of concern is the practical inconvenience and potential detriment that the inability of PAs to prescribe can cause for patients. Included within the array of potential harmful sequelae that patients could potentially experience, are delays in receiving essential medications, avoidable admissions to hospital, prolonged waiting times for treatment, and clinical complications due to delays in treatment. Admittedly, the clinical impact of delays in treatment caused by PAs being unable to prescribe medicines and complete clinical pathways is unlikely to be serious in the majority of cases. This is due to the fact that in, most cases, it would be possible for PAs to identify another healthcare professional who would be able to prescribe any medications that were required, on an essential or emergency basis.

However, although helpful, this 'solution' would not allow for those less controlled situations in which assistance may be required, such as overnight and in emergencies when senior clinicians are less likely to be available. Nor would it allow for those situations in which PAs are working in more geographically isolated areas, such as the remote and rural parts of the country, when senior assistance may be more difficult to access or locate. In these circumstances, the potential for patients to suffer harm could be significant, particularly if the treatment required involved medications such as bronchodilators or steroids for those patients having an acute exacerbation of Chronic Obstructive Pulmonary Disease (COPD). Should situations such as these arise, and PAs find themselves unable to access their supervisor in order for the requisite medications to be prescribed, it is entirely possible that the consequences for patients could be far more serious and, in some cases, life-threatening.

Further complicating this situation is the absence of an accredited educational framework to underpin PA practice. Although the curriculum and competence

⁴¹¹ Department of Health. Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century. Cm7013. London: HMSO. 2007

framework for the PA role⁴¹² may go some way to assist in assuring the requisite educational standards, in that it offers a benchmark in terms of the competencies to be attained by those seeking to perform this role, this would not completely resolve the problem given that these standards are not mandated by law. This means that, although it would be good practice for any institution who wished to train PAs to follow this approach, and most Higher Education Institutes would adhere to this, there would be no imperative for them to do so. Indeed, acknowledging the competitive environment in which academic courses are offered, with institutions competing with each other to attract sufficient numbers of high calibre students, it would not be unusual for institutions to build upon this curriculum and deliver their own local courses in the hope of attracting the most able candidates. In practice, this means that although standards of education would be similar, equivalence of education would not be able to be guaranteed, with variance in practice and standards of care almost certain to emerge through time.

Intrinsic to this problem are Issues surrounding the absence of a 'protected' title for PAs, given the loopholes in terms of public safety that this issue presents. These issues mainly derive from the fact that, since PAs are not statutorily regulated, they are not able to benefit from a title that is 'protected' in law. This means that anyone practising in a capacity that could be considered as being 'assistant to medicine' could, at least theoretically, hold themselves out as being a PA. This, in turn, means that the public would not be able to benefit from the safeguards that statutory regulation would afford. Central to these benefits are the assurance that all those practitioners whose names have been entered onto the Register have attained the requisite standards of training and education, and the same level of competence that is normally associated with membership of the profession. Thus, although PAs may have been prepared for their practice by credible and competent clinicians, the fact that their practice and education are not regulated, means that consistency of standards cannot always be guaranteed.

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⁴¹² Department of Health. The competence and curriculum framework for the Physician Assistant. London: HMSO. 2006

Compounding this situation is the fact that the absence of a 'protected' PA title would preclude the public from benefiting from the obligation on members of regulated groups to adhere to established standards and codes of conduct, ethics and performance, and to always maintain knowledge and competence⁴¹³. Under the current system, the PAMVR does not have a consistent approach to prevent those individuals who do not adhere to the relevant professional codes from practising. This means that, even if sanctions were to be applied to individual PAs, such as conditions imposed on their practice, these sanctions would be limited to their employer rather than to their practice as a whole. As a result, it is possible that PAs could obtain employment in a different location, despite having a poor employment record in their current location.

Considered by some as offering a possible solution to this problem, the Physician Assistant Managed Voluntary Register (PAMVR) that has already been established by the UK Association of Physician Assistants (UKAPA)⁴¹⁴ could go some way to assist. However, although helpful in offering a 'kite mark of quality', the PAMVR is limited in its impact, given that its voluntary status lacks the force of law and, therefore, cannot be mandated. The PAMVR also suffers from the absence of a high public profile, and from a lack of awareness among the public of its use as a vehicle through which complaints can be made and concerns can be registered. Thus, despite affording the public a level of protection by recommending membership of the UKAPA as a condition of appointment to PA posts, the fact that the PAMVR has no statutory support means that its ability to prevent those individuals who are unfit to practise is weak, and its 'regulatory' impact is limited.

Weaknesses in the voluntary system of registration can also be found in the fact that it relies upon effective close working relationships with colleagues and peers on a daily basis, in order to be effective⁴¹⁵. Alongside this is the fact that the PA role is associated with a degree of autonomy for practice that is not

⁴¹³ Council for Healthcare Regulatory Excellence. Protecting the public from unregistered practitioners: Tacking misuse of protected title. London: CHRE. 2010

⁴¹⁴ UK Association of Physician Assistants (UKAPA)

http://www.ukapa.co.uk/paregister/index.html (Last accessed 31.07.12)

⁴¹⁵ UK Association of Physician Assistants (UKAPA). Physician Assistant Managed Voluntary Register: Competence and curriculum framework for the Physician Assistant. London: UKAPA. 2012

always closely supervised or supported, such as when PAs attend upon patients in their homes in the absence of direct supervision. This means that the reliance that would normally be placed on effective close relationships and supervision by voluntary registration may not be able to be provided in these settings, and the risks to patient safety from unregistered practitioners would still be present.

It is also important to acknowledge that, in the current healthcare climate, policy makers could seek to reduce the costs of supervision in order to reduce the overall costs of healthcare. If so, this means that there may be an increased likelihood of PAs being required to work independently, or to work in environments where no employer or team member is present. If this possibility was to become a reality, this would mean that the level of supervision and support that would be provided to PAs may be reduced, and any such support that would be provided would be likely to be delivered remotely. As such, patients would be increasingly reliant upon accredited standards of PA education in order to be assured of their competence, and on the integrity and conscience of individual practitioners to ensure that their competence is maintained. They would also be dependent upon PAs adhering to professional codes of conduct and ethics, always working within the parameters of their practice, and always having patients' best interests as their primary concern.

With 'voluntary registration' through a body such as the UKAPA having been shown to be unable to provide the safeguards that are required for autonomous clinical practice, most notably a 'protected' title and accredited educational standards, this means that an alternative regulatory solution will need to be found if patients are to be protected from PAs and their practice. To be effective, this solution would need to be one in which the legislation that is required to enable independent prescribing would be able to be afforded. This would not only enable PAs to practise to their full capacity and enhance the quality of their care, but it would also assure the public that the required standards of proficiency had been satisfied and competence was maintained. At the moment, the only regulatory solution that would be able to provide PAs with a 'protected' title, accredited educational standards and the necessary

legislation, and the public with the protection they arguably deserve, is statutory regulation.

Of course, it is entirely possible that an alternative 'regulatory' solution could be found to resolve the prescribing 'issue', such as in the creation of new legislation that would allow prescribing rights to be granted to those practitioners who are members of professional bodies or organisations that are associated with Voluntary Registers. This would apply to those organisations that have satisfied the standards for accreditation set by the Professional Standards Authority (PSA), and hold 'Assured Voluntary Registers' (AVRs)⁴¹⁶. However, given that the PAMVR has already been shown to provide a weak form of 'regulation' and would not provide the regulatory safeguards that are being sought, this approach is unlikely to garner favour. As such, this again leaves statutory regulation as the only feasible solution.

2.3.2.2. The need for statutory regulation

Statutory regulation is well-recognised as providing a mechanism that reliably protects patients, and provides the public with essential regulatory safeguards⁴¹⁷. Included among these safeguards are the setting of high standards for the education and training of practitioners, controlled entry to the professions, 'protection' of title, and promoting and enforcing codes of ethics and conduct - all of which mitigate the risks to patients and provide the necessary regulatory oversight by outlining the boundaries of safe practice for clinicians in professional roles. With the benefits of statutory regulation clearly in evidence, the question that needs to be asked in relation to the PA role is not, therefore, whether statutory regulation would provide a feasible regulatory solution, but whether a convincing case can be made for statutory regulation to be extended to PAs.

⁴¹⁶ Professional Standards Authority. Accredited Voluntary Registers: Standards for organisations holding a voluntary register for health and social care occupations. London: PSA. 2012

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⁴¹⁷ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

As previously indicated, current healthcare policy⁴¹⁸ stipulates that only the minimum regulatory force that is required to achieve the desired effect should be used when seeking to ensure public protection. It also stipulates that any regulatory measures that are implemented must be consistent with the 'right-touch' approach to regulation. It also dictates that no new clinical groups will be statutorily regulated unless a compelling case can be made on the basis of a risk to public safety, and alternative methods, such as AVRs, are not sufficient to manage the risks posed. This means that the issues that need to be addressed in relation to PA practice are whether a compelling case for statutory regulation can be made on the basis of the risks posed to patients, and whether the proposed method of regulation satisfies the 'right-touch' principles.

Working on the basis that those practitioners who are employed as PAs are in positions of trust, in which they have access to privileged confidential information by virtue of their role as healthcare professionals, this issue alone suggests that they should be statutorily regulated. Indeed, this would enable PAs to be bound by professional regulatory codes, and would help to assure patients that their personal information would be managed appropriately. This argument is strengthened significantly when one considers that PA practice frequently involves the performance of a wide range of interventions, some of which may be intimate or invasive, and may be carried out in a range of settings. It is heightened further still, when one is reminded that the baseline educational standards for PAs are not protected through regulation, meaning that variance in practice is possible. Given that all interventions and procedures are associated with a degree of risk⁴¹⁹ - no matter how small - and that these risks are known to be magnified when procedures are carried out in less controlled settings, such as in patients' homes, this means that the risks that are posed to patients by PA practice could be considerable. They are also likely to be magnified when not 'protected' by statute. As such, it is clear that a regulatory system that provides patients and the public with the necessary regulatory safeguards in terms of accredited educational standards, a defined

⁴¹⁸ Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

⁴¹⁹ Department of Health. An organisation with a memory, Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. London: HMSO. 2000

level of competence, and a recognised professional regulatory code, needs to be provided.

When one also acknowledges that statutory regulation is the only regulatory vehicle that would afford PAs 'protection' of title, and 'protection' of title is the only mechanism that would be able to restrict the PA title to those practitioners who have attained the requisite educational standards, arguments in favour of statutory regulation are persuasive. Indeed, in the absence of a 'protected' title being afforded to PAs, this means that any healthcare practitioner whose practice could be described as assisting that of medicine could, theoretically, hold themselves out as being a PA. This would apply irrespective of whether those individuals had satisfied any identified educational standards. This means that, in the event of statutory regulation not being provided, patients would be exposed to unnecessary and unjustifiable risk.

With statutory regulation also offering PAs the only robust platform from which they can be held sufficiently accountable for their actions, and the only mechanism from which prescribing legislation may be granted, it is submitted that this approach would provide the only practicable solution to the problems presented. Working on the basis that this argument is persuasive, this leaves those who are responsible for championing the PA cause to convince policymakers that statutory regulation satisfies the 'right-touch' approach.

In order for PAs to successfully demonstrate that statutory regulation is compliant with the 'right-touch' principles, it is incumbent on them to show that statutory regulation is proportionate to the risks posed to patients. It is also incumbent on them to show that this approach would provide a consistent and targeted response, be sufficiently transparent so as to be able to withstand scrutiny, and would hold practitioners suitably to account⁴²⁰. With those responsible for overseeing the PAMVR and representatives from the various 'medical' Royal Colleges confident that a convincing case for statutory regulation can be made, it remains to be seen how their arguments will be received.

⁴²⁰ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010

Central to the arguments that are likely to be presented is the contention that statutory regulation is proportionate to the risks it seeks to mitigate. Linked to this is the belief that PA practice poses a significant risk of adverse incidents, due to the high level of complex decision-making skills that are employed in a wide range of environments. This is particularly the case when one considers that the risks that are associated with PA practice are expected to increase in line with the range of advanced procedures that PAs are set to perform, and the increased numbers of practitioners that may, in the future, perform them. Also central to these arguments is accountability, with proponents of statutory regulation likely to assert that the statutory approach would enable all those with an interest in PA practice to have an influence on it, and enable the associated risks to be captured and addressed. Underpinning this assertion is the level of confidence that the public is known to have in the statutory regulatory process⁴²¹; confidence that is likely to be relied upon in the event of an adverse incident that could potentially be detrimental to the public's confidence in professional practice being reported by the media, and brought into the public domain.

Further supporting the case for the statutory regulation of PAs is the assertion that the statutory approach would pose a consistent and proportionate regulatory burden on practitioners, and on those regulating them. Strengthening this argument is the assertion that statutory regulation would offer consistency in education and in the interpretation of competence across the UK, through the conferring of a 'protected' title, and thus provide uniformity of standards. In so doing, this would avoid the risks that are potentially associated with disparate standards of education and training, and offer the public a transparent and targeted mechanism through which they could scrutinise PA activities. This would be in contrast to the PAMVR, which hosts only 65% of the profession and, as such, does not offer a comprehensive response⁴²².

⁴²¹ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

Shemilt S. A UK perspective. The physician assistant role: An evidence base to support statutory registration for physician assistants. Aberdeen: University of Aberdeen. 2012

Completing the case for statutory regulation is the argument that the statutory approach would provide the only reliable mechanism by which the registration status and credentials of PAs could be assured, thus giving the public the confidence that PAs have been educated to the requisite level and are licensed to practise. Supporting this argument is the assertion that the scope of PA practice is so different from that of other occupations, such as Clinical Nurse Specialists and Nurse Practitioners, that it warrants a separate regulatory response.

If one accepts the argument that a compelling case for statutory regulation has been made, this begs the question of which of the existing professional regulatory bodies would be the most appropriate to host PAs. Although an issue that is of secondary concern to this thesis, this discussion is, nonetheless, interesting, in that it draws attention to the different approaches that would be taken by the relevant regulatory bodies, and the associated criteria for entry. It also paves the way for some of the wider issues surrounding the regulation of advanced nursing practice to be considered, and, in particular, for an analysis of which of the existing professional regulators may be most suitable for this purpose.

Proposed by many^{423,424,425,426} as the professional regulatory body that is likely to offer the most straightforward solution, it is doubtful whether PAs would be able to satisfy the Health and Care Professions Council's (HCPC) criteria for eligibility for statutory regulation⁴²⁷. Indeed, with the HCPC stipulating autonomous practice, independent treatment judgments and full responsibility for actions as essential prerequisites, it is possible that the PA 'dependent practitioner' status, which deems supervision, inter-dependence and teamwork integral to their role, could preclude them from entry. With attempts to register Physician Assistants

⁴²³ Armitage A, Shepherd S. A new professional in the healthcare workforce: role, training, assessment and regulation. Clinical Medicine 2005;5(4):311-314

⁴²⁴ Woodin J, McLeod H, McManus R, Jelphs K. Evaluation of US-trained Physician Assistants working in the NHS in England. University of Birmingham. 2005

⁴²⁵ Begg PAP, Ross NM, Parle JV. Physician Assistant Education in the United Kingdom: The first five years. The Journal of Physician Assistant Education 2008;19(3):47-50

⁴²⁶ Royal College of Anaesthetists. PA(A) supervision and limitation of scope of practice: Position Statement (May 2011 revision)

⁴²⁷ Health Professions Council. Guidance for occupations considering applying for regulation by the Health Professions Council. London: HPC. 2004

(Anaesthesia) having recently been put on hold - on the basis that Voluntary Registers should be considered in the first instance⁴²⁸ - this means that arguments submitted by PAs (Anaesthesia) in their application for statutory regulation⁴²⁹ have not yet been considered formally, and a decision regarding the extent to which they satisfy the HCPC's criteria has yet to be made.

Also presented among the potential options for consideration, is the possibility that the GMC could regulate PAs. Considered to be a feasible option by some⁴³⁰, given that all PAs work to a medical model and act in an assistant capacity to doctors, this seems to be a reasonable proposition. In fact, when one considers that, in some cases, PAs are appointed to posts in areas where it is difficult to recruit doctors, this would seem to be a sensible solution. However, given that the GMC has historically only regulated medical practitioners, and shows little sign of widening its scope in the foreseeable future, this 'solution' is unlikely to provide a viable option, at least in the short term.

Of course, the NMC could also offer a potential solution for the regulation of PAs. Indeed, with a precedent for this approach having already been provided, in that the NMC has amended its Register in order to accommodate the separate profession of midwifery, it is possible that this approach could provide a feasible solution. However, given that midwifery has consistently tried to 'disentangle' itself from nursing, on the basis of being too closely aligned with it rather than being perceived as a profession in its own right, it is possible that PAs could reject the NMC as an option, on the basis that PA practice could, through time, also be perceived as being too closely aligned with nursing rather than recognised as a separate profession. Alternatively, in the event that PA practice is considered as being on a par with that of traditional 'advanced nursing

⁴²⁸ Health Professions Council. Application for the regulation of Physicians' Assistants (Anaesthesia) by the Association of Physicians' Assistants (Anaesthesia). Executive summary and recommendations. London: HPC Council meeting 31 March 2011

⁴²⁹ Health Professions Council. Application for the regulation of Physicians' Assistants (Anaesthesia) by the Association of Physicians' Assistants (Anaesthesia). London: HPC Council 31 March 2001

⁴³⁰ The Scottish Government. UK Government White Paper - Trust, Assurance and Safety - The regulation of health professionals in the 21st Century - Implementation in Scotland. Overarching Steering Group Meeting 29 April 2009

practice', and as presenting an equivalent level of risk to patients, it is possible that the NMC could present a feasible regulatory solution.

Thus faced with a number of options, PAs have three hurdles to overcome - the lack of professional autonomy, the absence of statutory regulation (and, therefore, a 'protected' title), and the inability to prescribe independently. With the lack of autonomous practice potentially preventing their regulation by the HCPC, and the inability to prescribe independently reinforcing their lack of autonomy, these problems could be overcome, at least in part, by the introduction of legislation that would allow PAs to prescribe independently.

In order for PAs to progress from their current situation, and to be able to practise to their full potential, three solutions are possible. First, the HCPC could relax or amend its criteria for eligibility, such that autonomous practice and independent decision-making would no longer feature as essential prerequisites. Secondly, the rules surrounding prescribing legislation could be relaxed or amended, such that PAs would be permitted to prescribe independently (on a par with nurse independent and supplementary prescribers), or new legislation could be introduced to enable them to prescribe independently. Alternatively, PAs could pursue statutory regulation with another professional group, such as the GMC or the NMC, with the GMC likely to emerge as the preferred candidate.

If one accepts that the HCPC is unlikely to amend its criteria for eligibility, on the basis that this could potentially be perceived as diluting the professional status of those who value clinical autonomy as an integral part of their role, and as potentially weakening the professional accountability that is central to statutory regulation, this option does not seem likely to garner favour. With the rules surrounding prescribing legislation similarly unlikely to be amended, given the considerable hurdles that nurses and other non-doctors have had to overcome in order to enable the current situation surrounding non-medical prescribing to be achieved, this 'solution' also seems unlikely to present a feasible option. This leaves regulation with the GMC or NMC as the most likely solution, albeit recognising that regulation with the GMC would require a precedent to be set in terms of changing its constitution. With support for these

options arguably to be found in the Law Commissions Review into the regulation of healthcare professionals⁴³¹ - which advocates for more consistency and partnership working across the regulators - it is possible that one of these options could provide the answer.

2.3.3. Surgical Care Practitioners

Similar difficulties to those found with PAs have also been encountered in relation to the regulation of the Surgical Care Practitioner (SCP) role. Defined as non-medical practitioners who perform surgical interventions and pre-and post-operative care under the direction and supervision of a consultant surgeon⁴³², the aim was that the introduction of SCPs would increase surgical capacity, reduce waiting times, and enable waiting time and access targets to be met⁴³³. With their implementation following upon the success of early pioneers, it was originally intended that this initiative would legitimise and build upon the 'expanded roles' that nurses and Operating Department Practitioners (ODPs) had already started to undertake, and provide a formal platform for their practice, rather than representing any real form of innovation⁴³⁴.

Notable in its evolution and featuring among those pioneers to have had the most significant impact on the development of SCPs are Suzanne Holmes - a nurse at the John Radcliffe Hospital in Oxford, who worked alongside a cardiac surgeon, stripping out veins for cardiac bypass surgery⁴³⁵ - and Gillian Erickson⁴³⁶, a theatre nurse from Merseyside, who performed unsupervised

⁴³¹ Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

 $^{^{432}}$ Department of Health. The curriculum framework for the Surgical Care Practitioner. London: HMSO. 2006

⁴³³ Laurance J. NHS revolution: nurses to train as surgeons. The Independent; 6 December 2004:6 ⁴³⁴ Kinley H, Czoski-Murray C, George C, McCabe C, Primrose J, Reilly C, Wood R, Nicolson P, Healy C, Read S,Norman J, Janke E, Alhameed H, Fernandez N, Thomas E. Extended scope of nursing practice: a multi-centre randomised controlled trial of appropriately trained nurses and pre-registration house officers in pre-operative assessment in elective general surgery. Health Technology Assessment 2001; 5(20)

⁴³⁵ Holmes S. Development of the cardiac surgeon assistant. British Journal of Nursing 1994:3(5):204-210

⁴³⁶ Hunt L. The case for nurses who wield knife. The Independent. Monday 24 June 1996

biopsies and cyst removal. Also influential in raising the profile of nurses who had taken on surgical roles, was Valerie Tomlinson, a theatre nurse from Treliske in Cornwall, who came under high profile scrutiny and intense media scrutiny for assisting with the removal of a patient's appendix^{437,438}. Indeed, in many ways, it was the case of Valerie Tomlinson that 'lifted the lid' on nurses performing informal surgical roles, and led to the level of interest in SCP practice that currently exists today. However, in recent years, those practices associated with Malcolm Clarke - a nurse at Leicester General Hospital, who became highly respected for performing carpal tunnel surgery⁴³⁹ - and Jill Martin, a nurse from London, who performed 381 minor operative procedures under local or general anaesthesia⁴⁴⁰, have also attracted interest, and have arguably had the most significant impact on SCP practice as it is currently known.

With support for SCPs coming from the Royal College of Nursing (RCN)⁴⁴¹ and the Royal College of Surgeons (RCS)⁴⁴², both of whom acknowledge the benefit of the SCP role, but urge caution in the need for proper supervision, this initiative demonstrates just how far advanced nursing practice has come. So, too, does evidence which shows that preparation for diagnostic cardiac catheterisation⁴⁴³ and low-risk cardiac surgery⁴⁴⁴ is equally safe whether performed by SCPs or junior doctors, and that SCPs are able to run surgical out-patient and follow-up

⁴³⁷ Whose hand on the knife? MP voices public's fears over nurse who took out appendix. Daily Mail (London) 13 January 1995

⁴³⁸ Cooper G. Appendix nurse to keep surgery job. The Independent. Friday 27 January 1995 ⁴³⁹ Newey M, Clarke M. Getting patients back to work after carpal tunnel surgery. Journal of

Peri-operative Practice 2008:18(2):60-63

⁴⁴⁰ Martin S, Purkayastha S, Massey R, Paraskeva P, Tekkis P, Kneebone R, Darzi A. The Surgical Care Practitioner: A feasible alternative. Results of a prospective 4-year audit at St Mary's Hospital Trust, London. Annals of Royal College of Surgeons of England 2007;89(1):30-35
⁴⁴¹ Nicholas M. The surgical care practitioner: a critical analysis. Journal of Perioperative Practice 2010;20(3):94-9

⁴⁴² Royal College of Surgeons of England. Surgical assistants: College position statement: 'Surgical titles in the NHS'. London: Royal College of Surgeons of England. July 2010

⁴⁴³ Stables RH, Booth J, Welstand J, Wright A, Ormerod OJ, Hodgson WR. A randomised controlled trial to compare a nurse practitioner to medical staff in the preparation of patients for diagnostic cardiac catheterisation: the study of nursing intervention in practice. European Journal of Cardiovascular Nursing 2004;3:53-9

Alex J, Rao VP, Cale AR, Griffin SC, Cowen ME, Guvendik L. Surgical nurse assistants in cardiac surgery: a UK trainee's perspective. European Journal of Cardiothoracic Surgery 2004;25:111-115

clinics safely⁴⁴⁵. With many hospitals also continuing to appoint SCPs on the basis that they provide reassuring continuity in the theatre environment, and play a useful role in bridging the gap between consultant supervision and 'independent operating', not to mention their role in enhancing trainee educational exposure and promoting patient safety as trainees move on ⁴⁴⁶, their future seems secure.

Nevertheless, with concerns remaining that surgeons of the future will be less experienced than their predecessors, and that SCPs will be permitted to perform 'parallel lists' and practise unsupervised in adjoining theatres to consultants⁴⁴⁷ - a practice that is no longer considered acceptable for junior surgeons - controversy surrounding the SCP role shows no sign of abating. In fact, with their remit contentious, and their role encompassing a wider range of procedures than that which was originally envisaged⁴⁴⁸, concerns remain that the introduction of SCPs represents nothing more than a misguided attempt by the government to reach arbitrary targets, and to trick patients into accepting lower standards in return for lower costs⁴⁴⁹. With criticism also coming from junior doctors, who perceive SCPs as diluting the already reduced surgical exposure that is available to trainee surgeons, and as limiting the amount of consultant time and supervision that is available to them, not to mention the potential for jeopardising patient safety⁴⁵⁰, it is clear that cynics have yet to be convinced.

Alongside these concerns is uncertainty surrounding the continuing professional development (CPD) requirements and performance criteria that SCPs are expected to achieve. With CPD closely linked with fitness to practise, and fitness to practise closely aligned with acceptable standards of care, this raises questions surrounding patient safety and the management of clinical risk.

⁴⁴⁵ Earnshaw JJ, Stephenson Y. First two years of a follow-up breast clinic led by a nurse practitioner. Journal of the Royal Society of Medicine 1997;90:258-259

Jones A, Arshad H, Nolan J. Surgical care practitioner practice: one team's journey explored. The Association for Perioperative Practice 2012;22(1):19-23. ISSN 1467-1026

⁴⁴⁷ Nicholas M. The surgical care practitioner: a critical analysis. Journal of Perioperative Practice 2010;20(3):94-9

⁴⁴⁸ Kneebone R, Darzi A. New professional roles in surgery. BMJ. 2005;330:803-4.

⁴⁴⁹ Shannon C. Doctors object to a wider role for Surgical Care Practitioners. British Medical Journal 2005;330(7500):1103

⁴⁵⁰ Bruce CA, Bruce IA, Williams L. The impact of surgical care practitioners on surgical training. Journal of the Royal Society of Medicine 2006;99(9):432-433

Indeed, with some doctors concerned that SCPs may not be able to respond quickly when complications arise⁴⁵¹ - premised on the assertion that no surgery is basic, procedures are only minor in retrospect, and complications can arise at any time - this has led to momentum growing to support the view that SCP practice should be restricted to simple operative techniques, rather than routine surgical operations⁴⁵².

Proposals for direct entry to SCP roles for non-healthcare graduates have also generated interest, amid concerns that these practitioners would not be able to satisfy rigid clinical educational and practical requirements⁴⁵³. However, with surgical training now competency-based rather than time-served, and, therefore, less based on an 'apprenticeship' model of training, it seems that these concerns may have begun to be resolved. In fact, if one accepts that the mark of a competent 'surgeon' is the ability to know when an operation is indicated, the attendant risks and benefits, the optimal timing of intervention, the precise method by which the procedure will be carried out, and an awareness of the likely complications and how to deal with them - with the issue of who holds what instrument at what stage of the procedure beyond this point secondary⁴⁵⁴ - the origin of SCPs no longer seems to be an issue. Indeed, with also grown for surgical training to become standardised^{455,456,457}, and some commentators⁴⁵⁸ going so far as to say that surgical care may, in the future, become the product of a system of delegated function and performance - in which lead clinicians issue instructions and

 $^{^{451}}$ Nicholas M. The surgical care practitioner: a critical analysis. Journal of Perioperative Practice 2010;20(3):94-9

⁴⁵² Bruce CA, Bruce IA, Williams L. The impact of surgical care practitioners on surgical training. Journal of the Royal Society of Medicine 2006;99(9):432-433

⁴⁵³ Nicholas M. The surgical care practitioner: a critical analysis. Journal of Perioperative Practice 2010;20(3):94-9

⁴⁵⁴ Nashef S. Personal view: What makes a surgeon? Knowledge, judgement, accountability. Annals of Royal College of Surgeons of England (Suppl) 1999;89:44-45

⁴⁵⁵ Royal College of Surgeons of England. Assistants in surgical practice: a discussion document. London: Royal College of Surgeons of England. 1999

⁴⁵⁶ Department of Health. Responses to the national curriculum framework for Surgical Care Practitioners. London: DH. 2005

⁴⁵⁷ Department of Health. The national curriculum framework for Surgical Care Practitioners consultation: Summary of responses. London: DH. 2005

⁴⁵⁸ Jones A, Arshad H, Nolan J. Surgical care practitioner practice: one team's journey explored. The Association for Perioperative Practice 2012;22(1):19-23

delegated aspects of care are delivered by other healthcare professionals - it may be that these concerns have already been addressed.

Of particular relevance to aspiring SCPs, who are unlikely to rotate between placements, and who will, therefore, be well-placed to acquire the necessary experience and expertise required for safe clinical practice, this widened approach to entry offers a constructive way forward. Indeed, when one considers the impact that the projected shortfall in medical staffing numbers⁴⁵⁹ could potentially have on practice, this more encompassing approach to workforce development could go some way to providing a solution. However, with concerns still remaining regarding SCP safety, and their remit potentially ranging from arthroscopy to cruciate ligament surgery, Dupuytren contracture release to tendon transfer, excision of malignant melanoma to skin grafting, and hernia repair to varicose vein surgery⁴⁶⁰, this does not address the question of what constitutes an acceptable scope of SCP practice, leaving this important issue yet to be resolved.

Another issue that has invited controversy, and that has yet to be resolved, is that relating to the SCP title. With doctors expressing concern that the word 'surgical' in the SCP title could be confusing to patients and potentially mislead them into thinking that SCPs are medically qualified, momentum has grown for this title to be changed⁴⁶¹. Also linked to this concern is disquiet surrounding the extent to which patients are informed about the discipline of the person who will be operating on them, leading to questions being asked regarding the validity of any consent that may have been given. With evidence^{462,463,464}

⁴⁵⁹ Shemilt S. A UK perspective. The physician assistant role: An evidence base to support statutory registration for physician assistants. Aberdeen: University of Aberdeen. 2012

⁴⁶⁰ Department of Health. The curriculum framework for the Surgical Care Practitioner. London: HMSO. 2006

⁴⁶¹ British Medical Association. New healthcare role will confuse patients, BMA warns. Press release 10 February 2006

⁴⁶² Kingsnorth AN. Training SCPs to perform inguinal hernia surgery: results of the Plymouth Action On programme. Annals of the Royal College of Surgeons of England (Supplement) 2005;87:242-243

⁴⁶³ Moorthy R, Grainger J, Lattis SG, Scott A. Are patients happy with SCPs operating? Bulletin of the Royal College of Surgeons of England 2006;88(3):101-103(3)

⁴⁶⁴ Martin S, Purkayastha S, Massey R, Paraskeva P, Tekkis P, Kneebone R, Darzi A. The Surgical Care Practitioner: A feasible alternative. Results of a prospective 4-year audit at St Mary's Hospital Trust, London. Annals of Royal College of Surgeons of England 2007;89(1):30-35

suggesting a mixed response from patients, regarding whether it is acceptable for non-medical SCPs to perform operative procedures under direct or indirect supervision, this matter clearly warrants further analysis.

Seeking to address this issue, and learn more about the way in which SCP roles are perceived by patients, a number of researchers have reported interesting findings. Notable among these findings are those from Moorthy et al's study⁴⁶⁵ of 374 patients who attended ENT out-patient departments, which sought to ascertain the views regarding the suitability and acceptability of SCPs performing basic surgical procedures. Having invited participants to consider whether, in principle, they would allow members of the surgical team, other than consultant surgeons, to operate on them in relation to procedures such as the removal of 'small lumps and bumps' or the insertion of grommets, Moorthy et al also sought to identify whether the degree of supervision given to SCPs was Intrinsic to this was an acknowledgement of the different levels of an issue. support that supervision can offer, with direct supervision denoted as the situation whereby the consultant surgeon would be present in theatre and actively supervising, and indirect supervision denoted as the situation in which the consultant surgeon would be present in the hospital complex, but would not be actively supervising.

Interestingly, Moorthy *et al* found that, of those patients surveyed, the majority (82%) incorrectly believed SCPs to be medically qualified, and little more than half (52%) said that they would be prepared to allow an SCP to perform such a procedure on them under direct supervision. This raises doubts regarding the acceptability of SCPs to patients, particularly when one considers the fact that 89% of patients indicated that they would be prepared to allow a fully supervised junior doctor, who was specialising in surgery, to perform the same procedure. With as few as 12% of patients also reporting that they would be prepared to allow an SCP to operate on them under indirect supervision, compared with 46% who would prepared for a junior doctor specialising in surgery to perform the same procedure under the same level of supervision, this

⁴⁶⁵ Moorthy R, Grainger J, Lattis SG, Scott A. Are patients happy with SCPs operating? Bulletin of the Royal College of Surgeons of England 2006;88(3):101-103(3)

inevitably raises questions surrounding public confidence surrounding SCPs, and casts doubt upon what the role of the SCP should actually be.

When considered objectively, it would be possible to conclude from these findings that patients would prefer to be operated on by medically qualified members of the surgical team, including junior doctors, rather than SCPs. It would also be possible to conclude that the development of posts to allow SCPs to operate unsupervised is something that patients would not support. However, given that this study was solely undertaken by doctors, and assumes the objective disclosure of balanced comprehensive information surrounding the preparation and training of SCPs to perform these roles - something that has not been able to be verified - it would be prudent to exercise caution when interpreting these findings, rather than drawing any firm conclusions from them.

Findings from a related study by Kingsnorth et al⁴⁶⁶ into the training of an SCP to perform inguinal hernia surgery have also raised concerns. With results showing that, despite having been given appropriate training, the SCP in question was only able to complete one procedure unassisted, this raises questions surrounding the acquisition of competence, and casts doubt upon whether the SCP curriculum⁴⁶⁷ is long enough or detailed enough. These questions are all the more pertinent when one considers that the training provided to the SCP in question included exposure to 800 hours of operating theatre time in relation to hernia surgery, assisting at 150 inguinal hernia operations, and performing 60 procedures under direct supervision and 6 procedures under direct supervision. With Kingsnorth et al reaching the conclusion that the training of SCPs to perform hernia surgery is neither cost-effective - given that they have a long learning curve and are relatively small in number - nor safe, on the basis that even small inguinal hernias can be technically challenging and, therefore, cannot be classed as minor procedures, this does not bode well for their future.

⁴⁶⁶ Kingsnorth AN. Training SCPs to perform inguinal hernia surgery: results of the Plymouth Action On programme. Annals of the Royal College of Surgeons of England (Supplement)

⁴⁶⁷ Department of Health. The curriculum framework for the Surgical Care Practitioner. London: HMSO. 2006

Alternatively, if one accepts the contrasting findings from Martin *et al's* study⁴⁶⁸ of 381 patients undergoing minor surgical procedures over a 4 year period - including the excision of lipoma, sebaceous cysts and spider naevi under local or general anaesthesia - it is entirely feasible that the opposite conclusion could be reached. In this case, Martin *et al* based their study on a service provided by a single SCP who had extensive experience as a theatre nursing sister, and who had undergone intensive in-house training comparable to that of a newly qualified doctor. In this analysis, Martin *et al* found that, of those patients contacted, 67% were aware that their surgery was going to be performed by an SCP, with 98% adding that it would have made no difference to them if a doctor had performed their surgery. Indeed, with 98% of patients also indicating that they would be happy to be seen and treated by the SCP again, and would recommend her to others, and all reporting that they were completely satisfied with the care received - only 11 post-operative complications were encountered - these findings arguably present the SCP role in a more positive light.

Admittedly, it is possible that these findings may be skewed towards the individual SCP in question rather than the SCP role in general, and that an element of bias may have influenced the results. However, given that the study was conducted over a 4 year period and, therefore, involved a realistic prospect of patients returning for further treatment and being treated by the SCP at a future date, any such bias is likely to be insignificant. Further, when considered alongside the belief that patients are unlikely to take kindly to, or provide positive feedback in relation to, those whom they consider to have misled or improperly treated them, it is unlikely that they would report satisfaction when they were not, in fact, content. Accordingly, if one accepts Martin *et al*'s conclusion that the SCP role is a safe, feasible and acceptable alternative for patients⁴⁶⁹, it seems reasonable to conclude that their future is relatively secure.

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⁴⁶⁸ Martin S, Purkayastha S, Massey R, Paraskeva P, Tekkis P, Kneebone R, Darzi A. The Surgical Care Practitioner: A feasible alternative. Results of a prospective 4-year audit at St Mary's Hospital Trust, London. Annals of Royal College of Surgeons of England 2007;89(1):30-35
⁴⁶⁹ Martin S, Purkayastha S, Massey R, Paraskeva P, Tekkis P, Kneebone R, Darzi A. The Surgical Care Practitioner: A feasible alternative. Results of a prospective 4-year audit at St Mary's Hospital Trust, London. Annals of Royal College of Surgeons of England 2007;89(1):30-35

Of course, these findings do not fully address concerns surrounding the SCP title, nor do they take account of all of the issues that have been raised by doctors. However, one approach that could go some way towards addressing these issues is to adopt the proposal advocated by doctors, namely to change the title of those performing this role from SCP to 'Surgical Assistant'. In so doing, this would not only more accurately reflect the role performed by these practitioners and, therefore, more fully inform patients regarding their status^{470,471,472}, but it is likely that this proposal would also resolve some of the lingering controversy surrounding the scope of SCP practice.

With support for this position also coming from a study by the Royal College of Surgeons of Edinburgh into the care provided by Podiatric Practitioners⁴⁷³, this proposal seems likely to gather momentum. This is particularly the case when one considers that 95% of those patients surveyed erroneously believed that their surgery was performed by a doctor, having understood the title 'Consultant Podiatric Surgeon' to imply a medical qualification, and having assumed that only doctors were permitted to operate. Also lending support to this position are findings from a poll of 2,034 patients conducted by the Royal College of Surgeons of England⁴⁷⁴, which revealed similar misconceptions regarding the discipline of treating clinicians. Indeed, with findings from this poll revealing that 95% of patients expected their 'surgeon' to be medically qualified, 90% would be concerned if their 'surgeon' did not have a medical qualification, and 92% believed that the word 'surgeon' on a job title should be restricted by law, this matter clearly warrants further attention.

On the other hand, opposing arguments have been presented which suggest that those performing the SCP role could consider the 'assistant' title to be pejorative, and as significantly undermining the credibility of SCPs in the eyes of

⁴⁷⁰ Kingsnorth AN. Training SCPs to perform inguinal hernia surgery: results of the Plymouth Action On programme. Annals of the Royal College of Surgeons of England (Supplement) 2005;87:242-243

⁴⁷¹ British Medical Association. New healthcare role will confuse patients, BMA warns. Press release 10 February 2006

⁴⁷² Moorthy R, Grainger J, Scott A, Powles JW, Lattis SG. Surgical Care Practitioner - a confusing and misleading title. Bulletin of The Royal College of Surgeons of England 2006;88(3):98-100(3)

⁴⁷³ Royal College of Surgeons of Edinburgh. Surgeons News. January 2005;4(1):83-84

⁴⁷⁴ Royal College of Surgeons of England. A public poll on the word surgeon. London: RCS(Eng) Patient Liaison Group. 2012

the public⁴⁷⁵. If these arguments are accepted, this suggests that agreement surrounding any proposed change to the SCP title may still be a long way off. However, working on the basis that the potential for patients to be misled regarding the discipline of their treating clinician, which could potentially jeopardise the integrity of the therapeutic relationship, would far outweigh any concerns surrounding practitioner reputation and 'gain', it seems that support for a change in title is much more likely to prevail.

Acknowledging that issues surrounding role definition and professional identity have yet to be resolved, inter-professional differences have yet to be fully set aside, and arguments surrounding the suitability and appropriateness of nurses to perform surgical interventions continue to linger, it is true that progress associated with the introduction of SCPs has been variable. Nevertheless, given that demand on services and pressure on waiting times are unlikely to ease, and changes associated with the preparation of doctors in training are unlikely to end, it seems reasonable to conclude that SCPs will have a role in the modern clinical workplace. Assuming that this will be the case, attention now needs to turn to identifying the most effective way of ensuring patient safety, inspiring public confidence, selecting and 'protecting' an appropriate professional title, and identifying the most appropriate regulatory body to oversee SCP practice.

2.3.3.1. The issues in context: the lack of a 'protected' title

Although it is a relatively recent concept, the SCP role is not entirely new, having emerged from earlier innovations such as those relating to the ODP, Theatre Practitioner and 'Surgeon Assistant' As such, the idea of non-doctors performing surgical procedures is similarly not new, with clinicians having already been exposed to new surgical models, and patients having already been exposed to new types of practitioner. What is new, however, is the reduction in hours worked by doctors in training, and changes in their education, both of

⁴⁷⁶ Royal College of Surgeons of England. Assistants in surgical practice: a discussion document. London: Royal College of Surgeons of England. 1999

⁴⁷⁵ Moorthy R, Grainger J, Scott A, Powles JW, Lattis SG. Surgical Care Practitioner - a confusing and misleading title. Bulletin of The Royal College of Surgeons of England 2006;88(3):98-100(3)

which have raised the profile of SCPs and extended the scope of their practice. This means that the risks that are posed to patients from SCP practice are likely to be greater, thus lending weight to the argument that more robust regulatory safeguards are needed.

If one accepts this argument, and also accepts that the practice of medicine is based on an inexact science, it follows that one would also accept that SCP practice is based on an inexact science, given that it is largely founded on medicine. If so, this implies that the risks that are associated with SCP practice are likely to be considerable, given that its parameters have yet to unfold and the associated risks have yet to emerge. Alongside this is the assumption that the risks that are associated with clinical practice are closely correlated with the complexity of procedures, with the assumption being that risks rise directly in line with the level of complexity, and inversely with the level of experience of practitioners. This suggests that, if the risks that are posed to patients by SCPs are to be minimised, and patients are to be protected from those practitioners who may not be properly prepared, SCPs should either perform less complex procedures, or their experience and level of competence should be increased.

Complicating this situation is the fact those practitioners who are on the learning curve, and those who are inexperienced, are often unaware of the limits of their knowledge and competence. As such, they do not always know that which they do not know, with insight often gained only after risks have materialised or errors have occurred ⁴⁷⁷. This is of particular relevance during the transition from confident, competent professional in relation to traditional practice, to that of clinical novice in a new and enhanced role. It is also of particular relevance when one considers that the current situation in healthcare is one in which practitioners, most notably nurses, are able to expand their practice in any way they see fit, subject, of course, to knowledge and competence having first been attained.

Underpinning these concerns is the fact that, at present, the SCP title is not 'protected' by law. This means that it is not an offence for any practitioner

⁴⁷⁷ Launer J. Unconscious incompetence. Postgraduate Medical Journal 2010;86(1020):628

wishing to hold themselves out as an SCP to do so. As such, patients could find themselves exposed to treatment at the hands of unprepared or unprincipled practitioners, with the potential for harm running high. Closely associated with this is the absence of accredited educational standards that those practitioners who wished to use legitimately the SCP title would be expected to adopt. However, given that, as with PAs, there is currently no regulatory mechanism to enforce these standards, this means that the risks are high, and safeguards are low.

Given that statutory regulation is known to provide patients with the necessary safeguards in relation to practitioners' practice, it seems sensible to contextualise the significance of these issues, with a view to determining their impact on practice. Acknowledging the controversy that was generated by her actions, the case of Valerie Tomlinson, the theatre Nursing Sister from Cornwall who assisted with the removal of a patient's appendix during surgery, would seem to provide a useful platform upon which to base this discussion. In fact, given that Sister Tomlinson found herself sanctioned by employers and under scrutiny by the nursing regulator as a consequence of her actions, this case would seem to provide an appropriate vehicle from which to address the range of regulatory issues that are associated with SCP practice.

Essentially centred on whether it was appropriate and reasonable for a nurse to take on the mantle of surgeon and perform surgical procedures, the arguments that ensued in the case of Sister Tomlinson focused on the acceptability of nurses performing surgical procedures and their education and preparation to perform this role. They also focused on the extent to which the patient in question was aware of who would be performing the procedure, and whether he had consented to this.

Unfortunately, there are conflicting reports surrounding what actually happened in Theatre that day. This has led to unresolved questions surrounding whether Sister Tomlinson prepared the patient, made the incision, removed the patient's appendix and sewed up the wound, or whether she merely completed the

procedure while the accompanying surgeon left the room^{478,479}. However, what is not in dispute is that she actively participated in the procedure, had no formal surgical training, was not a recognised SCP, and the patient in question was only made aware of her involvement after the event. As such, this raises questions about Sister Tomlinson's (nurse) training and education and the extent to which these had prepared her for this role, and the extent to which her competence had been assessed beforehand. It also leads to questions surrounding her primary motivation for performing the procedure, whether she routinely expanded her practice in this way, and the extent to which the patient in question's safety featured in her decision to act in the way outlined. Importantly, within the context of the current discussion, it also raises questions surrounding the adequacy of the existing regulatory safeguards that applied in relation to her nursing role.

Although no harm befell the patient concerned, who made a good recovery and chose not to complain or pursue a civil action upon being informed of the situation after the event, the outcry that followed this incident stimulated considerable debate. In fact, it divided opinion strongly over the suitability and appropriateness of nurses being permitted to practise in this way. Of course, considered within the modern healthcare context, and with the benefit of hindsight, the conclusion may be reached that Sister Tomlinson was simply a nurse 'before her time', and an unwitting pioneer of advanced nursing practice. In fact, if such a situation were to arise again today, it is highly unlikely that actions such as these would be considered significant, and it is almost certain that they would not generate anything like the same level of interest or controversy. Instead, it is much more likely that it would be considered a 'normal' part of SCP practice, or a natural extension of the SCP role.

However, an issue that would be more likely to attract attention nowadays is that of whether the nurse - or SCP - in question had completed relevant training and education programmes, and the way, and the extent to which, his or her

⁴⁷⁸ Hall C. Nurse suspended after 'taking out man's appendix'. The Independent Friday 13 January 1995

⁴⁷⁹ Whose hand on the knife? MP voices public's fears over nurse who took out appendix. Daily Mail (London) 13 January 1995

competence had been assessed. Underpinning this would be the question of how those practitioners who *have* been suitably prepared for such a role can be identified, and whether a 'protected' title should be afforded. Also likely to stimulate discussion, would be the scope of practice of the nurse or SCP in question, and the nature of any safeguards that may have been in place to ensure that his or her competence was maintained. Related to this would also be questions surrounding the extent to which the patient in question had been informed regarding who would be performing their procedure, and whether their informed consent had been obtained, with the nature of any regulatory safeguards that were in place and the extent to which these had been adhered to featuring centrally in this analysis.

Underpinning all of these issues are wider concerns surrounding openness and transparency, which sit at the heart of clinical practice and form the basis of safe high quality healthcare⁴⁸⁰. These issues go to the heart of the public's confidence in the healthcare professions, and underpin the trust that is inherent in the patient-practitioner relationship. Also central to high quality healthcare is the need for clinicians to communicate openly and honestly with patients, including the need to explain their discipline, experience and status, so that patients are clear regarding the credentials and credibility of those attending upon them. Not only is this important in demonstrating transparency and integrity in the clinical therapeutic relationship, but it would also go a long way to minimise any potential confusion that could arise in the event of patients mistaking the identity of their treating clinicians.

Of particular significance nowadays, given the almost universal abolition of the traditional uniform worn by nurses and the distinctive white coat worn by doctors, the potential for patients to be confused regarding the professional identity of their treating clinician is real. Indeed, with clinicians, particularly those in hospital settings, tending to wear more practical, but less discriminatory, clinical attire such as hospital 'scrubs', and all adopting the use of symbolic insignia of function, such as stethoscopes, this makes their

⁴⁸⁰ Department of Health. Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. Cm 5363. London: DH. 2002

professional identity harder to differentiate. As such, it is not difficult to see how patients can become confused. This is particularly case when one is reminded that the SCP title is not 'protected', meaning that any practitioner who wished to could hold themselves out as such.

If one also accepts that patients are now more actively involved in their care, take a greater interest in the decisions that affect them, and have a more questioning and engaged attitude towards their treatment and interventions, it seems likely that they will also take a more active interest in the qualifications and competence of those treating them. It is also likely that they will look to the professional titles that their practitioners hold for information regarding their status, education and training, and seek reassurance from professional Registers that the relevant professional standards have been satisfied. However, given that the statutory safeguards that would be sought are not currently provided, this means that patients and the public would not be able to be provided with the reassurance they require.

Inherent in this discussion is the assumption that patients would expect to be consulted regarding the discipline of their treating clinician, informed about the potential risks and benefit of any procedures, have their informed consent obtained before any procedures are performed, and be protected from any 'rogue' practitioners who may seek to mislead them. However, given that the wider body of advanced nursing practice - in this case, SCP practice - is unregulated, and the title of SCP is not 'protected', this means that their education, qualifications and training cannot be verified. Further, given that there is no ceiling on the scope of permissible practices that advanced nurses - including SCPs - may undertake, this means that there is no limit on the range of procedures they may legitimately perform, and there are no regulatory safeguards in place to prevent those who are not suitably trained and qualified as SCPs from attempting to perform them. This, in turn, raises serious questions regarding the extent to which patients, and the public, are protected from such practitioners, and their safety is assured.

2.3.3.2. The need for a professional identity

Given that the majority of clinicians who are practising as SCPs are derived from other healthcare groups, such as nursing or ODP backgrounds, and are, therefore, already registered with a professional regulatory body, this would suggest that the main issue that need to be addressed in relation to SCP practice is one that is less regulatory in nature, and one that is more professionally focussed. This assumes that, for the most part, consistency in the educational standards, codes of conduct and clinical competencies that are required by each of the regulatory bodies would already be provided, and that SCPs from the different professional backgrounds would be trained and held accountable to the same standard. However, as the recent review by the Law Commissions⁴⁸¹ and the resultant policy paper⁴⁸² have shown, this is an assumption that cannot be relied upon, with considerable differences having been shown to exist in the approach that is taken between the various regulatory bodies when determining their standards and applying their codes. This infers that the professional standards and codes to which SCPs from different disciplines would be required to adhere would be variable, rather than consistent, and that they may be held accountable to a different standard. Accordingly, this suggests that the regulatory issues that underpin SCP practice have yet to be resolved.

If one accepts this argument, this leaves the question of which of the professional regulators would be the most appropriate to govern and oversee SCP practice, yet to be determined. Once addressed, this would enable the issues that have been identified to be addressed - namely those that relate to consistency in educational standards, professional codes and clinical competencies - with the conferring of a 'protected' title considered likely to be able to provide the consistent safeguards that are being sought. This, in turn, begs the question of which of the professional regulators would be responsible for deciding upon the name of an appropriate 'protected' title for SCPs, and for

London: Law Commission. 2012

⁴⁸¹ Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: Policy Paper.

ensuring that those practitioners upon whom this title would be bestowed satisfied and adhered to the relevant regulatory requirements.

Although any of the main professional regulators could potentially fulfil this function and oversee the practice of SCPs - most notably the HCPC, NMC or GMC - it is possible that the GMC would emerge as the favoured option. assumption is made on the basis that the practice of SCPs is more closely aligned with that of doctors, and, therefore, medicine, than any of the other professional groups. Alternatively, if one accepts that SCP practice is so distinct from that of any existing professional group, such that it constitutes a new body of practice, it could be concluded that an entirely new form of regulation is needed. If so, this leaves the HCPC the most likely professional regulator to emerge, with arguments similar to those that have already been presented in relation to the regulation of PA practice needing to be addressed.

It is also possible that the NMC could emerge as a possible option, and that a new part of the NMC Register could be 'opened-up' for SCPs. However, given that SCP practice is arguably more aligned with medicine, rather than nursing, and attracts practitioners from a wider range of backgrounds rather than being drawn mainly from nursing, this option does not look likely to prevail. When added to the difficulties that the NMC is currently facing, and the scrutiny it is under^{483,484}, not to mention the prospect that the NMC may be required to regulate nursing Health Care Assistants (HCAs) in the future 485,486, this again does not look like being a viable option.

On the other hand, if one rejects the argument that the solution to the problems surrounding SCP practice lies in regulation, and considers that they are more likely to be found in the professional bodies, this would suggest that an

by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

⁴⁸³ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

⁴⁸⁴ House of Commons Health Committee. Annual accountability hearing with the Nursing and Midwifery Council. Seventh Report of Session 2010-2012. HC 1428. London: HMSO. 2011 ⁴⁸⁵ The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided

⁴⁸⁶ Royal College of Nursing. Quality with compassion: the future of nursing education. Report of the Willis Commission on Nursing Education 2012. (The Willis Commission Report). London: RCN. 2012

alternative approach, such as that which would involve the professional Royal Colleges would be more appropriate. If so, this implies that the Royal Colleges would be called upon to delineate the parameters of an acceptable scope of SCP practice, oversee the actions of practitioners, and assure the quality of the requisite educational and professional framework. However, if one accepts that the role of quality assuring the standards of education and ensuring the fitness to practice of practitioners are the functions of the regulators, with the professional bodies, in turn, responsible for setting the requisite educational standards, this suggests that a combined approach that would involve both the regulators and the professional bodies would be required.

Of course, underpinning these arguments is the overriding issue of the lack of a 'protected' SCP title. This issue, in itself, indicates that the regulatory issues have not been resolved, with the granting of statutory regulation and the conferring of an associated 'protected' title automatically providing the safeguards that are being sought. Thus, until and unless statutory regulation is provided, any changes to SCP practice are likely to be piecemeal and, as such, have limited impact.

Given that the education of SCPs is already underpinned by a curriculum and competence framework⁴⁸⁷ that has already been acknowledged by the relevant (medical) Royal Colleges, the professional dimension to this solution would seem to have already been satisfied, in that the educational requirements have already been delineated. This assumes, of course, that further endorsement of the relevant educational standards would not also be required by the (nursing) Royal College. This is an assumption that would need to be tested, and may not in fact be verified, given that many of those practitioners who are currently performing the role of SCP originally derive from nursing, and hold a professional nursing qualification. In the event that this assumption is not borne out, and endorsement from *all* the relevant Royal Colleges would be required, this implies that further work would be needed to achieve the required consensus surrounding educational standards, and that an agreed framework may take longer to achieve.

⁴⁸⁷ Department of Health. The curriculum framework for the Surgical Care Practitioner. London: HMSO. 2006

If one accepts these arguments, and, in particular, the argument that a combined professional and regulatory solution is needed, this still leaves the question of which of the professional healthcare regulators would be most suitable for this purpose. With momentum for change in the form of 'protecting' an appropriate professional title most likely to come from medicine, rather than nursing, and to derive from pressure from doctors and professional bodies rather than regulators, this again suggests that the GMC could provide the most appropriate regulatory solution. However, irrespective of the regulatory body that is most likely to prevail, this still leaves the question of whether a 'ceiling' should be imposed on the scope of permissible SCP practice in the interests of patient safety, and, if so, the level at which this 'ceiling' should be set.

Working on the basis that innovation is associated with a heightened level of risk - at least until the relevant experience and expertise have been acquired - and that advanced nursing roles are, in many ways, innovative, and, therefore, risky - this suggests that arguments that favour the imposition of a 'ceiling' on the scope of SCP practice may carry weight. Supporting this position is the argument that procedures are only minor in retrospect, and risks can, and will, materialise at some stage. Alternatively, if one considers that part of being an autonomous healthcare professional is the obligation to be accountable for one's actions, and being able to assess and decide upon an appropriate level of risk - including having the discretion to determine if, and when, to use one's skills based on an assessment of individual patients' needs - this suggests that the imposition of a 'ceiling' may not be appropriate.

Considered objectively, if one accepts that patients' best interests should underpin all interventions, all interventions are associated with risk, and public protection is the responsibility of the regulators, this suggests that arguments in favour of the regulators imposing a 'ceiling' on practice should prevail. This assumption places patient safety above all other factors, and, as such, is a position with which few could reasonably argue. However, if one accepts that

the professional nursing 'code'⁴⁸⁸ - and the professional codes that are provided by each of the other healthcare regulators - are also premised on patients' best interests, with practitioners compelled to ensure that all actions taken by them are beneficial to patients, it is possible that one could conclude that professional regulatory codes could, in themselves, be sufficient to provide the necessary safeguards. If so, this would rely upon the integrity of nurses, and other healthcare professionals, to ensure that their knowledge and competence are always maintained, to act always within the scope and parameters of their practice, and to acknowledge any limitations or weaknesses in their practice, with their overriding duty being always to ensure that patients' best interests take precedence over any personal gain.

Working on the basis that both of these arguments are equally persuasive, this suggests that a compromise position may be more appropriate. If so, this would suggest that a position in which SCPs would not have complete freedom to perform any surgical procedure that would theoretically be possible, but would also not have an arbitrary ceiling imposed on their practice, would result. If supported by a robust educational framework, that was reviewed regularly by *all* relevant professional bodies and updated in line with healthcare developments, this would not only ensure that SCP practice remained relevant and practicable, but would also provide patients and the public with the reassurance that their safety and protection had been secured.

2.3.4. Emergency Care Practitioners

Implemented under the auspices of *Reforming Emergency Care*⁴⁸⁹, and resulting directly from the *Changing Workforce Programme*⁴⁹⁰, the Emergency Care Practitioner (ECP) role is also an interesting concept, and one of the first new roles to have received central government funding beyond pilot study

⁴⁸⁸ Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

⁴⁸⁹ Department of Health. Reforming emergency care: first steps to a new approach. London: DH. 2001

⁴⁹⁰ Department of Health. Changing workforce programme: New ways of working in healthcare. London: HMSO. 2002

completion. Derived from the Practitioner in Emergency Care (PEC) concept, which was first devised by the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) and the Ambulance Service Association (ASA)⁴⁹¹, this initiative epitomises the notion of the 'hybrid' practitioner, and what is understood to be advanced nursing practice. Consisting mainly of emergency nurses and ambulance paramedics, who undergo training and acquire competencies associated with the parallel profession, the intention was that ECPs would constitute a new breed of autonomous practitioner, capable of working across organisational and professional boundaries, and able to provide seamless high quality care.

With their aim focused on achieving ambulance response targets, avoiding unnecessary hospital admissions, reducing ED waiting times, and saving money and hospital bed-days, ECPs are received positively by patients, who consider them favourably when compared with traditional healthcare providers^{492,493}. They are also considered favourably by other healthcare professionals, many of whom consider ECPs to signify the future of mobile urgent healthcare delivery, and to represent a flexible workforce that is able to respond to patients' unscheduled healthcare needs in a timely way⁴⁹⁴. Much of this support derives from their encompassing remit, which involves ECPs treating patients with a wide range of undifferentiated and undiagnosed healthcare problems in a variety of settings, with interventions carried out by ECPs in the out-of-hospital setting avoiding the traditional situation in which many of these patients would routinely be taken to hospital.

Thus armed with a repertoire of skills, the aim of this initiative was that ECPs would be able to reduce inter-professional handovers, enhance the speed and quality of patient journeys, and ensure that care was delivered in the most

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Joint Royal Colleges Ambulance Liaison Committee. The future role and education of paramedic ambulance service personnel (Emerging concepts). London: JRCALC. 2000
 Adams A, Wright K, Cooke M. Evaluation of the NHS Changing Workforce Programme's Emergency Care Practitioner Pilot Study in Warwickshire. University of Warwick. 2005
 Mason S, O'Keefe C, Coleman P, Edlin R, Nicholl J. Effectiveness of emergency care practitioners working within existing emergency service models of care. Emergency Medicine Journal 2007;24:239-243

⁴⁹⁴ Department of Health. Emergency care ten years on: reforming emergency care. London: HMSO. 2007

appropriate location and at the most appropriate time⁴⁹⁵. Inherent in this aim was acknowledgement of the ability of ECPs to make autonomous clinical decisions, demonstrate enhanced diagnostic skills, carry out relevant investigations, and exercise clinical judgement, with access to senior expertise and support available through telemedical systems if needed. Also underpinning this aim was the assumption that ECPs would be able to deliver complete episodes of care, either by discharging patients on scene, or by referring them to other agencies where appropriate⁴⁹⁶. As such, and with their practice supported by legislation that allows them to 'prescribe' certain emergency medicines under relevant legislation⁴⁹⁷, and to administer a specific range of medicines under PGDs⁴⁹⁸, the result has been for the scope of ECP practice to be more autonomous than that of practitioners from either of the originating professions.

Having been piloted in 17 sites^{499,500} and trialled in three environments, feedback in relation to ECP practice has been favourable⁵⁰¹. In fact, high levels of patient satisfaction and positive self-reported health outcomes have been reported whether ECPs are employed in ambulance services, where they respond to low-priority calls initiated by ambulance control, Minor Injury Units in which an ambulance control call-out system is retained, or in General Practice, where call-outs from GP surgeries involve the provision of out of hours care and home visits. With evidence⁵⁰² also revealing that ECPs fulfil a broader public health

⁴⁹⁵ Department of Health. Delivering the NHS Plan: next steps on investment, next steps on reform. London: HMSO. 2002

⁴⁹⁶ Department of Health. Right skill, right time, right place. The Emergency Care Practitioner Report. London: HMSO. 2004

⁴⁹⁷ The Prescription Only Medicines (Human Use) Order 1997. SI 1997 No 1830 Article 7

⁴⁹⁸ Department of Health. HSC 2000/026. Patient group directions (England only). London: DH. 2000

⁴⁹⁹ Mason S, Coleman P, Ratcliffe J, Turner J, Nicholl J. A national evaluation of emergency care practitioners. Phase one. Report to the Department of Health. Sheffield: School of Health and Related Research. 2004

⁵⁰⁰ Mason S, Coleman P, O'Keefe C, Ratcliffe J, Nicholl J. The evolution of the emergency care practitioner role in England: experiences and impact. Emergency Medicine Journal 2006;23:435-439

⁵⁰¹ Halter M, Ellison G. Evaluation of the Emergency Care Practitioner role in London: A study of the processes and outcomes of clinical decision-making. London: Kingston University and St George's, University of London. 2008

⁵⁰² Mason S, O'Keefe C, Coleman P, Edlin R, Nicholl J. Effectiveness of emergency care practitioners working within existing emergency service models of care. Emergency Medicine Journal 2007;24:239-243

and primary care outreach role in rural and urban locations than traditional healthcare providers, and reviews of their practice⁵⁰³ showing that patients have fewer investigations, more immediate referrals at initial consultation, more clinical treatments, and are more likely to have a home 'disposal' when seen by ECPs rather than their usual service providers, ECPs are seen as providing a welcome addition to the healthcare team.

Now working to a national curriculum and competence framework⁵⁰⁴, and required to demonstrate minimum levels of clinical experience and satisfy a national assessment process, it is hoped that some of the concerns that were originally associated with ECP practice may have been alleviated. Featuring among those concerns to have been raised were questions surrounding whether it was always appropriate to base the success of the ECP role on outcome measures, such as reduced conveyance levels and cost-savings, or whether the emphasis should have been focused more on clinical effectiveness and outcomes⁵⁰⁵. Also featuring within these concerns were questions surrounding whether it was always safe or appropriate to allow ECPs to 'discharge' patients, or whether further assessment or referral may have been more appropriate, in the interests of patient safety.

With the curriculum and competence framework focusing on the development of competence in clinical ability and decision-making, and with ECPs now required to undertake CPD in line with other healthcare professionals, their practice is arguably now more robust and underpinned by more open and transparent competencies. However, the creation of this framework does not completely resolve the difficulties that have arisen, with most ECPs having been found not to comply with the original plan, in which they were expected to maintain and update generic skills through rotations in pre-hospital, primary and acute care, and demonstrate ongoing learning, knowledge and competence using a portfolio

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⁵⁰³ Cooke M, Fisher J, Dale J, McLeod E, Szczepura A, Walley P, Wilson S. Reducing attendances and waits in emergency departments: a systematic review of present innovations. London: SDO. 2004

⁵⁰⁴ Department of Health. The competence and curriculum framework for the Emergency Care Practitioner. London: DH. 2006

⁵⁰⁵ Cooke M, Fisher J, Dale J, McLeod E, Szczepura A, Walley P, Wilson S. Reducing attendances and waits in emergency departments: a systematic review of present innovations. London: SDO. 2004

approach⁵⁰⁶. Indeed, with anecdotal evidence showing only sporadic adherence to this approach, inconsistent levels of supervision, unclear governance arrangements, and limited, if any, rotation of ECPs through primary and acute care - with most ECP practice now effectively based within ambulance services - the extent to which their competence has been able to be assured across all three domains is questionable.

Nor does the creation of a curriculum and competence framework enable potential problems associated with confusion of professional identity among ECPs to be addressed. This situation has arisen because, although most ECPs are now based in ambulance services, and are, therefore, more likely to originate from ambulance paramedics, some ECPs still originate from nursing or other 'paramedical' backgrounds. For this latter group of ECPs (namely non-ambulance paramedics), this has resulted in the situation whereby they 'belong' to neither one professional group nor the other, and are vulnerable to competing systems of regulation, and, therefore, accountability. In fact, the situation still remains in which some of these ECPs have retained registration with their original professional body - the 'lead regulator' - while being subject to the operational regimens of both ^{507,508}.

Underpinning these issues is the fact that the ECP title is not statutorily regulated, and, therefore, not 'protected' by law. This means that, in addition to practitioners being unclear of their identity, patients and the public will also be confused. Also reinforcing this is the fact that, with the lack of regulation comes the fact that accredited standards of education cannot be assured.

With their remit extending beyond traditional boundaries, and confusion of accountability potentially arising in the absence of a clear regulatory framework for those ECPs who hold dual registration with two regulatory bodies, this leaves the unanswered question of 'who regulates who' and which of the 'competing

⁵⁰⁶ Skills for Health. Measuring the benefits of the Emergency Care Practitioner. Leeds: Skills for Health. 2007

⁵⁰⁷ Department of Health. The regulation of non-medical healthcare professionals: a review by the Department of Health (The Foster Report). London: HMSO. 2006

⁵⁰⁸ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. June 2010

regulatory codes should apply. This is particularly relevant in those situations in which something has gone wrong, and in those situations in which the practice or conduct of ECPs has been called into question, and where disciplinary sanctions are being considered. Further heightening these concerns is anecdotal evidence which suggests that ECPs are perceived by the public to have a clinical portfolio similar to that of junior doctors; a status which many are unable to justify. So, too, are more recent evaluations 509,510,511, which show variable evidence of the impact of ECPs on services, and a dearth of evidence regarding the associated risks to patient safety 512,513. As such, it is clear that this situation warrants further analysis.

2.3.4.1. The issues in context: confused accountability

For those nurses who have extended their practice, such that it satisfies the curriculum and competence framework for ECP practice, the potential for them to be registered with two different statutory regulatory bodies⁵¹⁴ can be problematic. This situation is more applicable to the application of regulatory codes, rather than educational standards, given that all ECPs, from whatever professional background, are now likely to be working to the same generic competencies provided for in the curriculum and competence framework, and to have been assessed as having attained the same clinical and educational standards. Rather, the problems that could potentially arise are those that are associated with the actions that could, and should, ensue when something goes wrong, given the absence of a separate statutory regimen.

⁵⁰⁹ Cooper S, O'Carroll J, Jenkin A, Badger B. Collaborative practices in unscheduled emergency care: role and impact of the emergency care practitioner quantitative and summative findings. Emergency Medicine Journal 2007;24(9):625-629

⁵¹⁰ Mason S, O'Keefe C, Coleman P, Edlin R, Nicholl J. Effectiveness of emergency care practitioners working within existing emergency service models of care. Emergency Medicine Journal 2007;24:239-243

⁵¹¹ Cooper S, Grant J. New and emerging roles in out of hospital emergency care: A review of the international literature. International Emergency Nursing 2009;17:90-98

⁵¹² Cooke M. Emergency care practitioners: a new safe effective role? Quality Safe Health Care 2006;15(6):387

⁵¹³ Woollard M. Paramedic practitioners and emergency admissions. British Medical Journal 2007;335(7626):893-894

⁵¹⁴ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. June 2010

Working on the basis that differences exist between the various professional regulatory bodies - as evidenced in the recent Law Commissions Review⁵¹⁵ - this means that, in the event of something going wrong, confusion and conflict could potentially arise when seeking to determine which of the two regulatory bodies would have responsibility for holding practitioners to account, and for applying any disciplinary sanctions that may be warranted. On the face of it, this may not seem to be a serious problem. However, deeper analysis shows that, if left unresolved, this situation could potentially leave patients unsure of the professional standards to which practitioners will be held to account, and could leave the regulatory bodies, themselves, potentially reaching different conclusions when faced with the same set of circumstances. This, in turn, means that a completely different finding and determination could be made in any associated fitness to practise cases that may result, or in response to any investigations or disciplinary matters in which misconduct or malpractice may have been alleged.

Added to this complexity are potential difficulties that could also arise in the event of one regulatory body being aware of sanctions on a practitioner's practice, but the other is not; such as where conditions have been imposed on a practitioner's practice. In cases such as these, it is entirely possible that the practitioner in question may choose not to disclose the relevant findings to the regulatory body that has not imposed the sanctions, leaving the practitioner - at least theoretically - able to practice, without sanction, under the auspices of the other regulatory body. Of course, this analysis does not take account of the duty and responsibility of practitioners to inform and disclose to their employer any sanctions that have imposed on their practice. Nor does it take account of the expectation that regulators would share or provide reciprocal access in relation to fitness to practise cases to the other health professional regulators. This situation also assumes that any investigations or proceedings that may have been undertaken by one of the regulatory bodies were not first initiated by the practitioner's employer; a sequence of events that, if initiated by the employer, would normally result in the regulator in question informing the practitioner's

⁵¹⁵ Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

employer of any progress on the matters in question, and any determinations that had been made.

Of particular significance to those nurses who have advanced their practice such that it constitutes a new clinical role, and brings them into contact with two potentially competing regulatory masters, this situation highlights the difficulties that could potentially ensue when statutory regulation and 'protection' of title are not afforded to new professional groups, and those in new clinical roles. It also indirectly raises concerns surrounding the potentially different findings that could be reached, and the different sanctions that could potentially be applied in the event of an ECP's conduct or performance being called into question. In fact, it raises the real possibility of different findings being reached when action is taken by the NMC - in the case of nurses - and the HCPC - in the case of ambulance paramedics, in response to the same set of circumstances. This situation could quite feasibly arise in those cases where ECPs choose to remain registered with their originating regulatory body, but where their ECP colleagues performing the same clinical role could be subjected to different regulatory standards and codes.

Arguably an unsatisfactory situation from the perspective of those ECPs who seek to do their best to act professionally and to adhere to professional codes, this situation could leave some practitioners unsure regarding which regulatory guidance to follow, and others assessed against different standards. Given that this situation is unsatisfactory from the perspective of practitioners, and leaves patients at risk of being cared for by practitioners who are held accountable to different standards, this leads to the position whereby the credibility of regulators and the public's confidence in professional regulation could potentially be undermined. On this basis, it is submitted that a compelling case for the statutory regulation of advanced practice and new clinical roles, such as ECPs, can be made on the basis that this approach would provide the necessary consistency and transparency, and enable the associated risks to be managed effectively. This, in turn, leaves the question of which regulatory body would be most appropriate for this purpose.

2.3.4.2. The need for a single regulatory body

From a legal perspective, only one regulatory body can undertake statutory regulation for a distinct profession. However, from an individual perspective, practitioners may be registered with more than one regulated profession if appropriately qualified and wishing to practise both⁵¹⁶. At the moment, those individuals who wish to practise as ECPs can choose to retain their original registration - the NMC in the case of emergency nurses, or the HCPC in case of ambulance paramedics - or satisfy the additional requirements to enable them to register and practice with both.

This means that, in practice, those individuals performing the role of ECP are not bound by a uniform set of standards, with differences in regulatory codes holding them accountable to potentially different standards. Interestingly, this could quite feasibly result in the situation whereby ECPs who are employed by the same healthcare organisation, and who are working alongside each other performing the same clinical role, could be held accountable to different standards, and have different regulatory sanctions applied. This would be the case, irrespective of whether they took the same decision when faced with the same set of circumstances, and acted in a similar way. Given that the aim of regulation is to provide a transparent mechanism for ensuring public protection, and to provide patients with a consistent standard of care from those practitioners who have been deemed fit to practise, it is submitted that the current regulatory system that underpins ECP practice provides neither the transparency nor the consistency that are required, but instead leads to potential division and double standards among practitioners. As such, it is submitted that a compelling case for statutory regulation and a 'protected' ECP title has been convincingly made.

An alternative approach would, of course, be for ECPs to be recognised as a new professional group and to be regulated by one regulatory body, with a new Register 'opened up' specifically for them. This could be achieved by the HCPC - who currently regulate ambulance paramedics - regulating them, or the NMC or

⁵¹⁶ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. June 2010

the GMC. However, given that the current direction of policy travel prohibits the statutory regulation of new professional groups except in compelling cases⁵¹⁷, this option would only be available to ECPs if their role was accepted as being sufficiently different from those of existing professions such that it constituted a discrete activity, or the risks associated with their practice could be shown not to be satisfied by other existing regulatory means. Working on the basis that the role of the ECP is one of the few clinical roles to span professional, geographic and clinical boundaries, and one of the few roles that is focused on expanding the boundaries of emergency and urgent care in this way, it is possible that ECPs would be able to satisfy these criteria.

As intimated earlier, it is currently the case that most ECP roles are now performed by ambulance paramedics, with relatively few nurses choosing to expand their practice in this way. Due, in part, to local variation in the way that ECPs are utilised, and the extent to which they are 'permitted' to practise to their full skill set, this has resulted in the situation in which ECPs are now considered by some⁵¹⁸ to represent an advanced form of paramedic practice, rather than advanced nursing practice. Nevertheless, given that a significant number of nurses still choose to practise in this way, the ECP role cannot be discounted as a legitimate form of advanced nursing practice.

This situation is further complicated by the fact that ECP practice is associated with questionable levels of supervision, variable levels of prescribing ability, diverse scopes of practice, and poor clinical audit^{519,520}. This variation is particularly notable when one considers that nurses are able to prescribe medicines independently, but ambulance paramedics are only permitted to prescribe certain emergency medicines independently, and only in emergency

⁵¹⁷ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. February 2011 ⁵¹⁸ Thompson W, Meskell P. Evaluation of an Advanced Nurse Practitioner (Emergency Care) - An Irish perspective. The Journal for Nurse Practitioners 2012;8(3):200-205

⁵¹⁹ Mason S, O'Keefe C, Coleman P, Edlin R, Nicholl J. Effectiveness of emergency care practitioners working within existing emergency service models of care. Emergency Medicine Journal 2007;24:239-243

⁵²⁰ Skills for Health. Measuring the benefits of the Emergency Care Practitioner. Leeds: Skills for Health. 2007

situations⁵²¹. In fact, in some cases, this situation has led to the perception that ECPs are glorified paramedics rather than being autonomous practitioners⁵²². Admittedly, this situation has started to be addressed, at least in part, by the introduction of university-based degree courses which focus on enabling ECPs to provide an evidence-based rationale for their practice, and develop autonomous clinical skills. However, although offering a partial solution, given that these educational standards are not mandated in law and cannot be enforced, this does not address lingering doubts regarding potential regulatory duplication, and leaves unanswered questions surrounding the efficacy of those forms of regulation that are currently in place.

2.3.5. Immediate Care Practitioners

Considered by many to be at the cutting-edge of non-medical practice, the concept of 'immediate medical care' is also said to epitomise advanced nursing practice. Defined as the provision of skilled medical help at the scene of an accident or medical emergency, and during transport to hospital⁵²³, it represents a sphere of practice that has evolved gradually from the special interests of doctors⁵²⁴. Founded on the support that is offered by clinical 'volunteers' to ambulance services free of charge^{525,526}, and featuring centrally in the newly formed sub-speciality of Immediate Medical Care⁵²⁷, it comprises six areas of professional practice and a number of cross-cutting themes, each of which recognises the knowledge, skill and experience required for autonomous practice. Central among these themes are the ability to work with emergency

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http://www.basics.org.uk/ (Last accessed 31.07.12)

http://www.basics-scotland.org.uk/ (Last accessed 31.07.12)

⁵²¹ The Prescription Only Medicines (Human Use) Order 1997. SI 1997 No 1830 Article 7

Thompson W, Meskell P. Evaluation of an Advanced Nurse Practitioner (Emergency Care) - An Irish perspective. The Journal for Nurse Practitioners 2012;8(3):200-205

⁵²³ Mackenzie R, Bevan D. A license to practise pre-hospital and retrieval medicine. Emergency Medicine Journal 2005;22(4):286-293

⁵²⁴ Porter KM. Training doctors in prehospital care: the West Midlands (UK) approach. Emergency Medicine Journal 2004;21(4):509-510

⁵²⁵ British Association for Immediate Care (BASICS)

⁵²⁶ British Association for Immediate Care, Scotland (BASICS Scotland)

⁵²⁷ Intercollegiate Board for Training in Pre-hospital Emergency Medicine. Sub-speciality training in pre-hospital emergency medicine. Curriculum framework and assessment blueprint. London: IBTPHEM. 2012

medical teams and systems, provide pre-hospital emergency care and use pre-hospital equipment, provide support in rescue and entrapment situations, provide safe patient transfer and retrieval, and demonstrate emergency preparedness and responsiveness.

Although based on the principles enshrined in *Good Medical Practice*⁵²⁸, and originally considered to be the preserve of medicine, the concept of immediate medical care is also now practised by a wide range of non-medical clinicians, most notably nurses and ambulance paramedics. Incorporating the concepts of team (crew) resource management^{529,530} and the principles of good clinical governance⁵³¹, it is focused on ensuring the provision of safe and timely high quality care to all those who require intervention, particularly when in extremis. As such, it relies upon those practitioners who have chosen to practise in this way having a highly developed skill set, the ability to make complex clinical decisions, and maintaining knowledge and competence that is regularly updated. This is particularly the case when one considers that the skill set of those practitioners who have chosen to practise in this way includes a wide range of complex and traditionally medical interventions, such as endotracheal intubation, rapid sequence induction, cricothyroidotomy, thoracotomy, chest drain insertion, and amputation - all of which carry a significant risk profile.

As an area of practice that is almost exclusively delivered in uncontrolled and potentially hostile out-of-hospital environments, immediate medical care does not lend itself to the support that is typically offered by internal hospital support mechanisms. This means that the systems that would normally be relied upon by practitioners to assess and manage clinical risks are weakened, leaving patients and the public reliant upon the integrity of individual practitioners, and their adherence to regulatory codes, to provide the necessary safeguards. Further complicating this situation is the fact that most Immediate Care Practitioners (ICPs) practice outside of the NHS in their capacity as 'volunteer'

⁵²⁸ General Medical Council. Good Medical Practice. London: GMC. 2009

⁵²⁹ Department of Health. An organisation with a memory: Report of an expert group on learning from adverse events in the NHS. London: HMSO. 2000

⁵³⁰ Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Washington: Institute of Medicine. 2000

⁵³¹ Department of Health. A first class service: quality in the new NHS. London: HMSO. 1998

practitioners, and rely upon volunteer team members and schemes for their support, with the concept of paid ICPs working in the NHS having only recently begun to emerge.

With the voluntary nature of ICP practice meaning that more reliance is placed on practitioners adhering to regulatory codes, being responsible enough to undertake only those activities that they are competent to perform, and complying with guidance that has been issued by professional bodies, the role of regulation in relation to ICPs is arguably more important than it is in relation to other new roles. This is particularly the case given the nature and magnitude of the risks that are involved. Indeed, with the absence of statutory regulation denoting the absence of accredited educational standards, this means that the requirement to achieve a defined level of education and competence in order to practice as an ICP is conspicuous by its absence. This, in turn, leaves patients and the public at risk of being treated by those practitioners who may not have attained the level of competence that is required for safe practice, and at risk of receiving substandard care.

Derived from multiple clinical backgrounds, and performing an essentially medical role, it is true to say that non-medical ICPs are credited with having a clinical portfolio that is not dissimilar to that of doctors. They are also required to maintain knowledge, skills and competence commensurate with their scope of practice, to meet the same standards as doctors, and to have appropriate indemnity arrangements in place^{532,533}. As such, immediate medical care offers non-medical ICPs a breadth and depth of practice beyond that associated with other new roles, and epitomises the meaning of true inter-professional practice. However, given that the voluntary nature of immediate medical care means that ICPs do not come under the 'control' of mainstream healthcare, this means that their monitoring and governance arrangements - including the requirement to comply with organisational policies, and formal audit and supervision - are

⁵³² Porter K. Code of practice between immediate care doctors and ambulance NHS Trusts. Emergency Medicine Journal 2005;22:822

Department of Health. Health Care and Associated Professions (Indemnity Cover) Order 2013. A paper for consultation: A joint consultation by the four UK health departments. London: DH. 2012

inconsistent. This, in turn, renders their practice all the more risky, given that the necessary safeguards are not in place.

Seeking to define the requisite standards for immediate medical care and the underpinning standards of education and training, voluntary organisations such as BASICS⁵³⁴ and BASICS (Scotland)⁵³⁵ have developed and delivered a range of training courses over the years. Central among these programmes are first level courses, such as Pre-Hospital Emergency Care (PHEC)⁵³⁶, which are attended and delivered by multi-disciplinary professionals on an equal basis, and denote the minimum level of practice that must be satisfied before individuals are able to practise as an ICP. Also central among these programmes is the Diploma in Immediate Medical Care of the Royal College of Surgeons of Edinburgh $(DipIMCRCS(Ed))^{537}$ - widely acclaimed as the 'gold standard' immediate care qualification, and undertaken and examined by multi-professional colleagues on an equal basis - with candidates and examiners considered to equally credible. However, given that these qualifications - with the exception of the DipIMCRCS(Ed) - are developed, delivered, and accredited by voluntary organisations, are not mandated by law and, therefore, do not constitute a license to practise, this means that there is no way of guaranteeing to patients that those individuals who hold themselves out as practising in the field of immediate medical care have been prepared to the same level, and are practising to the same clinical standards.

In this context, it is true to say that the sub-speciality of immediate medical care is unique in acknowledging the contribution of all of practitioners, expecting an equivalent standard from them, and holding them equally to account, irrespective of their professional discipline or status. Aiming to build upon this foundation, it is intended that the recently formed sub-speciality of

⁵³⁴ British Association for Immediate Care (BASICS)

http://www.basics.org.uk/ (Last accessed 31.07.12)

http://www.basics-scotland.org.uk/ (Last accessed 31.07.12)

⁵³⁶ Pre-Hospital Care course (PHEC)

http://www.basics.org.uk/basics_education/phec (Last accessed 01.08.12)

⁵³⁷ The Royal College of Surgeons of Edinburgh. Diploma in Immediate Medical Care regulations 2010

http://www.fphc.info/downloads/02a%20DIMC%20Regulations%20with%20effect%20from%20OCT% 202010.pdf (Last accessed 01.08.12)

⁵³⁵ British Association for Immediate Care, Scotland (BASICS Scotland)

immediate medical care⁵³⁸ will go some way to formalise this situation, and provide a stronger platform from which the relevant clinical standards can be developed and subsequently enforced. However, given that this sub-speciality and the curriculum framework that underpins it is currently focused on the practice of hospital-based medical ICPs, with no parallel mechanism having yet been put in place for non-medical ICPs or General Practitioner (GP) volunteers who work outside of the hospital system, this means that patients are effectively provided with different levels of 'protection' from different categories of ICP. With patients and the public arguably entitled to the same standard of care and the same level of 'protection' from all ICPs, irrespective of their discipline or designation, this is a situation that clearly warrants intervention.

2.3.5.1. The issues in context: disparate education and training

There can be few who doubt that the creation of a specific sub-speciality for immediate medical care⁵³⁹ represents a significant landmark in the profession's evolution. So, too, did 'opening up' of the DipIMCRCS(Ed) qualification to non-doctors in 1998, with nurses and ambulance paramedics being the only non-medical healthcare professionals who have been able to take up this ground-breaking opportunity. However, although intended as providing a professional framework for immediate medical care that would be accredited by the various Royal Colleges, the reality is that this new sub-speciality, which is still in its infancy, is viewed as an elite sub-speciality that is really only applicable to those *doctors* who are members of the relevant Royal Colleges, and, even then, only those who are currently practising in the in-hospital setting. Indeed, the reality is that most GPs, who were the original pioneers of immediate medical care, and the founders of most local immediate care schemes, do not see the sub-speciality as being particularly applicable to them. Rather, they consider it to be the domain of more junior and ambitious doctors in training, who wish to

⁵³⁸ Intercollegiate Board for Training in Pre-hospital Emergency Medicine. Sub-speciality training in pre-hospital emergency medicine. Curriculum framework and assessment blueprint. London: IBTPHEM. 2012

⁵³⁹ Intercollegiate Board for Training in Pre-hospital Emergency Medicine. Sub-speciality training in pre-hospital emergency medicine. Curriculum framework and assessment blueprint. London: IBTPHEM. 2012

develop a career in emergency medicine, of which immediate medical care will form a central part.

At the moment, other than the recently created sub-speciality, and the DipIMCRCS(Ed) examination - which is undertaken voluntarily and is not mandated by law - there is no form of standardisation or 'regulation' which underpins the practice of immediate medical care, and those who perform it. This statement does not negate the fact that those healthcare professionals who are currently practising as ICPs - namely nurses, doctors and ambulance paramedics - are already regulated by separate regulatory bodies, and are bound by their relevant regulatory codes. Rather, it acknowledges the fact that an additional level of protection, and, therefore, regulation, is required to address and take account of the considerably increased risks that are associated with immediate medical care. It also acknowledges the additional safeguards that are required to protect patients from those practitioners who are considered to be incompetent, and those who may otherwise be considered as providing substandard care. It also implies that the necessary additional safeguards could be provided through a system of accredited educational standards, with a more mature sub-speciality potentially able to fulfil this role. This, in turn, acknowledges the benefits that all types of ICP - including those from nursing and paramedical backgrounds - could potentially obtain from defined educational standards and competencies; benefit that is unlikely to be afforded in the absence of statutory regulation and the conferring of a 'protected' ICP title.

Seeking to contextualise the significance of these problems, most notably the complexity of immediate medical care and the severity of the risks that are posed to patients, it seems prudent to consider an example in which ICP practice is performed. The situation in which ICPs are called upon to manage the care of patients with chest trauma, that necessitates the insertion of a chest drain as a life-saving intervention, provides a useful platform for this discussion.

Given that the insertion of a chest drain in out-of hospital emergency situations is known to be fraught with risks, including those risks that are associated with massive external haemorrhage in the event of complications not being managed

effectively, it is clear that a high level of skill and competence of practitioners is required if patients are to be given the best chance of survival. It is also clear that, in order to practise autonomously, ICPs will need to be able to administer any medicines that are required. However, given that most non-medical ICPs are limited in their practice, in that they are hindered by the lack of an independent prescribing qualification, this means that they may not be able to complete interventions or episodes of care. In practice, not only would this call the scope of their practice and, therefore, the extent of their autonomy into question, but, given the absence of statutory regulation for this group, it would also lead to patients being exposed to double standards in care and disparate levels of competence. This situation could particularly arise when one considers that the ICP title is not 'protected' meaning that its use is not restricted to only those who have attained the requisite educational standards.

At the moment, the situation that exists is one in which essential, but risky, interventions such as the insertion of a chest drain are permitted to be performed by those ICPs who have been suitably trained and have been assessed as competent. In practice, as with the ECP title, competence is assessed during the courses referred to (for example, PHEC), and, as such, are not associated with accredited regulatory standards. Nor are they referred to in statute. Rather, this 'permission' to perform the procedure assumes that those individuals who have chosen to practise in this way will be competent to manage and complete any clinical interventions or episodes of care that they have embarked upon. This includes being able to manage the potential sequelae of their actions, and any complications that might unfold.

This argument, in turn, supports the contention that all individuals who hold themselves out as practising as an ICP should be subject to the same standards of training and education, assessed against equivalent competencies, and bound by the same governance and regulatory arrangements, in order to assure patients of a consistent standard of care. This equivalence of standards would, of course, be provided through a statutory title. However, given that there is no regulatory mandate that requires ICP courses to be accredited - other than the newly created sub-speciality, which is currently immature - there is currently no

way of ensuring that those purporting to practise as an ICP have been trained to the relevant standard, meaning that standards of care cannot be assured.

Further complicating this situation is the maintenance of practitioner competence, given the uncontrolled and unpredictable nature of immediate care practice, and the relative infrequency with which some interventions may need to be performed. Working on the basis that clinical skills - particularly those that are technical or intricate and require a high level of psychomotor skill - require regular practice in order to be maintained, and that the risks that are associated with technical procedures are associated with a higher level of risk, it follows that the risks that are associated when procedures are practised infrequently, will also be increased. This assertion adds weight to the argument that a robust system of regulation is required that would require practitioners to maintain their knowledge and skills, and assure the public of the education, quality and conduct of those adopting ICP roles, in the interests of patient safety.

Completing an analysis of those issues that are associated with the education and training of ICPs in the absence of statutory regulation, are arguments related to the lack of a 'protected' title. Although already addressed in relation to the SCP role, the same arguments hold true for ICPs, given that anyone who considers themselves to be an ICP could quite feasibly, and lawfully, hold themselves out as being an ICP. This means that, in practice, those individuals or healthcare professionals who have not undergone the relevant training as defined by current standards - such as the PHEC course or the DipIMCRCS(Ed) - but who, nevertheless, wish to hold themselves out as being an ICP, could legitimately do so, given that neither the practice nor the title of ICP are 'protected' in law. This means that patients would not be able to benefit from the safeguards that would normally flow from statutory regulation, namely the assurance that those practitioners who present themselves as ICPs are fit to practise, nor could they be assured that the practitioners in question would be bound by the relevant regulatory codes.

It is asserted that this situation presents a significant risk to patients, and could potentially jeopardise the public's confidence in the regulatory process. Indeed,

when these issues are considered alongside the potential for patients to misidentify non-medical ICPs as doctors, given the nature of their role, their assumed heightened skill set, and the absence of a distinctive uniform that would enable them to differentiate the discipline and status of those treating them, the risks are evident. When also added to the fact that, within the field of immediate medical care, the temptation exists for practitioners to perform interventions that may not always be clinically justified - particularly in entrapment situations or where long transfer journeys to hospital are anticipated - this makes arguments for regulatory intervention compelling.

2.3.5.2. The need for shared learning

Working on the presumption that immediate medical care represents one of the most high risk specialities - with obstetrics accepted as being the most high risk^{540,541,542} - and acknowledging the fact that regulation exists to protect the public, there can be few who would disagree that the current regulatory situation in relation to non-medical ICPs is unsatisfactory. With the situation currently existing, in which those doctors who practise immediate medical care are able to benefit from an accredited curriculum and competence framework⁵⁴³, and rules⁵⁴⁴ stipulating that the registration entry of these doctors can be annotated to indicate sub-speciality training upon satisfaction of a Royal College/Faculty-approved training programme, this suggests that the risks that are associated with immediate care seem to lie more with non-medical ICPs, rather than with doctors. If one accepts this argument, this begs the question of how and by whom non-medical ICPs should be regulated, who should oversee and accredit the standard of their post-registration education, and whether the

⁵⁴⁰ Fenn PT, Diacon SR, Gray A, Hodges R, Rickman N. The current cost of medical negligence in NHS hospitals: analysis of claims database. British Medical Journal 2000;320:1567-1571

⁵⁴¹ Symon A. Litigation and defensive clinical practice: quantifying the problem. Midwifery 2000;16(1):8-14

⁵⁴² National Audit Office. Handling clinical negligence claims in England. Report by the Comptroller and Auditor General, Session 200-2001. HC403

⁵⁴³ Intercollegiate Board for Training in Pre-hospital Emergency Medicine. Sub-speciality training in pre-hospital emergency medicine. Curriculum framework and assessment blueprint. London: IBTPHEM. 2012

⁵⁴⁴ General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 Articles 13(4)(b) and 13(5)(a)(b)

mechanisms that are currently in place within the NMC would suffice for this purpose.

Of the regulatory options that present themselves for consideration, only that which is offered by the NMC seems to be particularly straightforward. First, the GMC could regulate non-medical ICPs and allow them access to the subspeciality part of the medical Register, on a par with doctors, and allow them to follow the associated programmes of education, training and supervision. This would not only afford non-medical ICPs a level of 'standing' which is equivalent to that which is offered to doctors, but it would also send a clear message to the public that only one standard of immediate medical care would be acceptable. Admittedly, this 'solution' would involve breaking new ground, in that it would require a precedent to be set by the GMC. However, with the benefits that could be afforded to patients by this option, in terms of public protection, clear to see, and the importance of individual accountability to patients arguably reinforced, this approach could go a long way to assuaging concerns surrounding patient safety and ensuring public protection.

Secondly, non-medical ICPs could be given unlimited 'access' to the 'medical' sub-speciality curriculum, and the related materials and supporting tools, thus ensuring commonality of approach and consistency of standards. Although understood to be a long-term aim, it is likely to be some time before this position is realised. If afforded, this situation would result in all practitioners being required to satisfy the same educational criteria in order to practice legitimately as an ICP, and, as such, could go some way to affording patients a level of consistency in terms of public protection.

Thirdly, the NMC or HCPC - depending on whether the ICP in question derives from a nursing or ambulance paramedical background - could work with one of the professional bodies to devise a separate curriculum and competence framework for non-medical ICPs, and develop a recognised immediate care qualification similar to that which has been devised by medicine. With the registration entries of those non-medical ICPs who have attained the requisite educational standard similarly annotated to reflect the acquisition of related qualifications, this approach could also provide some commonality in terms of

how these practitioners could best be recognised. However, given that the PSA's preferred position⁵⁴⁵ is to restrict the annotation of Registers to exceptional circumstances - described as those situations in which annotation would be considered necessary to protect the public, and when accompanied by a critical mass of registrants in order to constitute a proportionate regulatory response - this approach may not present a viable option. On the other hand, if the number of practitioners that would be caught by this annotation was such that it was deemed to constitute a critical mass, then it is possible that this approach could provide the way forward.

Alternatively, a separate part of the NMC or HCPC Register - or both - could be opened up specifically for those non-medical ICPs practising in this field. This would result in an immediate care 'sub-specialty' being developed, with a competence framework based on the 'medical' curriculum also devised specifically for them. Although potentially leading to duplication of time and effort, and additional work in ensuring uniformity of standards, it is possible that this approach could go some way to providing the safeguards that are being sought.

Of course, it is entirely possible that a new statutory Register, created specifically for non-medical ICPs, could be devised. Overseen by a regulatory body such as the HCPC, this option would allow all non-medical ICPs to be regulated in the same way, and would enable uniformity of standards through adherence to an agreed curriculum, and a shared code of conduct and performance that would be applicable to all. Presenting a viable option, this option could also go some way to assist. However, although arguably presenting one of the most straightforward options, this solution is unlikely to materialise, given that the current direction of healthcare policy⁵⁴⁶ is to prohibit the establishment of new statutory Registers except in exceptional and compelling circumstances.

⁵⁴⁵ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. June 2010

⁵⁴⁶ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. February 2011

Finally, a more radical approach would be to create a single statutory Register under which all ICPs, both medical and non-medical, would sit. model, ICPs of all disciplines would benefit from the same 'protected' title, and would be bound to adhere to the same regulatory and educational standards. Not only would this provide patients and the public with equivalence in terms of clinical standards, but it would also provide the consistency and transparency of approach that is strongly required. With subdivisions potentially differentiating medical and non-medical ICPs, and reflecting any differences in their respective scopes of practice and related regulatory requirements, this approach would require all those wishing to practise in this area to satisfy the same educational and practice requirements, and adhere to the same governance arrangements. Arguably a logical step, assuming that some, if not all, of the changes proposed in the Law Commissions Review⁵⁴⁷ are accepted, including those that are aimed at providing consistency across the healthcare regulators where necessary in the public interest, it is likely to be a number of years before this 'solution' could come to fruition. Accordingly, it seems that one of the alternative proposals may be more feasible, at least in the short term.

2.4. The regulatory challenges facing new clinical roles

The clinical picture that is associated with those nurses who have chosen to advance their practice in new and more innovative ways is one that is both complex and complicated. These complexities are exacerbated by the fact that few controls are in place over the proliferation of new roles and titles that have been adopted by nurses, and those controls that do exist are limited in their impact. There are also few restrictions on the practices that may be legitimately performed by advanced nurses, meaning that they are free, at least theoretically, to expand their practice in almost any way they choose. However, despite these advances in practice and the assumed concomitant increase in clinical risk, there has been no reciprocal increase in regulatory intervention, meaning that the risks that are associated with advanced nursing practice are

⁵⁴⁷ Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

unlikely to have been addressed. This finding is particularly pertinent in the case of the NMC, given the recent reports from the PSA^{548,549} which highlight weaknesses in its governance and functions, and significant problems in its ability to manage fitness to practise cases - in relation to all forms of practice.

Given that the range of traditionally medical interventions that are currently undertaken and are able to be competently discharged by nurses is increasing, it follows that the risks that are associated with advanced nursing practice are likely to have increased. Indeed, given that the current direction of healthcare policy is for patients to receive care in a wider range of out-of-hospital settings, including closer to their homes 550,551, and out of hospital settings are considered to be associated with a higher level of risk, this means that regulatory intervention is needed if the risks associated with this practice are to be managed effectively, and the interests of patients are to be protected. This, in turn, requires those leading the development of advanced nursing practice to take decisive and responsive action in relation to the regulatory options that are available to them, cognisant of the challenges that face those undertaking new clinical roles, and the problems that require to be overcome. Central to these challenges are those that are associated with the misuse of titles, the absence of accredited educational standards, and the adequacy of provisions that would ensure the accountability and ongoing fitness to practise of practitioners.

2.4.1. 'Protection of title

As previously intimated, issues surrounding the absence of a 'protected' title for new clinical roles is problematic for those nurses who have chosen to advance their practice. This is especially the case in relation to those whose expansion to practice is such that it constitutes a new clinical role. This is particularly

⁵⁴⁸ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Interim report. London: CHRE. 2012

⁵⁴⁹ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

⁵⁵⁰ Department of Health. Our health, our care, our say: a new direction for community services. London: HMSO. 2006

⁵⁵¹ The Scottish Executive. Better health, better care: A discussion document. Edinburgh: The Scottish Executive. 2007

applicable when one considers that patients and the public are known to recognise and be reassured by health professional titles, and to associate them with competence and fitness to practise⁵⁵². It is also applicable when one considers that there is a risk to patient safety and public protection when unqualified people pass themselves off as registered healthcare professionals, when, in fact, they are not. Acknowledging the significance and potential impact of these problems, it is incumbent on health professional regulators and those that are responsible for leading and developing the healthcare professions, to respond to this situation, and to ensure adequate protection for patients and the public. Tackling the potential misuse of titles is central to this duty.

Protected titles for the various healthcare professions are enshrined in legislation 553,554,555. They are also used by healthcare professionals to indicate to patients and the public their field of practice. Those who have achieved the appropriate registration with the relevant regulatory bodies are authorised to use these titles, with those individuals who are not registered but, who nevertheless, choose to use them committing an offence. In some cases, legislation can also be used to protect function, in this case referring to the specific acts that are performed by practitioners, rather than their role. In other cases, legislative intervention can protect specific acts that form part of healthcare professionals' duties. This means that anyone who performs a 'protected' act without being registered is also committing an offence.

In practice, the misuse of protected titles is recognised as potentially undermining public confidence in the healthcare professions, and in the regulatory systems that have been established to oversee them⁵⁵⁶. This problem is exacerbated by the fact that health professional regulators have been unable to quantify the size and scope of the problem, due in part to the proliferation of new and unregulated roles and titles that have emerged. It is also due to the fact that the specificity of titles in legislation allows individuals to use variations

⁵⁵² Council for Healthcare Regulatory Excellence. Protecting the public from unregistered practitioners: Tackling misuse of unprotected titles. London: CHRE. 2010

⁵⁵³ The Nursing and Midwifery Order 2001 Article 44

⁵⁵⁴ The Health Professions Order 2001 Section 39

⁵⁵⁵ The Medical Act 1983 Part VI Section 49

⁵⁵⁶ Council for Healthcare Regulatory Excellence. Protecting the public from unregistered practitioners: Tacking misuse of protected title. London: CHRE. 2010

in such 'protected' titles without needing to be registered. In practice, this 'loophole' has the potential to mislead patients and the public, as it requires awareness on their part of the difference between registered healthcare professionals and unregistered practitioners.

Admittedly, health professional regulators could bring private and public prosecutions against those individuals who have chosen to misrepresent themselves as registered professionals. However, this is a course of action that is not without its problems - both in terms of resource and any potential precedent that may be set. As such, the decision to prosecute a fraudulent or 'rogue' practitioner is not one that would be taken lightly. In all cases such as these, the onus would be on health professional regulators to build a case that is supported by evidence to show that the public has been harmed, or is at significant risk of being harmed, by such individuals, and that it would be in the public interest to prosecute them. In order for this action to be in the public interest, there would need to be a realistic prospect that such a prosecution would be successful⁵⁵⁷, and would result in a conviction⁵⁵⁸. In all cases, this course of action would involve considerable time and cost; cost that would require to be diverted away from the delivery of core regulatory activities, and that would ultimately detract from the health professional regulators' ability to protect the public in other ways.

Under the current system, the decision to prosecute is an option that is available to all those healthcare professions that benefit from statutory regulation. However, given that those practitioners who have embarked upon new clinical roles are, for the main part, unable to benefit from specific statutory regulation, this leaves patients and the public without similar safeguards in relation to those who falsely represent themselves as being educated and as being able to practise in these new roles when, in fact, they are not. As such, this has left those responsible for leading these groups needing to find alternative means of reassuring patients and the public, and alternative ways in

⁵⁵⁷ Swain v Hillman [1999] EWCA Civ 3053, [2001] All ER 91 at [7]

Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

which to provide them with the necessary regulatory safeguards that they arguably deserve.

2.4.2. Defining educational standards

It has already been acknowledged that the delivery of modern healthcare is complex and complicated. So, too, is the infrastructure by which modern practitioners are prepared for practice, with educational programmes needing to keep up-to-date with clinical developments, and emerging roles and models of care. Requiring much of those embarking on them, such programmes demand exacting personal standards and a high level of personal commitment. Closely aligned with this is the imperative to do no harm, and to always act in patients' best interests⁵⁵⁹. Accordingly, the challenge for education providers lies in their ability to produce safe and accountable practitioners, capable of delivering high standards of care and inspiring public confidence.

With excellence in education recognised as the foundation for excellence in healthcare ⁵⁶⁰, and regulation recognised as the guarantor of educational standards ⁵⁶¹, those responsible for regulating the healthcare professions have a key role to play in assuring the quality of education. Responsible for controlling entry into the professions and the standards of those whom they register, their remit involves identifying the clinical and educational standards that are required for safe practice, and assuring the quality of those establishments delivering them. Linked not only to the attainment of pre-registration qualifications but also the requirements for ongoing registration - including the need to ensure that proportionate revalidation arrangements are in place ^{562,563} -

⁵⁵⁹ Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 5th Edition. New York, Oxford: Oxford University Press. 2001

⁵⁶⁰ Department of Health. Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century. Cm7013. London: HMSO. 2007

Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. February 2011

⁵⁶² Department of Health. Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century. Cm7013. London: HMSO. 2007

⁵⁶³ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. February 2011

their role is as much about sustaining, improving and assuring standards of education, as it is about identifying poor practice or inappropriate behaviour.

Seeking to improve its standards of education in recent years, and enhance the competence and credibility of those qualifying, nursing has focused its attention on securing an all-graduate profession at the point of registration⁵⁶⁴. Expected to be in place by 2013, and supported by both the DH⁵⁶⁵ and NMC⁵⁶⁶, the intention is that this move into Higher Education will enable more able applicants to be recruited, thus moving away from the perception that nursing is willing to accept the lowest common denominator in terms of educational qualifications, and more closely align the clinical professions. With diploma status offered to nurses by Project 2000⁵⁶⁷ in 1986 having already provided a middle ground for this, by offering an alternative pathway for those wishing to follow a more intellectual career path - rather than the traditional three-year certificate courses offered in schools of nursing - and the gradual introduction of three and four-year degree courses having satisfied those interested in more academic pursuits⁵⁶⁸, this goal is well on its way to being realised.

However, given that education needs to deliver fitness for practice at both initial and advanced levels, and patients expect to receive a high standard of care from all, irrespective of grade or status, concern has grown regarding the lack of similar progress in relation to post-registration nursing education. Linked with disquiet over the growing number of titles which suggest a higher level of practice, and concern that the associated levels of expertise may not have been acquired, momentum has now grown for a clear relationship to be established between job titles, levels of practice, clinical competence and educational attainment⁵⁶⁹. With the NMC⁵⁷⁰ and DH⁵⁷¹ also expressing concern that nurses

⁵⁶⁴ Nursing and Midwifery Council. Standards for pre-registration nursing education. London: NMC. 2010

 $^{^{565}}$ Department of Health. A high quality workforce: NHS next stage review. London: DH. 2008

⁵⁶⁶ Nursing and Midwifery Council. Standards for pre-registration nursing. London: NMC. 2010 ⁵⁶⁷ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. Project 2000: a new preparation for practice. London: UKCC. 1986

⁵⁶⁸ Royal College of Nursing. The Education of Nurses: A New Dispensation. Commission on Nursing Education (Chaired by Dr Harry Judge). London: RCN. 1985

⁵⁶⁹ Department of Health. Post-registration development: A framework for planning, commissioning and delivering learning beyond registration for nurses and midwives. The report of a task group convened and chaired by the Chief Nursing Officer. London: DH. 2004

may hold job titles that imply a level of knowledge and competence beyond that which they hold, and advocating for a standard level of practice beyond initial registration, it is clear that regulatory intervention is not only warranted, but is overdue.

2.4.2.1. Recognising post-registration qualifications

At the moment, the approach that has been taken by the various health professional regulators to recognise post-registration qualifications falls under three broad headings; controlling the use of particular titles, controlling entry to particular types of practice, and providing information in relation to additional post-registration learning that has taken place⁵⁷². As such, it offers an inconsistent and, arguably unclear, mechanism by which the public and professionals can identify and verify the qualifications and credentials of those claiming to have satisfied recognised programmes of post-registration education. Indeed, under the current system there is no parity in the approach that has been taken by the health professional regulators to recognising post-registration qualifications, and, therefore, no reliable way of differentiating the various post-nominal qualifications that are in use.

With regulators, such as the General Dental Council (GDC), having chosen to control the use of particular specialist titles by 'recognising' the qualifications of only those dentists who have gained very high-level specialist knowledge and skills in a focussed area of practice⁵⁷³, this means that other dental practitioners who have also chosen to expand their practice in a less specialised way are unlikely to be 'recognised'. This approach suggests that only the highest level of risk should be formally recognised, with patients and the public dependent upon the core regulatory mechanisms to provide the necessary safeguards where the

⁵⁷⁰ Employment Research Ltd. NMC consultation on a proposed framework for the standard of post-registration nursing. Report prepared by Jane Bell. May 2005

⁵⁷¹ Department of Health. Towards a framework for post-registration nursing careers: Consultation response report. London: DH. 2008

⁵⁷² Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

⁵⁷³ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

risks are considered to be less significant. Other regulators, such as the General Optical Council (GOC), have adopted an alternative approach, choosing instead to control entry to specialist types of practice - rather than the use of specialist titles⁵⁷⁴. In so doing, the difference in approach that has been taken by the various regulators is immediately apparent.

For its part, the GOC has also elected to annotate its Register so as to denote those practitioners who have attained the qualifications that entitle them to prescribe medicines. In adopting this approach, it has satisfied the legislative requirements which stipulate that entry to this type of practice must be limited to those with the appropriate qualification on the Register, thus providing the public with the protection - and the transparency - that they arguably deserve. In practice, this method of recognising post-registration qualifications - which is similar to that adopted by the NMC in relation to independent nurse prescribing ⁵⁷⁵ - is considered to be appropriate where there is a discrete extension of practice that requires competencies that go beyond those that are required for initial registration, and which are tied to a particular qualification and a perceived level of risk.

On the other hand, the approach that is taken to recognise post-registration qualifications by other regulators, such as the NMC - namely that which involves the annotation of Registers in relation to additional learning within one context in a particular field of practice - such as Specialist Community Public Health Nurses - is considered by some as providing a weaker form of assurance. This is particularly the case when one recognises that, although acknowledging the existence of a post-registration qualification on the Register, this annotation does not necessarily signify that practitioners have attained a higher level of competence than other nurses in the field as a result of that qualification. Rather, it denotes that they have completed a particular course of preparation or study, with the expectation being that other avenues will be used to enable

⁵⁷⁴ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

⁵⁷⁵ Nurses and Midwives (Parts of and Entries in the Register) Order. Statutory Instrument 2004 No 1765 Article 7(2)(a)

practitioners to develop and maintain their competencies within their field of practice.

Other regulators still, such as the General Medical Council (GMC), have adopted a slightly different approach to recognising post-registration qualifications, in that the acquisition of the relevant qualifications is tied to the entitlement for appointment to specialist or general practice posts in the NHS, rather than being an entitlement across the profession as a whole⁵⁷⁶. This approach is interesting in that it provides the public and professionals with transparency and consistency, given that doctors will not be appointed to senior posts if they have not first attained these qualifications. In this case, the implication is that the acquisition of these qualifications is indicative of the achievement of a defined level of competence. This approach would also arguably be considered to be proportionate and targeted, in that those qualifications that are recognised are tied to particular posts.

Although variable and, in some cases, lacking in transparency, it is clear that the regulatory bodies have attempted to put mechanisms in place to assure the integrity of the relevant qualifications that are held, or purported to be held, by practitioners. This is crucial to the integrity of professional Registers as a whole, in particular given their role as an authoritative source of information that it held on professionals, and is a central tenet of effective regulation. However, at the moment, it is unclear which of these approaches, if any, would provide the necessary regulatory safeguards in relation to the risks that are posed to patients and other members of the public when healthcare professionals take on new or higher levels of practice - such as those that are associated with new clinical roles. This is particularly applicable when practitioners take on roles and responsibilities for which they lack the necessary capability, and where employers and those in positions of authority do not have the appropriate safeguards in place to check their credentials of practitioners.

This suggests that although the source of the risk to patients and the public may be the same - given the similarity in the roles and responsibilities that are being

⁵⁷⁶ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

taken on by different healthcare professionals, and who arguably have differing levels of accountability for them - the nature and level of the risks that are presented may also vary accordingly. This means that, until and unless, an appropriate and acceptable approach to recognising formally the practice of those nurses who are practising in an advanced way has been found, the public will be forced to rely upon the adequacy of local governance arrangements to mitigate the risks that are posed to patients when individual professionals practise outside of their scope of practice, or where inappropriate safeguards are in place.

2.4.3. Accountability for practice

Defined as the state of being self-governing and free from external control or influence⁵⁷⁷, the notion of 'autonomy' refers to the freedom of professionals to manage the care and treatment of patients by reference to what they consider to be appropriate and in patients' best interests. Closely associated with this is the notion of authority, with patients presuming technical expertise on the part of those caring for them each time a consultation is undertaken or advice is imparted⁵⁷⁸. Reinforcing this notion of authority is the uncertainty and complexity that is inherent in clinical work, with professionals expected to exercise a degree of freedom in making relevant clinical decisions in individual cases, and exert control over the content of their work⁵⁷⁹.

Also embodying the notion of autonomy is the ability of practitioners to deal with, and be accountable for, the consequences of their actions across entire episodes of care, rather than being able to perform only a range of selected tasks in isolation. Underpinning this concept, and denoting the essence of advanced nursing practice, is the understanding that nurses will accept responsibility and accountability for their actions, rather than seeking to

⁵⁷⁷ Skar R. The meaning of autonomy in nursing practice. Journal of Clinical Nursing 2010;19(15-16):2226-2234

⁵⁷⁸ Klein TA. Implementing autonomous clinical nurse specialist prescriptive authority: a competency-based transition model. Clinical Nurse Specialist 2012;26(5):254-262

⁵⁷⁹ Weston MJ. Defining control over nursing practice and autonomy. Journal of Nursing Administration 2008;38(9):404-408

abdicate responsibility when faced with the consequences of their actions; a practice that they have historically tended to adopt^{580,581}. Given that a central tenet of the professional nursing 'code' is to "be personally accountable for actions and omissions ... and ... always ... justify ... decisions" ⁵⁸², this seems to be a legitimate expectation. However, when one considers that those doctors who have yet to be convinced of the merits of advanced nursing practice and new clinical roles continue to question the notion of accountability and autonomy in nursing, on the basis that nurses are not always able to anticipate and deal with the consequences of their actions⁵⁸³, this brings into question the whole notion of accountability for autonomous nursing practice, and challenges its basis.

Closed aligned with the need for accountability for practice is the notion of competence, with those responsible for preparing practitioners for new and advanced clinical roles required to ensure that they will be able to manage the consequences of their actions, and recognise and take action to minimise the associated risks⁵⁸⁴. Not only would this prepare advanced nurses effectively for the uncertainties, complexities and risks that are inherent in their practice, but it would also reinforce their individual responsibility to recognise any limitations in their knowledge and competence, and ensure that any, and all, actions they elect to undertake are in patients' best interests. It would also enable the required standards of professional practice to be maintained, provide the platform for effective quality assurance and professional accountability, and ensure that practitioners remain accountable for their own conduct and performance.

⁵⁸⁰ Walker SB, Lowe MJ. Nurses' views on reporting medication incidents. International Journal of Nursing 1998;4(2):97-102

⁵⁸¹ Johnstone MJ, Kanitsaki O. The ethics and practical importance of defining, distinguishing and disclosing nursing errors: A discussion paper. International Journal of Nursing Studies 2006;43(3):367-376

⁵⁸² Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008 p2

⁵⁸³ Nicholas M. The surgical care practitioner: a critical analysis. Journal of Perioperative Practice 2010;20(3):94-9

⁵⁸⁴ Wade GH. Professional nurse autonomy: concept analysis and application to nursing education. Journal of Advanced Nursing 1999;30(2):310-318

2.4.3.1. Establishing competence

The concept of 'competence' is not new to nurses, having originally been introduced to them in the late 1970s in the form of 'extended role certificates'. Permitting the performance of discrete medically-ordered tasks but little in the way of clinical judgement or discretion, these certificates were recognised as denoting a measure of ability to perform selected identified tasks, but were limited in their scope. Subsequently replaced and subsumed within the more encompassing 'scope of professional practice', and now a central tenet of the professional nursing 'code'⁵⁸⁵, competence continues to feature centrally in all discussions with nurses regarding the parameters of their practice, and in all fitness to practise decisions. Indeed, with regulators only willing to re-register and reaccredit those nurses who have been deemed competent, credible and suitably prepared for practice, determination of competence is poised to be the decisive factor in future nursing revalidation processes⁵⁸⁶.

The requirement for nurses to undertake only those duties for which they have been appropriately trained, and are confident and competent to perform, is well established as the cornerstone of professional practice. So, too, is the obligation to be aware of the limits of their knowledge and ability, and to refrain from undertaking those duties that they are neither safe nor competent to perform. However, despite being the basis of most, if not, all regulatory codes across all the healthcare professions, and featuring centrally in high level inquiries ^{587,588} and policy directives ^{589,590}, closer analysis shows that the term

⁵⁸⁵ Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

⁵⁸⁶ Nursing and Midwifery Council. Revalidation update. NMC Council meeting. Item 13 NMC/12/66 May 2012

⁵⁸⁷ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(i). London: HMSO. 2001

⁵⁸⁸ Department of Health. The Government's response to the recommendations of the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries. Cm 7015. London: HMSO. 2007

⁵⁸⁹ Department of Health. Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century. Cm7013. London: HMSO. 2007

⁵⁹⁰ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. February 2011

'competence' is poorly defined, thus begging the question of what competence actually is, and how it can best be determined.

Considered by some⁵⁹¹ as denoting the ability to operate at a safe standard, by others⁵⁹² as being synonymous with capability and fitness to practise, and by others still⁵⁹³ as signifying the ability to practise an entire role by combining individual competencies and exercise wider clinical judgement, the notion of competence is now taken to refer to the integration of skills, knowledge and attitudes that enable safe performance in a professional or occupational role⁵⁹⁴. Increasingly described in terms of individual 'competencies' that reflect linear and, sometimes, technical requirements that are required for a skill to be completed, it also incorporates the ability to use judgement and apply decisionmaking skills. Inherent in this description is the ability to know when it is clinically appropriate to apply designated skills, and when it is more appropriate to refrain from doing so. Also incorporating the requirement to provide a justified rationale for decisions, and serving as an indicator of the operational level of practitioner expertise, the concept of competence is now so widely embraced by the regulatory bodies that it is considered to be a shared value, and features centrally in all education curricula.

Widely acclaimed as the basis for this concept, Miller's 'pyramid of competence' recognises the importance of encapsulating the cognitive, behavioural and psychomotor skills that are required for practice, and acknowledges the need for the application and integration of all elements in order for safe practice to result. Able to be differentiated from 'performance', on the basis that performance relates to the physical carrying out of a skill rather than necessitating the knowledge regarding how or why it is being done, or having the ability to deal with the resultant consequences of one's actions,

⁵⁹¹ Harden RM, Gleeson FA. Assessment of clinical competence using an objective structured clinical examination. Medical Education 1979;13(1):39-54

⁵⁹² Wass V, Van der Vleuten C, Shatzer J, Jones R. Assessment of clinical competence. The Lancet 2001;357:557

⁵⁹³ Watson R, Stimpson A, Topping A, Porock D. Clinical competence assessment in nursing: a systematic review of the literature. Journal of Advanced Nursing 2002;39(5):421-431

⁵⁹⁴ Department of Health. The regulation of non-medical healthcare professionals: a review by the Department of Health (The Foster Report). London: HMSO. 2006

⁵⁹⁵ Miller G. The assessment of clinical skills/competence/performance. Academy of Medicine 1990;65:63-67

the competence-based approach has gained favour such that it is now widely accepted as the preferred format for most clinical developments in the UK. Indeed, such has been the level of support given to this approach that a number of colleges and faculties have adopted the competence-based approach as the basis for their curricula 596,597, with many of those responsible for developing new clinical roles 598,599,600 and specialties 601 having followed suit.

2.4.3.2. Curriculum and competence frameworks

The ability to make a decision regarding what constitutes appropriate treatment, and knowing and being able to recognise what constitutes an appropriate response, is recognised as being among the most important characteristics of healthcare professionals. This is in contrast to their technical skill, which is often assumed to be in place. So, too, is the ability to respond to unexpected events, to have a clear understanding of the limits of their expertise, and knowing how, when and from whom to seek help when it is needed. Indeed, it is this collective array of qualities, rather than time spent in training, that denotes the mark of a competent professional. Closely aligned with this position is Ryle's theory of cognitive behaviour⁶⁰², which recognises and draws upon three inter-related domains and recognises their collective and essential role in developing a specialised body of knowledge. Comprising these domains are propositional knowledge (knowing that something needs to be done), practical knowledge (the acquisition of skill, but on its own a poor

⁵⁹⁶ Endacott R, Edwards B, Crouch R, Castille K, Dolan B, Hamilton C, Jones G, MacPhee D, Manley K. Towards a Faculty of Emergency Nursing. Emergency Nurse 1999:7(5):10-16

⁵⁹⁷ Academy of Medical Royal Colleges. Common competences framework for doctors. London: Academy of Medical Royal Colleges. 2009

⁵⁹⁸ Department of Health. The competence and curriculum framework for the Physician Assistant. London: HMSO. 2006

⁵⁹⁹ Department of Health. The curriculum framework for the Surgical Care Practitioner. London: HMSO. 2006

⁶⁰⁰ Department of Health. The competence and curriculum framework for the Emergency Care Practitioner. London: DH. 2006

⁶⁰¹ Intercollegiate Board for Training in Pre-hospital Emergency Medicine. Sub-speciality training in pre-hospital emergency medicine. Curriculum framework and assessment blueprint. London: IBTPHEM. 2012

⁶⁰² Ryle A. Cognitive theory, object relations and the self. British Journal of Medical Psychology 1985;58(1):1-7

indicator of clinical expertise given that this could represent rote learning of a particular skill), and experiential knowledge (denoting that which is gained from personal experience).

Associated with this concept are educational 'curricula', denoting those educational plans or the ways in which subject areas within a syllabus are taught over a period of time. These were first used by doctors, but have now been completely replaced by a competency-based approach rather than being styled on a traditional syllabus in which training was based on a list of things to know. Rather, the approach that is now taken by doctors is to learn based on curriculum and competence frameworks that typically describe the range of activities that are needed to deliver a service, and a series of statements that define what those seeking to deliver that service need to know, and what they need to be able to do⁶⁰³. Also defined in terms of expected generic and specific outcomes, and the performance criteria that are associated with high quality care, these frameworks describe the knowledge, skills and attitudes that are expected at the various stages of training, and explain the means by which the determination of competence to practise will be made.

However, despite being welcomed by most, critics of the curriculum and competence approach to education and training are vocal in their opposition. Basing their arguments on the assertion that competence reflects a minimum rather than an excellent standard^{604,605,606} and is, therefore, necessary but not sufficient to guarantee performance, they aver that healthcare providers should be aspiring to high or, indeed, excellent standards rather than minimum standards. Arguably able to be overcome by including more generic competencies within frameworks, these concerns could be addressed by ensuring that performance criteria for role-specific competencies reflect high quality, rather than a minimum standard of, care. Also able to be overcome by

⁶⁰³ Clements R, Mackenzie R. Competence in prehospital care: evolving concepts. Emergency Medicine Journal 2005;22:516-519

⁶⁰⁴ Grant J. The incapacitating effects of competence: a critique. Journal of Health Science Education 2004;4:271-277

⁶⁰⁵ Rees CE. The problem with outcome-based curricula in medical education: insights from educational theory. Medical Education 2004;38:593-598

⁶⁰⁶ Talbot M. Monkey see, monkey do: a critique of the competency model in graduate medical education. Medical Education 2004;38:587-592

identifying the relevant performance criteria from the competence frameworks, highlighting these criteria as areas for discussion at the time of appraisal and revalidation, and tasking assessors with responsibility to ensure that individual practitioners always meet or exceed defined standards for their level of experience, it is possible that these apparent weaknesses could be resolved.

However, more worrying, perhaps, are those criticisms that are associated with the perception that competence frameworks serve only to reduce, diminish or otherwise undervalue traditional academic study and ability, given their highly prescriptive nature⁶⁰⁷. Linked also with concerns that they could restrict opportunities for practitioners to exercise clinical judgement and make individual clinical decisions based on clinical findings, the fear is that this approach could, in the future, lead to the situation whereby those trained under and working to this system, including advanced nurses, could be limited in their ability to deal with the consequences of their actions and, thus, be considered as skilled technicians rather than autonomous practitioners. Although these concerns could be potentially dismissed on the basis that all practitioners, including doctors, are now working to this model, and competency frameworks provide a strong platform upon which to base uniformity of standards, it is possible that this explanation and justification may not placate those who perceive clinical education, and medical education in particular, to have been 'dumbed down' by this approach⁶⁰⁸. With concerns thus remaining regarding the extent to which curriculum and competence frameworks will be able to offer or restrict practitioner autonomy, the extent to which they will be able to provide practitioners of the future who are fit to practise remains to be seen.

⁶⁰⁷ Clements R, Mackenzie R. Competence in prehospital care: evolving concepts. Emergency Medicine Journal 2005;22:516-519

⁶⁰⁸ Bundy C, Cordingley L, Peters S, Rock J, Hart J, Hodges L. A core curriculum for psychology in undergraduate medical education. A report from the Behavioural and Social Sciences Teaching (BeSST) Psychology Steering Group. Manchester: The Higher Education Academy. 2009

2.4.4. Assurance of ongoing fitness to practise

For some⁶⁰⁹, the primary role of ensuring the continuing fitness to practise of healthcare professionals should be that of reaffirming that registrants continue to meet the relevant regulator's core standards. Others⁶¹⁰ submit that ensuring that standards of conduct as well as competence should also form the backbone of continuing fitness to practise requirements. For most healthcare professionals, part of the assurance that they are fit to practise comes from their satisfaction of CPD requirements, and, in the future, compliance with revalidation principles and requirements. In all cases, however, healthcare professionals are required to demonstrate adherence to the regulator's standards, including maintenance of professional knowledge and skills, in order to prove that they are fit to practise.

To date, the approach that has taken by the professional healthcare regulators in order to ensure the competence and fitness to practise of practitioners has been to rely upon input-based continuing professional development (CPD) requirements. However, as recent high profile inquiries^{611,612} and a recent audit of nurses' professional portfolios by the NMC⁶¹³ have shown, this approach is not always reliable and does not, in itself, demonstrate continuing fitness to practise. Indeed, in some cases, it is perceived as being nothing more than a superficial process, with lip service only having been paid to the content of CPD portfolios of evidence of ongoing fitness to practise⁶¹⁴. Accepting these findings, and acknowledging the directive that emerged from 'The Foster Review'⁶¹⁵ and

⁶⁰⁹ Council for Healthcare Regulatory Excellence. An approach to assuring continuing fitness to practise based on right-touch regulation principles. London: CHRE. 2012

⁶¹⁰ Health Professions Council. Managing fitness to practise: A guide for employers and registrants. London: HPC. 2007

⁶¹¹ The Shipman Inquiry Fifth Report: Safeguarding patients, lessons from the past - proposals for the future. Cm6394. London: HMSO. 2004

⁶¹² The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

⁶¹³ Nursing and Midwifery Council. Review of evidence regarding the impact of continuing professional development (CPD) on the quality of practice. London: NMC. 2012

⁶¹⁴ House of Commons Health Committee. Annual accountability hearing with the Nursing and Midwifery Council. Seventh Report of Session 2010-2012. HC 1428. London: HMSO. 2011

⁶¹⁵ Department of Health. The Regulation of the Non-Medical Healthcare Professions. (The Foster Review). London: DH. 2006

'Trust, Assurance and Safety'⁶¹⁶, namely the imperative for all regulators to develop and implement a system of revalidation for practitioners, it seems prudent to consider the requirements that would be needed by a system of revalidation that would be expected to assure the fitness to practise of advanced nurses.

Working on the basis that any system of revalidation for nurses, of all levels, should be based on the 'right-touch' approach to regulation 617, it is incumbent on those who are responsible for implementing such a system to ensure that it is able to identify those areas where further investigation or remediation is needed, and to acknowledge those areas where poor practice exists or local systems are not robust enough to take responsive action. This implies that any such system would be required to satisfy the twelve key principles of revalidation that emerged from discussions with the Department of Health and the UK Non-Medical Revalidation Working Group⁶¹⁸, all of which correlate with the need for transparency, accountability, consistency and proportionality, and the need for the system of revalidation to be $targeted^{619}$. Also expected to feature in the development of an acceptable system of revalidation is the need for harmonisation, this being indicative of the need for common standards and systems to be developed across professional groups as far as possible, and for shared competencies to be developed in relation to specific aspects of direct care delivery⁶²⁰.

If one accepts the argument that an input-based model would not be able to satisfy these principles, and that a more robust approach is needed, this suggests that a system that is based on outcomes and output-based measures would be more appropriate. In order to be effective, this system would need to take account of those types of practice which pose the highest risk to patients

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outcomes. London: Better Regulation Task Force. 2005

⁶¹⁶ Department of Health. Trust, Assurance and Safety: The regulation of health professionals in the 21st Century. Cm7013. London: HMSO. 2007

⁶¹⁷ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010

 ⁶¹⁸ Department of Health. Principles for revalidation. Report of the Working Group for non-medical revalidation: Professional regulation and patient safety programme. London: DH. 2008
 619 British Regulation Task Force. Regulation - Less is more. Reducing burdens, improving

⁶²⁰ Department of Health. Principles for revalidation. Report of the Working Group for non-medical revalidation: Professional regulation and patient safety programme. London: DH. 2008

and the public, and ensure that a response that is proportionate to the risks posed is implemented. Featuring centrally among those factors that have been identified by the PSA⁶²¹ as presenting the greatest risks associated with fitness to practise are the effectiveness of undergraduate training and education, frequency of practice, level of autonomy, level of isolation, level of support, practice context, time since qualification, and workload. Also featuring centrally are the complexity of the task in question, the level of responsibility that individual practitioners have for patient safety, the likelihood and severity of treatment side-effects, and the level of invasiveness of the treatments involved.

Significantly, these findings correlate with evidence presented to the NMC⁶²² in relation to the risks that are associated with the fitness to practise of nurses and midwives. Indeed, this evidence also found that the highest risk factor in relation to nursing (and midwifery) is the quality of the setting in which care is delivered, with staffing levels and organisational culture also having been shown to be critical factors in ensuring the safe practice of practitioners. As such, this suggests that a more encompassing approach to revalidation that incorporates individual, team and organisational factors, and that includes third party review and feedback, would be the most appropriate approach to pursue.

The NMC is currently considering the options that will form the basis of an appropriate model of revalidation that will be submitted for formal consultation, and implementation in 2015⁶²³. Although proposals have yet to be formally formulated, it seems likely that the approach that will be adopted will be a staged process, with most of the proposed strategy for revalidation able to be implemented under current legislation⁶²⁴. Forming the first stage of this process is likely to be an enhanced system of 'renewal', in which registrants will be expected to complete a self-declaration form, that stipulates their adherence to

⁶²¹ Council for Healthcare Regulatory Excellence. An approach to assuring continuing fitness to practise based on right-touch regulation principles. London: CHRE. 2012

⁶²² Nursing and Midwifery Council. Revalidation update. NMC Council meeting. Item 13 NMC/12/66 May 2012

⁶²³ House of Commons Health Committee. Annual accountability hearing with the Nursing and Midwifery Council. Seventh Report of Session 2010-2012. HC 1428. London: HMSO. 2011 ⁶²⁴ The Nursing and Midwifery Order 2001 Article 10

the NMC's CPD requirements and PREP standards⁶²⁵. The information that is submitted by registrants will also be required to be verified by a third party⁶²⁶. It is possible that this stage would then be followed by the NMC requesting information from employers in order to verify claims that have made by nurses during the renewal process, and requesting that they provide evidence of good health and good character. Considered objectively and from a practical perspective, these requests are most likely to be made in relation to those individuals whose practice is considered to pose the greatest risk to the public, or where concern has been raised that claims that have been made by nurses have not been able to be substantiated.

Interestingly, the evidence that has been submitted to the NMC as the foundation upon which to build a model of revalidation for nurses (and midwives) is not supportive of the role of formal supervision in the revalidation of nurses. Rather, this evidence suggests that supervision has little impact on reducing risk, and points to good clinical governance and appraisal as having a positive impact. This is in direct contrast to the way in which statutory supervision has historically been received by midwives, and the acclaim in which it is held, which, as will be discussed in the next chapter, is considerable.

Of course, underpinning any model of revalidation and assurance of fitness to practise is the expectation that practitioners will adhere always to the principles that are enshrined in the professional regulatory code. Associated with this expectation, and closely linked with the assurance of fitness to practise of practitioners, is the question of whether revalidation is concerned with providing assurance that nurses (and midwives) are, and remain, capable of safe and effective practice, or whether it is more about raising standards. Also aligned with this is the question of whether revalidation should focus on behaviours and attitudes, or knowledge, skills and experience, or whether it is more related to ensuring accountability and trust rather than transparency and external assurance. With a final decision having yet to be taken regarding the model of revalidation that will ultimately be adopted, the answer to these

⁶²⁵ The Nursing and Midwifery Order 2001 Rule 13

 $^{^{626}}$ Nursing and Midwifery Council. Revalidation update. NMC Council meeting. Item 13 NMC/12/66 May 2012

questions can only be surmised. Until then, patients and the public will continue to rely upon nurses, including those whose practice is advanced and who have adopted new clinical roles, satisfying the NMC's PREP standards in order to show that they are fit to practise; standards which have already been acknowledged as being inadequate, and as having historically and consistently been poorly audited^{627,628}.

2.4.5. Managing clinical risks

As the product of an inexact science, and fraught with uncertainty, clinical practice is associated with a level of risk that is commensurate with the complexity of interventions, and the severity of disease processes. Also thought to be significant in determining the level of risk that is associated with procedures, is the experience level and competence of practitioners, with the assumption being that risks decrease in line with rising expertise. Complicating this situation is the inherent nature of clinical work, given that in healthcare there is no substitute for the learning and experience that is gained through direct contact with patients, and the fact that simulations, no matter how sophisticated, can offer only artificial, unrealistic and, therefore, limited opportunities for development 629,630. Alongside this are those risks that are associated with the desire to innovate, which are so often associated with those at the cutting edge of practice, those seeking to forge new relationships, and those striving to break down inter-professional barriers. However, with lip service only having been paid to many of these risks, and most new roles having escaped any form of rigorous assessment, the potential for harm may have been underestimated.

⁶²⁷ House of Commons Health Committee. Annual accountability hearing with the Nursing and Midwifery Council. Seventh Report of Session 2010-2012. HC 1428. London: HMSO. 2011

⁶²⁸ Nursing and Midwifery Council. Review of evidence regarding the impact of continuing professional development (CPD) on the quality of practice. London: NMC. 2012

⁶²⁹ Kneebone RL, Scott W, Darzi A, Horrocks M. Simulation and clinical practice: strengthening the relationship. Medical Education 2004;38(10):1095-1102

⁶³⁰ Murray C, Grant MJ, Howarth ML, Leigh J. The use of simulation as a teaching and learning approach to support practice learning. Nurse Education in Practice 2008;8(1):5-8

With excessive defensiveness at the other end of the spectrum potentially stifling innovation, and risk aversion sometimes acting to the detriment of patients, it is clear that a balance needs to be struck that enables new and more creative ways of working while ensuring patient safety. If one accepts this argument, and accepts that advanced roles often encompass the realms of both innovation and development - which invariably involve the taking of calculated risks - and human factors impact upon both, it follows that any assessment of risk that needs to take place has to take account of the severity of the risks posed, and the likelihood of them materialising. When considered alongside the findings from inquiries such as those relating to Bristol Royal Infirmary⁶³¹ and Mid-Staffordshire NHS Foundation Trust⁶³², both of which represent the potential outcome that could ultimately transpire when risks have not been addressed, it is clear that decisive action is needed to ensure that a suitably robust system of regulation is in place.

With current policy⁶³³ stipulating that any system of professional regulation must be proportionate and effective, while imposing the least cost and complexity consistent with securing patient safety and public confidence, any steps taken to regulate advanced nursing practice would need to be able to justify the additional costs that would almost certainly be incurred. Required to identify and address high risk areas through processes such as revalidation - for example where professionals take on more responsibilities or develop their practice over time - it is expected that regulators will make changes to existing regulatory structures only where new or different risks that require new standards of proficiency in order to be safely performed present. Acknowledging this, the question that, therefore, needs to be addressed is whether advanced nursing

⁶³¹ Department of Health. Learning from Bristol: The Report of the Public Inquiry situation into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(I). London: HMSO. 2001

⁶³² The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

⁶³³ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. February 2011

practice necessitates new standards of proficiency, and whether additional forms of regulation are required⁶³⁴.

Prevalent among the risks that are inherent in advanced nursing practice are inadequate training and education, poor skill retention, inexperience, dubious ability to deal with unforeseen complications, the potential for mistaken professional identity and misrepresentation, and inappropriate delegation. Each of these risks needs to be assessed and addressed, in order to ascertain their threat to patient safety. Inherent in this assessment of risk is the question of whether, by raising the bar on permissible nursing practice, this development has rendered those nurses who have advanced their practice more likely to be involved in clinical errors or mishaps, or whether this is an unfounded assumption.

When considered alongside this is the fact that, although advanced nurses may be expert practitioners on the nursing continuum by virtue of their expertise in relation to traditional nursing care, they are more likely to find themselves novitiates in relation to the medical aspects of care, this position reinforces the suggestion that the possibility of nurses being involved in clinical errors is likely to be increased. Indeed, if one also acknowledges the reality that patients react to situations differently, and with pattern recognition as the foundation to clinical diagnosis offering a partial solution only⁶³⁵, this confirms the possibility that the risks that are associated with advanced nursing practice are likely to increase. This situation is likely to be of concern to nurses who have, historically, been shielded from liability for their actions by doctors, who have generally 'protected' them from censure in the event of something going wrong.

As a result of this 'protection', nurses have arguably been lulled into a false sense of security, with the result being that they have not always been held to account for their practice, and in some cases, have little awareness of their

⁶³⁴ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

⁶³⁵ Elstein AS, Schwarz A. Clinical problem solving and diagnostic decision making: selective review of the cognitive literature. British Medical Journal 2002;324(7339):729-732

professional responsibilities and liability⁶³⁶. However, given that new ways of working have changed inter-professional relationships, and role redesign has blurred the boundaries of inter-disciplinary practice - such that nurses are now recognised as being professionals in their own right - it is likely to be the case that doctors will now no longer be willing to shield nurses from the consequences of their actions, and instead be more likely to see them held to account. If one accepts this argument, this suggests that the need for a new system of regulation that would hold advanced nurses suitably to account has never been more needed.

2.5. The adequacy of the current regulatory system

Working on the basis that the evidence that has been submitted and the arguments surrounding new clinical roles that have been presented are convincing, it is submitted that the regulatory framework that currently underpins advanced nursing practice is not fit for purpose. Nor does it provide the necessary assurance that it will deliver practitioners who are fit to practise. This is particularly evident in the case of those nurses who have advanced their practice to the extent that it constitutes a new clinical role. Indeed, as the examples presented have shown, the risks that are associated with these practices are often left unaddressed, leaving patients potentially exposed to practitioners who are either ill-prepared for the roles they are performing, and, in some cases unable to manage independently complete episodes of care.

Under the existing regulatory regimen, only those nurses who practise in traditional ways are regulated by statute. Neither advanced nursing practice in the traditional sense, nor advanced nursing practice that is associated with the adoption of new clinical roles, are regulated by statute. This means that, in relation to all but traditional nursing matters, patients and the public do not, and will not, benefit from the safeguards that would normally flow from statutory regulation, namely 'protection' of title and accredited educational standards. In practice, this means that there is nothing in law to dissuade those

⁶³⁶ McGowan B. 'Are we covered to do this?' the legal implications of expanding practice. Paediatric Nursing. 2003; 15(8):24-27

individuals who wish to hold themselves out as being an advanced nurse, and that there is little in the way of regulatory safeguards to protect the public from their efforts.

Admittedly, those areas of advanced nursing practice that were traditionally associated with extended nursing roles, and involved piecemeal additions to practice, do not, in themselves, warrant statutory regulation. Rather, employer-led codes and local systems of governance would seem to be proportionate to manage the risks that are posed to patients. This would be the case, at least in the majority of cases. However, when one considers the level of technical complexity and intricacy that is associated with some of those procedures that are associated with new clinical roles, and the level of complex decision-making that is involved in them, the severity and magnitude of the risks becomes immediately apparent.

Working on the basis that this unacceptable and unsatisfactory situation cannot be allowed to continue, it seems prudent to consider those alternative regulatory models where parallels may already exist with advanced nursing practice. Of all the alternative regulatory approaches that advanced nurses could pursue, that which is associated with the regulation of midwifery practice would seem to be the most straightforward. This is particularly the case when one considers that midwives, who are often said informally to represent the original advanced nurses, already benefit from a separate but related regulatory regimen to that which is afforded to nurses. Indeed, many, including the Health Select Committee⁶³⁷, have identified elements of this regulatory model, most notably statutory supervision, as an example of good practice. As such, it seems sensible to analyse the midwifery model with a view to identifying any lessons that may be learned from this.

⁶³⁷ House of Commons Health Committee. Annual accountability hearing with the Nursing and Midwifery Council. Seventh Report of Session 2010-2012. HC 1428. London: HMSO. 2011

2.6. The need for additional safeguards: a time for change

As a profession, nursing is unique in the extent to which it has been able to expand its boundaries of practice. Originally associated with the adoption of extended tasks that required additional levels of proficiency to perform them, and adopted by those nurses who were keen to demonstrate a level of ability beyond that which is associated with traditional nurses, it is now recognised as a much more mature and established profession. In fact, such has been the pace at which nursing has evolved, that expansions to nursing practice have developed far beyond the acquisition of additional tasks, such that, in many cases, they are now embodied in new clinical roles.

As a consequence of these opportunities, many more nurses have now sought to expand their practice in a myriad of ways. These ways range from those who have accepted responsibility for tasks which are beyond those associated with their initial registration - usually in order to expedite patients' care and improve their clinical journey - to those who have embraced new ways of working in a much more holistic way. However, although these developments are typically classed as being 'advanced', the way in which they have become manifest in practice is variable.

This has led to some nurses following recognised programmes of study, and being well-prepared to take on new roles. It has also led to others adopting roles in the absence of recognised training and education, and following unrecognised programmes of study. Having evolved through time, this situation - and the related disparity - has resulted in a proliferation of titles that comprise the advanced nursing practice continuum⁶³⁸. In practice, this means that at one end of this spectrum are those who are competent to take on the responsibilities that await them, and, at the other, are those who have adopted a range of self-styled titles, many of which are not understood and roles for which they are ill-prepared.

⁶³⁸ Duffield C, Gardner G, Chang A, Catling-Paull C. Advanced nursing practice: A global perspective. Collegian 2009;16(2):55-62

Although beneficial for patients and the public, it is clear that these developments are not without their risks. Indeed, with changes in regulation slow to follow practice, and reciprocal developments in arrangements to ensure accountability conspicuous by their absence, this has led to questions surrounding the extent to which patients are protected from those performing these new roles. Underpinning these concerns is recognition of the fact that, despite having advanced their practice, these nurses continue to be bound by the same regulatory and professional requirements as those associated with their more traditional colleagues, with no additional obligations having been imposed upon them in line with their increased responsibilities.

With few mechanisms currently existing through which to validate the training, education and credentials of those nurses purporting to practice in an advanced way, and many holding specialist titles that set them apart from traditional nurses, the situation has arisen in which the need to standardise and regulate advanced nursing practice is evident. However, rather than starting from the beginning and developing a unique approach to regulating their practices and managing the associated risks, it seems sensible to acknowledge and build upon those precedents has have already been established by the NMC for regulating separately specific groups of nurses.

Singled out for particular attention are those arrangements that have already been put in place to regulate the practice of midwives. Indeed, having been shown to be both reliable and effective, and having survived the test of time, midwives make the ideal comparator. Alongside midwives are related arrangements that have been put in place for Specialist Community Public Health Nurses. However, despite also benefiting from a separate part of the NMC Register, the arrangements that have been put in place for this group of nurses - who are able to be differentiated from traditional nurses by virtue of the Specialist Practitioner Qualification (SPQ) - have arguably been less robust. This has meant that although a regulatory framework for this group of nurses is in place, and should, *in principle*, be able to afford the public with an additional level of protection, the extent to which this additional layer of regulation has, *in practice*, been enforced is questionable.

Acknowledging these developments, and seeking to learn lessons from those nurses who have already developed their practice in a more innovative and structured way, it seems prudent to review the approach that these groups of nurses have followed and the way in which they have been regulated. The approach that has already been taken by midwives is particularly interesting, given the extent to which they have become recognised for having a specific body of expertise, and the strength of the regulatory mechanisms that underpin their practice. Proceeding on the basis that midwives are the original group of nurses who developed their practice - to the extent that midwifery is now recognised and respected as an established profession in its own right - this makes a comparison with midwives the logical next step.

Chapter 3

3. The regulation of advanced nursing practice: a comparison with midwifery

As a group, midwives hold a 'special' and esteemed position in society. Although this position can largely be attributed to the fact that midwives are the healthcare professionals that are most involved at one of the most significant times in peoples' lives - namely when their children are being born - part of this esteem is also understood to derive from the professional way in which they practice. For many people, particularly those who have an understanding of healthcare policy and history, much of this acclaim also arises from the fact that midwives have established for themselves a special discipline 'within' nursing and a discrete body of knowledge, and have been instrumental in devising and adhering to recognised codes of ethics and conduct from an early stage. Indeed, it could be argued that these factors are responsible for midwives having established the strong position that they currently hold within society, and within the healthcare team.

Acknowledging these developments and recognising the distinct role that midwives hold within healthcare, it seems sensible to take a closer look at their development to ascertain whether there is anything in their history that resonates with advanced nurses. Within this analysis, particular attention will be paid to the specific statutory regimen that underpins midwifery practice, with the aim of distilling those elements of midwifery regulation that could pertain to advanced nursing practice. Also underpinning this analysis is the question of whether midwives have merely established themselves as more proficient practitioners who require additional regulatory safeguards upon which to base their practice, or whether the nature of their role is so different from that of the other main clinical groups that separate statutory regulation is warranted.

Central to this analysis will be the question of whether advanced nurses should be regulated in a way similar to that which underpins the practice of midwifery, and, if so, whether it would be feasible for similar regulatory arrangements to be made. Working on the basis that advanced nurses could benefit from a form of regulation similar to that which is enjoyed by midwives, this chapter will seek to show that it would be possible to achieve change of the magnitude required, with minimal legislative intervention.

3.1. The practice of midwifery

Considered by some to be the original advanced nurses, and independent practitioners in their own right, midwives are said to epitomise advanced nursing practice⁶³⁹. Working autonomously to a model that is more aligned with medicine than with nursing, they are the lead healthcare professionals in cases of uncomplicated pregnancy, and the experts in normal childbirth⁶⁴⁰. As such, it is not unusual to see midwives, rather than doctors, attending on women during their pregnancy, up to and including delivery, and taking the lead in their care. Indeed, in some cases, women feel more comfortable dealing with midwives, and actively seek their care in preference to that which is offered by other healthcare professionals⁶⁴¹.

However, despite this, the scope of midwifery practice remains limited, in that midwives are still required by statute⁶⁴² to seek assistance when faced with circumstances that deviate from normal, and when interventions that fall outside of their sphere of practice are required. This means that, although legislation may have changed so as to enable midwives to deal with a wider range of situations, their practice remains relatively unchanged, given that it is still rooted in 'normality'. With the parameters of their practice 'restricted' in this way, this has effectively placed a 'ceiling' on the scope of midwifery

⁶³⁹ Davies R. Practitioners in their own right: an ethnographic study of the perceptions of student midwives. In: Robinson S, Thomson AM (Eds) Midwives, research and childbirth. London: Chapman & Hall. 1996;85-108

⁶⁴⁰ Midwifery 2020 Programme. Midwifery 2020: Delivering expectations. Cambridge: Jill Rogers Associates. 2010

⁶⁴¹ Harvey S, Rach D, Stainton MC, Jarrell J, Brant R. Evaluation of satisfaction with midwifery care. Midwifery 2002;18(4):260-267

⁶⁴² The Nursing and Midwifery Council (Midwives) 2004. Statutory Instrument 2004 No 1764 Rule 6(3)

practice, leading some commentators^{643,644} to question the extent of midwives' autonomy, and to ask whether they can really ever be truly autonomous.

As a source of considerable debate, both within and outside of the profession, questions surrounding the autonomy of midwives are entirely legitimate. These questions are largely derived from the fact that, under the current model of maternity care, most women are admitted to hospital to give birth, where hierarchical structures dominate. Given that the majority of midwives also currently work in the hospital environment, where doctors typically assume responsibility for women's care⁶⁴⁵, this approach reinforces the hierarchical relationship that traditionally existed between the professions and, in particular, the dominance of medical practitioners. In doing so, it casts doubt upon the notion of autonomous midwifery practice, and questions its validity as a concept. Nevertheless, despite this, midwives have maintained their influence over childbirth and retained their place in the public's consciousness, with the result being that they continue to be regarded as the main providers of maternity care, and the principal advocates for women during childbirth^{646,647}.

With their role embedded within the healthcare system, midwives are ideally placed to deliver the future vision of maternity care⁶⁴⁸. Central to this is their ability to adapt to the changing context within which care is delivered, and their resilience in being able to respond to the myriad of developments that have engulfed the profession. Indeed, it is this resilience that has enabled midwives to overcome the historic and well-documented struggles for control over

⁶⁴³ Fleming VE. Autonomous or automatons? An exploration through history of the concept of autonomy in midwifery in Scotland and New Zealand. Nursing Ethics 1998;5(1):43-51

⁶⁴⁴ Reid L. Midwifery: Freedom to practise? An international exploration of midwifery practice. Edinburgh: Elsevier Health Sciences. 2007

⁶⁴⁵ Midwifery 2020 Programme. Core Role of the Midwife Workstream. Final Report. 2010

⁶⁴⁶ O'Connell R, Downe S. A metasynthesis of midwives' experience of hospital practice in publicly funded settings: Compliance, resistance and authenticity. Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine 2009;13(6):589-609

⁶⁴⁷ Walsh D, Devane D. A metasynthesis of midwife-led care. Quality Health Research 2012;22(7):897-910

⁶⁴⁸ Midwifery 2020 Programme. Midwifery 2020: Delivering expectations. Cambridge: Jill Rogers Associates. 2010

childbirth⁶⁴⁹, and to resist attempts made by doctors and the medical profession to acquire authority over the maternity domain.

Significantly, the challenges that have beset midwives are not dissimilar to those that are currently facing advanced nurses. Indeed, with both having overcome attempts by doctors and the medical profession to assume control over their practice, and both having resisted challenges to authority over their respective domains, the similarities between them are considerable.

Of course, nurses and midwives also differ in many respects, not least in that midwives have a clearly defined client group and a reserved function. For the most part, they are also limited to dealing with normal physiology and health. Nurses, on the other hand, are able to deal with pathology, abnormality and ill-health across the clinical spectrum, as well as intervening in cases of normal health and well-being. Midwives also practise autonomously immediately after initial registration, and diagnose conditions, supply medicines, and refer women on to other professionals or specialisms at that point. This is in contrast with nurses, who typically acquire their expertise and ability to practise autonomously through post-registration education and practice.

Underpinning both professions are the regulatory systems that determine their practice, and, in particular, their professional and educational standards, and their codes of conduct and ethics. Given that nurses and midwives are both governed by the same regulatory body, and both are bound by the same professional code⁶⁵⁰, albeit with midwives occupying a separate part of the NMC Register and benefiting from separate secondary legislation⁶⁵¹, the parallels between the professions are such that a meaningful comparison can be made. Acknowledging these similarities, it seems sensible to take a closer look at the path that has been taken by midwifery during its transition into a mature and respected profession, and analyse the extent to which the regulatory model that currently underpins it may be applicable to advanced nursing practice.

649 Donnison J. Midwives and medical men: A history of the struggle for the control of childbirth.

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^{2&}lt;sup>nd</sup> Edition. London: Historical Publications Ltd. 1988

⁶⁵⁰ Nursing and Midwifery Council. NMC. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

⁶⁵¹ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Part VIII

3.2. The evolution of professional midwifery practice

Generally speaking, the practice of midwifery is characterised by three historic features, each of which has had a significant impact on its evolution. First, it was originally a female preserve into which men had to fight their way, and was less successful than other occupations in pursuing professionalisation. This meant that its role as an amateur occupation continued at a time when other occupational groups, such as physicians and surgeons, were organising themselves into specific professions through licensing and Acts of Parliament⁶⁵². This, in turn, resulted in midwifery having to compete with medicine and nursing to be recognised as a separate entity, and to have a distinct role in the provision of care.

Secondly, new models of maternity care were developed which impacted upon the role of the midwife in different ways. These developments, many of which were associated with the technical medical model and coincided with rising concern surrounding high mortality and morbidity rates, could be linked with increasing paternalism within society, and the increased role of the state in overseeing health and welfare. Thirdly, women became more empowered, not only as members of society and in occupations, but also as mothers. As such, they increasingly expected to be involved in decisions regarding their care, and to be consulted on all matters that affected them. This resulted in further models of care being developed as an alternative to the medical model, and in increasing calls from within the profession to advance the status of midwives⁶⁵³.

3.2.1. The early days

In the beginning, the practice of midwifery was delivered by local women whose only training was that they had given birth to children. Through time, this resulted in the situation whereby these women became designated as the 'wise

⁶⁵² Ministry of Health, Department of Health for Scotland, Ministry of Labour and National Service. Report of the Working Party on Midwives. Chaired by Mrs W Stocks (The Stocks Report). London: Ministry of Health. 1949

⁶⁵³ Aveling JH (1872). English Midwives: their history and prospect. Reprinted by Thornton JL. London: Hugh K Elliott Ltd. 1972

women' who would be called upon to attend births in their neighbourhoods. This, in turn, gave rise to a more formal midwifery role, and the model from which subsequent developments would emerge. Continuing for centuries, this framework saw midwives learn through an apprenticeship model, and share their knowledge and skills with future generations in the absence of external interference. However, with medical men exerting an increasingly powerful influence as time progressed, this situation was not to prevail, resulting in challenges being made to the control of childbirth that still resonate today.

At the start of the 20th Century, approximately 70% of births were attended by midwives and took place in the home⁶⁵⁴. At this time, midwifery was considered to be an integral part of working-class life and culture, with midwives acting as women's advocates and asserting their authority over maternity care. Accordingly, midwives became trusted supporters of women and attended the majority of births for those classed as being poor, while doctors attended on those more able to afford the medical fees⁶⁵⁵. However, around this time, concern also started to emerge surrounding high maternal and infant mortality rates, with the inference being that the lack of formal midwifery education and training was in some way causative. This resulted in the formation of the Midwives Institute⁶⁵⁶, a midwife-led organisation, which sought to improve the quality of midwifery practice and the status of midwives, by petitioning Parliament for their statutory regulation.

Strongly opposed to this notion of statutory regulation were doctors, whose concerns were mainly focused on the perceived threat to their livelihood posed by the wider availability of well-trained and affordable midwives. Also opposing this initiative were the more militant midwives, who perceived that statutory regulation would remove their autonomy, and result in them surrendering their

⁶⁵⁴ Donnison J. Midwives and medical men: A history of the struggle for the control of childbirth. 2nd Edition. London: Historical Publications Ltd. 1988

⁶⁵⁵ Ministry of Health, Department of Health for Scotland, Ministry of Labour and National Service. Report of the Working Party on Midwives. Chaired by Mrs W Stocks (The Stocks Report). London: Ministry of Health. 1949

⁶⁵⁶ Ashton RM. The Royal College of Midwives: past, present and future. International Journal of Gynaecology and Obstetrics 1979;17(2):124-127

'independence' to medical control⁶⁵⁷. Nevertheless, despite these concerns, which were the subject of heated and, at times, acrimonious debate, these efforts proved to be successful, resulting in statutory regulation being introduced with the passing of the first Midwives' Act for England and Wales⁶⁵⁸ and the establishment of the Central Midwives' Board (CMB). In practice, this afforded midwives professional status and 'protection' of title, as well as enabling them to benefit from more standardised training, education and governance. The result was that it was unlawful for anyone not certified under the Act to purport to be a midwife or to practise as such, and the practice of midwifery was restricted to those who were formally qualified.

Tasked with laying down conditions for registration and for issuing midwives' certificates, which effectively constituted their license to practice, the CMB had a central role to play in monitoring and ensuring high levels of practice. Charged also with responsibility for making the *Rules*⁶⁵⁹ that would underpin the regulation and supervision of midwives, and for setting associated examinations, the CMB had the authority to remove a midwife's name from the 'Roll' in the event of them being declared unfit for practice. Midwives, in turn, had the right of appeal against decisions made, albeit in a limited way, given the cumbersome and expensive nature of the appeals process.

In addition to these functions, the Act also made provision for local authorities to act as the 'local supervisory body' for midwives⁶⁶⁰. This included the power to exercise general supervision over midwives practising within their locales, and to investigate allegations of malpractice, negligence or misconduct. If satisfied that, following the relevant investigations, there was a case to answer, this would result in the local authorities reporting their findings to the CMB, and to the CMB, in turn, taking responsive action. Also included within these functions was the 'directive' which required local authorities to remain up to date regarding those women who were practising as midwives in their area. This meant that certified midwives who wished to practice were required to give

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⁶⁵⁷ Anisef P, Basson P. The institutionalization of a profession: a comparison of British and American midwifery. Work and Occupations 1979;6:353-372

⁶⁵⁸ Midwives Act 1902

⁶⁵⁹ Central Midwives Board. The Midwives Rules. London: Central Midwives Board. 1903

⁶⁶⁰ Midwives Act 1902 s8

written notice to the authorities of their intention to do so, and to submit repeated 'notices' on an annual basis, in order to be afforded the requisite permission.

Although subsequently added to by various amendments introduced over the years^{661,662,663}, the Act survived relatively intact until the advent of the NHS. So, too, did the fact that medical practitioners made up the majority membership of the CMB, which meant that midwives were effectively 'controlled' by medicine, and had limited opportunities to develop their practice. However, with the introduction of 'statutory supervision' came a change in emphasis, this being indicative of the esteem in which midwives were held, and the level of importance that was attributed to supervision by key stakeholders. In fact, such was the level of confidence that the public and the professions had in the statutory supervision process, that these requirements were carried forward into the NHS⁶⁶⁴, the only difference being that local health authorities would perform the role of supervising authority, rather than the local authorities. Significantly, these provisions still remain, and, together with the *Midwives Rules*⁶⁶⁵, constitute a unique form of regulation aimed at providing the highest possible quality of maternity care, and ensuring public protection.

Also notable among the amendments made around this time, were additional powers given to the CMB⁶⁶⁶ which enabled it to suspend midwives from practice, as opposed to removing them from the Roll. This gave the CMB greater powers to control the practice of midwives, and the flexibility to prevent them from practising for defined periods, but without going so far as to take the more definitive step of erasure. Also significant was the introduction of a salaried midwifery service⁶⁶⁷, in which local authorities would provide the service, and midwives would be employed to carry out its functions. However, although associated with obvious benefits for both midwives and the authorities, the fact that employment with the health authorities was not compulsory, meant that

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⁶⁶¹ Midwives Act 1918

⁶⁶² Midwives Act 1926

⁶⁶³ Midwives Act 1936

⁶⁶⁴ National Health Service Act 1946 s23

⁶⁶⁵ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Rule 42

⁶⁶⁶ Midwives Act 1918

⁶⁶⁷ Midwives Act 1936

midwives could act as 'independent' practitioners if they wished. Thus, despite creating an identifiable structure that enabled a uniform approach to the practice of midwifery to be taken, the fact that midwives could choose to practise in a different and more independent way meant that consistency of standards could not always be guaranteed, and variation was 'normal'. Interestingly, 'independent' midwives still exist today, albeit with a greater level of control over their practice⁶⁶⁸.

The refreshed version of the *Midwives Rules*⁶⁶⁹, published in 1919, which is credited with helping to delineate the boundaries of safe practice, was also significant in the evolution of professional midwifery practice. Indeed, it is this document that is attributed with requiring midwives to summon aid in all cases of illness of either mother or child, or any abnormality occurring during pregnancy, labour or the 'lying-in' period; a requirement that is still reflected in modern midwifery practice⁶⁷⁰. Also issued at the same time, was a list of conditions and abnormalities to which the *Rules* applied. Notably, this list remains in place today and is largely unchanged, the only meaningful difference being the severity of the abnormality and the absence of foetal problems.

Collectively, this legislation, underpinned by the initial action taken by the Midwives' Institute, established the regulatory framework that governed the practice of midwifery and the qualifications for 'Supervisors of Midwives' prior to the introduction of the NHS. Indeed, such was the level of support that was received by the Midwives' Institute and the regard in which it was held for enabling this to happen, that by 1941 it had evolved into the College of Midwives, and by 1947 it had received a Royal Charter. Since then, it has been known as the Royal College of Midwives (RCM), and is now recognised as the authoritative source of professional advice to midwives when seeking to improve the health of mothers and their babies. It is also the main professional body to whom policy makers turn when seeking to bring about change in maternity service provision.

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⁶⁶⁸ Royal College of Midwives and Nursing and Midwifery Council. The feasibility and insurability of independent midwifery in England. London: Flaxman Partners Ltd. 2011

⁶⁶⁹ Central Midwives Board. The Midwives Rules. London: Central Midwives Board. 1919

⁶⁷⁰ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 6(3)

The period that immediately preceded the advent of the NHS can, thus, best be described as one of relative stability, both professionally and from a regulatory perspective. Indeed, with the position of midwives established alongside doctors, and the necessary regulatory safeguards having been reinforced through legislation, the platform from which midwives could practice seemed to be secure. However, despite introducing much needed change in the form of a health service in which the provision of care would be free at the point of delivery ^{671,672}, the advent of the NHS had a significant and, arguably, destabilising effect on the delivery of maternity care, and on the scope of midwifery practice.

3.2.2. The medicalisation of pregnancy and childbirth

Prior to the introduction of the NHS, midwives were acknowledged as being the first point of contact for women who were pregnant and going through childbirth. At this time, the majority of women gave birth at home, with childbirth considered to be an essentially natural process⁶⁷³. However, with the inception of the NHS came a more rapid shift towards hospital births than that originally envisaged, with the result being that by 1958 the home birth rate had fallen by 34%⁶⁷⁴. Also emerging was a shift in the model of maternity care, partly due to free antenatal care being made available to all women, with the result being that General Practitioners (GPs) rather than midwives became their first point of contact. This development, alongside the shift towards more hospital-based care, heralded the onset of the medicalisation of childbirth, and signalled the point at which midwives' autonomy began to be eroded.

Also significant in limiting the 'freedom' of midwives around this time, was legislation⁶⁷⁵ which led to the centralisation of hospital and midwifery services, and the management of both within one organisation; in this case the hospital

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⁶⁷¹ National Health Service Act 1946

⁶⁷² National Health Service (Scotland) Act 1947

⁶⁷³ Aveline JH. English Midwives: their history and prospect. 1872. Reprinted by Thornton JL. London: Hugh K Elliott Ltd. 1972

⁶⁷⁴ Marshall JE, Kirkwood S. Autonomy and team work. In Fraser D. Professional studies for midwifery practice. Edinburgh: Churchill Livingstone. 2000

⁶⁷⁵ National Health Service (Reorganisation) Act 1973

hierarchical structure. As a result, those community midwives who had hitherto been relatively autonomous found themselves subject to more scrutiny and control, most notably by hospital consultants who assumed clinical authority over those women who had been admitted to hospital, and accepted responsibility for their care. This led to midwifery being perceived as a subordinate hospital-based profession under the 'control' of obstetricians, rather than an autonomous community-based profession founded on a woman-centred model of care⁶⁷⁶, and marked the end of midwifery-led care as it was originally known.

Central to these developments was the increased use of technical obstetric interventions, which were originally considered as being the medical preserve. Coinciding with a falling normal birth rate and a reduction in maternal mortality rates, this led to the perception that a causal link existed between the two, with hospital-based births and obstetric intervention viewed as being the main factors responsible for reducing maternal mortality, and pregnancy viewed as only ever being normal in retrospect⁶⁷⁷. This, in turn, culminated in publication of the *Peel Report*⁶⁷⁸, a government-commissioned review of domiciliary midwifery and maternity bed needs, which, despite the lack of any substantial evidence, recommended that provision should be made for a 100% hospital birth rate, and the phasing out of smaller, more isolated units. In practice, this meant that not only would there be no choice for women regarding their place of giving birth, but midwives' autonomy would also be further eroded.

Under threat, and with technological advances and increased obstetric interventions affecting women's control, such as the artificial rupture of membranes, cardiotocography (CTG), epidural anaesthesia and the increased use of forceps, particularly during labour, midwives found themselves with a limited scope of practice and limited involvement in clinical decision-making⁶⁷⁹. In fact,

⁶⁷⁶ Johanson R, Newburn M, Macfarlane A. Has the medicalisation of childbirth gone too far? British Medical Journal 2002;324:892-895

⁶⁷⁷ McFarland N. Models of care and midwifery in the millennium. British Journal of Midwifery 1999;9(12):745-748

⁶⁷⁸ Maternity Advisory Committee. Domiciliary and maternity bed needs. Chaired by Sir John Peel. (The Peel Report). London: HMSO. 1970

⁶⁷⁹ Marshall JE, Kirkwood S. Autonomy and team work. In Fraser D. Professional studies for midwifery practice. Edinburgh: Churchill Livingstone. 2000; 127-141

such was the change in practice around this time that those midwives who trained during this period were considered by some⁶⁸⁰ to perform the role of medical assistant, rather than independent practitioner. As a result, midwives became immersed in a highly sophisticated, technical and controlled environment in which women typically emerged as recipients of care provided by specialists, rather than active decision-makers in a natural process, and specialists emerged as being in control of the entire process.

Fundamental to this change in direction, was the assumption that hospital-based births were safer for women and their babies⁶⁸¹. Premised on the *Peel Report*, and subsequently reinforced in the *Short Report*⁶⁸², which focused on maternity care from the perspective of perinatal mortality rather than maternal mortality, this assumption reinforced the drive towards hospital births, meaning that midwives continued to be side-lined and their role continued to be diminished. As a result, not only did 'home-based' midwifery effectively disappear, but so, too, did the place of midwives as experts in normal births. Along with this expertise also went the loss of practical midwifery skills, in favour of interventionist methods which many midwives were forced to adopt against their professional judgement⁶⁸³. This meant that, in reality, women had relatively little choice but to accept the technical medical model, and adhere to a more mechanised system, rather than experience a more natural form of childbirth.

3.2.3. The shift towards woman-centred care

With concern growing that adequate consideration was not being given to the views of women, issues surrounding the quality of care that they could expect to receive began to gain prominence. Supported by research⁶⁸⁴ which validated

⁶⁸⁰ Towler J, Bramall J. Midwives in history and society. London: Croom Helm. 1986

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⁶⁸¹ Beech B. The benefits of home birth: evidence of safety, effectiveness and women's experience. Association for Improvements in the Maternity Services. 2012

⁶⁸² Short Committee. Perinatal and neonatal mortality. Social Services Committee Second Report 1979-1980. Chaired by Short R. (The Short Report). London: HMSO. 1980

⁶⁸³ Reid L. Turning tradition into progress: moving midwifery forward. RCM Midwives Journal 2002;5(8):250-254

⁶⁸⁴ Green JM, Coupland VA, Kitzinger JV. Expectations, experiences, and psychological outcomes of childbirth: A prospective study of 825 women. Birth 1990;17(1):15-24

concerns surrounding the emotional and psychological aspects of care, and reinforced by consumer organisations which raised the profile of women's anxieties and gave a platform for their complaints, these findings provided evidence of a lack of support for such an interventionist approach. Instead, inherent in these findings was strong support for the autonomy of both women and midwives, with each advocating for the other as a natural ally for improved choice, continuity of care, and the right of women to have control over their bodies during childbirth. This culminated in widespread support for a social model of maternity care that placed women, rather than organisations, at the centre of care, and in growing momentum for women to be given more choice and a greater say in their options for care.

Subsequently incorporated into health policy^{685,686}, the notion of consumer choice and the importance of involving women in the decisions that affect them now feature centrally in all midwifery developments. However, it was arguably not until publication of the *Winterton Report*⁶⁸⁷ and *Changing Childbirth*⁶⁸⁸ that midwives began to regain control over 'normal' childbirth, and women had their 'voices' restored to them. Significantly, and in contrast with earlier reports, these findings emphasised the importance of managing normal pregnancy and birth, rather than focusing on abnormality, and concluded that there should be a shift away from looking at mortality rates as a measure of clinical outcome, in favour of measures aimed at delivering woman-centred care.

Signifying a landmark change in maternity policy, these reports created a climate of empowerment in which women felt able to recover their control, and midwives felt able to reassert their autonomy. Also acknowledging that women should have access to appropriate care during childbirth, these findings enabled a revised model of care to be developed in which women with normal pregnancies would be cared for in low-technology community settings, with

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⁶⁸⁵ Audit Commission. First class delivery: Improving maternity services in England and Wales. London: Audit Commission. 1997

⁶⁸⁶ Scottish Executive. A framework for maternity services in Scotland. Edinburgh: Scottish Executive. 2001

⁶⁸⁷ House of Commons Health Committee. Second Report: maternity services (The Winterton Report). London: HMSO. 1992

⁶⁸⁸ Department of Health. Changing childbirth; Report of the Expert Maternity Group. London: HMSO. 1993

midwives as the lead professional, and high-technology hospital-based care would be reserved for women with complications or special needs⁶⁸⁹. Now embedded in high level policy initiatives^{690,691}, and forming the basis of future maternity service provision, these developments paved the way for midwives to develop their role as autonomous practitioners, and for women's expectations to be satisfied.

3.2.4. Midwifery-led care

It is estimated that approximately 900,000 women will give birth in the UK each year⁶⁹². Most are likely to receive the majority of their care from a midwife. Inherent in this projection is a model of childbirth based on continuity and choice, with the aim being to deliver services that are woman and familycentred, and in which the needs of women, rather than practitioners, will prevail. Central to this model is the expectation that midwives will have a key role in providing the majority of care for healthy women, act as the lead coordinator of care for women with complex pregnancies, share the care of high-risk women who deliver within their locales, and directly refer women and their babies to specialists and services across primary and secondary care sectors⁶⁹³. In so doing, their role is to minimise the risks to women's safety by facilitating the earliest possible interventions for those presenting with medical, obstetric or social complications, and by ensuring effective liaison between all relevant parties. Inherent in this model is also the expectation that midwives will assist with providing home births for those women who wish to choose this option, and normalise the process of childbirth as far as possible⁶⁹⁴.

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⁶⁸⁹ Hatem M, Sandall J, Devane D, Soltani H, Gates S. Midwife-led versus other models of care for childbearing women. Cochrane Database of Systematic Reviews. Oct 8(4):CD004667. 2008

 $^{^{690}}$ Department of Health. Maternity matters: choice, access and continuity of care in a safe service. London: DH. 2007

⁶⁹¹ The Scottish Government. A refreshed framework for maternity care in Scotland: The Maternity Services Action Group. Edinburgh: The Scottish Government. 2011

⁶⁹² Midwifery 2020 Programme. Midwifery 2020: Delivering expectations. Cambridge: Jill Rogers Associates. 2010

⁶⁹³ Midwifery 2020 Programme. Midwifery 2020: Delivering expectations. Cambridge: Jill Rogers Associates. 2010

⁶⁹⁴ Midwifery 2020 Programme. Core Role of the Midwife Workstream. Final Report. 2010

Within the UK, two philosophies underpin this model of care, both of which rely on the autonomy of midwives. On the one hand, there is growing emphasis on the provision of holistic midwifery-led care, rather than the technical medical model^{695,696}. On the other hand, there is support for a related, but more community-based approach, in which care is delivered by a team of midwives who collectively manage a discrete caseload of women^{697,698}. Underpinning both philosophies is the expectation that midwives will be suitably prepared for these roles, and will be held accountable for their actions and decisions.

3.1.4.1. The holistic approach

Able to be applied in a range of settings, including hospital units, birthing centres and the community, the holistic approach to midwife-led care is founded on the premise that pregnancy and childbirth are essentially normal life events during which care should be provided by a known and trusted midwife⁶⁹⁹. Also premised on the assertion that most women with uncomplicated or 'low-risk' pregnancies have the natural ability to experience birth with no or minimal routine intervention⁷⁰⁰, this model reinforces the right of women to be able to choose, and have control over, the decisions that affect them. Intrinsic to this approach is recognition of the benefits that this model of childbirth can afford, albeit acknowledging that, in cases of substantial medical or obstetric complications, some aspects of care may need to be provided in consultation with other healthcare professionals.

 $^{^{695}}$ Zander L, Chamberlian G. ABC of labour care place of birth. British Journal of Midwifery 1999;318(7185):721-723

⁶⁹⁶ Sinclair M. Midwifery-led care: local, national and international perspectives. RCM Midwives Magazine 2002;5(11):380-383

⁶⁹⁷ Biro MA, Waldenstrom U. Team midwifery care in a tertiary level obstetric service: A randomised controlled trial. Birth 2000;27(3):168-173

⁶⁹⁸ Biro MA, Waldenstrom U, Brown S, Pannifex JH. Satisfaction with team midwifery care for low and high-risk women: a randomised controlled trial. Birth 2003;30(1):1-10

⁶⁹⁹ Hatem M, Sandall J, Devane D, Soltani H, Gates S. Midwife-led versus other models of care for childbearing women. Cochrane Database of Systematic Reviews. Oct 8(4):CD004667. 2008

⁷⁰⁰ Department of Health. Maternity matters: Choice, access and continuity of care in a safe service. London: DH. 2007

Of course, also underpinning the midwifery-led model of care is the need for safety and continuity, both of which were found to exist in a review of 12,276 women who elected for midwifery-led care in 2008⁷⁰¹. Seeking to explore the clinical and cost-effectiveness of this model when compared with other models of childbearing, and to ascertain the optimal model of care for routine healthy pregnancy, this study by Hatem *et al* reported positive findings in relation to adverse outcomes and the level of obstetric risk across all phases of childbirth. With some of the studies contained within this review^{702,703} also reporting higher rates of spontaneous vaginal birth, and lower rates of Caesarean Section, episiotomy, severe perineal injury and neonatal admission to Special Care Baby Units (SCBUs), this model seems to have gained support.

Admittedly, the exclusion of women with significant maternal disease and substance misuse from some of these studies may have influenced these findings. As such, these findings need to be treated with caution, particularly those that relate to women with substantial medical or obstetric complications. Interestingly, this reservation was also expressed in earlier studies by Waldenstrom and Turnbull⁷⁰⁴ and Hodnett *et al*⁷⁰⁵, both of which pointed to a trend towards higher rates of perinatal mortality and neonatal morbidity when these groups of women were included in hospital-based midwife-led units. In each case, adverse outcomes were attributed to failure to detect complications, failure to initiate appropriate action, and/or failure of the tertiary hospital response. However, with overall findings from Hatem *et al*'s review reporting similar or reduced rates of intervention, similar clinical outcomes and complication rates, and high levels of maternal satisfaction and cost-

⁷⁰¹ Hatem M, Sandall J, Devane D, Soltani H, Gates S. Midwife-led versus other models of care for childbearing women. Cochrane Database of Systematic Reviews Oct 8(4):CD004667. 2008

⁷⁰² Fraser W, Hatem-Asmar M, Krauss I, Maillard F, Breart G, Blais R. Comparison of midwifery care to medical care in hospitals in the Quebec Pilot Projects study: clinical indicators. Canadian Journal of Public Health 2000;91(1):15-11

Saunders D, Boulton M, Chapple J, Ratcliffe J, Levitan J. Evaluation of the Edgware Birth Centre Middlesex. London: North Thames Perinatal Public Health. 2000

Waldenstrom U, Turnbull D. A systematic review comparing continuity of midwifery care with standard maternity services. BJOG: An international journal of obstetrics and gynaecology 1998;105:1160-70

Hodnett ED, Downe S, Edwards N, Walsh D. Home-like versus conventional institutional settings for birth. Cochrane Database of Systematic Reviews Aug 15(8): CD000012. 2012

effectiveness when the midwifery-led approach was compared with consultantled care, this model looks to present a viable option.

3.1.4.2. Team midwifery

Also shown to be effective in providing high quality maternity care are 'team midwifery'⁷⁰⁶ and 'caseload midwifery'⁷⁰⁷, with both models revealing greater continuity in terms of relationships, by ensuring that women receive all their care from a named midwife or their 'practice partner'⁷⁰⁸. Able to be differentiated from the more technical medical model, in which obstetricians or GPs retain overall responsibility for care, this approach acknowledges the multidisciplinary network of consultation, while retaining the midwife's core role. Yet to be financially quantified and have its risks fully evaluated, findings to date suggest that there is no statistically significant difference in maternal and infant outcomes when this approach is compared with standard models of care⁷⁰⁹. However, with studies from Australia^{710,711} revealing high levels of maternal satisfaction, and highly valued and supportive relationships with women, this model looks to be encouraging.

With support for midwifery-led care also found in a systematic review of the cost-effectiveness of nursing and midwifery carried out by Caird $et\ al^{712}$, and a

⁷⁰⁶ Biro MA, Waldenstrom U. Team midwifery care in a tertiary level obstetric service: A randomised controlled trial. Birth 2000;27(3):168-173

North Staffordshire Changing Childbirth Research Team. A randomised study of midwifery caseload care and traditional 'shared-care'. Midwifery 2000;16(4):295-302

⁷⁰⁸ Rowley M, Hensey M, Brinsmead M, Wlodarezyk J. Continuity of care by a midwife team versus routine care during pregnancy and birth: a randomised trial. Medical Journal of Australia 1995;163:289-293

⁷⁰⁹ Benjamin Y, Walsh D, Taub N. A comparison of partnership caseload midwifery care with conventional team midwifery care: labour and birth outcomes. Midwifery 2001;17(3):234-240 ⁷¹⁰ Johnson M, Stewart H, Langdon R, Kelly P, Yong L. A comparison of the outcomes of partnership caseload midwifery and standard hospital care in low risk mothers. Australian Journal of Advanced Nursing 2005;22(3):21-27

⁷¹¹ Williams K, Lago L, Lainchbury A, Eagar K. Mothers' views of caseload midwifery and the value of continuity of care at an Australian regional hospital. Midwifery 2010;26(6):615-621 ⁷¹² Caird J, Rees R, Kavanagh J, Sutcliffe K, Oliver K, Dickson K, Woodman J, Barnett-Page E, Thomas J. The socioeconomic value of nursing and midwifery: A rapid systematic review of reviews. London: Social Science Research Unit, University of London. 2010

related study by Sutcliffe *et al*⁷¹³, which compared midwifery-led care with doctor-led care, it is possible that midwifery-led care could provide the way forward. Indeed, with both studies revealing no significant difference in infant outcomes, including foetal loss and neonatal death, when comparing midwifeled care in low-risk pregnancies with doctor-led care, arguments in its favour are convincing. So, too, are those findings which point to improvement in a number of maternal outcomes, including pregnancy-induced hypertension, spontaneous vaginal birth and breastfeeding initiation, and fewer procedures during labour, including instrumental deliveries, episiotomies and the use of analgesia and anaesthesia. When added to the fact that midwife-led care also appears to be effective in reducing antenatal hospitalisation and foetal monitoring in labour, and in increasing women's satisfaction with their care, this inspires confidence in the midwifery-led process and bodes well for the future of autonomous midwifery practice.

Interestingly, findings from these studies do not bear out the suggestion that midwife-led care makes a positive difference in relation to Caesarean Section rates. Neither do they compare favourably in relation to complications associated with malpresentation, perineal trauma, mean labour length, manual removal of the placenta, haemorrhage, anaemia, depression, amniotomy, induction, augmentation of labour or the use of intravenous fluids. However, they do signify the important contribution that continuity of carer can make, by supporting the development of meaningful and therapeutic relationships, enabling midwives to act as a 'bridge' across services to integrate care, and by improving outcomes. Nevertheless, with debate continuing regarding whether the most important factor in maternity care is continuity of *care* or continuity of *carer*⁷¹⁴, it is not yet certain whether team midwifery or caseload midwifery will provide the way forward.

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⁷¹³ Sutcliffe K, Caird J, Kavanagh J, Rees R, Oliver K, Dickson K, Woodman J, Barnett-Paige E, Thomas J. Comparing midwife-led and doctor-led maternity care: a systematic review of reviews. Journal of Advanced Nursing 2012;68(11):2376-2386

⁷¹⁴ Curtis P, Green J, Renfrew M. Continuity of carer: what matters to women? A review of the evidence. Midwifery 2008;16(3):186-196

3.1.4.3. The way forward

Looking to the future, it is anticipated that there will be a steady rise in the number of women with complex medical and obstetric conditions⁷¹⁵. It is also likely that there will be further reconfiguration of maternity services, with the result being a smaller number of tertiary facilities in which complex specialist services will be housed, and an increased number of midwife-led units in which most maternity care will be provided. If this vision materialises, it is likely to polarise the provision of maternity services into 'high risk' and 'low risk' environments. This implies that midwives may be required to deal with more complex conditions in low-risk environments, such as those associated with the physical and social needs of women, and those who are misusing drugs and alcohol. If this turns out to be the case, this means that it is feasible and, indeed, likely, that the scope of midwifery-led practice could extend into the realms of abnormality and ill-health, bringing with it implications for the regulation of midwifery practice and education.

It is also possible that midwives will want to continue to care for all categories of women, whether or not they have straightforward pregnancies, albeit with obstetricians taking the lead in high-risk cases where women experience substantial complications of pregnancy. Indeed, it is likely that the management of specific complications or defined 'medical' conditions could, through time, become a part of core midwifery practice, with midwives supported by a range of other healthcare professionals, including anaesthetists and paediatricians, where applicable. At the same time, it is also recognised that those women who oppose traditional models of maternity care, on the basis that they run contrary to the desire to 'keep childbirth natural and dynamic'716, will continue to seek greater autonomy in their decision-making, and request assistance from those 'independent midwives' who work outside of NHS Accordingly, it seems likely that midwives will find themselves structures. caring for women with more complex pregnancies, as well as taking the lead in

⁷¹⁵ Midwifery 2020 Programme. Midwifery 2020: Delivering expectations. Cambridge: Jill Rogers Associates. 2010

⁷¹⁶ NHS Quality Improvement Scotland. Pathways for maternity care. Edinburgh: NHS QIS. 2009

cases of normal pregnancy, bound always by professional and regulatory standards.

3.2.5. Midwifery as a profession

As previously stated, prior to the inception of the NHS, responsibility for governing the midwifery profession fell to the CMB. With the CMB already recognised as providing a strong platform from which midwifery could proceed, the introduction of the NHS initially brought about little change, other than to consolidate the underpinning Acts into one statute⁷¹⁷. This meant that the regulation of midwifery essentially remained the same, with midwives continuing to be subject to the statutory provisions laid out in the *Midwives Rules*⁷¹⁸. However, with the publication of the *Briggs Report*⁷¹⁹ into the nature and purpose of nurse training some years later, came far-reaching changes to the regulation of both nursing and midwifery, the majority of which still apply today.

Commissioned at a time of uncertainty regarding the planned reorganisation of the NHS, the aim of the *Briggs Report* was to review the management of limited nursing and midwifery resources in order to make the best use of available manpower. Focused also on reorganising the provision of training, so that the needs of both professions could be considered collectively, it was hoped that its recommendations would result in a more unified approach to professional leadership, and a more coordinated approach to education. After much debate, the recommendations from the *Report* culminated in a change in the governance structure of the professions, and the creation of a single statutory body with responsibility for raising the standards of their training and education, rather than the disparate array of bodies that were in some way connected with them.

Also considered within the related deliberations, was the retention of a separate statutory body for midwives that would oversee and decide upon the regulation

⁷¹⁸ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Rule 42

⁷¹⁷ Midwives Act 1951

⁷¹⁹ Report of the Committee on Nursing (The Briggs Report). Cmnd 5115. London: HMSO. 1972

of profession-specific issues. However, despite acknowledging the 'real and important differences' that existed between the professions, this proposal was rejected on the grounds that there were no aspects of midwifery practice upon which a body dealing with all aspects of nursing could not pronounce. Fundamental to this was the belief that all midwifery students should also be qualified nurses; a situation that prevailed in Scotland at that time, and has since received intermittent favour. Also central was the belief that amalgamating the statutory responsibilities for the 'basic' and 'post-basic' training of nurses and midwives would strengthen communication between the professions, which had not always been consistent or effective, and improve their negotiating position with governments both at home and abroad.

With a unitary structure for the training and deployment of nurses and midwives favoured, and the recommendations from the *Briggs Committee* having been accepted, the way was paved for dissolution of the CMB (and the related bodies in Scotland and Northern Ireland) and the formation of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC). Subsequently enshrined in legislation⁷²¹, these recommendations culminated in the creation of the National Boards, with each Board having responsibility for overseeing the training and education of nurses and midwives in their respective jurisdictions. From this stage onwards, nurses and midwives have been 'jointly' regulated, albeit with midwives continuing to benefit from secondary legislation in the form of *Rules*, including specific provisions associated with statutory supervision. Accordingly, although governed by shared primary legislation, the impact of additional safeguards for midwives has meant that, for all practical purposes, the professions have been subject to different forms of regulation.

Seeking also to preserve the legacy of autonomous midwifery practice that the profession had developed, *Briggs* hoped that the establishment of a Standing Midwifery Committee, comprised mainly of practising midwives, would enable those issues particular to midwifery to be addressed. In so doing, it was hoped that this would acknowledge the uniqueness of midwives, and enable their

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Davies C, Beach A. Interpreting professional self-regulation. A history of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting. London: Routledge. 2000
 Nurses, Midwives and Health Visitors Act 1979

prominent role in educating junior doctors and midwives to be retained. With its remit embedded in statute, it was also envisaged that the creation of such a committee would provide midwives with a suitable platform from which to be consulted, and thus enable them to advise on and influence all matters related to midwifery directly. Still in existence today, and forming a significant part of the NMC's infrastructure, the Midwifery Committee is acknowledged as the primary body with responsibility for developing and implementing midwifery policy⁷²².

3.3. The regulation of midwifery practice

Having benefited from a long and distinctive history of professional regulation, it is true to say that midwives have contributed significantly to the statutory regulatory structure that now underpins midwifery practice. On the one hand, the early dominance of medical men, the detailed practice rules that delineated the limits of their responsibilities, and local supervision and funding arrangements, all bear the mark of the profession's relatively humble origins. On the other hand, midwives are proud of the extent to which they have been able to interpret positively processes that could be perceived by some as being restrictive or controlling. This is most evident in their *Rules*, which could potentially be construed as providing evidence of the low level of trust that doctors had, and, perhaps, still have, in midwives. However, for the most part, the *Midwives Rules*, including statutory supervision and the associated arrangements for annual notification of intention to practise, are viewed by midwives as representing their right to be autonomous practitioners, and the profession's acknowledgement of the primacy of public protection⁷²³.

Governed by separate regulatory regimens, and believed to have differing interpretations of the *Rules*, it is, perhaps, not surprising that tension and misunderstanding are said to have lingered between nurses and midwives⁷²⁴.

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⁷²² The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Rule 41

⁷²³ Davies C, Beach A. Interpreting professional self-regulation. A history of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting. London: Routledge. 2000

Powell Kennedy H, Lyndon A. Tensions and teamwork in nursing and midwifery relationships. Journal of Obstetric, Gynaecological and Neonatal Nursing 2008;37(4):426-435

Indeed, with midwives said, informally, to consider themselves as being superior to nurses, and unhappy at being affiliated with them, this perceived difference in status may go some way to explain the conflict that is said to have existed between the professions since they were 'joined' under a shared regulatory regimen. Thus, despite the benefits of a joint regulatory approach being reinforced in subsequent legislation^{725,726}, the reality is that dissatisfaction with this situation has prevailed, with midwives continuing their campaign for separate statutory regulation^{727,728}.

Admittedly, this issue may become less contentious in the future, assuming that the Law Commissions' proposal⁷²⁹ to have a consistent approach to regulation across the healthcare professions is accepted. Indeed, it is entirely possible that the findings of the Law Commissions' Review - which are intended to be incorporated into statute in 2014 - could result in far-reaching changes to the regulation of *all* of the healthcare professions. If so, such a development could potentially see midwives benefit from an alternative form of regulation, either separately or by being merged with another professional regulator, such as the General Medical Council (GMC). Until then, those midwives who wish to practise will continue to be registered with the NMC, with the NMC, in turn, continuing to set standards for their education, practice and supervision. In the meantime, opinions will remain divided regarding whether the practice of midwifery is sufficiently different from nursing as to constitute a different professional entity, and whether a separate regulatory response is warranted.

Of course, underpinning these debates are the inherent benefits that statutory regulation can afford, and the advantages they confer on midwifery. Focused primarily on protecting the public from those midwives who are unfit to practise, statutory regulation places on midwives the onus to adopt the attitudes

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⁷²⁵ Nurses, Midwives and Health Visitors Act 1992

⁷²⁶ Nurses, Midwives and Health Visitors Act 1997

Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: Policy Paper. London: Law Commission. 2012

⁷²⁸ Royal College of Midwives. Response to the Law Commissions' consultation on the Regulation of Health Care Professionals. London: RCM. 2012

⁷²⁹ Law Commissions of England and Wales, Scotland and Northern Ireland. Regulation of healthcare professionals and regulation of social care professionals in England: A joint consultation paper. LCCP202/SLCDP153/NILC12(2012). London: Law Commission. 2012

and behaviours that are conducive to public safety and protection, and instils in them the duty always to comply with these⁷³⁰. Inherent in this duty, is the imperative for midwives always to act in the public interest, demonstrate a high degree of self-control and self-discipline, and adhere to a code of conduct and ethics. Also inherent in this duty, is the requirement to achieve and maintain competence through education that is tested, certified and accredited by their professional body⁷³¹.

Crucially, as with any regulatory system, the impact of professional regulation on midwifery is also dependent on personal accountability, with midwives required to account for their conduct as well as their performance and practice personally. As such, the 'success' of any system of regulation can never be guaranteed, with much depending on the integrity of individual practitioners, as well as professional standards. However, accepting that when processes break down, or are at risk of doing so, the factors that are typically found to be causative derive from clinical systems and processes rather than the actions of practitioners alone⁷³², it is likely that a system of regulation that provides patient safety through the correct balance of robust standards, strong leadership and accountability will prevail. In the case of midwives, this culture is largely derived from their *Rules*; the discriminator that is often said to represent the cornerstone of safe midwifery practice.

3.3.1. Midwives Rules

Recognised as incorporating the standards that are required for registration and safe practice, and the qualities that can reasonably be expected from practising midwives and their supervisors, the *Midwives Rules*⁷³³ and associated 'code of

⁷³⁰ The UK Inter-Professional Group. Professional regulation: A position statement by the UK Inter-Professional Group. London: UKIPG. 2002

⁷³¹ Council for Healthcare Regulatory Excellence. Report of a seminar on professionalism and regulation in healthcare. London: CHRE. 2008

⁷³² Wachter R. Personal accountability in healthcare: searching for the right balance. London: The Health Foundation. 2012

⁷³³ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764

professional conduct'⁷³⁴, comprise the system of regulation that currently underpins midwifery practice. Considered by some⁷³⁵ as affording women and their babies a level of protection beyond that which is offered by most other healthcare professions, it is these *Rules* and the associated supervision requirements that are often said to distinguish midwives from other healthcare professionals⁷³⁶. Although acknowledged as being restrictive in the early days, given that midwifery had only started to move towards more educated practice, the *Rules* have gradually widened so as to enable development and innovation, while at the same time maintaining the boundaries of safe practice. This is particularly significant in relation to the autonomy of midwives, with 'widening' of the *Rules* responsible for removing the reference to the relationship between midwives and doctors that originally existed⁷³⁷, and for eliminating the requirement for midwives to defer to doctors and follow their instructions when both were present at a case.

Representing a clear move away from a narrow interpretation of the *Rules*, this 'broadened' approach to the role of midwives resonated with the general desire to build a flexible framework for professional practice that had begun to emerge within nursing at the time⁷³⁸. Also resonating with the more liberated approach to professional development that nurses had started to adopt in the form of $Scope^{739}$, this change in emphasis signalled acknowledgement of midwives' accountability for practice, and acceptance of their role as autonomous practitioners. Subsequently reinforced in further versions of the *Rules*, and with the onus remaining on midwives to ensure that all decisions and interventions were in the best interests of women and their babies, this more enabling

⁷³⁴ Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

⁷³⁵ Osbourne A, Wallace V, Moorhead C, Jones D, Thomas N, Esson P, Demilew J, McElligott M, Kirby J, Rogers C. Statutory supervision of midwives: A resource for midwives and mothers. London: Quay Books. 2007

⁷³⁶ International Confederation of Midwives. Global standards for midwifery regulation. International Confederation of Midwives. 2011

⁷³⁷ The Nurses, Midwives and Health Visitors (Midwives Amendment) Rules Approval Order 1986. Statutory Instrument 1986 No 786

⁷³⁸ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. Project 2000: a new preparation for practice. London: UKCC. 1986

⁷³⁹ United Kingdom Central Council for Nursing, Midwifery and Health Visiting. The Scope of Professional Practice. London: UKCC. 1992

approach to practice continues to underpin the role of statutory supervision, and has a central place in ensuring public protection.

Currently under review, and with a revised version of the *Rules* expected to come into force in early 2013⁷⁴⁰, it seems reasonable to assume that separate secondary legislation for midwives is here to stay. Of course, this assumes that 'evidence' surrounding the effectiveness of midwifery supervision, which was recently presented to the NMC⁷⁴¹, will not result in any meaningful change. This is an assumption that has yet to be proven. However, working on the basis that statutory midwifery supervision is here to stay, it seems reasonable to consider whether similar secondary legislation could assist with the regulation of advanced nursing practice, and the extent to which this could provide the public with the level of protection that is arguably required.

3.3.1.1. Clinical authority: a license to practise

The imperative for midwives to give notice formally of their intention to practise, or of their intention to hold a post for which a midwifery qualification is required, to each Local Supervising Authority (LSA) in whose area they intend to practise, is enshrined in law⁷⁴². Outlined in Rule 3 of the *Midwives Rules*⁷⁴³, this directive seeks to ensure that midwives are aware of and understand their limitations, practise always within the limits of their competence, and carry out only those interventions they have been authorised to perform. As such, it confers on them a licence to practise, in the absence of which their practice would be deemed to be unlawful. With legislation⁷⁴⁴ also stipulating that this requirement needs to be satisfied before employment as a midwife can be commenced, the primary purpose of this *Rule* is to safeguard women and their

 $^{^{740}}$ Nursing and Midwifery Council meeting. Review of the Midwives rules and standards. Item 11 NMC/12/143. October 2012

Nursing and Midwifery Council meeting. Evidence review paper: midwifery supervision. Item 11, Annex 1. September 2012

⁷⁴² The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Rule 42(1)(b)

⁷⁴³ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 3

⁷⁴⁴ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 3 Guidance Note 5

babies from those midwives who are unsafe or untrained, and from those who may otherwise put them at risk.

Applicable to all qualified midwives, irrespective of their status or seniority, and required to be submitted annually along with the relevant documentation required for re-registration⁷⁴⁵, this 'notification' is intended to provide the LSAs and, ultimately, the NMC, with an accurate picture of how many midwives are practising at any given time. It is also intended to engender within midwives a sense of individual accountability for practice, and instil in them the duty to ensure that their competence is always maintained. Interestingly, this *Rule* also permits those midwives who have not complied with this directive, but who unexpectedly find themselves having to act in an emergency situation, to submit this 'notification' within 48 hours of their practice commencing⁷⁴⁶. This means that those women who are in need of assistance, and who call upon the services of such a midwife, will not be disadvantaged, and those midwives who attend upon them will not be deemed to have acted unlawfully, as long as the 'notification' is submitted within the specified period.

Although originally devised as a means of ensuring that LSAs had a comprehensive picture of those midwives who were practising in their locales, which was deemed to be necessary in the early days given that *all* midwives practised independently at that time, this system is still considered necessary today, albeit for different reasons. Nowadays, it is regarded as providing a safeguard for the public, in that it enables the NMC to determine whether those who have notified the LSA of their intention to practise are currently on the Register and, as such, are entitled to practise. In so doing, it provides an effective mechanism for identifying those midwives who are not entitled to practise, such as those who have been suspended from practice or those whose names have been erased from the Register. It also enables the NMC to identify those midwives who are 'bogus', and prevent them from obtaining employment, assuming that the relevant pre-employment checks have been carried out.

745 Nursing and Midwifery Council. The PREP Handbook. London: NMC. 2011

⁷⁴⁶ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 3(3)

3.3.1.2. The scope of midwifery practice

Currently forming the basis of Rule 6 of the *Midwives Rules*⁷⁴⁷, and potentially featuring within those investigations that could result in suspension from practice, the scope of permissible midwifery practice has become a source of controversy and debate 748,749,750. Denoting the range of practice permitted by the profession as a whole, and the breadth of autonomous practice for which each midwife is personally accountable, Rule 6 stipulates that practising midwives shall not provide any care, or undertake any treatment they have not been trained to give. Consistent with their duty to ensure that they have the knowledge and skills required for safe practice, this Rule reinforces the obligation of midwives to update their knowledge and skills and work within the limits of their competence, as directed in their professional 'Code'⁷⁵¹. Providing the exception to this Rule is the emergency situation (referred to earlier), and the situation in which deviation from the 'norm', which is currently outside the midwife's sphere of practice, becomes apparent in a woman or baby during the antenatal, intranatal or postnatal period. In both these circumstances, midwives are required to call upon a relevant and appropriately qualified healthcare professional with the necessary skills and experience to assist them in providing care⁷⁵².

Underpinning this directive is the imperative for midwives to ensure that they acquire competence in any new skills that are required for their practice, and always ensure that the needs of women and their babies have primacy. Founded on the accepted definition of midwifery activity, as agreed by the International Confederation of Midwives, the International Federation of Gynaecologists and

⁷⁴⁷ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 6(2)

⁷⁴⁸ Watson J, Turnbull B, Mills A. Evaluation of the extended role of the midwife: the voices of midwives. International Journal of Nursing Practice 2002;8(5):257-264

⁷⁴⁹ Rogers C, Bloomfield L, Townsend J. A qualitative study exploring midwives' perceptions and views of extending their role to the examination of the newborn baby. Midwifery 2003;19(10):55-62

⁷⁵⁰ Smith R, Leap N, Homer C. Advanced midwifery practice or advancing midwifery practice? Women and Birth 2010;23(3):117-120

⁷⁵¹ Nursing and Midwifery Council. The code: Standards of conduct, performance and ethics for nurses and midwives. London: NMC. 2008

⁷⁵² The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 6(3)

Obstetricians, and the World Health Organisation⁷⁵³, this directive underpins all 'clinical' midwifery developments and is responsible for determining the scope of practice of individual midwives. Included within its ambit is the ability of midwives to conduct deliveries under their own responsibility, care for newborns and infants, undertake preventative measures, detect abnormal conditions, and implement emergency measures in the absence of medical help. As such, its impact is extensive.

Notable within this context, is the fact that developments in maternity care can often become an integral part of midwives' practice, and, through time, become incorporated into core midwifery preparation and training⁷⁵⁴. So, too, is the fact that some developments in maternity care and obstetric practice may require individual midwives to learn new skills, although these may not become part of core midwifery practice. This means that while the sphere of 'general' midwifery practice may be continually evolving, the extent to which this affects and impacts upon individual midwives is variable.

Significantly, in those circumstances where developments in practice are limited to a smaller group of midwives who have been trained and deemed as being competent to perform them, Rule 6^{755} requires their employing authority to have in place a locally agreed guideline, which adheres to NMC standards, in place for this. Midwives, in turn, are required to adhere to this guideline, and to ensure that they remain clinically and educationally up to date. Possibly suggesting a degree of foresight on the part of the NMC, or its Midwifery Committee, it is possible that this guidance may be indicative of the profession having become sufficiently mature so as to anticipate the difficulties that may arise when policy dictates that a change in midwifery practice is required. Alternatively, it may be that this guidance to the *Rule* was simply intended as providing a general regulatory safeguard, with the intention of protecting the public, and governing the practice of those midwives who seek to perform those activities that are not part of the traditional midwifery role.

⁷⁵³ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764

Rule 6 Guidance Note 12

⁷⁵⁵ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 6 Guidance Note 12

Interestingly, while this guidance provides the safeguards referred to above, it leaves another loophole open, in that some of the terminology within Rule 6 is open to interpretation. This means that, in reality, the *Rule* surrounding the scope of midwifery practice may not be as robust as was initially thought, and may not offer the level of assurance that was originally intended. This is particularly the case in relation to the imperative for midwives to refer women to appropriately qualified practitioners in cases where there is 'a deviation from the norm which is outside [their] current sphere of practice', with the term 'the norm' having been left open to interpretation, and its meaning providing the focus for debate.

In practice, two interpretations of this phrase are possible. On the one hand, where midwives have been trained to care for women with conditions that are outside the sphere of traditional midwifery practice, and have incorporated these into their everyday scope of practice, it is possible that they could interpret these conditions as constituting *their* 'norm'. This could occur in cases such as those where ultrasound scanning or instrumental deliveries are required perform these procedures under a strict interpretation of the *Rules*. Alternatively, it is possible that as midwives assume responsibility for new aspects of practice, such as those which may be adopted as a consequence of the EWTD⁷⁵⁹ or Modernising Medical Careers (MMC)⁷⁶⁰, these developments could expand the scope of 'general' midwifery practice beyond traditional boundaries, and become the 'norm'. This means that responsibilities once considered the domain of other practitioners, most notably doctors, could become part of core midwifery practice, and be adopted by all midwives.

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⁷⁵⁶ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 6(3)

⁷⁵⁷ Tinsley V. Rethinking the role of the midwife: midwife Ventouse practitioners in community maternity units. MIDIRS Midwifery Digest 2001;11(Suppl 2):S6-S9

⁷⁵⁸ Department of Health, Social Services and Public Safety. Audit of acute maternity services. Final report Vol 1. PriceWaterhouseCoopers. 2006

⁷⁵⁹ The Working Time Regulations 1998. Statutory Instrument 1998 No 1833 amended by Statutory Instrument 2003/1684. The Working Time (Amendment) Regulations 2003 No 1684

⁷⁶⁰ Department of Health. Modernising medical careers: the next steps. The future shape of foundation, specialist and general practice training programmes. London: HMSO. 2004

On the other hand, it could be that the term 'the norm' was originally intended as applying to the conditions and presentations themselves, rather than to the interventions and skills required to manage them. If so, the emphasis would be on how the clinical 'norm' is defined during pregnancy and childbirth, and what would constitute a deviation from this, albeit accepting that the definition of what constituted 'normal' would be subject to change as science and technology develop. The revised definition of the 'norm' would, in turn, impact upon the way in which clinical presentations are classified, and the way in which the 'revised' range of 'normality' would be interpreted. If one accepts this analysis, it follows that one would also accept that the description of what would constitute the scope of 'normal' midwifery practice would need to change accordingly. This means that presentations once considered 'abnormal' could become the new 'norm', and the parameters of permissible midwifery practice could be expanded in this way.

Irrespective of the interpretation of this phrase that midwives choose to follow, it is clear is that both interpretations would have the same effect; namely that both would result in an expansion of the boundaries of permissible midwifery practice. As such, this would mean that the scope of practice of those midwives who wished to take advantage of developments in practice would effectively be classed as 'advanced', albeit acknowledging that the term 'advanced midwifery practice' does not always sit comfortably with midwives⁷⁶¹. This, in turn, raises the question of whether 'advanced midwifery practice' actually exists as a formal entity, or whether, like nursing, this is a relative concept that only makes sense when applied to some other sphere of practice.

3.3.2. Advanced midwifery practice: a feasible concept?

There is little doubt that the role of the nurse has expanded over recent decades, with most of the developments in their practice arising from changes in

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⁷⁶¹ Smith R, Leap N, Homer C. Advanced midwifery practice or advancing midwifery practice? Women and Birth 2010;23(3):117-120

the working patterns of doctors in training^{762,763}. As such, it is easy to see how the concept of advanced nursing practice has arisen, and how its relationship to medicine has evolved. However, in the case of midwifery, opinions vary regarding the scope of midwifery practice, and whether, and the extent to which, this should be expanded. Opinions also vary regarding whether 'advanced midwifery practice' is a feasible and legitimate concept, given that midwives are able to practise autonomously at the point of registration, or whether this is simply a manifestation of role and career development⁷⁶⁴. If one accepts that some form of advancement beyond registration is possible, this raises the question of whether the regulatory mechanisms that are currently in place can provide the necessary safeguards, or whether some additional form of public 'protection' is required.

Recognised as being a controversial concept, and one that, for some midwives, goes against the core principle of promoting normality in pregnancy and childbirth, the notion of 'advanced midwifery practice' is often resisted by midwives on the basis that it is likely to involve some form of technical advancement, and a more medicalised approach to childbirth⁷⁶⁵. For some midwives⁷⁶⁶, it runs contrary to the philosophy of 'keeping childbirth natural and dynamic', and is at odds with the holistic approach to woman-centred care. On the other hand, for those midwives who perceive advanced practice as enabling them to provide autonomous care to women in a wider range of environments, such as in specialist clinics⁷⁶⁷ or outpatient delivery suites⁷⁶⁸, rather than simply extending their technical skills and assuming responsibility for 'medical' tasks, the concept is considered more positively and received far more favourably.

⁷⁶² The Working Time Regulations 1998. Statutory Instrument 1998 No 1833 amended by Statutory Instrument 2003/1684. The Working Time (Amendment) Regulations 2003 No 1684

⁷⁶³ Department of Health. Modernising medical careers: the next steps. The future shape of foundation, specialist and general practice training programmes. London: HMSO. 2004

⁷⁶⁴ Smith R, Leap N, Homer C. Advanced midwifery practice or advancing midwifery practice? Women and Birth 2010;23(3):117-120

⁷⁶⁵ Robotham M. Special delivery. Nursing Times 2000;96(18):49-51

⁷⁶⁶ Kennedy HP. A model of exemplary midwifery practice: Results of a Delphi study. Journal of Midwifery and Women's Health 2000;45(1):4-19

⁷⁶⁷ Macrory F, Boyd S. Developing primary and secondary services for drug and alcohol dependent mothers. Seminars in Fetal and Neonatal Medicine 2007;12(2):119-126

⁷⁶⁸ Haxton J, Fahy K. Reducing length of stay for women presenting as outpatients to delivery suite: a clinical practice improvement project. Women & Birth 2009;22(4)

Of course, in reality, far from being a static concept, the practice of midwifery and the core role of the midwife have evolved considerably over the years. Far removed from the days when midwives would 'scrub in' and hand surgeons the 'tools' required to perform an episiotomy or repair a perineal tear, or the SHO would 'sign-off' the midwife's CTG readings (even although the midwife was likely to have more experience in reading them), the situation nowadays is far different. Today, it is commonplace to see midwives suturing wounds, assessing and acting on CTGs, inserting intravenous cannulae, administering medications, 'topping-up' epidurals, artificially rupturing membranes, and performing Doppler scan⁷⁶⁹; all practices that were once considered as falling within the medical domain. Accordingly, it seems reasonable to conclude that 'advanced midwifery practice' does exist as a legitimate concept, albeit one that has yet to be formally recognised as such by the profession.

Irrespective of the scope of practice that midwives choose to adopt, or the level at which they choose to practice, the ability to make effective clinical decisions remains, and will always remain, the cornerstone of safe midwifery practice⁷⁷⁰. In order to be effective, this requires a robust educational system that enables the acquisition of the requisite knowledge and skills, and the ability to assimilate and act upon the relevant facts. This assumes that the preregistration standards⁷⁷¹ that form the basis of safe midwifery practice have been achieved, and appropriate post-registration education that enables autonomous practice has been undertaken, leaving midwives prepared and suitably empowered to take on the roles that await them. However, this is an erroneous assumption, and one that is not always borne out in practice.

⁷⁶⁹ Madden E. Embracing change: maintaining standards. In Reid L. Midwifery: Freedom to practise? An international exploration of midwifery practice. Edinburgh: Elsevier Ltd. 2007 ⁷⁷⁰ McKenna H, Richey R, Keeney S, Hasson F, Sinclair M, Poulton B. An exploration of nursing and midwifery roles in Northern Ireland's Health and Personal Social Services. Ulster: NIPEC. 2005 ⁷⁷¹ Nursing and Midwifery Council. Standards of proficiency for pre-registration midwifery education. London: NMC. 2009

3.3.2.1. Autonomous midwifery practice

Defined as the "freedom to make discretionary and binding decisions consistent with one's scope of practice, and the freedom to act on those decisions"⁷⁷², autonomy is the concept that is most frequently cited in relation to advanced practice. Referring to the intellectual flexibility and discretionary capability that allows options to be considered and decided upon, rather than the routine performance of tasks or instructions, it denotes the ability to make choices and accept responsibility for these decisions and the resultant sequelae. associated with the notion of empowerment and accountability for practice⁷⁷³, autonomy is the criterion that is most said to differentiate advanced clinical practitioners from those who wish to practise in a more traditional way⁷⁷⁴. Underpinning this is the belief that education will have prepared practitioners to practise competently, knowledgably, and with confidence. However, as studies by Pollard⁷⁷⁵ and Baird⁷⁷⁶ have shown, the reality is somewhat different, with many midwives stating that, while their education prepared them properly for practice, it did not prepare them for the associated autonomy that inevitably ensued.

As with nurses, the educational preparation of midwives has varied considerably over the years. Both are now all-graduate professions, although midwives have a choice of whether to follow the direct entry route into the profession, or to first qualify as a nurse before training as a midwife. In theory, nurses may also choose to first qualify as midwives before joining the nursing profession, but the reality is that this approach is less common in practice, and one that is rarely followed. As such, it is not uncommon to find a significant proportion of midwives who are 'dual-qualified', meaning that they hold concurrent registrations as both nurse and midwife with the NMC.

⁷⁷² Batey M, Lewis F. Clarifying autonomy and accountability in the nursing service: Part 1. Journal of Nursing Administration 1982;12(9):13-18 p15

⁷⁷³ Lewis FM, Batey MV. Clarifying autonomy and accountability in nursing service: Part 2. Journal of Nursing Administration 1982;12(10):10-15

⁷⁷⁴ Daly WM, Carnwell R. Nursing roles and levels of practice: a framework for differentiating between elementary, specialist and advancing nursing practice. Journal of Clinical Nursing 2003;12(2):158-167

Pollard K. Searching for autonomy. Midwifery 2003;19(2):113-124

⁷⁷⁶ Baird K. Exploring autonomy in education: preparing student midwives. British Journal of Midwifery 2007;15(7):400-405

For some commentators, this difference in preparation is significant in relation to midwives' autonomy. For example, in Pollard's study⁷⁷⁷, those midwives who were educated by the direct-entry route were found to be more capable of autonomous practice than their nurse-trained counterparts. For those midwives who first qualified as a nurse, the issue of whether genuine midwifery autonomy was possible, and could actually be achieved within the current healthcare system, was questionable, with some going so far as to say that the ongoing dominance of the medical profession presented a real barrier to autonomous midwifery practice.

Interestingly, these findings are borne out by previous studies, such as those conducted by Clarke⁷⁷⁸ and Fleming⁷⁷⁹, which called into question the whole notion of autonomous midwifery practice, and challenged its validity as a legitimate concept. Indeed, both contested the blanket acceptance of midwifery as an autonomous profession, as defined by the World Health Organisation⁷⁸⁰, on the basis that midwives typically work in a healthcare system that is heavily dominated by medicine and nursing, meaning that autonomy is not possible within this context. Instead, both considered the parameters of midwifery practice to be defined by the use of policies, procedures and protocols, rather than supported by independent decision-making, thus negating the concept of autonomous practice as an entity in its own right.

These findings correlate with the view that, in some cases, high-technology machinery has replaced clinical judgement and substituted for clinical decision-making. This view is attributed, in part, to the medicalised nature of care and consumerism within the NHS, with some commentators suggesting that the perceived reliance of midwives on equipment and technology is in some way causative. In other cases, the use of technology has been identified as constituting best practice, particularly in hospital settings, where it is readily available, despite its use not always being clinically indicated. Alternatively, it

777 Pollard K. Searching for autonomy. Midwifery 2003;19(2):113-124

⁷⁷⁸ Clarke RA. Midwives, their employers and the UKCC: an eternally unethical triangle. Nursing Ethics 1995;2:247-253

Fleming VE. Autonomous or automatons? An exploration through history of the concept of autonomy in midwifery in Scotland and New Zealand. Nursing Ethics 1998;5(1):43-51

⁷⁸⁰ World Health Organisation. International definition of the midwife. Geneva: WHO. 1966

is possible that one could interpret this finding differently and reach the alternative conclusion, namely that the use of such equipment has *increased* midwives' ability to make clinical decisions and to practise autonomously. If so, and if one accepts that technology is here to stay, this could point to midwives of the future potentially managing a wider range of conditions and presentations than is currently the case, including those that are considered to be 'abnormal'.

Acknowledged as an issue in Sinclair *et al*'s survey of midwives' views of the use of technology in assisting birth⁷⁸¹, particularly in relation to CTG tracings, it seems that this view of technology as expanding the scope of midwifery practice may have some foundation. Indeed, with Sinclair *et al*'s findings showing that while midwives generally reject the notion of being dependent on machines, those who use them are more likely to trust and be comfortable with them, this suggests that technology may have a place in promoting autonomous midwifery practice. Working on the basis that this will be the case, particularly in situations where difficulties in childbirth are encountered, it seems reasonable to conclude that the scope of midwifery practice will continue to evolve, with technology potentially assisting in providing some of the necessary clinical safeguards.

3.3.2.2. Advanced or specialist roles?

Also a source of controversy, and stimulating much debate, is the question of whether midwives are already advanced practitioners at the point of registration, given that they are capable of autonomous practice at this stage^{782,783}, or whether this 'advanced' status is only acquired following a period of post-registration practice, experience and education. With opinions divided, and this issue yet to be resolved, two standpoints are possible. If one accepts that the ability to practise autonomously is synonymous with advanced practice,

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⁷⁸¹ Sinclair M, Gardner J. Midwives' perceptions of the use of technology in assisting childbirth in Northern Ireland. Journal of Advanced Nursing 2001;36(2):229-236

⁷⁸² Sookhoo ML, Butler MS. An analysis of the concept of advanced midwifery practice. British Journal of Midwifery 1999;7(11):690-693

⁷⁸³ Lewis P. Editorial: A framework for advanced practice. British Journal of Midwifery 2003;11(5):260-1

and that midwives are in, in fact, autonomous practitioners, this would mean that all midwives are, in fact, 'advanced practitioners' at the point of registration. If so, this would negate the concept of 'advanced midwifery practice' as a separate entity. Alternatively, if one considers that arguments surrounding advanced practice centre on issues of competence and professional preparation, and that competence is only really acquired through post-registration practice and experience, then the concept of 'advanced practice' as it is applied to other groups, most notably nurses, could quite feasibly lend itself to the midwifery arena.

Working on the basis that the latter interpretation is more likely to be adopted, it is possible that a sequential and staged model of competence would apply. Such a model would see midwives progressing from a base level of competence through to an expert level, such as that which is described in the models of development proposed by Dreyfus⁷⁸⁴ and Benner⁷⁸⁵. This approach would be likely to gain favour with those who consider that, upon graduation, midwives have a basic level of competence that is developed and improved through practice and experience, thus enabling them to practice at an 'advanced' or 'expert' level at a future date. However, this premise presumes, and is reliant upon, the fact that levels of practice exist and are able to be identified within midwifery; a presumption that, as has already been indicated, would be open to challenge.

Interestingly, this debate surrounding 'advanced midwifery practice' is not restricted to the UK, with problems of definition also existing in a number of other countries; most notably in Australia, Canada and New Zealand⁷⁸⁶. In Australia, the notion of advanced midwifery practice has received particular attention, with studies from Haxton and Fahy⁷⁸⁷ highlighting the positive contribution that 'advanced midwives' can safely and effectively make to

⁷⁸⁴ Dreyfus SE. The five-stage model of adult skill acquisition. Bulletin of Science Technology Society 2004;24(3):177-181

⁷⁸⁵ Benner PE. From novice to expert: excellence and power in clinical nursing practice. London: Prentice Hall. 1984

⁷⁸⁶ Smith R, Leap N, Homer C. Advanced midwifery practice or advancing midwifery practice? Women and Birth 2010;23(3):117-120

⁷⁸⁷ Haxton J, Fahy K. Reducing length of stay for women who present as outpatients to delivery suite: A clinical practice improvement project. Women Birth 2009;22(4):119-127

reducing the length of stay for those women admitted to hospital with pregnancy concerns. In Canada, which does not follow a national system of regulation, and where some provinces and territories have yet to recognise and be convinced of the merits of midwifery as a profession, 'advanced midwifery practice' is largely dependent upon the acquisition of 'advanced-level competencies'. Interestingly, these competencies - including epidural monitoring and the application of scalp electrodes, vacuum extractions, and the repair of third degree tears⁷⁸⁸ - are incorporated within the 'normal' scope of midwifery practice in other jurisdictions, thus indicating the disharmony that exists surrounding this concept.

For its part, New Zealand follows a similar approach to that which is adopted by some commentators within the UK, and recognises midwives as autonomous practitioners at the point of registration. Within the UK, the view that is asserted by midwives is that which reinforces their ability to work at an advanced or specialist level upon qualification, with midwives rejecting completely the notion of Higher Level Practice on the basis that there is no justification for this⁷⁸⁹. This position is supported by the fact that areas of practice once considered to be advanced, such as vaginal examinations, venepuncture, intravenous cannulation, reflex testing, ordering and interpreting pathology tests, and prescribing and administering medications, already feature within the undergraduate curriculum, and, as such, form part of the midwife's core role⁷⁹⁰.

However, despite this, a number of new midwifery roles have started to emerge within the UK, under the guise of 'advanced midwifery practice', largely in response to political and professional drivers. These include specialist and consultant midwifery roles, of which the Consultant Midwife is the most high profile. Although still in their relative infancy, evidence⁷⁹¹ suggests that

⁷⁸⁸ Canadian Midwifery Regulators Consortium. Canadian competencies for midwives. Winnipeg: Canadian Midwifery Regulators Consortium. 2008

⁷⁸⁹ Warwick C. Editorial: higher level practice - have you a view? British Journal of Midwifery 2003;11(3):132-133

⁷⁹⁰ Midwifery 2020 Programme. Core Role of the Midwife Workstream. Final Report. 2010

⁷⁹¹ Guest DE, Peccei R, Rosenthal P, Redfern S, Wilson-Barnett J, Dewe P, Coster S, Evans A, Sudbury A. An evaluation of the impact of nurse, midwife and health visitor consultants. London: King's College. 2004

Consultant Midwives have had a positive impact on developing and improving midwifery-led services, and, in particular, on increasing the number of midwifery-led low-risk births, reducing medical interventions and increasing breast-feeding rates. Evidence⁷⁹² also exists to suggest that positive outcomes have been experienced where midwives assume responsibility for the care of women with special needs in pregnancy, such as teenagers and young women with alcohol and drug addiction problems, and those with diabetes. Arguably denoting a level of horizontal specialisation, and the acquisition of expertise in a defined area rather than technical advancement, this form of development has been shown to have particular value, particularly in remote and rural areas where access to the wider range of healthcare professionals is not always available⁷⁹³.

Although initially resisted by midwives on the basis that the creation of 'subspecialities', as a means of providing a clinical career pathway for the more experienced midwives, would be detrimental to the profession as a whole⁷⁹⁴, this reluctance to accept 'advanced midwifery practice' seems to have now been overcome. Indeed, the reality is that Consultant Midwives and specialist roles now feature prominently in the clinical arena, and are generally well-received⁷⁹⁵. Accordingly, with concerns relating to potential fragmentation of the profession into specialist practice areas having been addressed, and anxiety that a more medicalised view of pregnancy and birth would potentially deskill midwives not having materialised, it seems reasonable to conclude that 'advanced midwives' will continue to be recognised, and feature prominently in the modern clinical landscape.

If one accepts this premise, it logically follows that questions may, in the future, start to be asked regarding the regulation of 'advanced midwifery practice'. If

⁷⁹² Department of Health, Social Services and Public Safety. Audit of acute maternity services. Final report Vol 1. PriceWaterhouseCoopers. 2006

⁷⁹³ Alexander J, Anderson T, Cunningham S. An evaluation by focus group and survey of a course for midwifery ventouse practitioners. Midwifery 2002;18(2):165-172

⁷⁹⁴ Begley CM, O'Boyle C, Carroll M, Devane D. Educating advanced midwife practitioners: a collaborative venture. Journal of Nursing Management 2007;15:574-584

⁷⁹⁵ Humphreys A, Johnson S, Richardson J, Stenhouse E, Watkins M. A systematic review and meta-synthesis: evaluating the effectiveness of nurse, midwife/allied health professional consultants. Journal of Clinical Nursing 2007;16(10):1792-1808

so, it is likely that those arguments that have already been rehearsed in relation to advanced nursing practice may start to be revisited, albeit with a different clinical focus. Yet to be formally raised as an issue, and therefore only an assumption at this stage, any associated arguments are likely to focus on the robustness of post-registration educational standards, and the ability of the current regulatory system to address the associated risks. In the meantime, midwives, their employers and the public will continue to look to the *Midwives Rules* and statutory supervision, in particular, as the main vehicle through which midwives will be held to account for their practice, and through which they will be provided with the necessary regulatory safeguards.

3.3.3. Statutory supervision

Mandated by statute⁷⁹⁶, and the hallmark of professional practice, the provision of statutory supervision is the benchmark that sets midwifery apart from the other healthcare professions. Of paramount importance to the regulation of professional midwifery practice, and subsumed within the *Midwives Rules*, it is the vehicle through which the autonomy of midwives is controlled, and their personal and professional accountability is enforced⁷⁹⁷. Currently enshrined within the detailed provisions of Rule 12⁷⁹⁸, and incorporating the responsibility to develop and maintain safe practice, it encompasses the requirements that midwives must satisfy in order to practise lawfully.

Included in these requirements is the imperative for midwives to have an identified 'Supervisor' appointed by the LSA⁷⁹⁹, and to adhere to arrangements surrounding contact, communication, record keeping and support. Also included within them is the requirement for midwives to meet with their Supervisor, at least once a year, in order to review their practice and identify their training

⁷⁹⁶ The Nursing and Midwifery Order 2001. Statutory Instrument 2002 No 253 Article 43

⁷⁹⁷ Duerden J. Supervision at the beginning of a new century. In failure to progress: The contraction of the midwifery profession. London: Routledge. 2002

⁷⁹⁸ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 12

⁷⁹⁹ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 12(1)

needs⁸⁰⁰. For their part, Supervisors are required to provide 24-hour access to supervision, this being necessary to provide midwives with the requisite support at the time when it is most needed⁸⁰¹. Collectively, these processes provide midwives with a unique opportunity to discuss their development, receive guidance on how to address any weaknesses, and reflect on and revisit their practice. It also provides 'Supervisors of Midwives' with the opportunity to be apprised of and 'investigate' any adverse incidents that may have involved midwives in some way, and to address those situations that have resulted in actual or potential harm.

Aimed primarily at providing midwives with the opportunity to reflect on their practice, and Supervisors with the opportunity to explore midwives' understanding of their accountability, the intention is that this supervision arrangement will enable any gaps in the midwife's knowledge and/or competence to be identified and subsequently addressed. It is also hoped that this approach will provide midwives and their Supervisors with the opportunity to reflect on any trends in practice, review any complaints, and learn lessons from any investigations that may have been carried out. Intended to be challenging, as well as constructive, it is also expected that supervision meetings would enable the boundaries of safe practice to be explored, albeit not at the expense of the interests of those whom midwives are intended to serve.

With the overriding aim of statutory supervision being to protect the public, it is incumbent on Supervisors to take action where women or their babies are perceived to have been put at risk. It is then for Supervisors, and, where relevant, the Local Supervising Authority Midwifery Officers (LSAMOs) to respond to adverse incidents, and determine the appropriate course of action that should be taken⁸⁰². Acknowledging that, in these circumstances, the definition of what may constitute a risk and, therefore, an adverse incident can vary

⁸⁰⁰ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 12(2)(b)

⁸⁰¹ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 12(2)(d)

⁸⁰² Nursing and Midwifery Council. Standards for the preparation and practice of supervisors of midwives. London: NMC. 2006

considerably^{803,804,805}, Supervisors and LSAMOs have a suite of options available to them. First, they could conduct a supervisory investigation into the midwife's practice. This would enable the relevant facts to be obtained and considered in context. Secondly, they could instigate a period of supervised practice, and monitor the midwife's progress in relation to the area in question over the designated period⁸⁰⁶. Alternatively, they could suggest changes in practice, and provide appropriate ways in which to support those midwives whose practice has fallen below the requisite standard⁸⁰⁷. However, for the most part, sanctions are not required, with guided reflection generally found to be sufficient in providing the requisite level of support, and the direction that is needed for effective professional development⁸⁰⁸.

Essentially focused on midwives and their practice as individuals, and on their care and the location in which it is delivered, statutory supervision is generally considered to be a positive mechanism that provides midwives with a unique opportunity to learn from their experiences, and to develop their knowledge and competence⁸⁰⁹. Often confused with, but distinct from, the process of 'clinical supervision' that is undertaken by nurses and other allied health professionals^{810,811}, it is a much more structured and tightly governed process. As a formal process that is independent of both employers and employment, statutory midwifery supervision seeks to provide a supportive and proactive approach to the management of critical incidents, rather than having a punitive

⁸⁰³ Stanhope N, Crowley-Murphy M, Vincent C, O'Connor AM, Taylor-Adams SE. An evaluation of adverse incident reporting. Journal of Evaluation in Clinical Practice 1999;5(1):5-12

⁸⁰⁴ Department of Health. An organisation with a memory, Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. London: HMSO. 2000

⁸⁰⁵ Woloshynowych M, Rogers S, Taylor-Adams S, Vincent C. The investigation and analysis of critical incidents and adverse events in healthcare. Health Technology Assessment Programme 2005;9:19

 $^{^{806}}$ Nursing and Midwifery Council. Standards for the supervised practice of midwives. London: NMC. 2007

⁸⁰⁷ Local Supervising Authority Midwifery Officers' Forum (UK) and Nursing and Midwifery Council. Modern supervision in action. London: LSAMO National Forum (UK). 2009

⁸⁰⁸ Yearley C. Guided reflection as a tool for CPD. British Journal of Midwifery 2003;11(4):223-226

⁸⁰⁹ Ralston R. Supervision of midwifery: a vehicle for introducing reflective practice. British Journal of Midwifery 2005;13(12):792-796

⁸¹⁰ Clouder L, Sellars J. Reflective practice and clinical supervision: an interprofessional perspective. Journal of Advanced Nursing 2004;46(3):262-269

⁸¹¹ Driscoll J. Practising clinical supervision: A reflective approach for healthcare professionals. 2nd Edition. London: Bailliere Tindall 2006

function⁸¹². In doing so, it reinforces the primary aim of professional regulation by promoting best practice, preventing poor practice, and intervening in circumstances where unacceptable practice has been identified^{813,814}.

Nevertheless, working on the basis that supervision on its own cannot be guaranteed to capture every instance where further learning is needed, it is clear that additional regulatory safeguards are needed. In fact, with much depending on the relationship between individual midwives and their supervisors, it is true to say that this process is not without its limitations, particularly in those situations where line managers also assume the role of supervisor management ^{815,816,817,818}. Also problematic are those situations in which supervision is provided to 'independent midwives', with difficulties in meeting their needs often encountered as a result of these midwives not being part of the NHS, and, therefore, not being able to benefit from its internal structures and processes ^{819,820}.

However, despite these limitations, concerns related to the possibility that supervision which is statutory in nature, and linked to a governance function, may not be conducive to effective communication and could imply a form of surveillance 821,822,823,824,825, have not materialised. Also failing to materialise,

⁸¹² Porteous C. A review of supervisory investigations and supervised practice programmes. British Journal of Midwifery 2011;19)7):453-458

⁸¹³ Midwifery 2020 Programme. Core Role of the Midwife Workstream. Final Report. 2010

⁸¹⁴ Phipps J. Statutory supervision: Achieving the balance. British Journal of Midwifery 2012;20(10):736-739

⁸¹⁵ Kirkham M, Stapleton H. Midwives' support needs as childbirth changes. Journal of Advanced Nursing 2000;32(2):465-472

⁸¹⁶ Cooke H. The surveillance of nursing standards: an organisational case study. International Journal of Nursing Studies 2006;43(8):975-984

⁸¹⁷ Cutliffe J, Hyrkas K. Multi-disciplinary attitudinal positions regarding clinical supervision: A cross-sectional study. Journal of Nursing Management 2006;14(8):617-627

⁸¹⁸ Henshaw AM, Clarke D, Long AF. Midwives and supervisors of midwives' perceptions of the statutory supervision of midwifery within the United Kingdom: A systematic review. Midwifery 2011;1-11

⁸¹⁹ Flint C. Supervision of midwives: Are we celebrating our shackles? The Practising Midwife 2002;5(2):12-13

⁸²⁰ Kurutac J. Supervision and non-NHS midwives: Understanding a range of practices. British Journal of Midwifery 2009;19(7):458-462

⁸²¹ Torrance E, Adshead J. How supervision of midwives supports and impacts on the clinical governance agenda. British Journal of Midwifery 2002;10(3):156

⁸²² Capito C. Supervised practice programmes: help or hindrance. British Journal of Midwifery 2009;17(11):700-707

are those concerns related to the sustainability of statutory supervision that were raised during the formation of the NMC, and the associated fears that it would be abolished. Indeed, rather than succeeding, these arguments were easily defeated on the basis that the removal of this form of supervision would be a retrograde step, not only for midwives, but also for women and their babies^{826,827}. Also dismissed were those arguments that suggested that the main impact of statutory supervision was to hinder the profession by providing it with unwanted straight-jacket that prevented innovation and development⁸²⁸. Nevertheless, with questions now starting to be asked by the NMC regarding the impact of statutory supervision on the practice of midwifery and the quality of maternity care⁸²⁹, it seems prudent to take a closer look at this form of supervision in order to determine its ability to provide the necessary regulatory safeguards, and the extent to which it is able to hold midwives to account.

3.3.3.1. An effective regulatory safeguard?

As previously stipulated, the requirement for midwives to submit notification of their intention to practice is laid down in statute. So, too, is their requirement to adhere to, and satisfy, statutory supervision requirements, and to meet formally with their 'Supervisor' on a regular basis. Given the reflective nature of this process, it is here that any developments or expansion in a midwife's 'scope of practice' would be expected to be identified, and any associated training and development needs highlighted. However, while on the face of it, this arrangement looks to be relatively straightforward, the reality is that it can

⁸²³ Gould D. The price of greatness is responsibility. British Journal of Midwifery 2009;17(7):416

⁸²⁴ Warwick C. Statutory supervision of midwives: adding value to the profession. British Journal of Midwifery 2009;17(11):686

⁸²⁵ Barker K. Promoting supervision of midwifery to women. British Journal of Midwifery 2012;20(6):454

⁸²⁶ Stapleton H, Duerden J, Kirkham M. Evaluation of the impact of the supervision of midwives on professional practice and the quality of midwifery care. London: ENB. 1998

⁸²⁷ Kirkham M. Developments in the supervision of midwives. Manchester: Books for Midwives Press. 2000

⁸²⁸ Jones SR, Jenkins R. The law and the midwife. Oxford: Blackwell Publishing Ltd. 2004

⁸²⁹ Nursing and Midwifery Council meeting. Evidence review paper: midwifery supervision. Item 11, Annex 1. September 2012

sometimes be a complicated and complex process. This is particularly the case when one considers that human beings are fallible, supervisors are reliant upon the information that is provided to them, and midwives may not always fully declare the extent of their practice. In addition, the relationship that exists between midwives and their supervisors may not always be conducive to effective dialogue, meaning that open and constructive exchange of information may not always be forthcoming. As such, this leaves issues surrounding the efficacy of statutory supervision open to question, particularly in relation to safeguards surrounding the scope of permissible midwifery practice.

At the moment, evidence attesting to the effectiveness of statutory supervision is limited, particularly in relation to its impact on public protection. Indeed, most of the evidence that does exist consists of opinion and anecdote, rather than quantitative data or analysis. With the evidence⁸³⁰ that is currently available equivocal at best, and reports of confusion surrounding the function of supervision cited by both those providing and receiving it, this does not inspire confidence in this historic process. Also unconvincing are concerns surrounding the apparent lack of leadership that is said to be shown by some Supervisors, the experience level of some of those appointed as Supervisors, and the perception among some within the profession that supervision is aimed more at protecting the interests of midwives than protecting the public^{831,832,833,834,835}. Also concerning are reports that, in some cases, supervision may be used as a means of controlling and intimidating midwives, rather than supporting them, with the

⁸³⁰ Henshaw AM, Clarke D, Long AF. Midwives and supervisors of midwives' perceptions of the statutory supervision of midwifery within the United Kingdom: A systematic review. Midwifery 2011;Dec 13:1-11

⁸³¹ Kirkham M. the culture of midwifery in the National Health Service in England. Journal of Advanced Nursing 1999;30(3):732-739

⁸³² Kirkham M, Stapleton H. Midwives' support needs as childbirth changes. Journal of Advanced Nursing 2000;32(2):465-472

⁸³³ Jones K, Edwards D. Ten years of midwifery supervision. British Journal of Midwifery 2003;11(10):S38-S39

⁸³⁴ Powell A. Starting as we mean to go on: Supporting newly qualified practitioners. British Journal of Midwifery 2005;13(11):726

⁸³⁵ Osbourne A. Supervision: the changing world of midwifery. British Journal of Midwifery 2007;15(9):552-555

inference being that their practice has in some way been restricted, rather than developed⁸³⁶.

With tension apparent in some aspects of the supervisory role, and the role of midwifery supervision in promoting safety in maternity services receiving superficial attention only^{837,838,839}, it is clear that further work is needed to demonstrate its impact on the practice of individual midwives, and on the midwifery service as a whole. It is also clear that further research is needed to provide evidence of the impact of statutory supervision on promoting patient safety and preventing maternal and child deaths, with the emphasis on outcomes rather than on structures and processes. In the meantime, midwives, their supervisors, the NMC and the public will continue to look to the reports that the LSAMOs submit to the NMC annually⁸⁴⁰, to provide evidence of the link between supervision, public protection and the quality of care.

Recognised as being a source of valuable information, the annual LSAMO reports provide an overview of supervisory activities, and the outcome of audits of midwives' practice against the *Rules*. In fact, some commentators⁸⁴¹ consider that LSAs and LSAMOs are the ideal organisations to provide evidence of the impact of statutory supervision, given that they are independent of both providers and commissioners of services. Looking to the future, it is possible that these reports could be further strengthened and become even more valuable, by providing evidence that public protection and women's health and well-being are being maintained, rather than limiting their reports to a descriptive account of how these aims have been achieved.

⁸³⁶ Fowler D. Student midwives and accountability: are mentors good role models. British Journalof Midwifery 2008;16(2):100-104

⁸³⁷ The King's Fund. Safe births: everybody's business. An independent inquiry into the safety of maternity services in England. London: King's Fund. 2008

⁸³⁸ Smith AH, Dixon AL, Page LA. Health-care professionals' views about safety in maternity services: a qualitative study. Midwifery 2009;25(1):21-31

⁸³⁹ Sandall J, Homer C, Sadler E, Rudsill C, Bourgeault I, Bewley S, Nelson P, Cowie L, Cooper C, Curry N. Staffing in maternity units: Getting the right people in the right place at the right time. London: The King's Fund. 2011

⁸⁴⁰ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 16

⁸⁴¹ Bacon L. What does the future hold for the role of the Local Supervising Authority? British Journal of Midwifery 2011;19(7):439-442

A more detailed account of the concerns that have arisen over the year, and the role of supervision in alerting LSAs to or averting crises, would also be beneficial, as would more robust evidence of impact and outcomes. Not only would this information provide valuable insight, but it would also go some way to providing evidence of the links between supervision investigations and those Serious Untoward Incident Investigations that have been reported to the National Patient Safety Agency or Scottish Patient Safety Programme. This, in turn, would enable those areas of 'risky' practice that have been addressed through supervision to be correlated with findings reported nationally, but, and more fundamentally, it would also demonstrate to patients and the public in a transparent way that their safety and protection have primacy. Significantly, and perhaps most importantly for the profession, this information would also provide the clarity, consistency and accountability that can reasonably be expected from a statutory system such as this.

3.3.3.2. Conflict with local policies?

Of course, no discussion surrounding the effectiveness of statutory supervision would be complete without an acknowledgement that conflict has sometimes been reported by midwives when seeking to abide by the *Midwives Rules*, while still complying with local employment policies. This is a legitimate concern that has been expressed by a number of midwives, with failure to comply with either directive potentially resulting in sanction. Admittedly, most of these concerns have been resolved, at least in part, by the changes made to the most recent version of the *Rules*, published in 2004⁸⁴². In particular, in stipulating that midwives should refer women to a "qualified health professional [with] the necessary skills and experience" in circumstances where there is a deviation from normal that is outside their sphere of practice⁸⁴³ (such as in cases involving neonatal resuscitation), rather than a specific person, this has avoided the situation that arose in the past regarding who constituted the most appropriate person to call. Indeed, until the *Rules* were changed, those midwives whose

Rules 2004. Statutory Instrument 2004 No 1764
 The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764
 Rule 6(3)

local policies required them to call upon the assistance of a team member, such as a Neonatal Nurse Practitioner, in the first instance, could find themselves potentially in breach of the *Rules*, which originally required them to refer to doctors in such circumstances⁸⁴⁴.

With this situation having largely been resolved, this leaves statutory supervision and the LSAMO annual reports as the main vehicles through which any future conflict can be identified, and any resolution implemented. This process is particularly important, given that the role of the midwife is continually expanding. This means that the role of Supervisors of Midwives and LSAMOs in identifying and capturing all relevant issues is even more important than was originally the case, with responsibility lying with them to ensure that appropriate responsive action can be taken when required. In fulfilling this role, not only does this provide the public, the profession and the NMC with the necessary assurance that the midwives are practising in concordance with the *Rules*, but it also enables any relevant trends or issues arising from complaints and investigations to be identified and acted upon. Importantly, from a public protection perspective, this also provides evidence of midwives' ongoing fitness to practice, and, as such, enables the NMC to discharge its overriding duty.

Further analysis by the PSA, in the form of an annual performance review⁸⁴⁵, is also helpful in providing the public and the profession with the necessary assurance that the approach taken by the NMC to fulfil its statutory obligations is appropriate, and proportionate to the risks posed. Aimed at providing the necessary assurance that the quality of care provided by midwives is safe and effective, the primary purpose of the PSA in these circumstances is to ensure that the approach taken by the NMC to govern the practice of midwifery is compliant with the 'right-touch' principles of regulation; namely that which is required to achieve the desired effect.

⁸⁴⁴ The Nurses, Midwives and Health Visitors (Midwives Amendment) Rules Approval Order 1998. Statutory Instrument 1998 No 2649

⁸⁴⁵ Council for Healthcare Regulatory Excellence. Performance review report 2011/2012. Annual report Vols I and II. London: CHRE. 2012

3.4. The 'right-touch' approach to midwifery regulation

It has already been established that current healthcare policy is based on a 'right-touch' approach to regulation⁸⁴⁶. This means that only the minimum regulatory force that is required to protect the public should be applied. Accordingly, it is clear that any system of midwifery regulation needs to fulfil its statutory obligations in a cost and clinically effective way, while adhering to the underlying principles of proportionality, consistency, accountability, transparency and efficacy^{847,848}. Acknowledging this, it seems prudent to take a closer look at the *Rules* that differentiate midwives from other healthcare professionals, and consider the extent to which these satisfy the 'right-touch' criteria.

Working on the basis that Rule 6 provides midwives with a broad, albeit defined, framework within which to practice, while still allowing for innovation and creativity, the issue that needs to be addressed is whether the *Rules* represent a consistent and targeted regulatory response that is proportionate to the risks posed, and whether they hold midwives sufficiently accountable for their practice. Central to this analysis is the extent to which this *Rule* can be properly enforced and complied with, the extent to which it is likely to give rise to anomalies and inconsistencies, and the extent to which the necessary safeguards can be achieved through alternative means.

At the moment, the practice of midwifery, and its underpinning legislation, is based on the concept of 'normality'. The associated *Rules* and supervision requirements are similarly founded on the management of normality in pregnancy and childbirth. Underpinning this is recognition of the fact that the risks that are associated with midwifery and obstetric practice are significant⁸⁴⁹, even when pregnancies are considered to be 'normal', and acknowledgement that the implications of something going wrong can be catastrophic. Thus,

⁸⁴⁶ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010

⁸⁴⁷ Hampton, P. Reducing administrative burdens: effective inspection and enforcement. (The Hampton Review Final Report). Norwich: HMSO. 2005

⁸⁴⁸ Better Regulation Commission. Risk, responsibility and regulation. Whose risk is it anyway? London: Better Regulation Commission. 2006

⁸⁴⁹ Harpwood V. Negligence in healthcare: Clinical claims and risk. London: Informa Publishing Group. 2001

although based on limited formal evaluations, and with their practice restricted to a defined client group, it is submitted that the current system of regulation that underpins midwifery practice is effective, proportionate and consistent with the risks posed to patients, and provides both women and the public with the regulatory safeguards that they necessarily require.

Of course, given that modern healthcare is increasingly reliant upon new ways of working to deliver services, it seems likely that midwives, along with other healthcare professionals, will be expected to develop their knowledge and skills such that they are able to practice to their full potential, and care for a wider range of women with a wider range of needs. In some cases, this development may extend to assuming responsibility for roles and activities not traditionally associated with their profession. Acknowledging this, and accepting that women with wider health and social care problems are expected to feature in the rising number of births, it seems likely that the care of these women may be reflected in any expansion of the scope of midwifery practice. It is also likely that increased complications associated with childbirth will feature in the growing number of older mothers with co-morbidities, many of whom may be found to be less fit for pregnancy⁸⁵⁰, with the result being that the scope of midwifery practice will need to evolve to take account of these difficulties.

Potentially of huge practical and clinical significance, it is possible that change of such magnitude could transform the face of midwifery practice. The extent and impact of this change would be dependent upon whether the boundaries of practice were expanded so as to incorporate a defined range of procedures, or to encompass a wider range of unspecified interventions. With both options potentially necessitating a change in primary and secondary legislation, in the event that they explicitly encompass 'abnormality', the implications for midwifery practice and regulation would be considerable. This would particularly be the case if the boundaries of practice were expanded such that this was considered to represent a formal system of 'advanced midwifery practice'.

⁸⁵⁰ Midwifery 2020 Programme. Midwifery 2020: Delivering expectations. Cambridge: Jill Rogers Associates. 2010

If this was to be the case, and 'advanced midwives' were to emerge formally as a result of this change, the question that would then be likely to be asked is whether the current regulatory arrangements that are in place are sufficiently robust so as to assure the public of their safety in relation to such practices, and whether they would be able to hold midwives suitably to account. Underpinning these questions would also be the issue of midwifery education and training. These would particularly relate to whether midwifery education was sufficiently robust and well-developed so as to prepare midwives properly for the responsibilities that await them, and whether universities and other formal education institutions would be equipped to prepare midwives for this more modern purpose. Related questions would also be likely to be asked surrounding the registration entries of such midwives, and the extent to which those midwives who had undergone and satisfactorily completed additional education and training would be able to be differentiated from the more traditional midwives. In these circumstances, the expectation is likely to be that the registration entries of these midwives would in some way be amended so as to reflect their advanced skills. If such an amendment was possible, the issue would then be what form such an amendment should take, and to whom it should apply.

As previously indicated, current healthcare policy is unsympathetic to changes being made to existing regulatory structures⁸⁵¹. With those responsible for implementing healthcare policy also unsympathetic to changes being made to professional registers, particularly where these changes are perceived as being for the benefit of the professions and healthcare professionals, rather than the protection of the public⁸⁵², it is unlikely that a favourable response to any request to amend the midwifery Register would be forthcoming. As such, it is unlikely that the registration of those midwives who have chosen to 'advance' their practice would be annotated, unless it could be shown that the circumstances surrounding this request were 'exceptional'.

⁸⁵¹ Department of Health. Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers. Cm8008. London: HMSO. 2011

⁸⁵² Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

In order to satisfy this 'exceptional' requirement, the midwifery profession would need to be able to satisfy the PSA and convince policy leads that such an amendment would be necessary in the public interest, and would apply to a sufficient number of registrants such that this would be considered as constituting a proportionate regulatory response⁸⁵³. It would also need to satisfy the PSA that the developments within the profession represented genuine advancement, rather than a natural part of career progression, and that in undertaking the associated responsibilities, midwives would be posing a different level of risk to patients such that new and distinct standards of proficiency were required to perform them. With 'advanced nurses' having yet to make a convincing case for annotation of the nursing Register, it seems unlikely that any related request for such an amendment from 'advanced midwives' would be met with a more favourable response. However, this is an assumption that is open to rebuttal.

3.5. The regulation of advanced nursing practice: applying the midwifery model

At the moment, the regulatory system that underpins the practice of midwifery is rooted in normality, while also preparing midwives to care for women with complex, medical, obstetric and social needs. Alongside nurses, midwives are currently regulated by the NMC, with both afforded the same regulatory rights and privileges, albeit with midwives having a separate 'part' of the Register devoted to them, given their different professional sphere. This means that nurses and midwives are both bound by the same professional 'code,' which outlines the standards of conduct, ethics and performance with which both must comply, but with midwives having additional profession-specific requirements imposed upon them. In practice, this means that the only real difference that exists between the professions is the secondary legislation with which midwives must comply, with the inference being that the public requires a greater level of protection from midwives than they do from nurses.

⁸⁵³ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

For some, this additional level of protection is underpinned by the assumption that midwives pose a greater level of risk to the public than that posed by This assumption does not always sit comfortably with midwives, nurses. particularly those who are not convinced of the benefits that the Rules and statutory supervision can afford^{854,855,856}. For others, it is a reasonable assumption to make, particularly given the severity of the consequences that can arise when the risks associated with midwifery and obstetric practice materialise^{857,858}. As such, this thesis does not seek to propose that the statutory provisions that underpin midwifery practice in the form of secondary legislation should be removed. Rather, it seeks to consider whether similar safeguards should also be afforded to advanced nurses, and thereby afford the public an equivalent level of protection from those nurses who have advanced their practice beyond traditional boundaries, and who arguably pose a greater degree of risk to their safety than midwives.

3.5.1. A proportionate regulatory response?

Although midwifery is essentially rooted in normality, the same cannot be said of nursing, whose scope spans all ages and the entire healthcare spectrum. As such, it could be argued that the risks associated with nursing practice are greater than those associated with midwifery, particularly given that the statutory limitations that apply to midwives in terms of 'normality' do not apply to nurses. If one accepts this premise, it follows that one would also accept that the risks associated with advanced nursing practice would be magnified even further, particularly given the potential scope of 'advanced nursing practice'. Indeed, when one considers that there is no formal ceiling or

⁸⁵⁵ Warwick C. Statutory supervision of midwives: adding value to the profession. British Journal of Midwifery 2009;17(11):686

⁸⁵⁴ Deery R. An action-research study exploring midwives' support needs and the effect of group clinical supervision. Midwifery 2005;2(12):161-176

⁸⁵⁶ Henshaw AM, Clarke D, Long AF. Midwives and supervisors of midwives' perceptions of the statutory supervision of midwifery within the United Kingdom: A systematic review. Midwifery 2011;1-11

⁸⁵⁷ Fyle J, MCGlynn AG, Jokinen M. Flying lessons: risk management and the NPSA. Midwives Magazine. October 2002

Phipps J. Statutory supervision: Achieving the balance. British Journal of Midwifery 2012;20(10):736-739

limitation on the scope of permissible nursing practice, and the fact that the few statutory restrictions that do remain, namely those associated with termination of pregnancy⁸⁵⁹ and certification of death⁸⁶⁰, are likely to be lifted in the foreseeable future, this argument is persuasive.

Proceeding on the basis that the risks associated with advanced nursing practice are likely to be commensurate with the complexity of the skill or intervention in question, it further follows that the safeguards that would be required to underpin such practice would also need to be heightened. If heightened safeguards were accepted as being necessary, this could provide the public with the corresponding level of 'protection' that they deserve, and demonstrate both to them and the professions, that public protection and patient safety have primacy. Working on the basis that this argument is convincing, and that additional regulatory safeguards for advanced practice are necessary in the interests of the public, the question that now needs to be asked is what form these safeguards should take, and how they should be applied.

Given that midwives and nurses have similar origins, and both are currently regulated by the same statutory body and bound by the same professional 'code', it seems logical to consider whether advanced nurses could also benefit from having a separate 'part' of the NMC Register opened up to them, similar to that which has been provided for midwives. It would also be reasonable to consider whether the creation of a separate Advanced Nursing Committee would also have merit and should also be constituted, similar to that provided in the form of the Midwifery Committee. This would ensure that those issues that are related to 'advanced nursing practice' are able to be adequately considered and appropriately addressed, and do not become subsumed within the general array of wider nursing issues that the NMC is required to consider, as is currently the case. This would also demonstrate, in an open and transparent way, that the risks posed by advanced practice of this kind are being taken seriously by the profession and, perhaps more importantly within the current climate, that the NMC as the professional regulator is taking these risks seriously. If so, the issue that would then need to be addressed is whether having a separate 'part' of the

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⁸⁵⁹ Abortion Act 1967 Ch 87

⁸⁶⁰ Births and Deaths Registration Act 1953 Part II

Register and an identified Committee would constitute a proportionate regulatory response, and whether this would enable the associated risks to be appropriately captured and effectively addressed. The related issue that would also need to be addressed within this context is whether these risks could be managed, and the associated safeguards could be provided, by existing or alternative means.

Taking the second point first, the adverse scrutiny that has faced the NMC over recent years, particularly in relation to its fitness to practise processes and finance and governance functions^{861,862,863,864}, bears testimony to the fact that the NMC is not currently fulfilling its duties at a level commensurate with the level of protection that the public requires. At the moment, the ongoing analysis and scrutiny by the PSA refers to nursing practice as a whole, and does not, in any way, differentiate, or seek to differentiate the competence, fitness to practise or associated issues that pertain to those nurses who are practising at an advanced level. As such, it is not possible to obtain quantifiable data on these issues. However, working on the basis that the process for identifying risks and ensuring the fitness to practise of those practising in a traditional way have been shown not to be robust or reliable, it logically follows that the management of risks associated with those practising at a higher and, therefore, more complex level, cannot always be assured. On this basis, it is asserted that the risks associated with 'advanced nursing practice' are not able to be appropriately or effectively managed by existing means.

Accepting this premise, one now needs to turn to the first point above, namely whether, and the extent to which, a change in the NMC's regulatory structure so as to accommodate 'advanced nursing practice' would be an acceptable alternative means of providing the necessary regulatory safeguards. In practice, this means whether a separate 'part' of the NMC Register would represent a

⁸⁶¹ Council for Healthcare Regulatory Excellence. Special report to the Minister of State for Health Services on the Nursing and Midwifery Council. London: CHRE. 2008

⁸⁶² Council for Healthcare Regulatory Excellence. Fitness to practise audit report. Audit of health professional regulatory bodies' initial decisions. London: CHRE. 2011

⁸⁶³ Council for Healthcare Regulatory Excellence. Audit of the Nursing and Midwifery Council's initial stages fitness to practise process. London: CHRE. 2011

⁸⁶⁴ Council for Healthcare Regulatory Excellence. Strategic review of the Nursing and Midwifery Council: Final report. London: CHRE. 2012

proportionate and consistent response, and whether this would provide a sufficiently targeted and transparent mechanism that would hold advanced nurses sufficiently to account. Given that midwives have enjoyed the benefit of a separate 'part' of the Register since the time of the *Briggs Report* in 1972⁸⁶⁵, which has since been reinforced in subsequent legislation^{866,867},⁸⁶⁸, it seems improbable that any arguments that may be submitted *in principle* against the opening of a separate part of the Register would carry weight. Instead, challenges are more likely to arise from the question of why a change of this magnitude should be afforded to advanced nurses, rather than any other group, and whether an approach of this sort would provide a cost and clinically effective regulatory solution.

As previously stated, in order to present a compelling case for change, arguments would need to be presented to support the premise that the risks that are associated with advanced nursing practice are such that the public requires an additional level of protection to safeguard them from harm, and this protection cannot be afforded by existing or alternative means. Putting to one side the minor point that structural change of the kind suggested could technically be considered an 'alternative' means, the more detailed case that would need to be made is that secondary legislation, similar to that which is afforded to midwives in the form of the Rules, could reasonably provide the safeguards that are being sought. In particular, convincing arguments would need to be made that legislation of this kind would provide advanced nurses with the necessary anchor upon which to build strong educational and clinical foundations, and would provide a robust and coherent system that would hold them suitably to account. Subsequent arguments would need to be presented that this approach would instil confidence in the profession, and in nurses something that has arguably thus far been lacking - and demonstrate to the public that their needs come first. Accepting that this would be a way forward, the question that would then need to be addressed is what form these Rules would take, and how they would be applied.

⁸⁶⁵ Report of the Committee on Nursing (The Briggs Report). Cmnd 5115. London: HMSO. 1972

⁸⁶⁶ Nurses, Midwives and Health Visitors Act 1979

⁸⁶⁷ Nurses, Midwives and Health Visitors Act 1992

⁸⁶⁸ Nurses, Midwives and Health Visitors Act 1997

Working on the basis that the *Rules* are considered to be appropriate and proportionate when applied to midwives, and, as such, satisfy the principles of right-touch regulation⁸⁶⁹, it seems reasonable to proceed on the basis that they could be applied horizontally to the advanced nursing context. Indeed, there is no logical reason why the *Rules* should not be 'transferred' in this way. The only difference would be in the statutory basis and the sphere of practice of nurses and midwives, which would be reflected in the detail contained in the *Rules* and associated Guidance Notes, and the way in which these were implemented.

3.5.2. A consistent and targeted approach?

As previously discussed, the *Midwives Rules* are generally accepted by midwives as reinforcing their right to practise autonomously, and by the profession as acknowledging the primacy of public protection⁸⁷⁰. Applicable to all practising midwives, the *Rules* are consistently applied, irrespective of status or seniority, with transparent safeguards being provided in the form of annual reports sent by the LSAMOs to the NMC. Presenting a formal account of progress made and developments that are in train, these reports also provide evidence of investigations and complaints that have been made, in order that practice can be developed in the interests of all concerned. LSAs also have an important role to play in providing scrutiny and oversight, particularly in relation to the monitoring of those midwives whose practice has given cause for concern, thus reinforcing the need to ensure the fitness to practise of those midwives who attend upon women.

However, acknowledging that the success of any scheme of *Rules* is dependent upon their quality, integrity, relevance, validity and reliability, and the consistency with which they are implemented, much would depend upon the quality and content of any such *Rules* and the way in which they would be applied to 'advanced nursing practice'. Referred to here as the '*Nursing Rules*', for the purpose of this thesis and for ease of differentiation from the *Midwives*

⁸⁶⁹ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010 ⁸⁷⁰ Davies C, Beach A. Interpreting professional self-regulation. A history of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting. London: Routledge. 2000

Rules, it would be expected that any version of the Nursing Rules that would be published would incorporate key sections similar to those that are contained within the Midwives Rules. This would demonstrate that a consistent and risk-based approach to regulating this area of practice was being taken, as well as showing that lessons had been learned from the regulation of other healthcare professions.

Of course, while the structure of any such system of Nursing Rules may be similar, the extent to which they would work in practice is dependent on their content, and the way in which they were implemented. As a minimum, it would be prudent to include reference to the scope of permissible advanced nursing practice that would be encompassed within the Nursing Rules, albeit acknowledging that, in the case of advanced nurses, this scope could potentially be broad. A Nursing Rule that was devoted to the 'Notification of intention to practice' could also be helpful as this would reinforce the notion of clinical competence, and the individual responsibility of advanced nurses to maintain and update their knowledge and competence, and perform only those tasks that they are competent to perform. Not only would this provide patients with the necessary regulatory safeguards, but this would also reinforce the individual accountability of advanced nurses for their practice. However, whether a related system of 'notification' by the LSA to the NMC of the scope of practice of individual advanced nurses would be beneficial and proportionate is something of a moot point, as this would depend on whether a formal system of statutory supervision was to be imposed, and, if so, what form this would take.

On the other hand, *Nursing Rules* that are specifically devoted to 'Suspension from practice' and 'Responsibility and sphere of practice' would be both beneficial and proportionate, as these would be consistent with the approach taken by midwives. They would also, and, perhaps more importantly, demonstrate even further the accountability of advanced nurses and provide patients with the additional safeguards they arguably require. Other rules that are currently adopted by midwives, such as those relating to the administration of medicines and record keeping, could feature within the *Nursing Rules*, but they could equally remain in their current format, given that they are applicable to all Registered Nurses. Leaving these issues to be addressed in their current

format would seem to be the proportionate and most cost-effective way to proceed, and would demonstrate a targeted approach to the selection and application of the *Nursing Rules*. However, one area that would be likely to invite controversy, and could result in challenge to any form of *Nursing Rules*, is that relating to statutory supervision, with the question of if, and how, such a system should be implemented, likely to provoke particular debate.

Although there is limited evaluative evidence of the impact of statutory midwifery supervision on clinical outcomes and the quality of maternity care, that which does exist is, on balance, favourable. The problem lies in the fact that the weaknesses in this evidence are largely due to the fact that what evidence is available is anecdotal and qualitative, with a robust methodology conspicuous by its absence. However, if one considers that one of the primary aims of statutory supervision is to provide a supportive and constructive framework for practice, in which open dialogue is promoted in order to encourage development and accountability and ensure patient safety, then the anecdotal evidence that is available is largely supportive of this. Accordingly, it is possible that one could conclude that such an approach could have a place in the *Nursing Rules*.

Interestingly, within this context, it is notable that very few midwives are referred to the NMC on the basis of allegations of misconduct or incompetence. While the exact reasons for this are not known, it is possible that this finding may be as a result of statutory supervision. If so, it is possible that any additional support and development that may have been provided to those midwives who required it, in the form of statutory supervision, may have minimised the risk of poor practice developing⁸⁷¹. In the event that this can be shown to be the case, this presents a strong case in favour of retaining statutory supervision within any version of the *Nursing Rules* that may be developed.

Of course, assuming that the 'midwifery model' of statutory supervision was to be favoured, the question of proportionality and cost-effectiveness would again come to the fore. Indeed, it is unlikely that any form of statutory supervision

⁸⁷¹ The Nursing and Midwifery Council (Midwives) Rules 2004. Statutory Instrument 2004 No 1764 Rule 5 Guidance Notes 6 and 7

that may be proposed would be implemented without the guarantee of protected time being afforded to both Supervisor and Supervisee. As with many initiatives, the question of funding would then be likely to feature as a prominent issue, as would the associated costs that would be associated with training, and the additional responsibilities that this role would confer. Indeed, it is entirely possible that the evidence of the impact of the statutory midwifery supervision that was recently considered by the NMC⁸⁷² could have its foundation partially on cost, with the NMC eager to ensure that it is not only focusing its attention on its core regulatory duties, but also demonstrating a renewed sense of financial awareness.

Further complicating this issue is the question of numbers, and the feasibility of implementing a statutory supervision scheme for advanced nurses. As previously indicated, approximately 670,000 nurses and midwives are currently registered with the NMC. Of these registrants, approximately 630,000 are nurses, with an estimated 40,000 midwives also on the Register. Under any scheme of statutory supervision that would be proposed, this would be intended as applying only to those nurses who would be considered as practising at an advanced level. However, as outlined earlier in this thesis, no clear definition of advanced nursing practice exists that would determine those nurses to whom this *Nursing Rule* would apply.

If one accepts that an 'advanced nurse' is a Registered Nurse who practises as a Clinical Nurse Specialist, Nurse Practitioner or Consultant Nurse, then this would narrow the field considerably. However, this would rule out many of those 'advanced nurses' who have advanced their skills beyond the level of those mentioned, such that their practice constitutes a new clinical role. Examples of those nurses who perform such roles would be Physician Assistants, Surgical Care Practitioners, Emergency Care Practitioners or Immediate Care Practitioners, all of which have been discussed previously. If these roles were also to be included in the 'definition', this would provide a more comprehensive 'list', but their numbers would not be considerable.

⁸⁷² Nursing and Midwifery Council meeting. Evidence review paper: midwifery supervision. Item 11, Annex 1. September 2012

Alternatively, if one chose instead to adopt a 'band' system, such as that promoted in the NHS Knowledge and Skills Framework⁸⁷³, then this would increase the numbers who would be 'caught' by the *Nursing Rules* considerably, with those nurses who have acquired a period of post-registration experience, potentially being considered as advanced. Accordingly, if this approach was selected, this would increase the number of nurses who would be eligible for statutory supervision, meaning that the costs would arguably be potentially prohibitive. Admittedly, this criterion could be further refined so as to delineate the duration and level of post-registration experience that would be required for eligibility. However, the wider the group that would potentially be 'caught' by the criteria, the less focused any form of supervision would be likely to be, meaning that evidence of its impact would be significantly reduced.

The issues that would also need to be considered within this context are those associated with the ratio of Supervisees that are allocated individual Supervisors, and the criteria that would determine who would be deemed suitable to perform the role of Supervisor. Also relevant would be details of the training and education that would be required for those advanced nurses who would wish to assume responsibility for such a role, and who would be responsible for delivering this. Admittedly, these issues are peripheral at this stage. However, in the event that a system of statutory supervision was implemented for advanced nurses, these issues would be likely to feature as significant factors.

Of course, it is entirely possible that statutory supervision could be considered but excluded from any proposed system of regulation for 'advanced nurses'. This decision could potentially be taken on the basis of cost, proportionality or feasibility. It could equally be taken because the system of statutory midwifery supervision has itself come under scrutiny, with its longevity and sustainability potentially coming into question. If so, it might be reasonable to conclude that, although, in theory, statutory supervision could provide the necessary regulatory safeguards, these safeguards could also be provided by a less time and resource-intensive regimen. An example of such an alternative regimen could possibly be

⁸⁷³ Department of Health. The NHS Knowledge and Skills Framework (NHS KSF) and the development review process. London: DH. 2004

to revisit the current system of 'notification to practise', and consider whether an expanded version of this would provide the NMC with the information that it requires and satisfy the 'right-touch' criteria, while still providing an effective regulatory response. A more lateral solution, and one that has not yet been addressed, it is unlikely that this option would gain favour, on the basis that it could potentially be perceived as adding an additional and unnecessary level of bureaucracy to an already struggling system. Alternatively, it may be concluded that an alternative regulatory approach, such as that which could be provided by one of the other regulatory bodies, would be more appropriate. This will be considered in more detail in the concluding chapter of this thesis.

3.6. The midwifery model: an appropriate regulatory framework?

Bound by the same regulatory body, and having evolved from similar origins, it is easy to see why the professions of nursing and midwifery are logical comparators. With nurses and midwives both having assumed responsibility for practices that, in the eyes of many, are be considered to be traditionally medical, this also makes a comparison sensible. So, too, does the fact that both professions have historically overcome periods of turbulence and disharmony in relation to medicine, with doctors having consistently fought to exert authority over the clinical domain. However, despite their similarities and both having overcome similar challenges, the differences that separate the professions are almost certain to feature in any discussion between them; most notably the fact that midwifery is essentially founded on normality, and midwives are able to practise autonomously at the point of registration.

The fact that these differences are significant is not in doubt. In fact, they reinforce the distinction in practice and scope between the professions, with midwives, in particular, benefiting from a title and function that are 'protected' by law⁸⁷⁴. They also highlight the different positions that nurses and midwives hold within society and within the healthcare team, with midwives acknowledged as enjoying a favoured place in the eyes of the public, given the

⁸⁷⁴ Nursing and Midwifery Order 2001 Article 44

nature of their work. However, although significant, these differences are not so encompassing that they would preclude any meaningful comparison between nurses and midwives, or an analysis of the regulatory systems that underpin their practice. Rather, they enable a meaningful and significant contrast to be made, with both professions potentially learning something from the other given the different ways in which their practice has evolved over the years.

Within the context of the current discussion, it is also important to acknowledge that there are similarities between the advanced nature of nursing practice, and the traditional - and evolving - nature of the practice of midwifery. Indeed, with both of these areas founded on the concept of autonomy and accountability for practice, both of which are underpinned by the notion of clinical competence, and practitioners from both disciplines having personal and professional accountability for ensuring that their practice remains up to date, this commonality provides the ideal platform upon which a discussion surrounding the regulation of advanced practice can be based.

Accepting that the system of regulation that currently underpins midwifery is more robust than that which governs the practice of nursing, it is possible that a similar system to that of midwifery could provide advanced nursing practice with the requisite regulatory safeguards. This acknowledges the benefits that a system of *Rules* and statutory supervision could potentially afford, and the advantages that a system of secondary legislation could confer. This includes the requirement to notify a designated person -the Supervisor in the case of midwives - of the practitioner's intention to practise in a given area, with statutory supervision providing additional regulatory safeguards in requiring practitioners to attend regular meetings in order to discuss and reflect on their practice and experiences, most notably the parameters of their practice, and the maintenance of their competence.

As already intimated, the application of this approach to the regulation of advanced nursing practice would, in principle, be appropriate and proportionate to the risks posed to patients. It would also enable advanced nurses to be held sufficiently accountable for their practice and provide a transparent approach to ensuring public protection. However, in order to be practicable and feasible,

and to satisfy 'right-touch' principles, the 'midwifery approach' would also need to be consistent and targeted, if it is to provide the solution that is being sought to the regulation of advanced nursing practice.

In order to be consistent and targeted, this approach to statutory regulation would require the definition of what constitutes 'advanced nursing practice' to be clarified. This, in turn, would require a distinction to be drawn between those forms of advanced practice that denote an extension to traditional nursing practice - such as the adoption of tasks such as venepuncture, intravenous cannulation, radiology interpretation and defibrillation - and those which are of sufficient magnitude such that they are considered to represent a discrete area of practice. With the latter form of advanced practice able to be differentiated on the basis that it is likely to constitute a new clinical role, the issue that would need to be addressed is which type of advanced nurse would be affected by any new system of regulation that would be introduced.

Working on the basis that early forms of advanced nursing practice, such as those referred to above, are now accepted as representing a form of career and professional advancement, rather a new area of practice, it is improbable that these would be considered appropriate to be included under any new regulatory regimen. This would particularly be the case when one considers that elements of practice that were once considered as being 'advanced', such as the administration of intravenous drugs, now feature in undergraduate nursing curricula and form part of traditional nursing practice. It would also be the case when one considers that any piecemeal extension to practice that is today considered as being 'advanced' is likely to become part of traditional nursing practice in due course. As such, it would no longer be considered 'advanced'. Accordingly, it would be more appropriate to reserve the 'advanced nursing title' and, therefore, any associated change in statutory regulation, to those aspects of advanced nursing practice that have been developed such that they constitute a new clinical role.

This is not to say that patients and the public would not require an additional form of 'protection' from those nurses who wish to develop their practice in a traditional way, through linear extensions to practice. Rather, it would seem to

be more appropriate to look to employer-led systems, such as those that would be able to be provided by clinical governance systems, to provide the necessary safeguards in these situations. This would mean that patients and the public would still be protected from those practitioners who adopt a range of self-styled and self-appointed titles - most, if not all, of which imply a level of advanced practice. Rather, it would fall to employers and local workforce planners to control the use of these titles, and prevent those nurses who have not attained the relevant level of skill that is implied in their titles from holding themselves out as practising in an advanced way when, in fact, they are not able to do so.

This approach would, in turn, leave those nurses who are practising in new clinical roles able to benefit from the new regulatory regimen, and would enable patients and the public to benefit from the additional level of protection that they arguably deserve. It would also mean that a targeted regulatory response could be provided to those areas of practice that are associated with the most significant risks to patients, and afford patients an additional level of protection, and, in so doing, comply with the 'right-touch' principles. It would also enable a system of statutory supervision to be introduced to support those advanced nurses who are undertaking new roles, as this would be considered to be proportionate, targeted and consistent, and would constitute a clinically and cost-effective response.

Significantly, it is possible that the 'midwifery' approach could be perceived as offering the most acceptable regulatory solution to advanced nurses, given that it would enable them to remain registered with the NMC. This would mean that the essence of nursing practice would be preserved, and, in so doing, could go some way to appease those nursing purists and academics who are likely to oppose an alternative health professional regulator as the body to regulate advanced nurses on the basis that this could potentially be perceived as diluting nursing's heritage. Alternatively, given that most, if not all, advanced nursing practice derives from medicine, it is possible that another healthcare professional regulator may be considered as providing a more appropriate regulatory solution. If so, this begs the question of which of the alternative

health professional regulators would provide the most appropriate response, and whether this approach would satisfy the 'right-touch' principles.

Chapter 4

4. Advanced nursing practice: The case for change

For more than two decades, the NMC and policy makers have grappled with issues surrounding the regulation of advanced nursing practice. Both assert their commitment to protect the public from those nurses who choose to practice in advanced as well as traditional ways, and to ensure that the necessary safeguards are in place. Both are also convincing in their assertion that the underpinning education of these practitioners must be robust enough to ensure clinical competence, and provide consistent standards of practice ^{875,876}.

However, despite this commitment, neither has implemented the regulatory safeguards that are needed to resolve the problems that are associated with advanced nursing. Nor have they addressed the associated plethora of titles that have been adopted by those nurses who purport to be advanced that are currently in use. This has resulted in the situation remaining whereby any nurse who has undertaken any form of learning beyond registration could hold himself or herself out as being 'advanced'. This, in turn, has resulted in the patients and the public being inadequately protected from those nurses who purport to practise in an advanced way, but who may not be qualified to do so, and has rendered the extent to which their safety is able to be assured unreliable.

To date, no template has been established for the successful regulation and accreditation of new nursing roles. This is the case despite years of discussion in the national and international literature⁸⁷⁷, and countless professional debates. Central to these discussions are questions surrounding the stage at which a new role becomes so distinct from traditional nurse training, such that it warrants a

⁸⁷⁵ Council for Healthcare and Regulatory Excellence. Advanced practice: policy summary. London: CHRE. 2009

⁸⁷⁶ Snow T. New head of NMC prepares to end impasse on advanced level practice. Nursing Standard 2010;24(21):12-13

⁸⁷⁷ Schober M, Affara F. Advanced nursing practice. Oxford: Blackwell Publishing Ltd. 2006:81-112

new or additional layer of regulation⁸⁷⁸. Also central to these discussions are attempts to align different levels of practice with the acquisition of higher levels of education, with evidence suggesting that the public expects to see regulation based on an assessment of competence, rather than attainment of education qualifications.

Within the UK, debates surrounding advanced nursing practice have largely focused on the extent to which 'advanced nursing practice' reflects career development over time, or whether it represents a new form of practice which poses a different type of risk to patients and requires new standards of proficiency to be performed safely⁸⁷⁹. Underpinning these debates is the assumption that when practices that are associated with one professional groupsuch as doctors - are undertaken by another professional group - such as nurses the risks that are associated with them will be greater, meaning that additional safeguards will be needed. Also underpinning this question is uncertainty surrounding whether an additional layer of regulation is required to provide patients and the public with the additional safeguards that they may require, or whether the safeguards that are already associated with initial level practice should suffice.

4.1. Expanded nursing roles

Discussions that have been presented in this thesis have shown that advanced nursing practice has evolved considerably in recent decades. Although originally associated with piecemeal extensions to practice, which resulted in the award of 'certificates of competence', and subsequently expanded so as to be associated with a new clinical title, developments have continued apace. Indeed, such has been the pace of change that roles such as the Clinical Nurse Specialist (CNS) and Nurse Practitioner (NP), which were considered to be the original advanced

⁸⁷⁸ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

⁸⁷⁹ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. 2010

roles and still exist today, are now seen as representing career progression over time rather than the development of a new clinical role.

However, new clinical roles *have* entered the clinical arena. The first of these roles was that of the Consultant Nurse (CN) which, as has been shown, was launched into the clinical arena amid a fanfare of publicity, and much acclaim. At the time, it was intended that this role would give nurses an equivalent status to that of 'medical consultants, and that they would work alongside their medical counterparts with a similarly devised job plan. Nevertheless, despite the acclaim with which these roles were received, and the publicity that accompanied them, it seems that they have not lived up to their expectations, nor have they provided the panacea that they were expected to bring. Rather, as time has gone on, they have become increasingly more different and disparate, with the result being that, in many cases, there is little commonality or consistency between them.

Of course, this is not to say that CNs do not have a valuable role to play in the clinical team. Nor does it suggest that their contribution is less meaningful than it once was. Rather, it reflects the fact that, as these roles have evolved, they have become more varied. They have also resulted in variable clinical standards and considerable variation in the ways in which they are carried out. In fact, the reality is that instead of being subject to robust scrutiny and rigor from the 'centre', the process that surrounds the appointments to these roles has been delegated downwards, and their underpinning criteria have been diluted.

This change in direction has resulted in the responsibility for appointing CNs falling to workforce planners, meaning that the consistency that was originally afforded when determining the calibre of those who are appointed and the way in which they apportion their time and how they conduct their role, has arguably been lost. As a result, these roles have developed into an extension of career development for nurses, in a similar way to that which has occurred in relation to the CNS and NP roles, rather than into the new clinical roles that were originally envisaged. Indeed, if one takes a closer look at what those in CN roles actually do, one will probably conclude that their roles are more aligned with those of the CNS and NP, despite having started out with different intentions.

This has resulted in these roles now being perceived by some as representing an opportunity for clinical and career advancement and promotion, rather than a new clinical entity.

4.2. New clinical roles

Nevertheless, as this thesis has shown, a number of new clinical roles have entered the clinical arena, all of which can be said to constitute a new clinical role. Although wide-ranging in number and set to increase further, it is clear that these new roles form a new clinical group. Indeed, it has been shown in the four new roles presented that many of those nurses who have accepted these roles are performing an essentially medical function.

Although each of the four roles that have been presented is distinct, each is also similar in that they each present a separate regulatory issue that a new regulatory model would be expected to resolve. Essentially revolving around the absence of statutory regulation to underpin their practice, and the associated benefits that a 'protected' title would confer, these issues are also associated with disparate standards of education and training, and the absence of a defined scope of practice. This means that, in practice, the extent to which those nurses practising in these roles will be held to account is unclear, and the extent to which patients and the public will be protected from their actions is questionable. In turn, this means that it is entirely possible for these nurses to escape liability for their actions, and for patients to be attended upon by nurses who are fit for neither practise nor purpose.

4.3. The regulation of advanced nursing practice

At the moment, the regulatory structure that underpins nursing practice, and the development of expanded clinical nursing roles - such as the CNS, NP and CN - has been able to address the risks that the associated practices present. However, in its current format, the NMC is not fit to manage and oversee the regulation of those nurses who have adopted new roles, and those who practise

in a genuinely advanced way. This means that change to the NMC's regulatory structure would need to be required in order to provide patients and the public with the safeguards they arguably require, or the solution would need to be found in another professional regulator.

4.3.1. The Nursing and Midwifery Council

Looking to the NMC as a possible solution, it is clear that the NMC is capable of introducing changes to its regulatory regimen, if it so wishes. This situation is evident in the additional level of statutory protection that it has already afforded to midwives, and which has stood the test of time. However, although showing that the NMC is capable of regulatory change, this thesis has also shown that the midwifery model is, itself, not without fault. This is most apparent in the fact that midwives continue to have a restricted scope of practice, and are required to revert to doctors when faced with situations that are considered not to be normal. It is also apparent in the model of statutory midwifery supervision, which although beneficial, is associated with a number of loopholes and weaknesses that have still to be addressed.

As such, it would not be appropriate to consider transferring the midwifery model horizontally, in order that it could accommodate advanced nursing practice. Rather, it would be more appropriate to identify those aspects of the midwifery model that could assist advanced nurses - such as having a separate part of the Register opened up to them, a protected title, defined educational standards and a model of supervision - and to identify other areas that could be improved upon, and from which they could learn.

It would also be inappropriate to apply the midwifery model directly, on the basis that advanced nurses have a very different remit, and a very different scope of practice to that which is currently enjoyed by midwives. Indeed, unlike midwives, advanced nurses do not have a statutory ceiling on the scope of their practice, treat people of all ages and genders in a range of situations - including when they are sick as well as when they are well - and are not underpinned by legislation which compels them to refer to doctors when faced with

circumstances that are not normal. This means that the risks that are associated with advanced nursing practice are considerably higher. It also means that the risks that are posed to patients by those nurses who attend upon them, and who purport to be advanced when, in fact, they are not, are also far greater. This, in turn, means that the level of protection that is required to protect patients from advanced nurses is also far greater than that which is provided in relation to midwives.

If one is convinced that nurses occupying new groups - such as those outlined in the four new roles presented - constitute a special group and pose increased risks to the public, then it is likely that one will also agree that the current regulatory system that exists within the NMC is not sufficient to protect them. It follows that one would also be likely to agree that additional regulatory safeguards are needed in order to protect the public. This makes the argument surrounding an additional form of statutory regulation compelling, particularly when one considers that the need to protect the public is the primary and most fundamental function of regulation.

Having already established that the midwifery model is effective in providing some of the safeguards that would be required, but would not be sufficiently robust to provide the public with the level of protection that they deserve, this means that advanced nurses will need to look elsewhere in order to find an appropriate regulatory solution. This leaves the question of which of the alternative existing regulatory bodies would be the most appropriate to address these risks satisfactorily, and provide the solution that is needed.

4.3.2. An alternative healthcare regulator

As has already been shown, the General Medical Council (GMC) presents the most obvious regulatory solution for advanced nursing practice. This is based on the fact that most, if not all, of the practices that are associated with the new clinical roles that have been outlined - and those that are likely to follow - derive from medicine. Indeed, in some cases, these roles have been devised

specifically to assist doctors, and have been developed on a quasi-medical model. This makes the case for statutory regulation with the GMC convincing.

Of course, this analysis presumes that the GMC would be willing to regulate practitioners from non-medical backgrounds, particularly nurses. If so, this would require a precedent to be set, given that the GMC has historically regulated only doctors and set standards for medical practice, and would mark a significant departure from its historical benchmark. However, even if this argument was persuasive, it is unlikely that the GMC would agree to regulate these advanced nurses on the basis that they are already 'housed' within a pre-existing regulatory body that would be able to accommodate its needs.

The Health and Care Professions Council (HCPC) could also offer the solution. However, although recognised as the regulatory body that those in new and quasi-medical roles would approach when seeking statutory regulation⁸⁸⁰, deeper analysis shows that the HCPC would not provide an appropriate solution. This is based on the fact that advanced nurses would be unable to satisfy all of the HCPC's criteria for eligibility⁸⁸¹, given that they are already regulated by another body, and alternative mechanisms are already in place by which the regulatory safeguards that are being sought could be achieved. This then leaves the question of which of the other regulatory bodies could provide the solution.

There is, of course, no reason *in principle* why the NMC could not address the risks that are associated with advanced nursing practice. There is also no reason *in principle* why the NMC would not be able to provide the requisite safeguards within the existing regulatory structure. These safeguards include the conferring of a 'protected' title, and the delineation of identified educational standards and competencies. However, if the NMC was minded to regulate advanced nurses, there are a number of issues that it would first have to overcome. Central among these issues are those associated with the high level scrutiny and intense political pressure that the NMC is currently under, which, as has already been shown, is significant. Also featuring centrally is the lack of an

⁸⁸⁰ The Health Professions Order 2001. Statutory Instrument 2002 No 254 Article 3(17)(a)

⁸⁸¹ The Health Professions Council. Guidance for occupations considering applying for regulation by the Health Professions Council. London: HPC. 2004

agreed definition for advanced nursing practice that is fit for modern purpose, and that would be able to differentiate clearly those nurses who were genuinely advanced from those who had chosen to expand their practice in a more traditional way.

In the event that the NMC is persuaded to make the regulatory changes that are required, it would be sensible for it to look to other regulators to learn lessons, in order that an appropriate regulatory model can be devised. Having already established that, although suitable for midwives, the midwifery model would not be ideal for advanced nurses, this leaves the GMC as the main regulator from whom the NMC could learn. Indeed, when one considers that it was not so long ago that the GMC was also under high level significant scrutiny - most notably in relation to the actions of Harold Shipman⁸⁸² and the events at Bristol Royal Infirmary⁸⁸³ - with questions having been asked about its stewardship of medical regulation⁸⁸⁴, and the GMC having only recently been singled out for praise, this makes a comparison between the NMC and GMC meaningful.

Central among the changes at the GMC from which the NMC could learn are those associated with the integration and alignment of all stages of medical education under the one continuum^{885,886,887}. By making this change, this has enabled the GMC to oversee the education of doctors at all stages of their clinical career, supported by the Royal Colleges and Faculties. With its practice founded on high quality education and training, both of which are the key to *Good Medical Practice*⁸⁸⁸, and high quality supervision recognised as being the

⁸⁸² The Shipman Inquiry Fifth Report: Safeguarding patients, lessons from the past - proposals for the future. Cm6394. London: HMSO. 2004

⁸⁸³ Department of Health. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 (The Kennedy Report). Cm5207(i). London: HMSO. 2001

⁸⁸⁴ Irvine D. The Doctor's Tale, Professionalism and Public Trust. London: Radcliffe Medical Press. 2003

⁸⁸⁵ Department of Health. The Secretary of State for Health's response to Aspiring to Excellence: Final report of the Independent Inquiry into Modernising Medical Careers. London: DH. 2008

⁸⁸⁶ Tooke J. Aspiring to excellence: Final report of the Independent Inquiry into Modernising Medical Careers (The Tooke Report). London: MMC Inquiry. 2008

⁸⁸⁷ General Medical Council. Final Report of the Education and Training Regulation Policy Review: Recommendations and options for the future regulation of education and training. London: GMC. 2010

⁸⁸⁸ General Medical Council. Good medical practice: guidance for doctors. London: GMC. 2009

key to excellence in clinical standards, the GMC also now provides an annual review of its 'medical education and practice processes' Focused on ensuring that its educational programmes are responsive to patients' needs, and informed by feedback and fitness to practise data, this approach has enabled it to provide more consistent standards and reduced variations in care, and deliver programmes in line with modern advances.

Alongside these developments are significant inroads that have been made to introduce a system of revalidation in medicine. Aimed at detecting those doctors who are not performing, and preventing them from practising clinically, revalidation will result in those doctors who have demonstrated learning and development commensurate with their posts, being awarded a 'licence' to Incorporated within the related arrangements are measures to practice. highlight concerns where there is scope for remediation, identify those areas where further investigation is required, and reveal poor practice where local systems are not robust enough or do not exist⁸⁹⁰. As such, the expectation is that the incidence of poor practice arising from doctors' conduct will be reduced, and the public's trust will be maintained, thus providing patients and the public with the reassurance that is needed. Given that most, if not all, advanced nursing practice derives from medicine, it seems reasonable to conclude that a similar - albeit not identical - model of revalidation could be provided for advanced nurses, thus enabling them to demonstrate to patients and the public that they are fit for both practice and purpose.

4.4. A new regulatory framework for advanced nursing practice

Despite its difficulties, and concerns that it may not be the most effective or efficient regulator, it is clear that the NMC is the body that is most appropriate to regulate advanced nursing practice, and to implement the changes that are required. This has been shown to be the case on the basis that nurses are still

London: GMC, 2012

⁸⁸⁹ General Medical Council. The state of medical education and practice in the UK: 2011.

⁸⁹⁰ Department of Health. Principles for Revalidation - Report of the Working Group for Non-Medical Revalidation. Leeds: DH. 2008

nurses, no matter how advanced their roles become, or the extent to which their advanced practice may be said to resemble that of medicine. Underlying this position is the fact that nurses have a different approach to care, and embody a more caring and compassionate function.

In order to provide a more robust and effective regulatory solution for advanced nurses, several options are possible for the NMC. First, it could continue to discharge its regulatory obligations in the way that has currently been adopted. However, given that this approach has already been shown to be unable to identify and differentiate those nurses who are advanced and to adequately protect the public from those nurses who purport to be advanced but are not fit to practise⁸⁹¹, this option will be dismissed on the basis that it has no logic.

Secondly, the NMC could retain the basic regulatory model that is in place, and supplement this by integrating all its education and practice functions under one regulatory umbrella, similar to the model that has been adopted by the GMC. This option would be dependent upon the NMC having first defined what advanced nursing actually means, and looks like in practice. It would also be dependent upon the NMC changing its approach, engaging more widely with stakeholders, and being more responsive to feedback. In the event that this option is accepted, it would be possible for the NMC to make any changes that would be necessary without the need for primary or secondary legislation, meaning that this solution would be reasonably straightforward to achieve. If so, it would also be prudent for the NMC to look to the GMC to learn further lessons, and to obtain relevant guidance.

Thirdly, the NMC could choose to adopt an approach that is more aligned to that which is associated with midwives, and open up a separate part of the Register for advanced nurses. Given that the NMC, through its model of midwifery regulation, has already been able to show that different types of nurse are able to be recognised - by virtue of a discrete body of knowledge and adherence to specific secondary legislation - there is no reason to suggest that advanced nurses would not be able to follow suit and adopt a similar regulatory model for

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⁸⁹¹ Nursing and Midwifery Council. Annual fitness to practise report 2011-2012. London: NMC. 2012

those nurses who are performing new clinical roles, such as those referred to in chapter 2. In the event of this option being selected, the NMC could choose to implement a regulatory model that relied upon a separate part of the Register being opened up for advanced nurses, with associated educational requirements and competencies devised against which clinical ability and competence could be measured. Alternatively, it could choose to implement a model of regulation that is supported by an associated system of *Nursing Rules*. If the latter approach is selected, it is possible, and, indeed, likely that secondary legislation would be required to implement the change that is required.

Significantly, particularly given the circumstances that are currently facing the NMC, all of these changes would enable the regulatory situation to be improved, with minimum intervention on the part of the NMC. Given that all of these options could be implemented without the need for additional statutory regulation or intervention - with the exception of a system of *Nursing Rules*, which would require secondary legislation - it would also enable change to be made while avoiding the need for the NMC to satisfy the criteria laid down by *Enabling Excellence*⁸⁹² and the 'right-touch' principles⁸⁹³. Importantly, this approach would also avoid the increase in costs that a new form of statutory regulation would be likely to entail. This would certainly be pleasing to nurses, politicians and the NMC, particularly in light of the adverse publicity that has recently been associated with the increase in NMC fee subscriptions - a rise that was largely attributed to an increase in fitness to practise cases^{894,895} and the inability of the NMC to deal with these effectively.

In acknowledging these options, and in recognising that change would be possible for the NMC to implement, it is important to also acknowledge the political will and momentum to regulate advanced nurses that had been generated prior to the most recent change in government and change in the direction of policy. Much of this momentum was generated by the recognition

⁸⁹² Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

⁸⁹³ Council for Healthcare Regulatory Excellence. Right-touch regulation. London: CHRE. 2010 ⁸⁹⁴ Nursing and Midwifery Council. Annual fitness to practise report 2010-2011. London: NMC. 2014

⁸⁹⁵ Nursing and Midwifery Council. Annual fitness to practise report 2011-2012. London: NMC. 2012

that few of those nurses who claimed to practise in an advanced way were found to actually have the qualifications they claimed to have ^{896,897}, and a number of nurses were found to have been practising beyond their level of competence ^{898,899,900,901}. This meant that the need for them to be recognised, and arguments surrounding their regulation had already been accepted.

Worthy of particular note is the fact that, not only had political leaders - in the form of the former Prime Minister, Gordon Brown - been convinced of the merits of regulating this group of nurses⁹⁰², but so too, had the former Chief Executive of the NMC been convinced of the benefits⁹⁰³. Indeed, in recent years the Professional Standards Authority (PSA)⁹⁰⁴ and the Department of Health (DH)⁹⁰⁵ had also indicated their support for this position, with discussions starting to focus on what form the required change should take and whether annotations should be permitted to the registration entries of those nurses who were practising in an advanced way^{906,907}. However, as has already been shown, this position changed with the advent of a new government and a new political landscape, which changed the way in which regulatory need is assessed and

⁸⁹⁶ Bostock N. 18% of nurses using NP title do not have the qualification. Healthcarerepublic 21 April 2008

⁸⁹⁷ Bostock N. One in six who use 'nurse practitioner' title do not have the qualification. Healthcarerepublic 23 April 2008

⁸⁹⁸ Castledine G. Practice nurse who expanded her role without appropriate training. British Journal of Nursing 2005;14(21):1141

⁸⁹⁹ Bostock N, Lepper J. Nurses working beyond competence. GP Online. December 14, 2007 http://www.gponline.com/News/article/772906/Nurses-working-beyond-competence/ (Last accessed 06.09.2010)

⁹⁰⁰ Kent K. Warning: nurses at work. Daily Mail (London), Mail Online. November 14, 2006 http://www.dailymail.co.uk/health/article-416299/Warning-Nurses-work.html (Last accessed 15.08.2008)

⁹⁰¹ Snow T. Nurses urged to resist prescribing requests outside their competence. Nursing Standard 2008;22(20):10

⁹⁰² Department of Health. Front line care: Report by the Prime Minister's Commission on the Future of Nursing and Midwifery in England. London: DH. 2010

⁹⁰³ Snow T. New head of NMC prepares to end impasse on advanced level practice. Nursing Standard 2010;24(21):12-13

⁹⁰⁴ Council for Healthcare Regulatory Excellence. Advanced practice: Report to the four UK Health Departments. London: CHRE. 2009

⁹⁰⁵ Department of Health. Advanced level nursing: a position statement. Leeds: DH. 2010

⁹⁰⁶ Council for Healthcare Regulatory Excellence. Managing extended practice: Is there a place for 'distributed regulation'? London: CHRE. June 2010

⁹⁰⁷ Health Professions Council. HPC Consultation on post-registration qualifications. London: HPC. 2011

addressed, with the approach taken having changed from one of regulatory need to one of regulatory minimalisation 908.

This brings the discussion back to the current situation, in which only those nurses who are practising in a traditional way are appropriately regulated, and where no additional provisions have been made for those nurses who have chosen to advance their practice in a more developed way. Given that the CNS, NP and CN roles are associated with extended and expanded practice - albeit to a very high level and sometimes to a higher level than those who have adopted new clinical roles - and their practice has not developed such that it constitutes a new clinical role, this suggests that the existing model of traditional regulation would suffice for these groups of nurses. This would be the case, even though these groups of nurses generally consider themselves to be advanced.

Rather, the new regulatory regimen would be required for those nurses whose practice is considered to be genuinely advanced and to constitute a new clinical role, such as those outlined in the four roles presented. This distinction has been reasserted as this group of nurses can be differentiated from those whose practice is advanced by virtue of a specialised skill set. Admittedly, this is likely to have been the vision that politicians had in mind when the CN role was first introduced, and, to a lesser extent, when the CNS and NP roles were first implemented. However, as time and practice have shown, these roles are more associated with career development over time, rather than new clinical roles, in contrast to the four roles that have been presented each of which constitutes a different clinical entity.

This leaves the NMC, as nursing's professional healthcare regulator, with the obligation to ask itself whether it wishes to see this discrete group of specialist nurses recognised in a distinct way. If so, it is possible that a model similar to that which has been adopted for midwives could be afforded to advanced nurses, with recognised educational requirements, clinical competencies, and codes of practice, ethics and behaviours being devised for them, supplementary to those which are already provided to traditional nurses. It is also possible that

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⁹⁰⁸ Department of Health. Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers. Cm8008. London: HMSO. 2011

this model could also see advanced nurses benefiting from a system of *Nursing Rules*, similar to the *Midwives Rules* which underpin midwifery practice, and a statutory Advanced Nursing Committee with a remit similar to that of the Midwifery Committee.

Admittedly, any regulatory model that would involve the creation of *Nursing Rules* or an Advanced Nursing Committee would require secondary legislation in order to be implemented. However, this would not be an insurmountable problem, and could be resolved with the requisite amount of drive and determination on the part of the NMC. As things stand, political changes have left the NMC to focus on delivering upon the core aspects of nursing regulation - an area in which it has already been identified as failing. Of course, this presumes that public protection from those nurses who are practising in an advanced way is not also a core regulatory duty. This is a presumption that is strongly rebutted. Indeed, it is asserted that if the Professional Standards Authority had made explicit reference to advanced practice within its reviews of the NMC, and recognised the fitness to practise of advanced nurses as also being a core regulatory duty, then it is likely that advanced nursing practice would now be given the attention that it arguably deserves.

There can be no doubt that all key stakeholders, including the public, politicians and nurses, are supportive of the NMC getting things right, and putting its house in order. There are similarly few who would argue against its primary focus as being on its performance of its core regulatory duties. However, if one is convinced that the public deserves to be protected equally from those who have chosen to practise in an advanced way as they are from those who have chosen to practise in a more traditional way, then one must also accept that the NMC is obligated to address this serious and important issue. In fact, if one accepts this argument, it follows that one will also accept the argument that the NMC cannot afford to wait much longer to make a decision in relation to advanced nursing, and would agree that this issue needs to be addressed as a matter of priority.

Considered collectively, these arguments present a compelling case for advanced nursing practice to be regulated. While it is accepted that this issue may not be able to be tackled immediately, given the current political

imperative, and acknowledging the imminent publication of the *Francis Inquiry*⁹⁰⁹ and the potential ramifications that this is likely to bring, it is imperative that this important issue, which arguably goes to the heart of public protection, remains on the NMC's agenda and becomes a priority.

Moving forward, it is averred that the NMC has a real opportunity to implement meaningful change, that will enable all types of nurses be to be distinguished in terms of their roles, competencies, codes and titles - and that this would provide the public with the level of protection that they arguably deserve. Indeed, it is asserted that if the NMC chose not to act, and the regulation of advanced nursing practice was to be taken out of its hands and into the hands of another professional regulator - such as the GMC- this would have huge and potential damaging ramifications for the future of advanced nursing and the profession as a whole. Accordingly, it is incumbent on the NMC to act, and to do so now. With failure to act not an option, and the absence of action signalling failure to address this unsatisfactory and potentially unsafe situation, this situation will serve only to reduce further public confidence in the regulatory process and the healthcare professions, jeopardise the integrity of the therapeutic relationship, and compromise patient safety and practitioner credibility.

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⁹⁰⁹ The Mid Staffordshire NHS Foundation Trust Inquiry. Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009 Volume 1. Chaired by Robert Francis QC (The Francis Inquiry). London: HMSO. 2010

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CASE LAW

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