Improving Legal Interpretations of Informed Consent in Practice

Jennifer O'Neill

B.Sc. (Hons.), Dip.H.E. (Med.), LL.B. (Hons.), FHEA

Submitted in fulfilment of the requirements for the Degree of Doctor of Philosophy by Published Work.

School of Medicine, Dentistry and Nursing,

College of Medical, Veterinary and Life Sciences,

University of Glasgow

October 2021

Abstract

The four publications included in this thesis embody a programme of research aimed at improving interpretations of informed consent to medical treatment in the United Kingdom (UK). Paper one considers the application of solidarity - often a concept associated with political debate - to bioethical issues. It examines leading conceptualisations of solidarity in healthcare and their relation to the practitioner-patient dynamic and standards of informed consent. In considering the interplay between ethical principles of solidarity and autonomy, the paper explains how current concepts of healthcare solidarity may undermine individual patient autonomy by creating imbalance in the practitioner-patient dynamic. Current constructs of solidarity are also considered to be exclusionary which, it is argued, may potentially lead to the othering of patients. The effects of patient exclusion and othering are examined in paper one and throughout the subsequent papers. In response to these issues, the novel concept of 'conjoint solidarity' is presented in contribution to the existing scholarship. It calls upon healthcare stakeholders (incorporating healthcare practitioners *and* patients) to adopt a duty to assist in the identification and achievement of improved healthcare outcomes. By recognising the epistemic value of both practitioners and patients, conjoint solidarity is said to promote an *inclusive* form of solidarity that promotes balance in the practitioner-patient dynamic and that will support, rather than undermine, autonomy. It is anticipated that by facilitating greater patient involvement in the decision-making process, trust can be rebuilt, and healthcare outcomes improved. From this ethical grounding, informed consent is explored through the subsequent three papers which address deficiencies in current interpretations of the legal standard for informed consent and propose new ways in which shared decision-making can be enhanced to mitigate against the kind of harms which have been witnessed in recent years.

Paper two explores the evolution of the legal standard of informed consent to medical treatment in the UK. It examines the development of the judicial precedence pertaining to informed consent through key cases such as *Bolam* v *Friern Hospital Management Committee* [1957], *Sidaway v Board of Governors* [1985], *Bolitho v City and Hackney HA* [1998], and *Montgomery v Lanarkshire* [2015]. Comparative analyses are drawn between concepts such as 'significant' and 'material' risk, and between the 'reasonable person' and 'particular patient' standards. It is argued that the legal interpretation of material risk is broad, and that patterns of judicial reasoning are suggestive of a move towards recognition of majority views on reasonableness. The paper describes how financial interests can influence healthcare practitioners to the extent that their practice may be harmful to the

patient and, therefore, concludes that potent financial interests – namely those likely to have greatest impact upon patterns of practice – may be interpreted as disclosable material risks under existing common law standards.

Paper three examines standards of informed consent in relation to the issues surrounding the use of pelvic (vaginal) mesh - as detailed in the 2020 Cumberlege Report - and questions whether improved interpretations of the informed consent process could mitigate against future harms. It is recognised that treatment selection - which remains a matter of professional judgement according to *Bolam v Friern Hospital Management Committee* [1956] - could be deemed exclusionary towards patients. Drawing on the concept of conjoint solidarity, it is suggested that patient-based evidence should be afforded greater consideration as part of evidence-based practice to promote a more inclusive healthcare system which affords greater recognition to the epistemic value of the patient to enhance overall shared decision-making. The concept of risk disclosure is also re-examined in relation to medical device implantation, and it is recommended that the long-term risks deriving from implantable devices, or indeed unknown risks associated with innovative treatment proposals, be deemed disclosable. In this way, patient autonomy can be upheld so that patients are afforded the opportunity to decide whether, or not, to incur such risk.

Paper four considers how the process of shared decision-making, which precedes informed consent, can be enhanced by facilitating active discussion [4]. In returning to the concept of relational autonomy, persuasion is presented as a means of promoting greater patient-practitioner dialogue and engagement which can allow patients to question and explore the information that is presented. The example of vaccine hesitancy is used to describe the ways in which the informed consent process can be used to tackle misinformation and promote confidence in medical treatments. The standard set out in *Montgomery* requires that patients be informed of benefits, material risks and reasonable treatment alternatives when consenting to medical treatment. On these grounds, it is suggested that informing patients of the benefits of vaccination could be a means of addressing misinformation. Threads of conjoint solidarity also run through the argument as it is suggested that disclosure of vaccination benefits, should relate to both the *individual* and *collective* benefits in terms of individual and herd immunity. This example is particularly reflective of the bridge which exists between relational autonomy and conjoint solidarity. The thesis then explores risks and expands upon the disclosure of 'individual risk'. It is suggested that risk of *not* vaccinating also be disclosed – both in terms of the risk of disease posed to individual and the most vulnerable in society. Persuasion is employed, not as a means of coercion, rather

as a means of engagement to ensure patients understand the information provided which may also help to address misinformation. Similarly, the patient is afforded the opportunity to 'persuade' the practitioner to understand their perspective, which is a departure from traditional models of the practitioner-patient relationship.

In presenting this work three key themes emerge: deficiencies in shared decision making arising from the practitioner-patient relationship, analysis of informed consent and its deficiencies, and proposals for improving interpretations of informed consent to ensure patients are engaged and informed. It is anticipated that the proposed recommendations will have utility for rebuilding patient trust and to enhance patient involvement to mitigate against recurrences of harms seen in the past.

Key Words: Conjoint Solidarity, Autonomy, Informed Consent, Relational Justice, Shared Decision Making, Healthcare Law, Ethics.

Acknowledgements

First and foremost, I would like to dedicate this thesis to my beloved grandad, [redacted]; my absolute hero and best friend. As I have grown older, I have come to realise that his greatest gift to me was his encouragement: he encouraged me to ask questions, to remain inquisitive and to never stop learning. This gift has not only shaped my academic life but has made me into the free-thinking woman I am today. This body of work is also in recognition of the circumstances in which we lost him, decades too soon. Due to a lack of informed consent, he was unknowingly subject to disproportionate risk. Risk, that he would not have agreed to incur, particularly given the limited benefit of the procedure, due to his absolute love of life. I hope that, in his memory, the recommendations made in this body of work will, in some way, improve healthcare for all, ensure that patient autonomy is respected, and that consent is *truly* informed.

This body of work is also dedicated to my inspirational mum, [redacted], who has provided me with constant support, encouragement and understanding. She has instilled a strong work ethic in me; always leading by example. My mum taught me the importance of moving forward no matter the set-back and to never be constrained by the limitations set by others. Had it not been for her belief in me, this work would not have been started, let alone finished. Thank you, Mum.

Also, with thoughts of my late granny [redacted] and uncle [redacted] who are much loved and always in my thoughts. And my late best friend [redacted], who wanted to see me become a different type of doctor; I know we would have had many a long debate about the issues raised in this thesis together!

I would like to thank the Scottish International Education Trust for the grant which supports this doctoral thesis (SIET Grant [T-C.FID324118]). I also extend a depth of gratitude to my advisor, Professor Al Dowie who has offered staunch support, advice and has played a vital role in providing reassurance during the times of doubt which inevitably arise during the trials and tribulations of publishing. I hope to remain friends and colleagues in years to come. Gratitude also goes to the host of friends, family, and colleagues who offered their support and patience during the writing of this thesis.

My thanks also go to others who have played a key role in identifying the opportunities to publish these papers - whether it be early discussions pertaining to ideas, reading early drafts, or providing research papers for consultation - each piece of advice or token of support has served as a steppingstone towards this end goal. I would also like to extend a broader debt of gratitude to my colleagues at European University Cyprus, particularly to Dean Professor Elizabeth Johnson for the opportunity to teach medical law and ethics which has been a great source of inspiration and motivation.

To the anonymous referees who have reviewed my manuscripts, my deepest thanks are extended – your comments, critiques and advised revisions, have undoubtedly strengthened these papers and the overall thesis.

Finally, to my much-loved miniature dachshund [redacted], who has spent endless hours sitting by my side as I drafted and re-drafted manuscripts. Most of this work was completed at home during the COVID-19 pandemic and he provided constant companionship, love, and support – his presence helped me to maintain the stamina to complete this work – albeit with the occasional distraction from his endearing ways!

Enlighten: Theses note: redactions due to personal data

Contents

Page

Publications included in the thesis

The papers have their original page numbers. They are included in the order shown.

[1] O'Neill J. (2021). Towards Conjoint Solidarity. *Bioethics*. 1-12. https://doi.org/10.1111/bioe.12940

[2] O'Neill J. (2021). Materiality of Conflict of Interest in Informed Consent to Medical Treatment in the United Kingdom. *Ethics & Behaviour.* DOI: https://doi.org/10.1080/10508422.2021.1963251

[3] O'Neill J. (2021). Lessons from the Vaginal Mesh Scandal: Enhancing the Patient-Centric Approach to Informed Consent for Medical Device Implantation. *International Journal of Technology Assessment in Health Car, 37(1), E53.* DOI: https://doi.org/10.1017/S0266462321000258

IV. Case for Persuasion in Parental Informed Consent to Promote Rational Vaccine Choices……..165

[4] O'Neill J. (2020) Case for Persuasion in Parental Informed Consent to Promote Rational Vaccine Choices. *Journal of Medical Ethics*. 10.1136/medethics-2020-106068

Author's Declaration and Copyright Information

Declaration of Originality

No portion of the work included in the thesis has been submitted in support of an application for another degree or qualification of this or any other university, institute of learning or professional body. I declare that the thesis embodies the results of my own work.

Copyright Statement

RIGHTS HOLDERS OTHER THAN THE AUTHOR AND DETAILS OF VERSIONS OF PAPERS INCLUDED IN THE PUBLIC ELECTRONIC VERSION OF THE THESIS		
Paper		**Rights holder**
1	The version included here is a pre-copyediting, author produced PDF of an article accepted for publication in **Bioethics** following peer review. The definitive publisher-authenticated version: [1][1] O'Neill J. (2021). Towards Conjoint Solidarity. *Bioethics*. 1-12. https://doi.org/10.1111/bioe.12940	The Author
2	The version included here is a pre-copyediting, author produced PDF of an article accepted for publication in the **Ethics and Behaviour**	The Author

	following peer review. The definitive publisher-authenticated version: https://doi.org/10.1080/10508422.2021.1963251	
3	The version included here is a pre-copyediting, author produced PDF of an article accepted for publication in the **International Journal of Technology Assessment in Healthcare** following peer review. The definitive publisher-authenticated version: O'Neill J. (2021). Lessons from the Vaginal Mesh Scandal: Enhancing the Patient-Centric Approach to Informed Consent for Medical Device Implantation. *International Journal of Technology Assessment in Health Car, 37(1), E53* is available here: doi:10.1017/S0266462321000258	The Author
4	The version included here is a pre-copyediting, author produced PDF of an article accepted for publication in the **Journal of Medical Ethics** following peer review. The definitive publisher-authenticated version: O'Neill J. (2020) Case for Persuasion in Parental Informed Consent to Promote Rational Vaccine Choices. *Journal of Medical Ethics* is available here: 10.1136/medethics-2020-106068	The Author

Licencing Agreements

Licensing Agreement for Paper 1

Bioethics

Published by Wiley (the "Owner")

COPYRIGHT TRANSFER AGREEMENT

Date: August 02, 2021

Contributor name: Jennifer O'Neill

Contributor address:

Manuscript number: BIOT-3511-10-20-SI.R2

Re: Manuscript entitled TOWARDS CONJOINT SOLIDARITY IN HEALTHCARE (the "Contribution")

for publication in Bioethics (the "Journal")

published by John Wiley & Sons Ltd ("Wiley")

Dear Contributor(s):

Thank you for submitting your Contribution for publication. In order to expedite the editing and publishing process and enable the Owner to disseminate your Contribution to the fullest extent, we need to have this Copyright Transfer Agreement executed. If the Contribution is not accepted for publication, or if the Contribution is subsequently rejected, this Agreement shall be null and void.
Publication cannot proceed without a signed copy of this Agreement.

A. COPYRIGHT

1. The Contributor assigns to the Owner, during the full term of copyright and any extensions or renewals, all copyright in and to the Contribution, and all rights therein, including but not limited to the right to publish, republish, transmit, sell, distribute and otherwise use the Contribution in whole or in part in electronic and print editions of the Journal and in derivative works throughout the world, in all languages and in all media of expression now known or later developed, and to license or permit others to do so. For the avoidance of doubt, "Contribution" is defined to only include the article submitted by the Contributor for publication in the Journal (including any embedded rich media) and does not extend to any supporting information submitted with or referred to in the Contribution ("Supporting Information"). To the extent that any Supporting Information is submitted to the Journal, the Owner is granted a perpetual, non-exclusive license to publish, republish, transmit, sell, distribute and otherwise use this Supporting Information in whole or in part in electronic and print editions of the Journal and in derivative works throughout the world, in all languages and in all media of expression now known or later developed, and to license or permit others to do so. If the Contribution was shared as a preprint, the Contributor grants to the Owner exclusivity as to any rights retained by the Contributor in the preprint.

2. Reproduction, posting, transmission or other distribution or use of the final Contribution in whole or in part in any medium by the Contributor as permitted by this Agreement requires a citation to the Journal suitable in form and content as follows: (Title of Article, Contributor, Journal Title and Volume/Issue, Copyright © [year], copyright owner as specified in the Journal, Publisher). Links to the final article on the publisher website are encouraged where appropriate.

B. RETAINED RIGHTS

Notwithstanding the above, the Contributor or, if applicable, the Contributor's employer, retains all proprietary rights other than copyright, such as patent rights, in any process, procedure or article of manufacture described in the Contribution.

C. PERMITTED USES BY CONTRIBUTOR

1. Submitted Version. The Owner licenses back the following rights to the Contributor in the version of the Contribution as originally submitted for publication (the "Submitted Version"):

a. The right to self-archive the Submitted Version on: the Contributor's personal website; a not for profit subject-based preprint server or repository; a Scholarly Collaboration Network (SCN) which has signed up to the STM article sharing principles [http://www.stm-assoc.org/stm-consultations/scn-consultation-2015/] ("Compliant SCNs"); or the Contributor's company/ institutional repository or archive. This right extends to both intranets and the Internet. The Contributor may replace the Submitted Version with the Accepted Version, after any relevant embargo period as set out in paragraph C.2(a) below has elapsed. The Contributor may wish to add a note about acceptance by the Journal and upon publication it is recommended that Contributors add a Digital Object Identifier (DOI) link back to the Final Published Version.

b. The right to transmit, print and share copies of the Submitted Version with colleagues, including via Compliant SCNs, provided that there is no systematic distribution of the Submitted Version, e.g. posting on a listserve, network (including SCNs which have not signed up to the STM sharing principles) or automated delivery.

2. Accepted Version. The Owner licenses back the following rights to the Contributor in the version of the Contribution that has been peer-reviewed and accepted for publication, but not final (the "Accepted Version"):

a. The right to self-archive the Accepted Version on: the Contributor's personal website; the Contributor's company/institutional repository or archive; Compliant SCNs; and not for profit subject-based repositories such as PubMed Central, all subject to an embargo period of 12 months for scientific, technical and medical (STM) journals and 24 months for social science and humanities (SSH) journals following publication of the Final Published Version. There are separate arrangements with certain funding agencies governing reuse of the Accepted Version as set forth at the following website: http://www.wileyauthors.com/funderagreements. The Contributor may not update the Accepted Version or replace it with the Final Published Version. The Accepted Version posted must contain a legend as follows: This is the accepted version of the following article: FULL CITE, which has been published in final form at [Link to final article]. This article may be used for non-commercial purposes in accordance with the Wiley Self-Archiving Policy [http://www.wileyauthors.com/self-archiving].

b. The right to transmit, print and share copies of the Accepted Version with colleagues, including via Compliant SCNs (in private research groups only before the embargo and publicly after), provided that there is no systematic distribution of the Accepted Version, e.g. posting on a listserve, network (including SCNs which have not signed up to the STM sharing principles) or automated delivery.

3. Final Published Version. The Owner hereby licenses back to the Contributor the following rights with respect to the final published version of the Contribution (the "Final Published Version"):

a. Copies for colleagues. The personal right of the Contributor only to send or transmit individual copies of the Final Published Version in any format to colleagues upon their specific request, and to share copies in private

sharing groups in Compliant SCNs, provided no fee is charged, and further provided that there is no systematic external or public distribution of the Final Published Version, e.g. posting on a listserve, network or automated delivery.

b. Re-use in other publications. The right to re-use the Final Published Version or parts thereof for any publication authored or edited by the Contributor (excluding journal articles) where such re-used material constitutes less than half of the total material in such publication. In such case, any modifications must be accurately noted.

c. Teaching duties. The right to include the Final Published Version in teaching or training duties at the Contributor's institution/place of employment including in course packs, e-reserves, presentation at professional conferences, in-house training, or distance learning. The Final Published Version may not be used in seminars outside of normal teaching obligations (e.g. commercial seminars). Electronic posting of the Final Published Version in connection with teaching/training at the Contributor's company/institution is permitted subject to the implementation of reasonable access control mechanisms, such as user name and password. Posting the Final Published Version on the open internet is not permitted.

d. Oral presentations. The right to make oral presentations based on the Final Published Version.

4. Article Abstracts, Figures, Tables, Artwork and Selected Text (up to 250 words).

a. Contributors may re-use unmodified abstracts for any non-commercial purpose. For online uses of the abstracts, the Owner encourages but does not require linking back to the Final Published Version.

b. Contributors may re-use figures, tables, artwork, and selected text up to 250 words from their Contributions, provided the following conditions are met:

(i) Full and accurate credit must be given to the Final Published Version.

(ii) Modifications to the figures and tables must be noted. Otherwise, no changes may be made.

(iii) The re-use may not be made for direct commercial purposes, or for financial consideration to the Contributor.

(iv) Nothing herein will permit dual publication in violation of journal ethical practices.

D. CONTRIBUTIONS OWNED BY EMPLOYER

1. If the Contribution was written by the Contributor in the course of the Contributor's employment as a "work-made-for-hire" in the course of employment, the Contribution is owned by the company/institution which must execute this Agreement (in addition to the Contributor's signature). In such case, the company/institution hereby agrees to the terms of use set forth in paragraph A above and assigns to the Owner, during the full term of copyright, all copyright in and to the Contribution for the full term of copyright throughout the world as specified in paragraph A above.

2. In addition to the rights specified as retained in paragraph B above and the rights granted back to the Contributor pursuant to paragraph C above, the Owner hereby grants back, without charge, to such company/institution, its subsidiaries and divisions, the right to make copies of and distribute the Final Published Version internally in print format or electronically on the Company's internal network. Copies so used may not be resold or distributed externally. However, the company/institution may include information and text from the Final Published Version as part of an information package included with software or other products offered for sale or license or included in patent applications. Posting of the Final Published Version by the company/institution on a public access website may only be done with written permission, and payment of any applicable fee(s). Also, upon payment of the applicable reprint fee, the company/institution may distribute print copies of the Final Published Version externally.

E. GOVERNMENT CONTRACTS

In the case of a Contribution prepared under U.S. Government contract or grant, the U.S. Government may reproduce, without charge, all or portions of the Contribution and may authorize others to do so, for official U.S. Government purposes only, if the U.S. Government contract or grant so requires. (U.S. Government, U.K. Government, and other government employees: see notes at end.)

F. COPYRIGHT NOTICE

The Contributor and the company/institution agree that any and all copies of the Final Published Version or any part thereof distributed or posted by them in print or electronic format as permitted herein will include the notice of copyright as stipulated in the Journal and a full citation to the Journal.

G. CONTRIBUTOR'S REPRESENTATIONS

The Contributor represents that: (i) the Contributor and all co-Contributors have the full power, authority and capability to enter into this Agreement, to grant the rights and license granted herein and to perform all obligations hereunder; (ii) neither the Contributor nor any co-Contributor has granted exclusive rights to, or transferred their copyright in, any version of the Contribution to any third party; (iii) the Contribution is the Contributor's original work, all individuals identified as Contributors actually contributed to the Contribution, and all individuals who contributed are included; (iv) if the Contribution was prepared jointly, the Contributor has informed the co-Contributors of the terms of this Agreement and has obtained their signed written permission to execute this Agreement on their behalf; (v) the Contribution is submitted only to this Journal and has not been published before, has not been included in another manuscript, and is not currently under consideration or accepted for publication elsewhere; (vi) if excerpts from copyrighted works owned by third parties are included, the Contributor shall obtain written permission from the copyright owners for all uses as set forth in the standard permissions form and the Journal's Author Guidelines, and show credit to the sources in the Contribution; (vii) the Contribution and any submitted Supporting Information contain no libelous or unlawful statements, do not infringe upon the rights (including without limitation the copyright, patent or trademark rights) or the privacy of others, do not breach any confidentiality obligation, do not violate a contract or any law, do not contain material or instructions that might cause harm or injury, and only utilize data that has been obtained in accordance with applicable legal requirements and Journal policies; and (viii) there are no conflicts of interest relating to the Contribution, except as disclosed. Accordingly, the Contributor represents that the following information shall be clearly identified on the title page of the Contribution: (1) all financial and material support for the research and work; (2) any financial interests the Contributor or any co-Contributors may have in companies or other entities that have an interest in the information in the Contribution or any submitted Supporting Information (e.g., grants, advisory boards, employment, consultancies, contracts, honoraria, royalties, expert testimony, partnerships, or stock ownership); and (3) indication of no such financial interests if appropriate.

Notwithstanding acceptance, the Owner or Wiley may (but is not obliged to) require changes to the Contribution, including changes to the length of the Contribution, and/or elect not to publish the Contribution if for any reason, in the Owner's or Wiley's reasonable judgment, such publication would be inconsistent with the Core Practices and associated guidelines set forth by the Committee on Publication Ethics (a not-for-profit organization based in the UK: https://publicationethics.org/core-practices) or would result in legal liability, violation of Wiley's ethical guidelines, or violation of journal ethical practices.

H. USE OF INFORMATION

The Contributor acknowledges that, during the term of this Agreement and thereafter, the Owner (and Wiley where Wiley is not the Owner) may process the Contributor's personal data, including storing or transferring data outside of the country of the Contributor's residence, in order to process transactions related to this Agreement and to communicate with the Contributor, and that the Publisher has a legitimate interest in processing the Contributor's personal data. By

entering into this Agreement, the Contributor agrees to the processing of the Contributor's personal data (and, where applicable, confirms that the Contributor has obtained the permission from all other contributors to process their personal data). Wiley shall comply with all applicable laws, statutes and regulations relating to data protection and privacy and shall process such personal data in accordance with Wiley's Privacy Policy located at: https://www.wiley.com/en-us/privacy.

[X] I agree to the COPYRIGHT TRANSFER AGREEMENT as shown above, consent to execution and delivery of the Copyright Transfer Agreement electronically and agree that an electronic signature shall be given the same legal force as a handwritten signature, and have obtained written permission from all other contributors to execute this Agreement on their behalf.

Contributor's signature (type name here): Jennifer O'Neill

Date: August 02, 2021

SELECT FROM OPTIONS BELOW:

[X] Contributor-owned work

[ ] U.S. Government work

Note to U.S. Government Employees

*A contribution prepared by a U.S. federal government employee as part of the employee's official duties, or which is an official U.S. government publication, is called a "U.S. government work", and is in the public domain in the United States. If the Contribution was not prepared as part of the employee's duties, is not an official U.S. government publication, or if at least one author is **not** a U.S. government employee, it is not a U.S. government work. If at least one author is **not** a U.S. government employee, then the non-government author should also sign the form, selecting the appropriate ownership option. If more than one author is not a U.S. government employee, one may sign on behalf of the others.*

[ ] U.K. Government work (Crown Copyright)

Note to U.K. Government Employees

The rights in a contribution prepared by an employee of a UK government department, agency or other Crown body as part of his/her official duties, or which is an official government publication, belong to the Crown and must be made available under the terms of the Open Government Licence. Contributors must ensure they comply with departmental regulations and submit the appropriate authorisation to publish. If your status as a government employee legally prevents you from signing this Agreement, please contact the Journal production editor. If this selection does not apply to at least one author in the group, this author should also sign the form, indicating transfer of those rights which that author has and selecting the appropriate additional ownership selection option. If this applies to more than one author, one may sign on behalf of the others.

[ ] Other

Including Other Government work or Non-Governmental Organisation work

Note to Non-U.S., Non-U.K. Government Employees or Non-Governmental Organisation Employees

If you are employed by the Australian Government, the World Bank, the World Health Organization, the International Monetary Fund, the European Atomic Energy Community, the Jet Propulsion Laboratory at California Institute of Technology, the Asian Development Bank, the Bank of International Settlements, USDA Agricultural Research Services, or are a Canadian Government civil servant, please download a copy of the license agreement from http://www.wileyauthors.com/licensingFAQ and upload the form to the Wiley Author Services Dashboard. If

your status as a government or non-governmental organisation employee legally prevents you from signing this Agreement, please contact the Journal production editor.

Name of Government/Non-Governmental Organisation:

_____

[ ] **Company/Institution owned work (made for hire in the course of employment)**
If you are an employee of Amgen, please download a copy of the company addendum from http://www.wileyauthors.com/licensingFAQ and return your signed license agreement along with the addendum. If this selection does not apply to at least one author in the group, this author should also sign the form, indicating transfer of those rights which that author has and selecting the appropriate additional ownership selection option. If this applies to more than one author, one may sign on behalf of the others.

Name of Company/Institution:

_____

Authorized Signature of Employer: _____

Date: _____

Signature of Employee: _____

Date: _____

Licencing Agreement for Paper 2

CC BY OPEN ACCESS LICENCE

This is a licence agreement under which you, the author, retain copyright in your article, and grant Taylor & Francis LLC (hereinafter 'Taylor & Francis') the exclusive licence to publish your article, including abstract, tables, figures, data, and supplemental material hosted by us, as the Version of Record in the Journal on an Open Access basis under a Creative Commons Attribution License (CC BY) http://creativecommons.org/licenses/by/4.0/ subject to the Terms & Conditions set out below.

ARTICLE TITLE ('Article'):	Materiality of Conflict of Interest in Informed Consent to Medical Treatment in the United Kingdom
ARTICLE DOI:	10.1080/10508422.2021.1963251
AUTHOR(S):	Jennifer ONeill
JOURNAL TITLE ('Journal'):	Ethics & Behavior
JOURNAL ISSN:	1532-7019

STATEMENT OF ORIGINAL COPYRIGHT OWNERSHIP / CONDITIONS

In consideration of the publication of the Article, you hereby grant with full title guarantee all rights of copyright and related rights in the above specified Article as the Version of Scholarly Record which is intended for publication in all forms and all media (whether known at this time or developed at any time in the future) throughout the world, in all languages, for the full term of copyright, to take effect if and when the Article is accepted for publication in the Journal.

GRANT OF PUBLISHING RIGHTS

I confirm that I have read and accept the full terms of the Journal's Article Publishing Agreement including the Terms & Conditions. I understand the article will be made available under the following access and use licence. I have read and understood the terms of this licence: Creative Commons Attribution License (CC BY).

I grant Taylor & Francis the rights to publish my article on an Open Access basis, in all forms and all media (whether known at this time or developed at any time in the future) throughout the world, including the right to translate the article into other languages, create adaptations, summaries or extracts of the article or other derivative works based on the article and the right to sub-license all such rights to others subject to the Terms & Conditions set out below, to take effect if and when the article is accepted for publication. If a statement of government or corporate ownership appears above, that statement modifies this assignment as described.

Signed and dated: **Jennifer ONeill, 03 August 2021 16:06 (UTC Europe/London)**

Taylor & Francis Group, LLC, 09 August 2021 13:34 (UTC Europe/London)

THIS FORM WILL BE RETAINED BY THE PUBLISHER.

TERMS & CONDITIONS

DEFINITION

Your article is defined as comprising (a) your Accepted Manuscript (AM) in its final form; (b) the final, definitive, and citable Version of Record (VoR) including the abstract, text, bibliography, and all accompanying tables, illustrations, data, and media; and (c) any supplemental material hosted by Taylor & Francis. This grant of license and these Terms & Conditions constitute the entire agreement and the sole understanding between you and us ('agreement'); no amendment, addendum, or other communication will be taken into account when interpreting your and our rights and obligations under this agreement, unless amended by a written document signed by both of us.

TAYLOR & FRANCIS' RESPONSIBILITIES

If deemed acceptable by the Editors of the Journal, we shall prepare and publish your article in the Journal. We may post your accepted manuscript as free-to-access in advance of the formal publication of the Version of Record (VoR). We shall publish the VoR in the Journal on an Open Access basis, viz., to be made freely available online with no subscription fee or article-pay-to-view fee or any other form of access fee or any publication embargo being applied. We reserve the right to make such editorial changes as may be necessary to make the article suitable for publication or as we reasonably consider necessary to avoid infringing third-party rights or breaching any laws; and we reserve the right not to proceed with publication for whatever reason.

If before publication we reasonably consider that the article should not be published, on the advice of our legal advisors, we may decline to publish the article, in which case we will refund you any Article Publishing Charge you have paid.

If after publication we reasonably consider that the article should be retracted or removed from our website, on the advice of our legal advisors, for example, because of a breach in your Author Warranties, we may retract and withdraw it, and in such case shall be under no obligation to refund you any Article Publishing Charge you have paid.

You hereby expressly grant us the right to bring an action for infringement of copyright in relation to your article, pursuant to US copyright code section 501, or any corresponding law elsewhere in the world.

If we do not receive payment of the applicable Article Publishing Charge six (6) weeks after we issue you an invoice; or six (6) weeks after Open Access publication if we have received insufficient invoice informationfrom you, we reserve the right to rescind the Open Access status of your article and to publish it on an alternative licence basis.

YOUR RIGHTS AS AUTHOR

These rights are personal to you, and your co-authors, and cannot be transferred by you to anyone else. You assert and retain the following rights as author(s):

1. The right to re-use your own work on a commercial or non-commercial basis, and in any way permitted under the Creative Commons Attribution License (CC BY), including but not limited to, translation, adaptation, and resale.
2. The right to be identified as the author of your article, whenever and wherever the article is published, as defined in US Law 94-553 (Copyright Act) and, so far as is legally possible, any corresponding rights we may have in any territory of the world.
3. The right to retain patent rights, trademark rights, or rights to any process, product or procedure described in your article.
4. The right to post and maintain at any time your 'Author's Original Manuscript (AOM), i.e., the unpublished version of the article created by you prior to peer review.

WARRANTIES MADE BY YOU AS AUTHOR

5. You warrant that:
    1. All persons who have a reasonable claim to authorship are named in the article as co-authors including yourself, and you have not fabricated or misappropriated anyone's identity, including your own.
    2. You have been authorized by all such co-authors to sign this Agreement as agent on their behalf, and to agree on their behalf the priority of the assertion of copyright and the order of names in the publication of the article.
    3. The article is your original work, apart from any permitted third-party copyright material you include, and does not infringe any intellectual property rights of any other person or entity and cannot be construed as plagiarizing any other published work, including your own published work.
    4. The article is not currently under submission to, nor is under consideration by, nor has been accepted by any other journal or publication, nor has been previously published by any other journal or publication, nor has been assigned or licensed by you to any third party.
    5. The article contains no content that is abusive, defamatory, libelous, obscene, fraudulent, nor in any way infringes the rights of others, nor is in any other way unlawful or in violation of applicable laws.
    6. Research reported in the article has been conducted in an ethical and responsible manner, in full compliance with all relevant codes of experimentation and legislation. All articles which report *in vivo* experiments or clinical trials on humans or animals must include a written statement in the Methods section that such work was conducted with the formal approval of the local human subject or animal care committees, and that clinical trials have been registered as applicable legislation requires.
    7. Any patient, service user, or participant (or that person's parent or legal guardian) in any research or clinical experiment or study who is described in the article has given written consent to the inclusion of material, text or image, pertaining to themselves, and that they acknowledge that they cannot be identified via the article and that you have anonymized them and that you do not identify them in any way. Where such a person is deceased, you warrant you have obtained the written consent of the deceased person's family or estate.
    8. You have complied with all mandatory laboratory health and safety procedures in the course of conducting any experimental work reported in your article; your article contains all appropriate warnings concerning any specific and particular hazards that may be

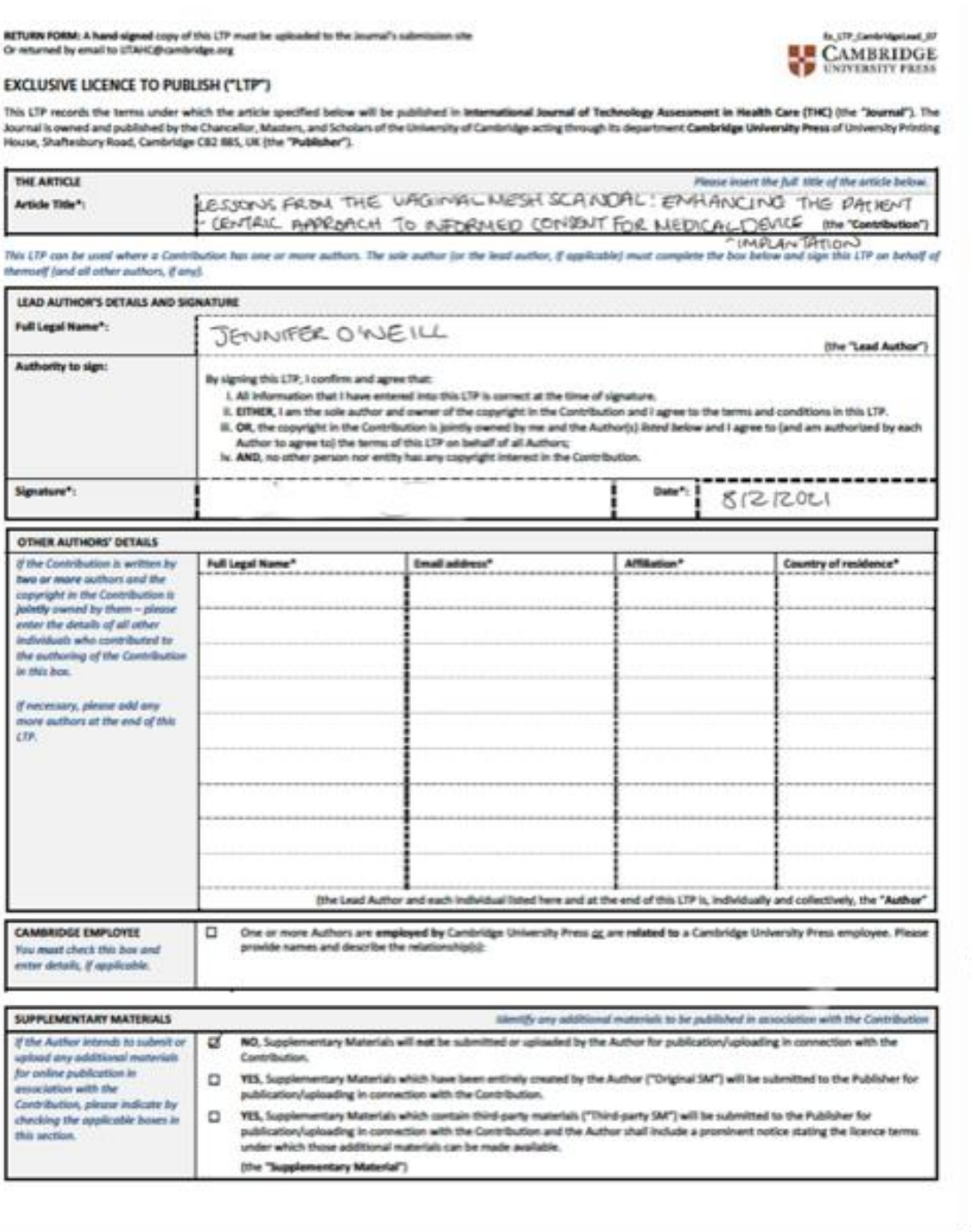
involved in carrying out experiments or procedures described in the article or involved in instructions, materials, or formulae in the article; your article includes explicitly relevant safety precautions; and cites, if an accepted Standard or Code of Practice is relevant, a reference to the relevant Standard or Code.

9. You have acknowledged all sources of research funding, as required by your research funder, and disclosed any financial interest or benefit you have arising from the direct applications of your research.
10. You have obtained the necessary written permission to include material in your article that is owned and held in copyright by a third party, which shall include but is not limited to any proprietary text, illustration, table, or other material, including data, audio, video, film stills, screenshots, musical notation and any supplemental material.
11. You have read and complied with our policy on publishing ethics.
12. You have read and complied with the Journal's Instructions for Authors.
13. You will keep us and our affiliates indemnified in full against all loss, damages, injury, costs and expenses (including legal and other professional fees and expenses) awarded against or incurred or paid by us as a result of your breach of the warranties given in this Agreement.
14. You consent to allowing us at our discretion to post an accepted manuscript (AM) versions of your article before we publish the Version of Record (VoR) in the Journal, on the basis that our quality assurance process may reveal errors which could affect the meaning and content of the precedent AM, and thus all legal disclaimers that apply to the Journal relate to any AM we post.
15. You consent to allowing us to use your article for marketing and promotional purposes.
16. You agree to provide us, if we so request, with access to and/or copies of any source research data and data sets used in preparing the article within fourteen (14) days of such request or such other time as may be agreed.

GOVERNING LAW

6. This agreement (and any dispute, proceeding, claim or controversy in relation to it) is subject to US copyright laws.

Licensing Agreement for Paper 3



RETURN FORM: A **hand-signed** copy of this LTP must be uploaded to the Journal's submission site
Or returned by email to IJTAHC@cambridge.org

fs_LTP_CambridgeLead_07

CAMBRIDGE UNIVERSITY PRESS

EXCLUSIVE LICENCE TO PUBLISH ("LTP")

This LTP records the terms under which the article specified below will be published in **International Journal of Technology Assessment in Health Care (IJHC)** (the **"Journal"**). The Journal is owned and published by the Chancellor, Masters, and Scholars of the University of Cambridge acting through its department **Cambridge University Press** of University Printing House, Shaftesbury Road, Cambridge CB2 8BS, UK (the **"Publisher"**).

THE ARTICLE — *Please insert the full title of the article below.*

Article Title*: LESSONS FROM THE VAGINAL MESH SCANDAL: ENHANCING THE PATIENT-CENTRIC APPROACH TO INFORMED CONSENT FOR MEDICAL DEVICE IMPLANTATION (the **"Contribution"**)

This LTP can be used where a Contribution has one or more authors. The sole author (or the lead author, if applicable) must complete the box below and sign this LTP on behalf of themself (and all other authors, if any).

LEAD AUTHOR'S DETAILS AND SIGNATURE

Full Legal Name*: JENNIFER O'NEILL (the **"Lead Author"**)

Authority to sign:

By signing this LTP, I confirm and agree that:

i. All information that I have entered into this LTP is correct at the time of signature.
ii. **EITHER,** I am the sole author and owner of the copyright in the Contribution and I agree to the terms and conditions in this LTP.
iii. **OR,** the copyright in the Contribution is jointly owned by me and the Author(s) *listed* below and I agree to (and am authorized by each Author to agree to) the terms of this LTP on behalf of all Authors;
iv. **AND,** no other person nor entity has any copyright interest in the Contribution.

Signature*: **Date*:** 8/2/2021

OTHER AUTHORS' DETAILS

If the Contribution is written by ***two or more*** *authors and the copyright in the Contribution is* ***jointly*** *owned by them – please enter the details of all other individuals who contributed to the authoring of the Contribution in this box.*

If necessary, please add any more authors at the end of this LTP.

Full Legal Name*	Email address*	Affiliation*	Country of residence*

(the Lead Author and each individual listed here and at the end of this LTP is, individually and collectively, the **"Author"**

CAMBRIDGE EMPLOYEE
You ***must*** *check this box and enter details, if applicable.*

☐ One or more Authors are **employed by** Cambridge University Press or are **related to** a Cambridge University Press employee. Please provide names and describe the relationship(s):

SUPPLEMENTARY MATERIALS — *Identify any additional materials to be published in association with the Contribution*

If the Author intends to submit or upload any additional materials for online publication in association with the Contribution, please indicate by checking the applicable boxes in this section.

☑ **NO,** Supplementary Materials will **not** be submitted or uploaded by the Author for publication/uploading in connection with the Contribution.

☐ **YES,** Supplementary Materials which have been entirely created by the Author ("Original SM") will be submitted to the Publisher for publication/uploading in connection with the Contribution.

☐ **YES,** Supplementary Materials which contain third-party materials ("Third-party SM") will be submitted to the Publisher for publication/uploading in connection with the Contribution and the Author shall include a prominent notice stating the licence terms under which those additional materials can be made available.

(the **"Supplementary Material"**)

1 STANDARD TERMS AND CONDITIONS

1.1 The Author hereby agrees to be bound by all terms and conditions in this LTP.

2 LICENCE

2.1 The term **"Contribution"** means the article written by the Author as identified on page one of this LTP and includes, without exception, all the following versions of the article:

2.1.1 **Submitted Manuscript Under Review ("SMUR")**: any version of the Contribution that is under formal review for inclusion in the Journal.

2.1.2 **Accepted Manuscript ("AM")**: the version of the Contribution that has been accepted for publication. This version may include revisions resulting from peer review but may be subject to further editorial input by the Publisher.

2.1.3 **Version of Record ("VoR")**: the version of the Contribution that is formally published in the Journal. This includes any '*FirstView* article' that is formally identified as being published before the compilation of a volume or issue as long as it is citable via a permanent identifying Digital Object Identifier (**"DOI"**). This does not include any 'early release article' that has not yet been fixed by processes that are still to be applied, such as copy-editing, proof corrections, layout, and typesetting. The VoR includes any corrected or enhanced VoR.

2.2 The term **"Supplementary Material"** means any additional written or illustrative materials submitted or uploaded to the Journal by the Author for publication in connection with the Contribution. Supplementary Material does not form part of the Contribution and will be made available in association with the Contribution in online format only. Supplementary Material may be original content created by the Author (**"Original SM"**) or it may be third-party material sourced and cleared in accordance with Clause 6 below by the Author (**"Third-party SM"**).

2.3 In consideration of publication of the Contribution, the Author hereby grants to the Publisher:

2.3.1 an exclusive licence to publish, reproduce, distribute, and sell the Contribution or any part of it in all forms and media and in all languages throughout the world, whether print, digital / electronic, whether now known or hereinafter invented, and to grant sublicences of all translation and subsidiary rights;

2.3.2 an exclusive licence to exploit all other rights in the nature of copyright, including rental, lending and database rights and all other publishing and print on demand rights in the Contribution;

2.3.3 a non-exclusive licence to publish, reproduce, distribute, and sell any Supplementary Material or any part of it in all forms and media and in all languages throughout the world, whether print, digital / electronic, whether now known or hereinafter invented, and to grant sublicences of all translation and subsidiary rights; and

2.3.4 a non-exclusive licence to exploit all other rights in the nature of copyright, including rental, lending and database rights and all other publishing and print on demand rights in any Supplementary Material.

2.4 The licences described in Clause 2.3 above shall, throughout this LTP, be referred to collectively as the **"Licence"**.

2.5 The Licence shall commence upon the Publisher's formal acceptance to publish the Contribution and shall endure for the legal term of copyright in the Contribution.

2.6 The Author hereby asserts his/her/their moral right always to be identified as the author of the Contribution in accordance with the provisions of the UK Copyright, Designs and Patents Act 1988.

3 GREEN OPEN ACCESS

3.1 **"Green Open Access"** refers to the Author's right to self-archive specified digital versions of the Contribution notwithstanding the Licence.

3.2 Under the Journal's current Green Open Access policy (which may be updated from time to time), the Author retains the non-exclusive, non-transferable, non-commercial right to re-use or deposit digital versions of the Contribution as specified in the table below:

Version	Author(s)'s personal webpage	Author(s)'s departmental / institutional repository	Non-commercial subject repository	Commercial repository / social media
SMUR	Any time	Any time	Any time	Any time
AM	On acceptance	**6 months** after initial publication of VoR	**6 months** after initial publication of VoR	**Abstract only** + link to COPP
VoR	**Abstract only** + link to COPP	**Abstract only** + link to COPP	**Abstract only** + link to COPP	**Abstract only** + link to COPP

3.3 For the avoidance of doubt, the Author accepts that:

3.3.1 reuse of the Contribution under the Green Open Access policy does not affect the Licence;

3.3.2 the Green Open Access policy does **not** permit the full Contribution, in AM or VoR form, to be placed on any commercial website, platform, repository or scholarly collaboration network including, but not limited to: *ResearchGate*, *Academia.edu*, *Mendeley* or *LinkedIn*.

3.4 All reuses of the Contribution under the Journal's Green Open Access policy must include:

3.4.1 a link to the Contribution on Cambridge University Press's Online Publication Platform (**"COPP"**) using a DOI link, e.g. *http://dx.doi.org/[DOI];*

3.4.2 a clear statement indicating what the end-users' rights are relating to their right to use the version of the Contribution in question; and

3.4.3 a clear statement that the Contribution has been accepted for publication and will appear in a revised form subject to peer review and/or input from the Journal's editor.

3.5 For further details and latest information about any updates to the Green Open Access policy, please follow the relevant hyperlinks at: **https://www.cambridge.org/core/services/open-access-policies.** In the event of any inconsistency between the Green Open Access policy provided online at the URL above and the provisions of Clauses 3.2 and/or 3.3 above, then the online Green Open Access policy information shall take precedence, (except that nothing in the online policy shall prevent the Author from using the Contribution as permitted under this LTP).

4 OTHER PERMITTED REUSE OF THE CONTRIBUTION

4.1 In addition to the reuse permitted by the Green Open Access policy, the Author may reuse the Contribution in accordance with the Publisher's content reuse policy, the provisions of which are detailed here: **https://www.cambridge.org/about-us/rights-permissions/faqs/**.

4.2 For any other reuse of the Contribution which is not covered under this LTP, the Author must approach the Publisher to request permission.

5 UNDERTAKINGS AND REPRESENTATIONS

5.1 The Author hereby undertakes and represents that:

5.1.1 each named Author has full authority and power to agree to this LTP;

5.1.2 the Lead Author has full authority to execute this LTP on behalf of the Author;

5.1.3 the Contribution is original and has not been previously published in whole or in part;

5.1.4 the Contribution and any Supplementary Material contain nothing that infringes any existing copyright or licence or any other intellectual property right of any third-party;

5.1.5 the Contribution and any Supplementary Material contain nothing that breaches a duty of confidentiality or discloses any private or personal information of any person without that person's written consent;

5.1.6 all statements contained in the Contribution and any Original SM purporting to be facts are true and any formula, instruction or equivalent contained therein will not, if followed accurately, cause any injury or damage to the user;

5.1.7 the Contribution and any Supplementary Material do not contain any libellous or otherwise unlawful material, or any material which would harm the reputation of the Publisher;

5.1.8 there are no actual or apparent conflicts of interest connected to the Contribution that have not previously been declared. A conflict of interest is understood to exist if an interest (financial or otherwise) exerts or appears to exert undue influence on the analysis or conclusions in the Contribution, the choice of subject matter, or in any other way that impedes or appears to impede the Author's objectivity or independence.

5.2 In the event that the Author is in breach of any of these undertakings the Publisher shall have the right to cease making the Contribution and/or any Supplementary Material available and/or to require that the Author makes any necessary revisions to the Contribution and/or any Supplementary Material (including any factual information). Any such revisions shall be governed by this LTP.

6 THIRD-PARTY MATERIALS

6.1 The Author further confirms that for (i) any Third-party SM and (ii) any other third-party material (including but not limited to textual, illustrative, audio and video content) within the Contribution:

6.1.1 licences to re-use said content throughout the world in all languages and in all forms and media have or will be obtained from the rights-holders;

6.1.2 appropriate acknowledgement to the original source of all such materials has been made; and

6.1.3 in the case of audio/video material, appropriate release forms have been obtained from the individual(s) whose likenesses are

represented in the Contribution and/or Third-party SM, as applicable.

6.2 Copies of all licences and/or release documentation acquired in accordance with Clause 6.1 above will, on request, be forwarded to the Journal's editor prior to publication of the Contribution.

7 MISCELLANEOUS

7.1 The Publisher cooperates with various copyright licensing schemes which allow material to be photocopied within agreed restraints (e.g. the Copyright Clearance Center in the U.S and the Copyright Licensing Agency in the UK). Any proceeds received by the Publisher from such licences, together with any proceeds resulting from sales of subsidiary rights in the Contribution, shall be used by the Publisher to support the continuing publication of its academic works.

7.2 The information contained in this LTP will be held for record-keeping purposes. The names of the Author may be reproduced in the Journal and provided to print and online indexing and abstracting services and bibliographic databases. The Publisher complies with applicable data protection and privacy laws in the collection, retention, storage, and use of personal data.

8 ENTIRE AGREEMENT

8.1 This LTP is made between, and contains the entire agreement between, the Publisher and the Author concerning the Contribution and supersedes all related prior agreements, arrangements and understandings (whether written or oral). No addition to or modification of any provision of this LTP shall be binding unless it is in writing and signed on behalf of the Publisher and the Author.

8.2 This LTP is governed by the law of England and Wales and is subject to the exclusive jurisdiction of the English courts.

ADDITIONAL AUTHORS' DETAILS

If the Contribution is written by two or more authors and the copyright in the Contribution is jointly owned by them – please enter the details of all other individuals who contributed to the authoring of the Contribution in this box.

If necessary, please photocopy this page and attach it to your LTP.

Full Legal Name*	Email address*	Affiliation*	Country of residence*

(the Lead Author and each individual listed here and at the beginning of this LTP is, individually and collectively, the "Author"")

PLEASE NOTE: Amended/alternative versions of this LTP will not be accepted and may delay or prevent publication

Licencing Agreement for Paper 4

Author Licence BMJ Publishing Group Limited (BMJ): The BMJ and BMJ Journals – BMJ wholly owned or co-owned journals

Parties

In this document references to "BMJ", "We" and "Us" are to **BMJ Publishing Group Limited** (a company incorporated in England with company number, 3102371 whose registered office is BMA House, Tavistock Square, London WC1H 9JR); and references to "You" are to the Submitting Author.

1. Definitions

1.1. The following definitions and rules of interpretation apply in this licence:

Authors:	the Submitting Author and any co-authors. Author shall mean any one of the Submitting Author or any co-author.
Author's Accepted Manuscript	the final draft version of the Work, which has been accepted for publication in the Journal & peer reviewed but not copyedited, typeset or published.
Author's Original Version (Preprint)	the pre review version of the Work that is submitted to the Journal or any earlier draft, which has not been peer reviewed.
Commercial Use	any use of any part of the Work for i) any commercial gain without the Agreement of BMJ, including without limitation, charging fees for delivery or access to the Work (whether on a standalone basis or included within any work), associating advertising to the Work or providing hosting services to other repositories or to other organisations (including where an otherwise non commercial site or repository provides a service to other organisations or agencies); or ii) to substitute the services provided by BMJ in relation to Work or the Journal the Work may be included within. This may include systematic distribution or articles by any means (such as print, email, posting, indexing or linking) and/or any use for promotional or marketing activities by commercial companies including for use by their customers or intended audiences (for example by pharmaceutical companies to healthcare professionals or patients).
Intellectual Property Rights:	all copyright and related rights, trademarks, service marks, trade, business and domain names, rights in goodwill or to sue for passing off, database right, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and all similar or equivalent rights or forms of protection in any part of the world.
Journal:	a journal published by BMJ.
Open Access Article(s):	a Version of Record which in accordance with BMJ's written policies (which may involve a requirement to pay an article publishing charge) is agreed with the Authors to be made available to access without charge, which may be re-used by third parties in accordance with clause 8.
Submitting Author:	the author who submits the Work to BMJ for publication in the Journal.
Version of Record:	the version of the Work published by BMJ in the Journal.
Work:	the work You have submitted for publication in the Journal. Work shall include all text, audio, video and audio-visual material, abstracts, databases, tables, data, diagrams, photographs and other images or illustrative material and including all drafts of the Work, the version of the Work accepted for publication by BMJ and the Version of Record.

1.2. Unless the context otherwise requires, words in the singular include the plural and in the plural include the singular.

1.3. Headings are for convenience only and do not affect the interpretation of this licence.

1.4. Any words following the term including or any similar expression shall be construed as illustrative only and shall not limit

the sense of the words preceding it.

1.5. A reference to a statute is a reference to such statute as amended.

2. Licence and publication of the Work

2.1. In consideration for BMJ evaluating whether to publish the Work, You grant a worldwide, irrevocable, royalty free, licence to BMJ (and, where the Journal is co-owned by BMJ to the co-owners of the Journal) in perpetuity to:

2.1.1. edit, adapt, publish, distribute, display, reproduce, translate and store the Work (and any derivative works based on the Work created under this licence) in all media and on all distribution platforms including social media platforms, whether now known or in the future developed or discovered, and whether as part of BMJ's products and services or as part of other content owned, controlled or represented by BMJ;

2.1.2. include the Work in collections of other work and create summaries, extracts, abstracts and other derivative works based in whole or in part on the Work;

2.1.3. convert the Work into any format, including audio;

2.1.4. exploit all subsidiary rights that exist or may exist in the future in the Work including in relation to metadata;

2.1.5. include electronic links from the Work to any third party material; and

2.1.6. licence third parties to do any or all of the above.

2.2. We will make every effort to consult with You or another Author if substantial changes are made. You acknowledge and agree that BMJ may in its sole discretion publish any versions of the Work submitted to BMJ by You and any peer reviews of the Work and responses from You, or another Author and third parties relating to the Work.

2.3. You hereby authorise BMJ to take such steps as BMJ considers necessary to prevent infringement of Intellectual Property Rights in the Work or infringement of rights granted to BMJ by You under this licence without recourse to You.

2.4. You agree that BMJ may retract the Version of Record or publish a correction or other notice in connection with the Version of Record at any time and without further recourse to You.

2.5. In the case of Work that has been submitted for publication as an Open Access Article only, BMJ will submit the Version of Record and any expression of concern or retraction or other notices to PubMed Central ("PMC") and its mirror sites promptly after publication by BMJ. For all other Works, where the funding body for that Work is identified as a funder here: http://www.sherpa.ac.uk/juliet/index.php ("Sherpa Funder") and that funder requires deposit to PMC and its mirror sites, the Author or its funding body may deposit a copy of the Author's Accepted Manuscript (but not the Version of Record) in PMC and its mirror sites (and which must include any expression of concern, retraction or other notices) after an embargo period of 12 (twelve) months from the publication date of the Version of Record or earlier if required by the Sherpa Funder.

3. Ownership of rights in the Work

3.1. All Intellectual Property Rights in the Work remain with the Authors (or their employers as the case may be) and each Author shall be permitted to make such use of the Work as it set out in clause 6.

3.2. The licence granted to BMJ in clause 2 is an exclusive licence other than: i) where the Work is created in whole or part by UK Crown employees whose work is subject to Crown copyright and their contribution to the Work cannot be licensed on an exclusive basis, ("UK Crown Employees"); ii) BMJ has agreed in accordance with clause 8.2 that CC-BY shall apply; or iii) where the Work is created in whole or part by US Federal Government officers or employees as part of their official duties. In those circumstances, the following applies:

3.2.1. The Work (or any part of the Work) created by UK Crown Employees is licensed to BMJ on the same terms as set out in clause 2 save that the licence in respect of their part of the Work shall be nonexclusive;

3.2.2. The Work is subject to clause 8.2 herein and therefore it is agreed that CC-BY shall apply. In such cases the Work is licensed to BMJ on the same terms as set out in clause 2 save that the licence shall be nonexclusive;

3.2.3. No licence is required from the Author to publish the elements of the Work created by US Federal Government officers or employees, as part of their official duties, however new international Intellectual Property Rights may apply to the Work, and therefore the terms of this Agreement shall continue to apply, other than where they are inconsistent with law.

4. Warranties

4.1. You warrant that:

4.1.1. You are authorised to enter into this Agreement on behalf of all Authors, including without limitation, to grant all rights and adhere to all obligations;

4.1.2. the Work comprises the original work of the Authors and has not been copied (in whole or in part) from any other work or material, or any other source;

4.1.3. no person other than the Authors named on the Work has been involved in the creation of the Work;

4.1.4. if the Work (or any part of the Work) has been created in the course of employment You have all necessary written releases required to enter into this licence from any employer;

4.1.5. other than as expressly permitted in clause 6 herein, the Work has not previously been published (in whole or in part) and (save in the case of US Federal Government officers or employees) You are the sole, unencumbered absolute legal and beneficial owner(s) of all Intellectual Property Rights in the Work (or You have obtained the necessary assignments or licences required for publication under this licence);

4.1.6. the Work does not infringe the Intellectual Property Rights, moral rights or any other right of any third party;

4.1.7. written consent has been obtained from patients if any part of the Work includes patient data (whether or not anonymised) and such written patient consent shall be provided to Us immediately if We request it;

4.1.8. to the best of Your knowledge:

a) the Work does not contain material that is obscene blasphemous, libellous, obtained directly or indirectly in breach of confidence or is otherwise objectionable;

b) all statements of fact in the Work are true and correct and no advice, formula, or instruction in the Work will, if followed or implemented by any person, cause loss, damage or injury to them or any other person;

4.1.9. You will not make any use of the Work other than as permitted under fair dealing provisions of the Copyright Design and Patents Act 1988 or as set out in this licence, without Our prior written consent;

4.1.10. declarations of competing interests submitted by the Authors are and shall remain accurate and You will notify Us in writing of any changes to such competing interests immediately; and

4.1.11. all information supplied to Us shall be accurate.

5. **Bribery and corruption.** You agree to comply with all applicable laws relating to anti-bribery and corruption including the Bribery Act 2010 and to comply with BMJ's anti-bribery policy (published on the website bmj.com). You must notify Us immediately if You become aware of, or have grounds for suspecting, fraud or malpractice in connection with the Work. For the purposes of this clause malpractice includes giving or receiving any financial or other advantage that may be construed as a bribe under the Bribery Act 2010 or any other applicable law).

6. **Permitted uses by owners of the Work**

6.1. Any Author may make the following uses of the Work under this Agreement provided such uses are not a Commercial Use. Each Author shall be entitled to:

6.1.1. reproduce a reasonable number (no more than 100) print copies of the Version of Record for personal use;

6.1.2. send an individual copy of the Version of Record to colleagues within their institution and/or department, collaborators on any project they are working on, and anyone who directly requests a copy from them, in print or electronic form provided that there is no automatic distribution, only a single copy is supplied to each to any of the aforementioned recipients, they make the recipient know their use must be personal and not a Commercial Use, that the Author ensures no fee is charged and may not distribute any copies on a systematic basis including by mass e-mailings;

6.1.3. include the Version of Record in a compilation of material for educational use in the Authors' institutions provided these are distributed free of charge to students, or are stored in digital format in data rooms for access by students as part of their course work, or distributed for in house training programmes at the Authors' institutions, or are distributed at seminars or conferences subject to a limit of 100 copies for each conference or seminar;

6.1.4. place the Author's Accepted Manuscript (but not the Version of Record unless the Work is agreed with BMJ to be an Open Access Article in which case it can be the Version of Record) and the published abstract of the Version of Record on:

i) that Author's own or institution's website (which must be non commercial); and/or

ii) Your institution's repository (and such an institution must be academic or scholarly);

6.1.5. place the Author's Accepted Manuscript (but not the Version of Record unless the Work is agreed with BMJ to be an Open Access Article in which case it can be the Version of Record) in a Scholarly Collaboration Network ("SCN") which has signed up to the STM article sharing principles here: http://www.stm-assoc.org/stm-consultations/scn-consultation-2015/ ("Compliant SCN's"), after an embargo period of 12 (twelve) months from the publication date of the Version of Record (and no embargo for Open Access Articles);

6.1.6. use a maximum of two figures (including tables) from the Work (unless separate copyright is held by a third party and in which case permission must be sought from the holder for any use), and selected text extracts of less than 100 words or series of text extracts totalling less than 300 words for quotation and use such excerpts in all media and future editions as long as the purpose of the use is scholarly comment, non commercial research or education use and full credit is given to the Authors and Us in accordance with normal scholarly practice and any quotations or excepts are unmodified;

6.1.7. in the case of Open Access Articles only, publish the Version of Record in any media after publication by BMJ strictly for non Commercial Use and free of charge or other consideration including depositing the Work in any repository of academic work; and

6.1.8. make any permitted uses of the Author's Original Version (Preprint), Author's Accepted Manuscript and Version of Record (which may predate rights granted in this licence) as defined and set out in the BMJ Author's Self Archiving Policies stated on the BMJ's website from time to time.

6.2. Unless otherwise stated herein, the Authors may not make any Commercial Use of any part of the Work.

6.3. An Author is permitted under this Agreement to include all or part of the Version of Record in a publication (including a book, essay, or position paper) that is not peer reviewed, which is authored or edited by You, provided that such use is not permitted where multiple works will be included in a single publication. BMJ acknowledges that such a use may be Commercial Use.

6.4. The Authors agree to publish or to procure publication of the following statements on the Work each time it is reused in accordance with clause 6.1 above:

6.4.1. In all cases of reuse, should a retraction, expression of concern, or significant correction be applied to the Version of Record by BMJ, the permitted reused version (in accordance with Clause 6.1) must state this and link clearly to the published notice.

6.4.2. for Open Access Articles:

6.4.2.1 where the Version of Record is republished on Your website, Your employer's website, or the website of any third party authorised by You under this licence:

"This article has been accepted for publication in [insert full citation including Journal, Volume and Issue] following peer review and can also be accessed online at [insert full DOI eg. http://dx.doi.org/10.1136/xxxxx]."

6.4.2.2 where any translations of the Work are permitted under any Creative Commons licence, must include the following statement:

"This is an unofficial translation of an article that appears in a BMJ publication. Neither BMJ nor its licensors has not endorsed this translation."

6.4.3. for all other articles:

6.4.3.1 where the Author's Accepted Manuscript of the Work has been republished in accordance with Clauses 2.5, 6.1.4 and/or 6.1.5:

i) *"This article has been accepted for publication in [insert full citation including Journal, Volume and Issue] following peer review, and the Version of Record of this article can be accessed online at [insert full DOI eg. http://dx.doi.org/10.1136/xxxxx]." and*

ii) *"© Authors (or their employer(s)) <year>" **[Add where a funder mandates:** "Reuse of this manuscript version (excluding any databases, tables, diagrams, photographs and other images*

or illustrative material included where a another copyright owner is identified) is permitted strictly pursuant to the terms of the Creative Commons Attribution-Non Commercial 4.0 International (CC-BY-NC 4.0) https://creativecommons.org/licenses/by-nc/4.0/]" and

6.4.3.2 where any translations of the Work are permitted *pursuant to the terms of the CC-BY-NC-4.0 license*, these must include the following statement:

"This is an unofficial translation of a manuscript accepted for publication by BMJ. Neither BMJ nor its licensors has not endorsed this translation."

6.5. BMJ requires that all reuse of the Work (other than an exact republication of the Version of Record- where permitted) must remove any BMJ trade marks (and co-owner trademarks-*if applicable*) (whether registered or unregistered).

6.6. All rights not expressly granted to the Authors under this Agreement are reserved to BMJ.

7. Reversion of Rights. If BMJ does not publish the Work within 12 months of accepting it for publication, the rights granted in this Agreement shall revert to the copyright owners.

8. Open Access Articles

8.1. Subject to clause 8.2, in relation to Open Access Articles, the Work may be reused under the terms of the Creative Commons Attribution-Non Commercial 4.0 International licence (CC BY-NC 4.0) or any subsequent versions of this licence as determined by BMJ.

8.2. Where research on which an Open Access Article is based is funded by the Wellcome Trust, UK Research and Innovation , NIH, or any other funder that mandates the use of CC-BY licence, or BMJ has expressly agreed that the CC-BY licence shall apply, the Work may be re-used under the terms of the Creative Commons Attribution 4.0 International Licence (CC BY 4.0) or any subsequent versions of this licence as determined by BMJ.

8.3. The Submitting Author is required to advise BMJ before publication whether the funding source is one of the bodies referred to in clause 8.2 and will be provided at the point of submission of the Work for publication.

9. Law and jurisdiction. This Agreement its subject matter and formation, are governed by English law and the courts of England shall have -exclusive jurisdiction to settle any dispute arising in connection with it.

10. General

10.1. This Agreement shall be binding on, and enure to the benefit of, the Authors and BMJ and their respective personal representatives, successors and permitted assigns, and references to any party shall include that party's personal representatives, successors and permitted assigns.

10.2. To the fullest extent permitted by law, We accept no liability to You in connection with the Work.

10.3. Each of the provisions set out in this Agreement operates separately. If any court or competent authority decides that any provision is unlawful or unenforceable, the remaining conditions will remain in full force and effect.

10.4. This Agreement including all information supplied to Us, howsoever relating to the Work, constitutes the whole agreement (the legally binding contract) between the Authors and Us relating to the Work and supersedes all prior arrangements (including any previous author licences You may have entered into) or understandings whether written or oral.

11. Permissions. Permission must be sought from BMJ for all uses not expressly set out as permitted uses under this licence. Please email: bmj.permissions@bmj.com.

Section 1

Explanatory Essay

References to the publications submitted are in square brackets [ ]. References to other papers are in round brackets ( ).

1. Theoretical and Conceptual Underpinnings

The four papers presented in this thesis incorporate theoretical and conceptual approaches aimed at improving informed consent by means not extensively addressed in the literature. This thesis will consider informed consent as it applies to adults with capacity – young persons, vulnerable adults or those with incapacity will be excluded from this body of work. Each paper, and approach, has its strengths and limitations. Paper one explores the nature of the practitioner-patient relationship and its influence on determining standards of informed consent whilst addressing the interplay between individual patient autonomy and collective healthcare solidarity [1]. Autonomy has etymological roots in the Greek word αυτόνομός (self-law) and is a concept with modern application to themes of 'self-governance' or 'self-determination'. As applied to the healthcare context, it has come to broadly represent patient rights of decision-making [1]. Whilst *political* solidarity has long underpinned European healthcare systems, there has - until recently - been little consideration of solidarity as applied *within* those healthcare systems (Giaimo & Manow, 1999; Whittall in Prainsack & Buyx, 2017: xi-xiv). Paper one considers how current interpretations of healthcare solidarity may undermine patient autonomy by promoting imbalance in the practitioner-patient relationship that could lead to exclusionary othering of patients - the effects of which are explored throughout the subsequent papers [1: 3-4] [2][3][4]. Instead, paper one proposes a new *inclusive* concept of *conjoint* solidarity be adopted [1]. Conjoint solidarity calls upon healthcare practitioners and patients - otherwise referred to as healthcare stakeholders - to adopt a duty to assist in the identification and

achievement of improved healthcare outcomes [1: 2]. As a concept, it embodies a series of recommendations which *support* autonomy, such as *inclusivity, mutual recognition of epistemic value and mutual persuasion;* threads of which run throughout the series of ensuing papers, connecting them in an overarching single body of work.

The subsequent three papers explore deficiencies in interpretations of the informed consent process and make key recommendations [2][3][4]. A recurrent theme identified is the failure to engage with patients in the decision-making process, from initial selection of treatment to a lack of information disclosure during shared decision-making. Recommendations include greater inclusion of patient epistemic contributions through recognition of patient-based evidence in the medical decision-making process [3]; enhanced stakeholder engagement through mutual persuasion [4]; and enhanced interpretations of material risk so that the long-term risks of device implantation [3]; potent and harmful practitioner conflict of interest [2] *and* relational forms of risk deriving from vaccine choices [4] are considered disclosable. Collectively, these recommendations aim to have utility for rebuilding patient trust and involvement. This explanatory essay will first consider the background of consent and the practitioner-patient relationship before exploring three key themes which, in presenting this work, have emerged for discussion:

Theme I: Deficiencies in Shared Decision-Making Arising from the Practitioner Patient Relationship.

Theme II: Analysis of Informed Consent and its Deficiencies.

Theme III: Proposals for Improving Interpretations of Informed Consent to Ensure Patients are Engaged and Informed.

2. Background

2.1. Consent and the Practitioner-Patient Relationship

There are divergent accounts of the historical origins of informed consent in the literature. Whilst historian Martin Pernick (1982) considers that "…*truth-telling and consent-seeking…"* behaviours have long been components of medical practice (in Faden *et al*., 1986: 56), psychiatrist Jay Katz (1984) contests that *"…the history of the physician-patient relationship from ancient times to present…bears testimony to physicians' inattention to their patients' right and need to make their own decisions…."* (3-4). This view is somewhat shared by colleagues Faden, Beauchamp and King (1986) who have written extensively on the subject. They explain how beneficence – a principle that has long been seen as the driving force of the practitioner-patient relationship – has historically been used to justify non-disclosure or 'benevolent deception' of the patient (60). Whilst cautioning that the *"…history of informed consent can no more be reduced to a linear narration of social events and practices than can the history of major concepts in Western thought such as "democracy," "autonomy," or "scientific law"…",* the colleagues agree with Katz that consent is a relatively novel concept in long history of the practitioner-patient relationship (Faden *et al*., 1986: 60, 68; Katz, 1984: 15-18). Furthermore, there appears to be consensus that standards of consent are inextricably linked to the dynamics of the practitioner-patient relationship (Faden *et al*., 1986).

The ancient principles outlined in the '*Corpus Hippocraticum*' or Hippocratic Oath(s) continue to have a prevailing influence over the practitioner-patient relationship to this day, despite promoting a form of authoritarian beneficence that views the physician as *"…the one who commands and decides, while patients are conceived as persons who must place themselves fully in physicians' hands and obey commands…*" (Faden *et al*., 1986: 62). Medical authoritarianism prevailed throughout the medieval period as Hippocratic and Christian ideals aligned to promote the notion of patient obedience (Faden *et al*., 1986: 63).

During the eighteenth century, the Hippocratic Oath – albeit with a *"…less authoritarian flavour…"* – was instated by newly established medical schools as a pledge to uphold professional values (Faden *et al*., 1986: 64). The Enlightenment period, that was synonymous with political and social reform, saw revolutionaries such as the physician Benjamin Rush, call for the "…*demystification of medicine…"* (Faden *et al*., 1986: 65). Whilst Rush promoted medical honesty - believing there to be a correlation between free choice and patient health - his prevailing concern was not one of patient autonomy, rather, that 'Hippocratic beneficence' and deception could damage the medical profession's reputation (Rush, 1801; Faden *et al*., 1986). Rush's former teacher, physician John Gregory, was similarly concerned with the medical profession's image and considered physicians duty-bound to educate patients about medicine - so long as such openness and honesty aligned with beneficence (Gregory, 1772). Gregory's premise was that medical practice would progress at a greater rate if *"…under the inspection and patronage of men qualified to judge their merit…"* (Gregory, 1772 in Haakonssen, 1997: 70). Therefore, whilst Pernick suggests that both Rush and Gregory sought to promote an "*Enlightenment version of Informed Consen*t", their proposals were not wholly borne of a concern for patient rights of autonomy (Pernick, 1982: 10; Faden *et al*., 1986).

The work of another prominent student of Gregory, Thomas Percival, was also highly influential. His landmark publication '*Medical Ethics'* – described as a "…*reinterpretation of the old Hippocratic guild ethos, seen through the eyes of an 18th century medical officer and Christian gentleman…*" - encouraged professional self-regulation (Percival, 1803; Boyd, 2005: 481). It would later form the basis of the American Medical Association's (AMA) first Code of Medical Ethics in 1847 (AMA, 1847). Yet it is criticised by Boyd as being "…*a prospectus for the style of professional medical ethics, self-regulating, paternalistic, and often benign, which typically prevailed until around the middle of the 20th century…*" and, by Faden and colleagues, for embodying the *"…the living creed of*

[authoritarian] professional conduct in the United States…" (Boyd, 2005: 481; Faden *et al*., 1986: 70). However, physician Worthington Hooker's "…*brilliant and ingenious…*" response to the AMA'S Code of Medical Ethics is considered by Faden and colleagues to be a *"…ringing, uncompromising denunciation of lying and deception in medicine…[that] demonstrates an extraordinary sensitivity to the feelings of patients and their needs for information…"* (Faden *et al*., 1986: 70). Hooker argues that there is no justification for benevolent deception, cautioning that "*…the good which may be done by deception in a few cases, is almost as nothing, compared with the evil which it does in many cases…"* (Hooker, 1850 :252). By the nineteenth century there was greater emphasis on professionalisation as medics sought to distinguish themselves from '*quackery'* and, whilst this meant that pre-surgical consent became routine, benevolent deception remained a common component of such consent. It was not until the early twentieth century that the risk of legal malpractice began to emerge (Faden *et al*., 1986: 76-82).

The impact that the atrocities of the Second World War had upon modern medical ethics is widely recognised (Germany, 1949). Drafted in response to the Doctors' Trials at Nuremberg in 1947, the Nuremberg Code cautions future generations with the now infamous opening words *"…[t]he voluntary consent of the human subject is absolutely essential…"* (Germany, 1949: s.1). The full text of this opening provision is a cautionary tale outlining the importance of "*capacity*", "*non-coercion*", and of patients having "…*sufficient knowledge…*" to make "*enlightened*" decisions (Germany, 1949: s.1). Despite its importance, Faden and colleagues (1986) were unable "…*to locate a single substantial discussion in the medical literature of consent and patient authorisation…"* prior before late 1950s - a time associated with the civil rights movement when individuals actively sought greater rights of equality across various aspects of society (87). They suggest that the *"…Nazi atrocities and the celebrated cases of abuse of research subjects in the United States raised suspicions about the general trustworthiness of the medical profession…"* had

contributed to patients' pursuit of protection (Faden *et al*., 1986: 87). By 1964 the World Medical Association (WMA) had introduced the Helsinki Declaration to provide ethical guidance on involving human subjects in research. However, both the original version, and its subsequent revisions, have been criticised for *'watering down'* the Nuremberg Code's objective (WMA 1964; Maehle, 2009: 606; Botbol-Baum, 2000:238; Germany, 1949). It, arguably, fell to Henry Beecher and his explosive 1966 article '*Ethics and Clinical Research'* to pave the way for stronger adherence to guidelines on informed consent to human experimentation in the United States (US). Therein he warned of "…*troubling practices…*" whereby *"…many…patients …never had the risk [of research participation] explained to them… [even when such risk was of] …grave consequences*…" (Beecher, 1966: 274). Nonetheless, it was not until 1979 that guidelines were published in the Belmont Report, seen as an *"…attempt to summarize the basic ethical principles…*" required of research ethics, such as *"…respect for persons…as autonomous agents…"* and *"…information, comprehension, and voluntariness…"* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; s.B.1, s.C.1, s.C.2).

Meanwhile, in the United Kingdom (UK), it was Maurice Pappworth's publication '*Human Guinea Pigs'* that exposed how National Health Service (NHS) patients were, similarly, being used for research without their knowledge or consent (Pappworth, 1967). Pressel (2003) explains that there is a close link between research consent and medical consent – a connection that is evident upon consultation of the case law pertaining to informed consent in the UK, where both forms of consent are founded in the tort of battery (1221-1223) [2]. Whilst this is explored in more detail in Theme II, it is pertinent to note that from 1956 to 2015 the prevailing legal standard on matters of treatment consent - established in case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 - facilitated medical paternalism, self-regulation and excluded patients from *meaningful* involvement medical

decision-making. In ruling that a practitioner would not be negligent so long as they had acted in *"…accordance with a practice accepted as proper by* a *responsible body of medical men…"* the judiciary facilitated imbalance within the practitioner-patient relationship (*Bolam v Friern Hospital Management Committee* [1957]: 587).

It was not until the Supreme Court ruling of *Montgomery v Lanarkshire* [2015] UKSC 11 that patients were afforded greater rights of involvement in medical decision-making. By recognising patients' right to be informed of the material risks, benefits, and reasonable treatment alternatives before consenting to treatment, the Supreme Court Justices effectively aimed to rebalance the practitioner-patient relationship (*Montgomery v Lanarkshire* [2015]: 81). To meet this standard, they placed a duty upon practitioners to tailor information to the needs of a '*particular patient'* thus creating a requirement for greater engagement. In doing so, a new era of healthcare was introduced in the UK, punctuated by terminology such as *'patient-centredness'*, *'patient-centricity* and '*shared*' or *'supported'* decision-making (see *Montgomery v Lanarkshire* [2015]: 87, 90; General Medical Council (GMC), 2020; Royal College of Surgeons (RCS), 2018). Patient-*centredness* may be *"…narrowly defined as [reflecting] the patient's active role in determining his or her treatment and care…"* and should be distinguished from the broader concept of patient-*centricity*. (Robbins *et al*., 2013: 350). The term '*centric'* has etymological roots in the Greek word κεντρικός which pertains to a central, regulatory point or focus (Etymonline.com, n.d.). As applied to health care, such centricity views a participant as the central *"regulating fulcrum*" from which the decision-making process is controlled (Curro *et al*., 2015; 3). Therefore, terms such as *'doctor-centric'* or *'patient-centric'* may relate to the seat of decision-making power in the patient-practitioner relationship. Robbins *et al* (2013) liken patient-centricity to a form of "…*patient sovereignty…*", describing it as a *"… dynamic process through which the patient regulates the flow of information to and from him/her via multiple pathways to exercise choices consistent with his/her preferences, values and beliefs…"* (350). A similar distinction can

be made between the terms '*shared'* and '*supported'* decision-making. The narrower term '*shared decision-making'* is defined as a *"…joint process in which a healthcare professional works together with a person to reach a decision about care…"* (National Institute for Clinical Excellence, n.d.) however, this may imply that the practitioner has a *"…major role in making the decision…"* (Hamilton, 2020). Notably, the Royal College of Surgeons of England (RCS Eng.) guidance on consent is aptly entitled *"Consent: Supported Decision Making*" (RCS Eng., 2018). Whilst it offers no formal definition of '*supported'* decision-making *per se*, the guidance explains that the *"…aim of the discussion about consent is to give the patient the [tailored] information they need to make a decision about what treatment or procedure (if any) they want…"* thus clarifying the practitioner's role as an advisory one (RCS Eng., 2018: 3). Whilst these distinctions are not necessarily made in the series of published papers, this explanatory essay considers *'patient-centricity'* and *'supported'* decision-making to reflect the legal standard of *Montgomery v Lanarkshire* [2015] most accurately. Yet, as will be seen, this legal standard has yet to be universally adopted into practice.

2.2. Poor Healthcare Outcomes

In the years following the *Montgomery v Lanarkshire* [2015] ruling, several large-scale inquiries into healthcare failings in the UK have been published which suggest that, in practice, *Bolam's* enduring legacy continues to influence interpretations of informed consent (Cumberlege, 2020; James, 2020; *Bolam v Friern Hospital Management Committee*, [1957]). 'First Do No Harm', the report by Julia Cumberlege, CBE – also referred to as 'The Cumberlege Report' - investigated the effect that sodium valproate, hormonal pregnancy tests and pelvic (vaginal) mesh use had in the UK. The report identified key, overarching themes associated with patient harm including: "…*no-one is listening - the patient voice dismissed…*"; "…*I was never told – the failure of informed consent…*" and "…*conflicts of interest – we deserve to know…*" (Cumberlege, 2020: 22, 33). Whilst parts of the report

precede *Montgomery v Lanarkshire* [2015], others – such as that pertaining to mesh - describe ongoing deficiencies in informed consent which transverse the period of *Montgomery's* induction and extend to as recently as 2019 (Cumberlege, 2020). 'The Inquiry into the Issues Raised by Paterson' ('The Paterson Report') examined the case of Ian Paterson - a surgeon who undertook unnecessary, mutilating surgeries on patients without adequately or truthfully involving patients in the consent process (James, 2020). The consent failings outlined by these inquiries are also supported by the findings of a recent multi-speciality study by Knight and colleagues (2019), said to represent the largest post-Montgomery study of informed consent. The study indicates that more than 75% of survey respondents (medical practitioners) were familiar with the *Montgomery v Lanarkshire* [2015] ruling, yet only 25% of those consulted had subsequently adjusted their practice (Knight *et al*., 2019: 282). Furthermore, up to 55.4% of patients consulted by the study had consented *on the day of surgery* – at which stage, "*significantly*" fewer practitioners were likely to disclose risks (Knight *et al.,* 2019: 279). The authors also identified a more general, widespread failure to inform patients of treatment alternatives - including the 'no treatment' option. They found that in over two thirds of cases, no relevant discussion on alternatives had taken place - whether that be at an earlier time (i.e., in the clinic) or on the day of the procedure itself (Knight *et al*., 2019: 279). These combined findings indicate that, in practice, consent processes remain deficient and require improvement (Knight *et al*., 2019).

3. Discussion

Theme I: Deficiencies in Shared Decision Making Arising from the Practitioner-Patient Relationship

The practitioner-patient dynamic has evolved from an independent relationship to one embedded within larger healthcare systems. Such healthcare systems must consider both the needs of the individual and the patient collective and so principles of healthcare solidarity and patient autonomy are relevant modern-day ethical considerations [1]. Paper one

explores solidarity through a chronological analysis. Whilst there is no single definition of the concept there is, however, consensus that it be characterised by some form of shared bonds [1].

3.1. The Origins of Solidarity

Notions of solidarity can be loosely traced back to antiquity - from the shared commitment of those in the basic social unit that was the Ancient Greek οἶκος, to the Roman concept of a shared legal duty to repay debts *obligatio in solidium* (Roy, 1999; Bayertz, 1999). Also widely employed in theological ethics as a means of promoting unity amongst a congregation, solidarity is, for example, expressly mentioned and enshrined within the Catechisms of the Catholic Church where solidarity is *"...articulated in terms of "friendship" or "social charity", [...and as...] a direct demand of human and Christian brotherhood...*" (Catholic Church, n.d.). Throughout *political* history, the pendulum has swung between apparently opposing ideals such as liberalism and communitarianism. In the 17th century, prevailing authoritarianism was met with the classic liberalism of the Enlightenment period. Prominent political thinkers, such as Hobbes (2010 [1651]), John Locke (1948 [1632]) and Jean-Jacques Rousseau (2018), favoured liberal views of the relationship between individual and society which recognised the social contract and thus acknowledged the role of solidarity in ensuring mutual protection. In his famed publication *'The Social Contract'*, Rousseau asserts that individuals are happiest when living in a '*State of Nature'*, yet he also acknowledges that such individuals may collectively unite to overcome hardships, thus providing '*mutual assistance'* to one another (Rousseau, 2018). Such liberal interpretations of social contract theory would eventually contribute to the French Revolution and its notions of '*liberté, égalité, fraternité'* that sought to encapsulate notions of freedom from oppression, equality, and fraternity (or solidarity) amongst the nation's citizens. Indeed, during the European Enlightenment period, various guises of solidarity were used to further political causes (Bristow, 2017). Whilst conservatives - who

opposed the revolutionaries' calls for radical reform - preferred the political pragmatism that favoured tried and tested tradition alongside incremental change, they also somewhat acknowledged the importance of solidarity (Gamble, 2012; Kekes, 1997). In his famed publication '*Reflections on the Revolution in France'*, moderate conservative Edmund Burke - fearing that liberal revolutionaries threatened the very fabric of society - called upon citizens to rally together to uphold honour (Burke, 1790: 28). In an early nod to communitarian ideals – and thus solidaristic traits – he emphasised that *"…[t]o be attached to the subdivision, to love the little platoon we belong to in society, is the first principle…of public affections…"* (Burke, 1790: 39). In the late 1800s, one of the fathers of modern sociology, Émile Durkheim (1984 [1893]), cautioned against individualism and proposed that his mechanical and organic forms of solidarity, which were aligned with the advancement of society, be extended to all. Nearly a century later, Rawls promoted his liberal "…*abstraction [of] the familiar theory of social contrac*t…" in his famed publication '*A Theory of Justice*' which proposes that individuals are equal due to an imaginary 'veil of ignorance' which hides any advantage they may or may not hold, thus creating an equal platform known as the '*original position*' (Rawls, 1971). It is from this '*original position*' that he proposes collective goals could derive from values such as freedom, equality, and opportunity (Rawls, 1971). Yet his approach was viewed by some as too liberal and may have contributed to a responsive rise in communitarianism ideals in the 1980s, as explored by Western scholars such as Alasdair MacIntyre (1981), Charles Taylor (1979; 1985) and Michael Sandel (1982) as a means of promoting the 'common good'. Sandel and Taylor are critical of liberals such as Rawls for failing to recognise that individuals are embedded within society, however it is pertinent to note that Rawls' recognises that *"…only in a social union is the individual complete…*" (Sandel, 1982; Taylor, 1985; Rawls, 1971: 460). Notably, communitarianism was also adopted as a means of describing the form of prescribed thinking associated with authoritarian regimes in Asia, which uphold the common good over individual rights (Fox, 1997). Therefore, Etzioni proposed a concept of '*responsive*

communitarianism' that is differentiated from such authoritarianism (Etzioni, 2003). '*Responsive communitarianism'* seeks to bridge the gap between the core values of individual rights and collective good; thus, remaining dynamic so as to pull society back towards the centre should it move to favour one over the other. 'Responsive communitarianism' shares similarities with the aim of conjoint solidarity which seeks to bridge the gap between the individual and collective need in a healthcare setting (Etzioni, 2003) [1]. Notably, responsive communitarianism also lends itself well to public health policy which can adapt to allow societies to deal with potential conflicts between individual and collective goods. For example, individual rights of medical autonomy upheld under Article 8 of the European Convention on Human Rights (ECHR) may be curtailed if the collective good requires, according to subsection 2 of the article (Council of Europe, 1952). According to Etzioni, this is not considered to be a form of paternalism, rather it is viewed as an intent to improve cultural norms that influence non-rational decision making and so is justified in relation to public health (Etzioni, 2013).

As a concept exclusively applied to the field of bioethics and healthcare, solidarity has been explored by several scholars. Paper one identifies a commonality in approach that necessitates the fulfilment of pre-requisites - such as bearing of costs, coercion or identifying similarity in others - a concept considered to present distinct difficulties in healthcare, particularly in relation to patient autonomy [1]. As will be explored, it is suggested that such models inadvertently promote exclusion and so threaten to undermine individual autonomy (see Prainsack & Buyx, 2011; Davies & Savulescu, 2019; Dawson & Jennings, 2012) [1]. Instead, an innovative notion of 'conjoint solidarity' will be presented to contribute to the existing scholarship. Conjoint solidarity is defined as deriving from the "*…shared goal of all healthcare stakeholders (encapsulating all healthcare professionals and service users) to accept a duty to assist one another to achieve improved healthcare outcomes…"* [1]. In building the case for this inclusive form of solidarity, paper one first identifies the

deficiencies in existing theories and then recommends that conjoint solidarity - which is founded upon mutual recognition of epistemic value amongst stakeholders and the 'pooling of information' - be adopted [1].

3.2. Solidarity at the Expense of Autonomy

In the comprehensive body of work produced for the Nuffield Council on Bioethics, Prainsack and Buyx (2011) present their three-tiered model of solidarity. Existing at the interpersonal, collective, and societal level, it incorporates *"…manifestations of the willingness to carry costs to assist others with whom a person recognises sameness or similarity…*" (s8.25: 87). Although a *"willingness"* to carry costs could be deemed reflective of autonomous decision-making, the requirement to bear costs could pressurise individuals - who wish to act in solidarity with others - into bearing costs when they otherwise would not have wished to do so (Prainsack & Buyx, 2011: s.8.25: 87) [1]. Their theory is applied to ethical issues in their 2017 publication, such as the governance of large biobank databases that contain biomedical data. The example of biobank governance is considered a pertinent one as it illustrates the way in which Prainsack and Buyx's model of solidarity promotes a broad model of consent that could directly undermine the hard-fought gains of *Montgomery's* informed consent in practice (Prainsack & Buyx, 2011; *Montgomery v Lanarkshire* [2015]; 28). Whilst biobanks may be of great public utility – given their scope to predict patterns of disease or health behaviours – they also present a data protection risk. This is particularly concerning for individuals who may subsequently be re-identified. Re-identified participants may, potentially, be profiled for exhibiting 'high-risk' health behaviours and, as a result, may face discrimination and exclusion from healthcare provisions (Prainsack & Buyx, 2011; 2017: 101). However, Prainsack and Buyx suggest that solidarity can balance *"…the value of public benefit [of biobanks] and the protection of personal goods"* whilst moving away from the "…*dominant…focus on individual autonom*y…" (2017: 99,119). Whilst they also assert that *"…autonomy of the person from*

whom the data [derives]…remains an important guiding principle…", their model of solidarity ultimately fails to reflect this (2017: 118). As will be explored there are several examples of the downplay of autonomy in both *their* proposal and those of their contemporaries.

3.2.1. In Relation to Respect for Bodily Integrity. Whilst Prainsack and Buyx (2017) acknowledge the *importance* of informed consent to protect against *"…intrusions into one's bodily integrity…"*, they also suggest that rights of bodily integrity are not applicable to the matter of biobank research (114). The right to bodily integrity has been described as the right to "*…exclude all others from the body, which enables a person to have his or her body whole and intact and free from physical interference…*" (Herring & Wall, 2017: 581) and is protected by Article 3 of the European Charter of Fundamental Rights (CFR) which states that *"…[e]veryone has the right to respect for his or her physical and mental integrity"* particularly *"…[i]n the fields of medicine and biology... [where] …the free and informed consent of the person concerned [must be obtained] according to the procedures laid down by law...*" (European Union, 2010, art. 3(1)(2)(a): 380). Whilst the enactment of the European Union (Withdrawal) Act 2020 means that the CFR will no longer *directly* apply in the UK, the ECHR *does* still apply. Accordingly, rights of bodily integrity remain protected under ECHR Article 8, the '*Right to Respect for Private and Family Life'* which is interpreted "*broadly*" to encompass *"…multiple aspects of the person's physical and social identity…"* (Council of Europe, 1952: art. 8; *Pretty v The United Kingdom* [2002]: 61; *Denisov v Ukraine* [2018]: 95). Therefore, whilst the potential risks associated with biobanks are unlikely to lead to *physical* interference with bodily integrity, the re-identification of participants could lead to potentially degrading treatment, prejudice, discrimination, and exclusion of those who display 'high risk' behaviours which could undermine values such as 'well-being', 'dignity' and 'psychological integrity' that are protected under Article 8 ECHR (Herring & Wall, 2017; *Beizaras & Levickas v Lithuania*

[2020]: 117; *Söderman v. Sweden* [2013]: 80; Council of Europe, 1952: art.8). Feminist ethics have also been used to argue that digital images of one's body (arguably also a form of biodata) could be considered to as "*…digital prostheses – [or] extensions of ourselves, of our will and agency – [that] do not merely represent us but also embody us…*" (Rey & Boesel, 2014 in Patella-Rey, 2018: 788). If, theoretically, this argument is extended to include digitalised data then one's DNA profile - the genetic blueprint of our physical identity that is commonly held in biobank databases - could be deemed to be a digital extension of the *physical* self so that interference with such data would constitute an inference with bodily integrity in its broadest sense. Indeed, as we look ahead to the mid twenty-first century - with the increasing integration of artificial intelligence (AI) with medicine - it is likely that our interpretation of bodily integrity will also need to adapt. So too will interpretations of autonomy, arguably in a manner that offers greater - not less - protection to individuals. It is to this end that constructs of solidarity which uphold autonomy, such as conjoint solidarity, are considered more desirable. Conjoint solidarity, by contrast, promotes an educationally intensive, rather than coercive, approach to the collective needs of society in a dynamic manner that is reflective of 'responsive communitarianism' (Etzioni, 2003) [1].

3.2.2. In Relation to the Importance of Informed Consent. Prainsack and Buyx (2017) appear to view informed consent as a litigious risk management tool - a *"…quasi-synonym for autonomy itself…"* - that merely acts as a 'stamp of approval' to confirm participant understanding and acceptance of risk (114, 117). Whilst possibly true from an *institutional* perspective, this interpretation of consent fails to acknowledge that, for the *participant*, truly informed consent promotes educated decision-making. Instead, Prainsack and Buyx (2017) conclude that *"…informed consent procedures are effectively aimed at preventing and minimising risk…"* and they subsequently *"…perpetuate[s] the implicit expectation that once participants are duly informed of as many risks as possible*

and of all efforts in place to prevent these risks from materialising, they will be 'safe' - which they never are…" (120). There is ambiguity surrounding this interpretation: when a researcher or practitioner discloses risk it is not to prevent those risks materialising, rather to ensure the individual makes an informed decision of whether to incur such risk. Indeed, their approach to information disclosure could be viewed as further undermining autonomy. Prainsack and Buyx (2017) explain that an *"…important feature…"* of their solidarity-based data governance model is that participants *"…who knowingly and voluntarily contribute data …are willing to accept costs…"* - with those costs equating to the acceptance of risk (110). Accordingly, individuals should be informed of the risks which a *"…reasonable person would normally expect…"* to be made aware of, or of "…*particular other risks…*" (Prainsack & Buyx, 2017: 107). Whilst the concept of '*knowingly*' accepting cost would appear to reflect the informed acceptance of risk '*as per informed consent*' and, similarly, the standard of disclosure would appear to relate to the legal '*reasonable person standard*', the authors simultaneously seek to downplay *how much* information need be known about such participation. Of the nature of participation, the authors propose that *"…[r]ather than being confronted with technical language detailing protocols and risks, potential participants should… [instead come to] …understand the …way a database operates, and for what goals…"* (2017: 119). Here, the focus shifts to disclosing information about the system of participation rather than its associated benefits or risks, which would traditionally be required in terms of informed consent. Of the associated risks, Prainsack and Buyx (2017) distinguish the risks of biobank participation from the "…*considerable…*" health risks associated with other forms of research by describing them as "…*very small, both in terms of the nature and the degree of risk…"* and *"…extremely rare…"* (110, 114, 116). Notably, from a legal perspective - albeit in terms of *treatment* consent - adjectives such as "…*considerable…*" and "*…very small…*" would indicate a quantitative assessment of risk that has been rejected by the courts on account of their failure to encompass the impact that a risk could have upon the life of such a reasonable person (Prainsack & Buyx, 2017: 114,

116; *Montgomery v Lanarkshire* [2015])[2]. In somewhat of a contradiction, the authors are also dismissive of such disclosure as *"…in the case of virtually all research biobanks, it is impossible to predict all the ways in which data and samples will be used in the future […and so…] informed consent models trying to achieve full risk reduction and disclosure at the moment of joining are doomed…"* (Prainsack & Buyx, 2017: 115). Furthermore, in terms of benefit, the authors encourage a 'collective' *commitment* to incur costs yet there is little corresponding explanation of 'collective' benefit to be enjoyed by individuals beyond broad generalisations such as 'future treatments' (2017: 105). Finally, the authors conclude that once a willingness to accept costs has been demonstrated – albeit without those risks necessarily being explicitly disclosed - a participant is deemed to have *"…accept[ed] a certain level of risk…"* which may include the loss of some of the "…*benefits…*" of autonomy, such as control over *"…future use of data…*" (2017: 119). It is to this end that the authors justify broad models of consent for biobank governance: where a participant initially consents to biobank data collection, such consent would be extended to other, similar uses of their data in future without the need to 're-consent' (Prainsack & Buyx, 2017: 115). Such limited information disclosure is in direct opposition to the ethos of conjoint solidarity which promotes 'pooling of information' to support relational autonomy [1].

3.2.3. In Relation to Exclusive Solidarity and Othering. A common theme identified in relation to current models of solidarity in healthcare is the potential for exclusivity and othering. For example, Prainsack and Buyx's requirement to carry costs (2011; s.8.25:87) could be deemed exclusionary and is described by Dawson and Jennings (2012) as an "…*unnecessary condition for solidarity…"* (74)[1]. Instead, they propose that individuals should 'stand up beside' one another in response to injustice or disadvantage, although this too could be viewed as placing unnecessary limitations upon the scope of solidarity by requiring individuals to sense injustice or acknowledge disadvantage in another (Dawson & Jennings, 2012: 74). Prainsack and Buyx (2011) also propose that individuals

need identify some form of "*…sameness or similarity…"* with another to foster solidarity. However, solidarity that is founded upon similarity could exclude dissimilar demographics within our diverse healthcare systems (34) [1]. Furthermore, it may also foster inter-generational, inter-racial or intersocietal tension which may erode empathy and contribute to dehumanisation of the patient [1]. Such dehumanisation may manifest in various ways such as gender or racial treatment bias. One study into gender treatment bias described how women in pain are less likely to be taken seriously than men upon admission to Accident and Emergency (A&E) departments (Chen *et al*., 2008). Hamberg (2008) describes gender treatment bias as a wider problem, encompassing a *"…large variety of conditions such as coronary artery disease, Parkinson's disease, irritable bowel syndrome, neck pain, knee joint arthrosis and tuberculosis [where] men are investigated and treated more extensively than women with the same severity of symptoms…"* (238). Similarly, a study by Hoffman and colleagues (2016) described racial treatment bias in the study into the attitudes of 418 medical students and residents. The authors found that "*…many white…*" medical practitioners falsely believed that there were "*…biological differences between blacks and whites…"* with those practitioners also demonstrating racial bias in their management of black patients experiencing pain (Hoffmann *et al*., 2016: 4299).

Another form of potentially exclusionary solidarity is described by Davies and Savulescu (2019), who closely align solidarity with the fulfilment of obligations. They propose that where individuals do not fulfil their solidaristic healthcare obligations they could forfeit benefits of healthcare access (Davies & Savulescu, 2019). In one example, Davies and Savulescu (2019) suggest that if patients autonomously make "*…unhealthy choices [this could] violate [the] obligations of solidarity…*" and lead to revocation of healthcare access (136). The authors apply this model to obesity and suggest that individuals are obliged to act upon a "*Golden Opportunity"* to address their inactivity (Davies & Savulescu, 2019: 133). This approach would appear to coerce patients to act in a certain way and may also

penalise those most in need of healthcare assistance [1]. Although the authors *acknowledge* that other factors influence obesity, a focus upon inactivity alone fails to acknowledge this (Davies & Savulescu, 2019: 138). In the UK, growing food insecurity and food bank utilisation - factors associated with "…*stress, depression, and weight-gain…*" - present an additional socio-economic barrier to healthy food choices that could contribute to obesity (Thompson *et al*., 2018: 100) [1]. It is therefore argued that penalising patient demographics who are subject to complex health and social care needs should not be considered the basis of solidarity in healthcare [1].

In exploring such exclusionary forms of solidarity further, paper one also considers Goodin and Spiekermann's (2015) political concept of *epistemic* solidarity that relates to 'elites' and 'masses'. They explain how political 'elites' have greater access to information compared to the 'masses', yet those 'masses' can overcome their disadvantage by 'pooling information' in a process they refer to as epistemic solidarity (Goodin & Spiekermann, 2015: 2). If applied to the healthcare setting, healthcare practitioners could represent knowledgeable 'elites' - a theory strengthened by considering the imbalance resulting from *Bolam's* professional judgement standard which excludes patients (see Themes II, III; *Bolam v Friern Hospital Management Committee* [1957] 587) [2][3] - whereas patients represent the epistemically 'disadvantaged masses' [1]. Patient 'masses' can, however, unite to overcome this imbalance, as is evidenced in the Independent Medicines and Medical Devices Safety Review (IMMDSR) in which patient support groups such as '*#MASHEDUPBYMESH'*, '*Sling the Mesh'* and '*Welsh Mesh Survivors'* collectively 'pooled' information to have their voices heard (Cumberlege, 2020; Independent Medicines and Medical Devices Safety Review, 2019: Written Evidence: Patient Groups) [1]. Indeed, the prelude to the Cumberlege Report (2020) praises such groups as being *"…well informed, knowledgeable, and research based…"* (pi). However, this current dynamic - of elites and masses - also promotes exclusion and othering of the patient who may be perceived as being

"…*unschooled, and too simple to know how to take care of [themselves]…"* by paternalistic practitioners (De Zulueta, 2013; Monya, 2004: 55) [1]. Such a model of the practitioner-patient relationship is therefore considered to be deficient and may contribute to adverse outcomes.

3.3. The Effects of Othering the Patient

Exclusionary othering and solidarity fostered in 'subgroups' within our healthcare systems can lead to othering, the erosion of empathy and eventual dehumanisation of the 'other' group [1]. De Zulueta (2013) explains how *"…doctors may [become] immersed in the white coat group of individuals…"* that excludes patients or, they may become overly focused upon treating the disease rather than the individual (65). As is explored in paper two, where practitioner interest takes precedence over professional duty to maintain the patient's interests as the primary concern, a conflict of interest may arise that can be harmful to patients (See Robertson *et al*., 2012) [2]. The effects of such othering, exclusion and conflict of interest are examined throughout this body of work by addressing the select body of healthcare inquiries outlined below which underline the need for an alternative, inclusive, approach to healthcare solidarity [1].

3.3.1. The Francis Inquiry, 2013. The Francis Inquiry into the Mid-Staffordshire NHS Foundational Trust examined evidence of widespread failings at Stafford Hospital in the period between 2005 and 2008. During this time *"…appalling care [standards were] able to flourish…"* including poor standards of infection control, widespread failure to address patients' basic hygiene needs and to provide essential assistance with eating and drinking (Francis, 2013: 1, 26, 30). The report concedes that "…*the system as a whole failed in its most essential duty – to protect patients from unacceptable risks of harm and from unacceptable, and in some cases inhumane, treatment that should never be tolerated in any hospital"* and that there was *"…no culture of listening*

to patients…" (Francis, 2013: s4, s1.9). Instead, HCPs were focused upon *their* collective goal of attaining Foundation Trust status which resulted in a "…*callous indifference…*" towards patients which resulted in such adverse outcomes (Francis, 2013: 13). De Zulueta (2013) blames an institutional "…*emphasis on dissimilarity…*" within Mid-Staffordshire NHS Trust for the patient exclusion and dehumanisation responsible for such disturbing outcomes and increased mortality (122).[1] The Report found that there was no need for a "…*radical reorganisation…*" of the health service, but instead called for a refocus upon a *"…commitment to common values throughout the system by all within it…"* which it considered to be "…*truly important…*" (Francis, 2013: s.1.119). The series of recommendations aimed to *"…put patients where they are entitled to be – the first and foremost consideration of the system and everyone who works in it…*" (Frances, 2013: s1.237). Such an approach, which values inclusion of patients, is reflected in the model of conjoint solidarity that will be outlined later in section 3.4 [1].

3.3.2. The Cumberlege Report, 2020. Whilst the Francis Report, 2013 specifically concerned Mid-Staffordshire NHS Trust, themes of epistemic imbalance and exclusion, have also been identified throughout the NHS in subsequent inquiries. The IMMDSR (2018; 2019) and subsequent Cumberlege Report, 2020 address concerns relating to the use of medicines and medical devices in the NHS from the 1950s until the present-day. They addressed three key areas:

- The ongoing use of anti-epileptic drug sodium valproate – albeit now under stricter conditions - despite being known to be a potent teratogen since first licensed in 1972 (Cumberlege, 2020 s4.1: 98).
- The continued use of hormonal pregnancy tests until the late 1970s, despite concerns of teratogenicity as early as 1958 (Cumberlege, 2020, s3.1: 62).

- The prolonged use of pelvic (vaginal) mesh for more than twenty years, despite patient reports of "*crippling, life-changing, complications*" (Cumberlege, 2020, s1.2).

This body of work focuses upon the report's analysis of pelvic (vaginal) mesh in papers two and three as the issues identified in relation to mesh transverse several themes touched upon in this thesis, such as conflict of interest, exclusion of the patient, inadequate information disclosure and erosion of trust [2][3]. Whilst some patients reported that their mesh implantation surgery was successful, harmful complications of mesh may still develop as they often take years to emerge (Cumberlege 2020, s5.5: 140) [3]. It is evident from the testimony of the patients who *did* suffer harm that there is a disconnect between practitioners and patients that impedes positive healthcare outcomes. Paper three explores the findings of the report and proposes that 'informed' elites – encompassing industry, practitioners, policy makers and even the judiciary – often exclude patients when determining whether a treatment represents a suitable standard of care (Cumberlege Report, 2020; see also *Bolam v Friern Hospital Management Committee* [1957]: 587) [3]. Furthermore, as addressed in Theme II, the law also dictates that patients are not involved in treatment selection, which remains a matter of professional judgement (*Bolam v Friern Hospital Management Committee* [1957]: 587). As the pelvic (vaginal) mesh inquiry illustrates, this creates epistemic imbalance that excludes the patient and may have contributed to the ongoing use of harmful vaginal mesh [3]. Mesh injured patients described how they were not only poorly informed of the risk of mesh implantation but that they were also subsequently ignored when they reported their "*taboo*" mesh-related symptoms (IMMDSR, 2018: s5.12.1). Patients who reported symptoms of dyspareunia were dismissed with comments such as "…*lucky girl, you now have a designer vagina…*" or "…*a lot of women would be very jealous…*" (see IMMDSR, 2018: Box 8, 167). Other patients reported being told that their symptoms were *"…all in [their] head and [that they] needed to see a psychiatrist…"* (IMMDSR, 2018: Box 7, 165). One mesh-affected patient described the culture of gaslighting patients as being

"*rife*" (Cumberlege, 2020: 17).[2] As a result, patient symptoms were flippantly disregarded and instead, the "…*blame and onus* [was put] *back on the patient…*" to such an extent that it constituted an "…*institutional denial of pain caused by mesh erosion…*" (IMMDSR, 2018: s5.12.3, s5.12.6: 167). This not only indicates a lack of empathy towards patients' pain and suffering but is also illustrative of a process of dehumanisation that leads to poor healthcare outcomes. As is argued in paper three, this failure to listen to, and involve, patients allowed the use of pelvic (vaginal) mesh to continue for far longer than it need have [3]. In her report, Cumberlege (2020) reminds healthcare practitioners and policymakers to *"…recognise that patients are its raison d'etre…"* – a profound statement that indicates that the practitioner-patient relationship needs to be rebalanced (pii).

3.3.3. The Inquiry into the Issues Raised by Paterson, 2020. Paper two also explores themes of patient exclusion in relation to conflict of interest and examines both the Cumberlege Report and Inquiry into the Issues Raised by Paterson, the 'Paterson Report' (James, 2020; Cumberlege, 2020) [2]. Paterson, a Consultant Breast Surgeon, driven by his own "*significant*" financial self-interest, embarked upon a decade-long campaign of patient deception (Rowland, 2019, s.5: 5). This involved incentivising general practitioners to recommend patients to his private practice. He also encouraged his existing NHS patients to see him privately, claiming they would otherwise face long NHS waiting lists for treatment - despite British Medical Association (BMA) guidance expressly prohibiting practitioners from initiating discussions about private practice with NHS patients (James, 2020: 19, 120; BMA, 2020). Through his private practice, Paterson sought to promote his own self-interest and financial gain. He often requested unwarranted investigations and then purposefully misinterpreted results so that further surgical interventions were indicated (James, 2020: 48, 88, 106, 120). He went so far as to erroneously inform some patients that they had cancer when they were free of the disease (James, 2020: 47). Furthermore, he often performed excessive, unnecessary, and even unproven treatments including his own

'cleavage sparing mastectomy'– a procedure with *"…no definition …[that] is not recognised practice…"* (Rowland, 2019, s.5: 5; James, 2020: 11, 52-53). Paterson actively misinformed patients and so perpetuated the concept of patients as disadvantaged, uninformed 'masses' [1][2]. He used a distorted version of a paternalistic practitioner-patient relationship which was fuelled, not by hard-line beneficence but instead by self-interest, to facilitate deception and dehumanisation of patients. For Paterson, patients were a 'means-to-an-end' rather than as individuals with their own, unique healthcare needs. Paper two explores how conflict of interest can propagate epistemic imbalance and may be associated with harmful outcomes for patients. It is to this end, that paper two argues that significant (or 'potent') financial conflicts of interest should represent a disclosable, material risk that the patient be informed of [2].

3.4. Towards Conjoint Solidarity

Having identified the potential impact that exclusionary models of solidarity may have upon the practitioner-patient dynamics, conjoint solidarity is proposed to add to the existing scholarship [1]. As a concept, conjoint solidarity is founded upon a model of inclusivity which promotes epistemic balance in the practitioner-patient relationship so that a united approach to healthcare be adopted. It is anticipated that this will uphold, rather than undermine, autonomy and can serves as a means of promoting trust and of collaboratively addressing healthcare issues [1].

3.4.1. Inclusivity and Relational Autonomy. In an adaptation of Goodin and Spiekermann's (2015) epistemic solidarity, it is proposed that 'elites' and 'masses' unite in healthcare to pool information *amongst all* healthcare stakeholders [1]. The term 'healthcare stakeholder' is preferred over 'practitioners' and 'patients' as it serves to signify an *inclusive* form of solidarity that unites those distinct groups which share the same goal - in this case, improved healthcare outcomes [1]. It is on this basis, that conjoint solidarity

calls upon healthcare stakeholders to *collectively* pool information as part of their *'duty to assist one another"* in achieving those outcomes [1: 2]. This is not intended to be a consequentialist ideal based purely on the attainment of the shared interests or goals of the collective. Rather, it is argued that *relational* autonomy enables an understanding of solidarity that takes the individual seriously without failing to show consideration for the needs and others. It is to this extent that conjoint solidarity describes 'the nature of duties' amongst individuals that arises *from* relational autonomy. Paper one develops this argument by exploring a spectrum of interpretations of autonomy through analysis of the well-established concept of 'self-interest' in moral theory. It concludes that a relational approach is the most appropriate to the healthcare setting [1]. Ordinate self-interest is a concept widely explored in Nicomachean ethics as a necessary part of the pursuit of *eudaimonia* (Aristotle, 2000 [n.d]). Whilst individualistic interpretations of autonomy hold the individual to be the ultimate point of reference in determining self-interest, in a way reflective of the 'self-absorption' of egotism, relational interpretations of autonomy reflect the prudent pursuit of self-interest [1]. This, it is argued, aligns with ethical egoism and *its* wider consideration of external influences such as family and community [1]. Paper one concludes that even when autonomy is interpreted as a liberal concept, such a social dimension exists that is suggestive of compatibility between autonomy and solidarity [1: 7].

Strength is given to this argument by consulting the work of Kant (2005 [1785]) who described autonomy in relation to individual self-governance yet simultaneously acknowledges that it should be interpreted in a *relational* manner. According to his maxim of universality, individuals are required to only act in a way which may be applicable to all (see Kant, 2005 [1785]). Further support of this notion of relational autonomy is offered by the idea of 'freedom as independence', as described in the Republican literature. Pettit, for example, describes freedom as the emancipation from the power that one agent has over another, which he calls '*antipower'* (Pettit, 1996: 577). In the *Metaphysics of Morals*, Kant

provides a stronger basis still for relational autonomy in outlining the *Universal Principle of Right* which holds that *"…[a]ny action is right if it can coexist with everyone's freedom in accordance with a universal law, or if on its maxim the freedom of choice of each can coexist with everyone's freedom in accordance with a universal law…"* (Kant, I. (1996 [1797]); 6:230). Therefore, the doctrine holds that moral autonomy reflects freedom of will rather than the independence from the choice of others. Accordingly, independent people are identified within the relational context of owing moral duties to others upon which their mutual independence or freedom are secured. Ripstein proposes that such Kantian ideals remain relevant to modern notions of equal freedom, such as in relation to the law on private rights and, indeed, within the wider penal system (Ripstein, 2009).

In '*A Theory of Justice',* Rawls also acknowledges a social dimension of liberalism when he proposes that free and equal individuals may choose to endorse and engage in social principles of justice (Rawls, 1971). This is further supported by the rich body of literature on social contract theory explored in paper 1 which demonstrates the potential alignment between liberalism – which promotes individual rights - and solidarity [1]. Building upon the theories of eminent scholars such as Hobbes, Locke and Rousseau, paper one identifies a broad consensus that the 'solidaristic' union may be supported by individual, rational choice to support the collective (Hobbes, 2010 [1651]); Locke, 1948 [1632]; Rousseau, 2018) [1]. Indeed, Rousseau's 'contract theory' concedes that social union is permissible so long as there is no net loss of freedom and acknowledges that 'mutual aid' or 'assistance' can be given to support the collective (Rousseau, 2018). This theme of mutual assistance underlies the principle of conjoint solidarity which distinguishes *itself* from other, consequentialist, notions of solidarity [1]. Prainsack and Buyx's proposal, which is rooted in the consequentialist outcome of the duty to assist, promotes an inordinate form of self-interest which holds that individuals should act *against* their own self-interest and, through an act of generosity, relinquish their own justifiable rights of autonomy (Prainsack & Buyx,

2011; Prainsack and Buyx, 2017) [1]. By contrast, conjoint solidarity describes an ordinate, prudent form of self-interest which aligns with ethical egoism. It promotes responsible action to safeguard the individual's legitimate wellbeing whilst considering others in the context of attaining improved healthcare outcomes. The crucial distinction is that conjoint solidarity and relational autonomy are viewed as twin pillars of decision-making which, together, promote rational thought for the individual and collective. It is upon this reasoning that conjoint solidarity distinguishes itself from the existing scholarship, as an *inclusive* form of solidarity that is founded upon free will and rational choice [1].

3.4.2. Benefits of Inclusivity. It is anticipated such a relational approach to conjoint solidarity will enrich standards and interpretations of informed consent in a manner that supports, rather than undermines, autonomy by promoting mutual assistance and collaboration amongst stakeholders. The benefits of inclusivity are outlined in paper 1 and include improved job satisfaction, increased morale, and improved trust. Enhanced trust is said to be linked to improved disclosure by both patients and practitioners that is likely to improve diagnostics, treatment selection and overall treatment adherence. It is further anticipated that it may tackle issues such as treatment bias and discrimination [1]. In considering the earlier example of biobank participation, under a conjoint solidarity model, biobank participants would be fully informed of the risks and benefits of participation - both from an individual and collective perspective. Such consent would likely be dynamic - as explored by Whitley *et al.* (2012) - to afford participants to the opportunity to reconsider their involvement. It is anticipated that such an approach is likely to have utility in building trust, particularly amongst demographics who are wary of involvement in medical science (Steinsbekk *et al.*, (2013) [1]. Paper one also considers how conjoint solidarity would be used to address questions of distributive justice in healthcare [1]. A relational approach to justice is proposed to align with conjoint solidarity and is considered preferable to egalitarian interpretations of justice which, whilst based upon principles of equality, may inadvertently

perpetuate disparity by failing to recognise *pre-existing* inequality [1: 10] (see also Agnol, 2005). Similarly, liberal egalitarian interpretations of justice, such as that described by Rawls, may be deemed exclusionary as they suggest that rights take the form of *opportunity* and the extent to which an individual takes *advantage* of opportunity determines their subsequent allocation of resources (Rawls, 1971). Indeed, Ter Meulen argues that if applied to healthcare justice, this could lead to the humiliation of those who fail to take advantage of their opportunities and the familiar pattern of exclusion, othering, and dehumanisation might arise [1: 10] (Ter Meulen, 2017).

Notably, due to the scope of paper one, only a cursory analysis of Rawls's overall work is provided, and it is prudent to acknowledge here that the Rawlsian form of distributive justice is not purely limited to opportunities alone. Rawls's '*equality of opportunity'* is but one of the subprinciples of the second principle of justice and, it may be argued, that the subsequent 'difference principle' - which governs resource distribution - could address other relevant issues of healthcare resource access. Rawls's difference principle holds that inequalities are just so long as they benefit the worst off in society (Rawls, 1971). However, such an approach may fail to account for disability. A future exploration of this discussion - beyond that which is included in paper one - may look to Sen's proposed *'capability approach'* which instead focuses upon individuals' freedom to achieve well-being and the opportunities for them to attain what they are capable of (see Sen, 1992). Sen's concept of 'basic capabilities' was further developed by Nussbaum who considered basic capabilities to encompass *"…that which individuals need for developing more advanced capabilities…"* (Sen, 1980; Robeyns, 2016; Nussbaum, 2000).

Further critique of Rawls's difference principle may be drawn from Cohen's work which argues that Rawlsian justice fails to look beyond 'coercive' institutions and so does not recognise the role of personal choice in maintaining 'non-coercive' informal institutions

such as families – the concept of free choice being critical to their existence. Indeed, the notion of free choice is also central to conjoint solidarity, yet Cohen simultaneously presents an 'incentives argument'. This holds that it may be just to provide incentives to those with special capabilities, advantage, or talent – even though this may lead to greater inequality – as such a move may lead to more goods being available to the worst off (Cohen, 1997 pp3-30). Paper one, instead, looks to *relational* justice which incorporates aspects of conjoint solidarity such as communication, cooperation, and dialogue amongst stakeholders and relational autonomy by recognising the inextricable links between individuals and society – without the need for such incentivisation which could undermine the validity of autonomy through coercion (Raines, 1989; Ter Meulen 2017; Casanovas & Poblet, 2008) [1]. It is suggested that by aligning interpretations of justice and solidarity in this manner, healthcare stakeholders can better recognise and accept individual responsibilities in relation to healthcare utilisation [1]. Whilst this is not proposed as a one-stop solution, it is intended to serve as a reference point for debate and contemplation. Furthermore, whilst conjoint solidarity, relational autonomy and relational justice necessitate greater dialogue with patients - which may raise concerns over time constrained on an already pressurised system - it is anticipated that this represents an investment so that the 'pooling of information' can facilitate improved interpretations of desirable healthcare outcomes and their attainment. By re-balancing the practitioner-patient relationship in this way, interpretations of informed consent can be enhanced which can help to rebuild trust [1].

4. Theme II: Analysis of Informed Consent and its Deficiencies

4.1. The Law of Informed Consent and its Enduring Paternalism

As outlined, epistemic injustice and paternalism have been facilitated by authoritarian constructs of the practitioner-patient relationship, by judicial deference to the medical profession and, more recently, through inaccurate interpretations of the new legal standard of information disclosure, such as those outlined by the GMC as described in paper two

(Austin, 2018; GMC, 2020) [2]. The second paper on conflict of interest addresses two key aspects of this thesis: the evolution of the common law standard of informed consent in the UK and the interpretation of disclosable material risk through an examination of the relevant case law and guidelines [2]. It is argued that, despite advances in legal standards, such changes have been slow to influence medical practice and so informed consent processes remain skewed towards the paternalistic in many areas [2][3]. This premise is supported by a 2021 study from Kennedy and colleagues which examines consent standards on labour wards. They found that "…*uncertainties and ambiguities in consent practice…sometimes falls short of legal and professional requirements…"* (Kennedy *et al*., 2021: 150). These findings were recently confirmed by the Ockenden Report which exposed maternity failures at The Shrewsbury and Telford NHS Trust and outlined essential action to *"…ensure women have ready access to accurate information to enable their informed choice of intended place of birth and mode of birth, including maternal choice for caesarean delivery…"* (Ockenden, 2022: 211). Whilst it is recognised that obstetrics is a complex and challenging area of practice, similar findings were also described in relation to surgical consent by Ricketts and colleagues (2019). In their 2019 review of the literature, the authors concede that *"…[a]necdotally, the number of 'lack of consent' claims against doctors has gone up in the past two years…"* and surgeons are probably obtaining consent with a *"…sense of unease…*" (Ricketts *et al*., 2019: 44). As will be explored, perhaps such unease could be attributable to the evolution of the current legal standard which may have created ambiguity [2].

4.2 Evolution of a Legal standard

For adult patients with capacity – that is, the ability to understand and process information to make a reasoned decision - the law is clear that consent must be obtained prior to treatment, however the requirements of such content have long been the subject of judicial analysis, particularly in relation to how much information a patient needs to reach such a decision (see *Devi v West Midlands RHA* [1980] C.L.Y 687) [2]. In 1957, the *Bolam* test

was established so that a practitioner would not be deemed negligent in treatment selection or information disclosure if their actions were in "*…accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art…*" (*Bolam v Friern Hospital Management Committee* [1957]: 587). Arguably, this ruling excluded patients from meaningful decision-making - an issue that Lord Scarman sought to address in the subsequent case of *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 when he proposed that disclosable information be determined by a *"reasonably prudent patient standard"* (800). He was, however, in the minority. Lord Templeman perceived the practitioner's duty of beneficence to outweigh the patient's right to be given *"…all [of] the information…"* about a proposed treatment, however information should be disclosed if a patient asked the relevant questions. Lord Bridge considered that practitioners should inform patients of *"…substantial risk of grave and adverse consequences…"* (*Sidaway v Board of Governors* [1985]: 904; 900). In adopting a 'reasonably prudent doctor' standard, Lord Diplock distinguished *himself* from the patient masses as he explained that a judge would want the *"…right to decide [what is] done to [their] body…[and] to be fully informed of any risks…"* whilst patients need not have access to such information (*Sidaway v Board of Governors* [1985]: 895; 897) [1][2]. The issue of information disclosure was revisited in *Pearce v United Bristol Healthcare NHS Trust* [1998] 48 BMLR 118 - although an unsuccessful case, it was an early attempt to refine the parameters of disclosable risk by introducing terminology such as '*significant'* risk and '*the [judgement of the] reasonable patient'* (124). A full account of the interceding case law is provided in paper two, however, it was not until the 2015 judgement in *Montgomery v Lanarkshire*, that disclosable risk was defined according to a test of materiality (81) [2].

4.3 Montgomery and Beyond

The Supreme Justices in *Montgomery v Lanarkshire* [2015] revisited the judicial reasoning in *Sidaway v Board of Governors* and rejected the *"profoundly unsatisfactory"* majority

view that placed a burden upon patients to ask the correct questions (*Montgomery v Lanarkshire* [2015]: 58; *Sidaway v Board of Governors* [1985]: 886). They also rejected the notion of a "*substantial*" risk standard recognising that decision-making involves consideration of other, non-quantifiable factors (*Montgomery v Lanarkshire* [2015]: 45, 58). They differentiated between the adjectives "*substantial*" and "*significant*", explaining they have "…*different shades of meaning…*" with the latter being to more appropriate term (*Sidaway v Board of Governors* [1985]: 900; *Montgomery v Lanarkshire* [2015]: 66). They clarified that significant risk is embedded within the wider concept of material risk as they outlined the new legal standard:

> An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it *(Montgomery v Lanarkshire* [2015]: 87).

This new test of materiality considers both a *reasonable* person standard and the needs of a *particular* patient. According to UK law, the 'reasonable person' is "…*the man on the Clapham omnibus…*' - a theoretical representation of the ordinary man with reasonable judgement (*McQuire v Western Morning News* [1903]:109). Whilst the Supreme Court Justices referred to this standard during their judicial reasoning, they appear to have instead adopted a collective version of this rule which may reflect the opine of '*passengers on the*

Clapham omnibus' [2]. Lords Kerr and Reed clarify that *"…no woman would, for example…likely [be willing] to face the possibility of a fourth-degree tear, a Zavanelli manoeuvre or a symphysiotomy with equanimity…"* (*Montgomery v Lanarkshire* [2015]: 94). This '*collective*' view of *women* appears to mark a departure from the individual reasonable man standard. Furthermore, Baroness Hale considers a collective analysis of 'mothers' when she describes the *"…risks that any reasonable mother would wish to take into account …in order to balance said risks against benefits in relation to each eventuality…*" *(Montgomery v Lanarkshire* [2015]: 121) [2]. Paper two argues that this 'collective' reasonable person standard could, potentially, facilitate the use of empirical evidence in court to address questions of materiality and causation [2].

The issue of materiality has been explored in the cases that followed *Montgomery v Lanarkshire* [2015]. In *A v East Kent Hospitals University NHS Foundation Trust* [2015] the Court of Appeal considered negligent non-disclosure of the material risk of restricted intra-uterine growth being linked to chromosomal abnormality. Ultimately, Justice Dingemans considered the risk to be:

> 'theoretical', 'negligible' or 'background', which in percentage terms is less that 1 in 1,000 [and so there was] … no need to discuss this risk with Mrs A and in any event any reasonable patient, and Mrs A, would not have wanted to know about it and would have ignored it in the same way that she had ignored the residual background risk of Down's Syndrome… (*A v East Kent* [2015]: 69).

However, the Justices in *Montgomery* clearly sought to emphasise that material risks cannot be *"reduced to percentages*" as material risk is both "…*fact sensitive, and sensitive to the characteristics of the patient…*" - an acknowledgement that patients are entitled to take *"…[their] own values, [their] own assessment of the comparative merits […of a*

treatment…]…" into account (*Montgomery v Lanarkshire* [2015]: 87, 89:115) [2]. Whilst the *East Kent* ruling potentially marked an early departure from the *Montgomery* standard, the 2017 case of W*ebster v Burton* upheld *Montgomery's* assertion that risk should not be reduced to percentages (*A v East Kent* [2015]; *Montgomery v Lanarkshire* [2015]; *Webster v Burton* [2017]). The court heard that despite ultrasound indications of polyhydramnios (excess amniotic fluid) there was negligent management of Ms Butler's pregnancy and a failure to offer an early induction of labour which could have avoided the subsequent umbilical cord compression and hypoxic brain injury sustained by her baby (*Webster v Burton* [2017]: 11; 2). Lord Justice Simon clarified that the *Montgomery* standard holds that assessment of risk cannot be reduced to percentages and, as such, Ms Butler should have been informed of "*…emerging but recent and incomplete material showing increased risk of delaying labour in cases with this combination of features…"* (*Webster v Burton* [2017]:29; 40).

The influence of the judicial reasoning in *Montgomery* cannot be understated - not only did it redefine the legal duty to give greater respect to patient autonomy but, in doing so, it placed a duty upon practitioners to get to know the 'particular' patient (*Montgomery v Lanarkshire* [2015]: 81) [2]. This can be seen in the way material risk is interpreted to facilitate consideration of the *"…significance of a given risk…"* in terms of the *"…nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives…"* (*Montgomery v Lanarkshire* [2015]: 89). However, in paper two, it is argued that this is not necessarily reflected in current guidance from the GMC which may, inadvertently, promote a paternalistic interpretation of the legal standard in advising practitioner to inform patients of the *"…recognised risks of harm…"* that *they*, the practitioner, believe "*…anyone in the patient's position would want to know…"* (GMC, 2020: 15) [2]. If interpreted as a requirement to disclose only the information that the *practitioner believes* that a patient need

know, then the guidance not only falls short of the legal standard, but may also fail to *"…treat […patients…] so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices…"* (*Montgomery v Lanarkshire* [2015]: 81) [2]. Such insufficient interpretations of the legal standard facilitate imbalance in the practitioner-patient relationship that is propagated by exclusionary forms of solidarity as described in paper one [1]. By instead adopting an *inclusive* approach to the practitioner-patient relationship – incorporating themes of conjoint solidarity and relational autonomy [1] – these interpretations of the legal standard may be improved. Papers two, three and four consider the parameters of 'materiality' in relation to disclosable risk and question whether interpretations should be expanded to potentially improve patient care. These papers also acknowledge that the subsequent case of *Duce v Worcestershire NHS Acute Hospitals Trust* [2018] EWCA 1307 determined that medical consent would now be interpreted as a two-staged process:

> First stage: The duty of care required in treatment selection is determined according to a test of professional judgement (*Bolam v Friern Hospital Management Committee* [1957]).
>
> Second stage: The duty of care required in disclosing information is according to a test of materiality (*Montgomery v Lanarkshire* [2015]).

This ruling restrained *Montgomery's* aim for greater patient-centricity and determined that matters of treatment selection remain subject to the traditionally paternalistic *Bolam* test (*Montgomery v Lanarkshire*, [2015]; *Bolam v Friern Hospital Management Committee*, [1957]: 583; Devaney & Holm, 2018) [2]. This is a pertinent distinction as, in paper three, it is argued that the *Bolam* test standard facilitates exclusive epistemic solidarity amongst healthcare practitioners that may undermine healthcare outcomes, particularly in relation to

treatment (*Bolam v Friern Hospital Management Committee* [1957]) [1][2]. As already emphasised, the pelvic (vaginal) mesh inquiry is a key example of how a disregard for patients' epistemic value during treatment selection may not be conducive to positive healthcare outcomes. As will be touched upon in Section 5.1, had patient concerns over mesh been heeded then implantation may not have been deemed best practice and fewer patients may, ultimately, have been maimed by the devices (*Bolam v Friern Hospital Management Committee* [1957]) [3]. Finally, it is of note that the decision in *Duce v Worcestershire* [2018] has further contributed to the ongoing judicial '*toing and froing'* on informed consent standards which have created uncertainty amongst the medical profession over informed consent requirements in practice [2].

5. Theme III: Proposals for Improving Interpretations of Consent to Ensure Patients are Engaged and Informed

Having outlined the deficiencies in the practitioner-patient relationship and of the deficiencies in legal and policy interpretations of informed consent, this thesis now turns to outline the potential solutions presented within this body of research as follows:

- First, consideration will be given to rebalancing the practitioner-patient dynamic through mutual persuasion, a practical application of conjoint solidarity and relational autonomy [4].
- Secondly, suggestions will be made on how to improve the first stage of consent in line with the prevailing *Bolam* standard (*Bolam v Friern Hospital Management Committee* [1957]: 582) [3].
- Finally, enhanced interpretations of material risk are considered in relation to information disclosure as a means of improving patient awareness of risk [2][3].

5.1 Rebalancing the Practitioner-Patient Dynamic

Paper four considers how to rebalance the practitioner-patient relationship. It examines the lack of trust in relation to vaccine hesitancy - defined as *"…the reluctance or refusal to vaccinate despite the availability of vaccines…"* - and concludes that a model of mutual-persuasion may present a solution (World Health Organisation (WHO), 2019) [4]. It explores parental consent to childhood vaccination - which often falls to those with parental responsibility - and considers how the process of shared decision-making can be enhanced through mutual persuasion to tackle vaccine hesitancy and underlying misinformation (Family Law Reform Act, 1969) [4]. As a form of prophylactic treatment, vaccination presents a unique challenge in developing trust as it aims to *prevent future disease* rather than treat existing illness. This means that the risk of side-effects, rather than disease, are often forefront. Vaccination represents one of the greatest achievements in medical science, having eradicated diseases such as Smallpox, yet has long been associated with suspicion (Williamson, 1984). However, Andrew Wakefield's now disproven and retracted study that linked the combined Measles, Mumps and Rubella (MMR) vaccine to Autism and Crohn's Disease has had lasting effect and has contributed to prevailing vaccine hesitancy amongst parents (Wakefield *et al*., 1998; Williamson 1984; Gayle 2019; Hardt *et al*., 2013). It has been suggested that vaccine hesitancy may also be attributable to a more generalised lack of trust in the medical profession and, according to Lalumera (2018) patients may perceive practitioners as being solely in pursuit of their own *"…hidden agendas [other] than public health, such as achieving benefits from Pharma companies…*" (20). Whilst some have argued that a vaccine mandate could provide a solution, paper four recognises that improving standards – and indeed interpretations - of informed consent could present a more sustainable solution by addressing these underlying causes of vaccine hesitancy such as misinformation and mistrust (Walker, 2019) [4]. To this end, a model of 'mutual persuasion' is proposed to re-balance the practitioner-patient dynamic [4].

According to MacLean (2006) the pre-*Montgomery* legal standard of informed consent simply involved a duty to bestow information on the patient, that *"…effectively abandon[ed] the patient to his or her fate…"* (328). He proposed that respect for autonomy requires an attempt be made to challenge an "…*apparently irrational decision…*" through a process of 'persuasion' that would allow the practitioner to challenge apparently irrational choices (MacLean, 2006: 331). Whilst, at law, there is no requirement for adults with capacity to make *rational* decisions, there is a requirement that patients fully understand the information given to them. According to MacLean (2006), by actively challenging irrational decisions, practitioners can ensure patients have sufficiently understood information. Persuasion is employed, not as a means of coercion, rather as a means of engagement and so, in this way, it can also be used to tackle vaccine misinformation whilst autonomy is upheld [1][4].

This approach is presented as a having several advantages. Ensuring patients *understand* the information presented to them is a necessary consideration for consent to be legally valid. It can simultaneously provide patients with an opportunity to ask questions or even persuade practitioners of their perspective (see *Montgomery v Lanarkshire* [2015]: 90) [4]. It is anticipated that mutual persuasion could promote greater depth of engagement between patients and practitioners which can help to improve the practitioner-patient dynamic and build trust [4]. As will also be addressed in Theme III, mutual persuasion also provides an opportunity to consider societal risks and benefits associated with vaccination as part of the decision-making process [4]. Therefore, the incorporation of mutual persuasion into shared decision-making can also serve to align relational autonomy with the principles of conjoint solidarity outlined in 'Theme I' [1][4]. By doing so, it raises patient awareness of social benefit and so may encourages patients and practitioners to adopt a duty to assist in attaining improved vaccination outcomes [1][4]. It could also have facilitated greater pooling of information between practitioner and patients in relation to the use of pelvic (vaginal) mesh, which could - arguably - have averted the ongoing use of mesh that maimed so many patients

[3]. Paper four outlines supportive measures that may facilitate this approach, such by improving patient access to trained healthcare practitioners (NHS Digital 2018) [4]. Investing time in supported decision-making can not only improve standards of informed consent but may also build trust, set more realistic patient expectations, and so enhance treatment compliance – all of which may improve outcomes and save time in the long-term (Graham *et al*., 2015; Frampton *et al*., 2017).

5.2 Improving the First Stage of Consent: Patient Input into Treatment Selection

As identified in Theme II, the case of *Duce v Worcestershire NHS* [2018] established that matters of treatment selection remains subject to a test of professional judgement. Paper three first explores the impact this might have on treatment selection standards by exploring the pelvic (vaginal) mesh inquiry and recommends a more *inclusive* approach to the first stage of consent be adopted [3]. Polypropylene mesh was first used in the treatment of abdominal herniae and, following a clinical trial that was heavily influenced by mesh manufacturer Ethicon, mesh was indicated for pelvic implantation in the treatment of stress urinary incontinence (SUI) and, subsequently, 'pelvic organ prolapse' (POP) (IMMDSR, 2018: 15-31; Gornall, 2018). Despite ongoing concerns over the efficacy of the treatment, it was rapidly adopted into practice as a quick and cheap alternative to the pre-existing treatment available. Patient concerns were disregarded so that the harmful practice continued for decades which indicates that qualitative evidence that is patient-based could have future utility in determining treatment standards (Cumberlege Report, 2020). Paper three, therefore, argues that *had* patient reports of complications been acknowledged earlier, then mesh implantation would not have been considered best practice [3]. Support is given to this argument by consideration of *Bolitho v City and Hackney Health Authority* [1996] All ER 771 which determined the *Bolam* test to be subject to additional considerations of logic and reasonableness, so that evidence-based practice may now be adopted to support a

test of professional judgement (243; *Bolam v Friern Hospital Management Committee* [1956]*:* 587) [2][3]. Evidence-based practice involves consultation of academic literature and clinical trial data to determine the best standard of care however such evidence may be subject to conflict of interest that may adversely affect such recommendations (Mulheron, 2010) [3]. This was case for the European Re-vascularisation Guidelines which set the standards of best evidence-based practice (Neumann, *et al*., 2019; Stone, *et al*., 2019) [2]. The industry-sponsored study that underpinned the guidance recommending stent use had actively suppressed data that found stents to be associated with 80% higher mortality rates (Cohen & Brown, 2020) [4]. Paper three, therefore, considers the value of patient-based evidence as a means of potentially mitigating against such evidential bias [3]. Whilst such qualitative evidence is often disregarded by practitioners in favour of quantitative data, patient-based evidence is increasingly used by organisations such as the National Institute for Clinical Excellence (NICE) (Sharma *et al*., 2015). It is therefore proposed that the limitations set by the prevailing *Bolam* standard be mitigated against by incorporating patient-based evidence (*Bolam v Friern Hospital Management Committee* [1957]: 587) [3]. This approach, which is reflective of concepts of conjoint solidarity and relational autonomy, pays recognition to the epistemic value of patients and could also help buffer against the financial bias addressed in paper two by consulting patient feedback on the success or failures of treatments [1][3].

5.3 Improving the Second Stage of Consent: Expanding Materiality

As outlined in Theme II, the introduction of a materiality standard in determining disclosable information for the purposes of informed consent marked a substantial shift towards greater patient-centricity, however the parameters of what constitutes material risks have not been fully tested by the courts through test cases (*Montgomery v Lanarkshire*, [2015] at 81). Papers two, three and four explore the boundaries of materiality and make suggestions for improved interpretations of materiality that may be beneficial in improving healthcare

outcomes. Research suggests that where patients are fully informed of risks through a process of shared decision-making, outcomes are more likely to be improved (Frampton *et al*., 2017).

5.3.1. Potent Financial Interests as Material Risks. Paper two recommends that material risk should be expanded to incorporate potent financial conflict of interest. Materiality is explored by way of a critical analysis of the case law to explore concepts such as 'significant' and 'material' risk, and the 'reasonable person' and 'particular patient' standards [2]. On such grounds, the paper then challenges current GMC guidelines, which influence practice, as being deficient interpretations of the legal standard (GMC, 2020). It reasserts that the practitioner, in establishing materiality, should actively engage in dialogue with individual patients in order to determine their respective values in line with the particular patient stipulation of *Montgomery v Lanarkshire* [2015]) [2]. It is argued that the legal interpretations of material risk are broad, and patterns of judicial reasoning suggest of a move towards recognition of majority views on reasonableness which could see empirical evidence playing a greater role in questions of materiality and causation in future (Spece and colleagues (2014). The paper concludes that potent financial interests – those which have a detrimental impact upon practice and are associated with erosion of trust – should be considered disclosable material risks [2].

5.3.2. Long Term Risks from Implants as Material Risks. Paper three recommends that disclosable risk should be expanded to consider the risk inherent to medical device implantation. It argues that risk disclosure has traditionally focused upon the immediate risk inherent to the surgical procedure - such as the risk of infection or rupture which could be addressed during the peri or post-operative periods — and not the long-term risk of device-induced tissue erosion (IMMDSR, 2018; *AH v Greater Glasgow and Clyde NHS* [2018] CSOH 57). Whilst it is accepted that practitioners may not have known of the

long-term risks of mesh implantation – and that in law practitioners cannot be expected to inform patients of unknown or unforeseeable risks - it is argued that unknown risk *was* foreseeable when implanting a device without long-term data to support its permanent use (*Duce v Worcestershire* [2018] at 43; Campbell *et al*., 2018). It is recommended that the risk disclosure be more widely interpreted to include longer term risks deriving from implantable devices, or indeed unknown risks associated with innovative treatment proposals [3]. In this way, patient autonomy can be upheld so that they are afforded the opportunity to decide whether, or not, to incur such risk.

5.3.3. Individual and Societal Material Risks in Public Health. Paper four also makes recommendations in relation to *both* material risks and benefits of vaccination. In adopting a model of mutual persuasion that can "…*appeal to …self-interest… [or a] sense of social obligation …or both…"* it is suggested that disclosure of vaccination *benefits* relate to both the *individual* and *collective* immunity (Bell *et al*., 2010: 853) [4]. This approach also reflects threads of conjoint solidarity and relational autonomy [1]. In relation to material risk, it is suggested that, alongside the risk of side-effects, the risk of *not* vaccinating also be discussed [4]. This would include the risk of disease posed to the individual and the wider risk posed to the most vulnerable in society. It is anticipated that expanding upon the interpretation of materiality to incorporate a collective, societal perspective can challenge vaccine misinformation and promote conjoint solidarity's duty to assist in promoting improved healthcare outcomes by tackling vaccine-preventable disease [1][4]. By interpreting materiality in its broadest sense, it is anticipated that trust in the practitioner-patient relationship be rebuilt - a factor associated with improved healthcare outcomes (Graham *et al*., 2015; Frampton *et al*., 2017)

6. Conclusion

This body of research considers the interplay between the practitioner-patient relationship and standards of informed consent. Themes of exclusion, othering, and dehumanisation are explored in relation to the practitioner-patient dynamic and are linked to poor healthcare outcomes. A new approach involving conjoint solidarity, relational autonomy and relational justice is proposed to rebalance and enhance this dynamic. The evolution of case law pertaining to informed consent is also addressed and deficiencies identified. Three key recommendations are made to improve interpretations of informed consent in the UK. First, that the practitioner-patient dynamic should reflect an inclusive and collaborative partnership that can serve as a vehicle to improve - not only standards of consent - but overall healthcare outcomes. Secondly, that patient-based evidence be afforded greater value when analysing treatment suitability to be more inclusive of patients. Finally, that material risk for the purposes of informed consent be interpreted more broadly. This, it is argued, will improve engagement, build trust, and potentially mitigate against the kind of harms that have been witnessed in the past.

References

A v East Kent University Hospitals NHS Foundation Trust [2015] EWHC 1038 QB

Agnol, D. D. (2005) 'Dworkin's Liberal Egalitarianism', *Kriterion*, 46(111), pp 55-59 (M.C Tonette,Trans).

AH v Greater Glasgow Health Board [2018] CSOH 57.

American Medical Association (AMA) (1846) 'Proceedings of the National Medical Conventions, Held in New York, May 1846, and in Philadelphia, May 1847 (Adopted May 6, 1847 and submitted for publication in Philadelphia, 1847), 94.

Aristotle. (2000 [n.d.]). *Aristotle: Nicomachean Ethics* (Cambridge Texts in the History of Philosophy) (R. Crisp, Ed.). Cambridge: Cambridge University Press. doi:10.1017/CBO9780511802058 Chapter X, 183-204

Austin, L. V. (2018) 'Grimstone v Epsom and St Helier University Hospitals NHS Trust: (It's Not) Hip to be Square', *Medical Law Review*, 26(4); pp665-674 DOI: https://doi.org/10.1093/medlaw/fwx053

Bayertz, K. (1999) Four uses of Solidarity. In K. Bayertz (ed) *Solidarity: Philosophical studies in contemporary culture* (Vol 5) (pp 3-28) Springer.

Beecher, H, K. (1966), 'Ethics and Clinical Research', New England Journal of Medicine, 274(24);1354-60, DOI: https://doi.org/10.1056/NEJM196606162742405

Beizaras and Levickas v Lithuania [2020] 41288/15 ECHR 19

Bell, S., Hindmoor, A., Mols, F. (2010) 'Persuasion as Governance: A State-centric Relational Perspective', *Public Administration,* 88(3) pp 851-970. DOI: https://doi.org/10.1111/j.1467-9299.2010.01838.x

Bolam v Friern Hospital Management Committee [1956] 1 WLR 582

Bolitho v City and Hackney Health Authority [1997] 3 WLR 1151

Botbol-Baum, M. (2000) 'The Shrinking of Human Rights: The Controversial Revision of the Helsinki Declaration', *HIV Medicine*, 1; pp 238-245, DOI: https://doi.org doi: 10.1046/j.1468-1293.2000.00035.x

Boyd, K. M. (2005). Medical Ethics: Principles, Persons and Perspectives: From Controversy to Conversation. Medical Ethics. 31: 481-486 DOI: https://doi.org/10.1136/jme.2003.005710

Bristow, W. (2017) "Enlightenment", The Stanford Encyclopaedia of Philosophy (Fall 2017 Edition),
Edward N. Zalta (ed.) Available at https://plato.stanford.edu/archives/fall2017/entries/enlightenment (Accessed 15th October 2021).

Burke, E. (1790) *Reflections on the Revolution in France and on the Proceedings in Certain Societies in London Relative to that Event in a Letter Intended to have been sent to a*

Gentleman in Paris. London. Available at https://socialsciences.mcmaster.ca/econ/ugcm/3ll3/burke/revfrance.pdf

Campbell, P., Jha, S., Cutner, A. (2018) 'Vaginal Mesh in Prolapse Surgery', *Obstetrics & Gynecology,*, 20, pp 49-56 DOI: https://doi.org/10.1111/tog.12454

Casanovas, P., Poblet, M. (2008) Concepts and Fields of Relational Justice. In: Casanovas, P., Sartor, G., Casellas, N., Rubino, R. (Eds). *Computable Models of the Law*. Lecture Notes in Computer Science, 4884; pp323-339. DOI: https://doi.org/10.1007/978-3-540-85569-9_21

Catholic Church (n.d.) 'Part Three: Life in Christ, Section One: Man's Vocation Life in the Spirit, Chapter Two: The Human Communion, Article 3 Social Justice, III Human Solidarity', The Vatican.
Vatican City. Available at https://www.vatican.va/archive/ENG0015/__P6Q.HTM (Accessed on 15th October 2021).

Chen, E. H., Shofer, F. S., Dean, A. J., Hollander, J. E., Baxt, W. G, Robeny, J. L., Sease, K. L., Mills, A., M. (2008) 'Gender disparity in analgesic treatment of emergency department patients with acute abdominal pain', *Clinical Investigation,* 15(5): 414-8, DOI: https://doi.org/10.1111/j.1553-2712.2008.00100.x

Cohen, G. A. (1997) 'Where the Action Is: On the Site of Distributive Justice', *Philosophy and Public Affairs,* 26(1): 3-30. DOI: https://doi.org/10.1111/j.1088-4963.1997.tb00048.x

Council of Europe (1952). *The European Convention on Human Rights*: Right to Respect for Private and Family Life. Strasbourg, Directorate of Information [online]. Available at https://www.echr.coe.int/Documents/Convention_ENG.pdf (Accessed on 15th October 2021).

Cumberlege, J. (2020). First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review. Jul 8 https://www.immdsreview.org.uk/Report/html

Curro, F. A., Robbins, D. A., Naftolin, F., Grill, A. C., Vena, D., Terrario, L. (2015) 'Person-centric clinical trials: defining the N-of-1 clinical trial utilising a practice-based translational network', *Clinical Investigation,* 5(2): 145-159 DOI: https//doi.org/10/4155/cli.14.126

Davies, B., Savulescu, J. (2019) 'Solidarity and Responsibility in Health Care', *Public Health Ethics.* 12(2); pp 133-144. DOI: https://doi.org/10.1093/phe/phz008

Dawson, A., Jennings, B. (2012) 'The Place of Solidarity in Public Health Ethics', *Public Health Review*, 34; pp 65-79, DOI: https://doi.org/10.1007/BF03391656

De Zulueta, P. (2013) 'Compassion in 21st Century Medicine: Is It Sustainable?', Clinical Ethics. 8(4); pp119–128, DOI: https://doi.org/10.1177/1477750913502623 (Accessed 15 October 2021).

Denisov v Ukraine [2018] 76639/11 ECHR 1061

Devaney, S., Holm, S. (2018) 'The Transmutation of Deference in Medicine: An Ethico-Legal Perspective', *Medical Law Review*, 26(2); pp202–224, DOI: https://doi.org/10.1093/medlaw/fwy013

Devi v West Midlands RHA [1980] C.L.Y 687

Duce v Worcestershire Acute Hospitals NHS Trust [2018] EWCA Civ. 1307

Durkheim, E. (1984 [1893]) *The Divisions of Labour in Society*, Macmillan

Etymonline (n.d.) *'centric'.* Available at https://www.etymonline.com/word/-centric Accessed 2 May 2022.

Etzioni, A. (2003) '*Communitarianism',* In Encyclopaedia of Community: From the Village to the Virtual World, Vol. 1, A-D, Karen Christensen and David Levinson, eds., Sage Publications, 2003, pp. 224-228, Available at SSRN: https://ssrn.com/abstract=2157152 (Accessed 15 October 2021).

Etzioni, A. (2013) '*Communitarianism*', In Encyclopaedia Britannica, 25 Sept., https://www.britannica.com/topic/communitarianism (Accessed 15 October 2021).

European Union (2010) 'Charter of Fundamental Rights of the European Union', *Official Journal of the European Union,* C83 (53): 380

European Union (Withdrawal) Act 2020

Faden, R. R, Beauchamp, T.L., King, M.P. (1986*) A History and Theory of Informed Consent*, Oxford: Oxford University Press

Family Law Reform Act, 1969

Fox, R. A. (1997) 'Confucian and Communitarian Responses to Liberal Democracy', *The Review of Politics*, 59 (3); pp561-92, DOI: https://doi.org/10.1017/S0034670500027728

Frampton, S.B., Guastello, S., Hoy, L., Naylor, M., Sheridan, S., Johnson-Fleece, M. (2017) 'Harnessing evidence and Experience to Change Culture: A Guiding Framework for Patient and
Family Engaged Care', NAM Perspectives, Discussion Paper, National Academy of Medicine, Washington, DC DOI: https://doi.org/10.31478/201701f.

Francis, R QC. (2013). The Mid-Staffordshire NHS Foundation Public Inquiry (2013) 'Report of the Mid Staffordshire NHS Foundation Trust Inquiry. Executive Summary. HC 947

Gamble, A. (2012) *'Oakeshott's Ideological Politics: Conservative or Liberal',* In E. Podoksik (ed) The Cambridge Companion to Oakeshott, Cambridge: Cambridge University Press, pp153–176.

Gayle, D. (2019) 'School Gates Breeding Grounds for Vaccine Myths, Says NHS Chief'. The Guardian. Available at https://www.theguardian.com/society/2019/oct/12/school-gates-breeding-ground-vaccine-myths-says-nhs-england-chief 12 Oct. (Accessed 15 October 2021).

General Medical Council (GMC) (2020). Decision Making and Consent. Published 30 September 2020, in effect from 9 November 2020. https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA (Accessed 15 October 2021).

Germany (Territory under Allied Occupation, 1946-1955: US Zone). (1949). Trials of war crimes before the Nuremberg Military Tribunals under Control Council Law No. 10, Nuremberg, October 1946 – April 1949. US Government Printing Office.

Goodin, B. and Spiekermann, K. (2015) 'Epistemic solidarity as a political strategy', *Episteme*, 12(4), pp 4239-457, DOI: https://doi.org/10.1017/epi.2015.29

Gornall, J. (2018) 'Vaginal Mesh Implants: Putting the Relations Between UK Doctors and Industry in Plain Sight. *British Medical Journal*, 363: k4164 DOI: https://doi.org/10.1136/bmj.k4164

Graham, J. L., Shahani, L., Grimes, R. M., Hartman, C., Giordano, T.P. (2015). 'The Influence of Trust in Physicians and Trust in the Healthcare System on Linkage, Retention and Adherence to HIV Care', *AIDS Patient Care and STDs.* 29(12), pp661-667, DOI: https://doi.org/10.1089/apc.2015.0156

Gregory, G. (1772) '*Lectures on the Duties and Qualifications of a Physician*'. London: W. Strahan and T. Cadell

Haakonssen, L. (1997) 'Medicine and Morals in the Enlightenment: John Gregory, Thomas Percival and Benjamin Rush', *Clio Medica*, 44(i-x); pp 1-24 PMID: 9468723

Hamberg, K. (2008) 'Gender bias in medicine', *Women's Health*, 4(3): 237-243. DOI: https://doi.org/10.2217/17455057.4.3.237

Hamilton, A. (2020) '*Conservatism*', In E. N. Zalta (ed) The Stanford Encyclopedia of Philosophy , Available at https://plato.stanford.edu/archives/spr2020/entries/conservatism (Accessed 15 October 2021).

Hamilton, L. (2020) '"Supported decision making" is a better term for emphasising doctors' role", *British Medical Journal*, 368;m98. DOI: https://doi.org/10.1136/bmj.m98

Hardt, K., Schmidt-Ott, R., Glismann, S., Adegbola, R.A., Meurice, F, P. (2013), 'Sustaining Vaccine Confidence in the 21st Century', *Vaccines*, 1(3); pp 204-224, DOI: https://doi.org/10.3390/vaccines1030204

Herring, J., Wall, J. (2017) 'The Nature and Significance of the Right to Bodily Integrity', *The Cambridge Law Journal*, 76 (3); pp 566-588, DOI: https://doi.org/10.1017/S0008197317000605

Hobbes, T. (2010 [1651]) In Shapiro, I. (ed), *'Leviathan: Or the Matter, Forme, and Power of a* Common-Wealth, *Ecclesiastical and Civil',* New Haven, CT: Yale University Press.

Hoffman, KM., Sophie T., R Axt, J., Oliver, MN. (2016) 'Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs about Biological Differences Between Blacks and Whites', *Proceedings of the National Academy of Sciences of the United States of America*, 19; 113(16); pp4296-4301. DOI: https://doi.org/10.1073/pnas.1516047113

Hooker, W. (1850), *Physician and Patient; or a Practical View of the Mutual Duties, Relations and Interests of the Medical Profession and the Community*. New York: Baker and Scribner.

Independent Medicines and Medical Devices Safety Review (IMMDSR) (2018). Written Evidence. Properties of Mesh. Published November 2019, Updated April 2020. Accessed at https://www.immdsreview.org.uk/downloads/Evidence/FOR_PUBLICATION_-_Properties_of_mesh.pdf on 4 June 2020

Independent Medicines and Medical Devices Safety Review (IMMDSR) (2019). Written Evidence. Patient Groups: Pelvic Mesh. Available at https://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20Patient%20Groups%20-%20Pelvic%20Mesh.pdf (Accessed on 15th October 2021).

James, G. (2020), Report of the Independent Inquiry into the Issues Raised by Paterson. February 2020. United Kingdom Government. HC31 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/863211/issues-raised-by-paterson-independent-inquiry-report-web-accessible.pdf

Kant, I. (1996 [1797]) in Gregor, M. (trans) *The Metaphysics of Morals*, Cambridge: Cambridge University Press

Kant, I. (2005 [1785]) in Denis, L. (ed) *Groundwork for the Metaphysics of Morals*, Peterborough: Broadview Press.

Katz, J. (1984) *The Silent World of Doctor and Patient*. New York: Free Press, Macmillan

Kekes, J. (1997), 'What is Conservatism?', *Philosophy*, 72(281); pp351–374, DOI: https://doi.org/10.1017/S0031819100057053

Kennedy, S., Lanceley, A., Whitten, M., Kelly, C., Nicholls, J. (2021) 'Consent on the Labour Ward: A Qualitative Study of the Views and Experiences of Healthcare Professionals', *European Journal of Obstetrics and Gynaecology and Reproductive Biology*, 264; pp 150-154,. DOI: https://doi.org/10.1016/j.ejogrb.2021.07.003

Knight, S.R., Pearson, R., Kiely, C., Lee, G., MacDonald, A. J., MacDonald, A., SSRG. (2019). 'Patient Consent in the Post-Montgomery Era: A National Multi-Speciality Prospective Study', *The Surgeon*, 17; pp277-283, DOI: https://doi.org/10.1016/j.surge.2018.08.009

Lalumera, E. (2018), 'Trust in health care and vaccine hesitancy. Open Edition Journal, *68*: 105-122. DOI: https://doi.org/10.4000/estetica.3553

Locke, J. (1948 [1632]). The Second Treatise of Civil Government and A Letter Concerning Toleration. Oxford: Blackwell.

MacIntyre, A. (1981), *After virtue: A Study of Moral Theory*. London: Duckworth

MacLean A.(2006). Autonomy, Consent and Persuasion. *European Journal of Health Law* 2006; 13:321-338, DOI: https://doi.org/10.1163/157180906779160274

Maehle, A. (2009) 'Book Review: History and theory of Human Experimentation: The Declaration of Helsinki and Modern Medical Ethics', *Medical History*, 53(4); pp606–607.

McQuire v Western Morning News [1903] 2 KB 100 (Eng.)

Montgomery v Lanarkshire [2015] UKSC 11

Monya, D. (2004) 'Towards Defining Paternalism in Medicine', *Virtual Mentor*. 6(2); pp55-57, DOI: https://doi.org/10.1001/virtualmentor.2004.6.2.fred1-0402

Mulheron, R. (2010) 'Trumping Bolam: A Critical Analysis of Bolitho's "Gloss"', *Cambridge Law Journal*, 69(3); pp 609-38, DOI: https://doi.org/10.1017/S0008197310000826

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). The Belmont report: Ethical principles and guidelines for the protection of human subjects of research. Bethesda, Md: The Commission.

National Institute for Clinical Excellence (n.d.) *'Shared Decision-Making'*. Available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making Accessed on 28 April 2022

Neumann, F.J., Sousa-Uva, M., Ahlsson, A., Alfonso, F., Banning, A.P., Benedetto, U., Byrne, R.A., Collet, J.P., Falk, V., Head, S.J., Juni, P., Kastrati, A., Koller, A., Kristensen, S.D., Niebauer, J., Richter, D.J., Seferovic, P.M., Sibbing, D., Stefanini, G.G., Windecker, S., Yadav, R., Zembala, M.O., & ESC Scientific Document Group. (2018). ESC/ EACTS Guidelines on Myocardial Revascularization, *European Heart Journal*. 40(2); pp 87-165, DOI: https://doi.org/10.1093/eurheartj/ehy394

NHS Digital (2018) Press Release: 'More women attend for Breast screening thanks to success of digital inclusion project', 30 October, Available at https://digital.nhs.uk/news-and-events/latest-news/more-women-attend-for-breast-screening-thanks-to-success-of-digital-inclusion-project On 12 November 2019 (Accessed 15 October 2021).

Nussbaum, M. (2000) *Women and Human Development: The Capabilities Approach*, Cambridge: Cambridge University Press

Ockenden, D. (2022). *Findings, Conclusions and Essential Actions from the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust: Our Final Report.* London, UK: Crown Copyright; 30 March 2022.

Pappworth, M. H. (1967) *Human Guinea Pigs: Experiments on Man*. London: Routledge and Kegan Paul.

Patella-Rey, P.J. (2018) 'Beyond Privacy: Bodily Integrity as an Alternative Framework for Understanding Non-Consensual Pornography', *Information, Communication & Society*, 21(5); pp786-791 DOI: https://doi.org/10.1080/1369118X.2018.1428653

Pearce v United Bristol Healthcare NHS Trust [1998] 48 BMLR 118, P124

Percival T (1803) *Medical Ethics; Or A Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons*; Manchester: S. Russell

Pernick, M.S. (1982) *'The Patient's Role in Medical Decision-making: A Social History of Informed Consent in Medical Therapy'*, In President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Making Health Care Decisions, Washington: IS. Government Printing Office Vol 3(3). Available at https://www.ncbi.nlm.nih.gov/nlmcatalog/100943264 (Accessed 15 October 2021).

Pettit, P. (1996) 'Freedom as Antipower', *Ethics,* 106(3): 576-604

Prainsack, B., Buyx, A. (2011). *Reflections on an Emerging Concept in Bioethics*. London: Nuffield Council on Bioethics.

Prainsack, B., Buyx, A. (2017). *Solidarity in Biomedicine and Beyond*. London. Cambridge University Press.

Pressel, D. M. (2003) *'Nuremberg and Tuskegee: Lessons for Contemporary American medicine*', Journal of the National Medical Association, 95(12), pp1216-1225 PMID: 14717481

Pretty v The United Kingdom [2002] 2346/02 ECHR 427

Raines, J. C. (1989) 'Toward a Relational Theory of Justice', *Cross Currents,* 39(2), pp129-141, Available at http://www.jstor.org/stable/24459593

Rawls, J. (1971) *A Theory of Justice*. Cambridge, MA: Harvard University Press

Rey, P. J., and Boesel, W. E. (2014), '*The web, digital prostheses, and augmented subjectivity*'. In D. Lee Kleinman & K Moore (Eds.), Routledge Handbook of Science, Technology and Society. Abingdon: Routledge

Ricketts, D., Roper, T., Rogers, B., Phadnis, J., Elsayed, S., Sokol, D. (2019) 'Informed Consent: The View from the Trenches', *Annals of the Royal College of Surgeons of England*, 101; pp 44-49 DOI: https://doi.org/10.1308/rcsann.2018.0140

Ripstein, A. (2009) *Force and Freedom: Kant's Legal and Political Philosophy*. 1st edn, Cambridge, Massachusetts: Harvard University Press. DOI: https:doi.org/ 10.4159/9780674054516

Robbins, D. A., Curro, F. A., Fox, M. D. (2013) 'Defining Patient-Centricity: Opportunities, Challenges, and Implications for Clinical Care and Research'. *Therapeutic Innovation & Regulatory Science*, 47(3): 349-355 DOI: https://doi.org/10.1177/2168479013484159

Robeyns, I. (2016) *'The Capability Approach'*, in E. N. Zalta (ed.) *The Stanford Encyclopedia of Philosophy*, Winter 2016 Edition. Available at https://plato.stanford.edu/archives/win2016/entries/capability-approach/ Accessed 2 May 2022

Robertson, C., Rose, S., & Kesselheim, A. (2012). Effect of Financial Relationships on the Behaviors of Health Care Professionals. A Review of the Evidence. *Journal of Law, Medicine and Ethics*, 40(3), 452- 466, DOI: https://doi.10.1111/j.1748-720X.2012.00678.x

Rousseau, J. (2018) '*Rousseau: The Social Contract and Other Later Political Writings'*, In V Gourevitch (ed) Cambridge Texts in the History of Political Thought (2nd Ed) Cambridge: Cambridge University Press.

Roy J. (1999).'Polis' and 'Oikos' in Classical Athens. *Greece Rome.* 46(1), 1-18.

Royal College of Surgeons of England (RCS) (2018). Consent: Supported Decision Making: A Guide to Good Practice. November, Available at https://www.rcseng.ac.uk/standards-and-

research/standards-and-guidance/good-practice-guides/consent/ (Accessed on 15th October 2021).

Rowland, D. (2019). Pounds for Patients? How private hospitals use financial incentives tow in the business of medical consultants. Centre for Health and the Public Interest (CHPI), Available at https://chpi.org.uk/wp-content/uploads/2019/06/FINAL-REPORT-POUNDS-4-PATIENTS-070619.pdf

Rush, B. (1801) *'On the Causes Which Have Retarded the Progress of Medicine, and the Means of Promoting Its Certainty and Greater Usefulness'*. Lecture Delivered Nov. 3, 1801, In Rush, B (ed) 'Sixteen Introductory Lectures', 154-55.

Sandel, M.J. (1982) *'Liberalism and the Limits of Justice'*, (2nd ed, 1998). Cambridge:: Cambridge University Press.

Sen, A. (1980) *'Equality of What?'* In McMurrin (ed.), 'Tanner Lectures on Human Values. Cambridge: Cambridge University Press

Sen, A. (1992) '*Inequality Re-examined'*, Oxford: Clarendon Press

Sharma, T., Choudhury, M., Kaur, B., Naidoo, B., Garner, S, Littlejohn, P., Staniszewska, S. (2015) 'Evidence informed decision making: The use of "colloquial evidence" at NICE', *International Journal Technological Assessment in Health Care*, 31(3); pp 138-46, DOI: https://doi.org/10.1017/S0266462314000749

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] A.C. 871 (Eng.)

Söderman v Sweden [2013] 5786/08 ECHR

Spece, R., Yokum, D., Okoro, A.G., & Robertson, C. (2014). An Empirical Method for Materiality: Would Conflict of Interest Disclosures Change Patient Decisions. *American Journal of Lifestyle Medicine,* 40; 253-274 PMID: 27530047.

Steinsbekk, K. S., Kåre Myskja, B., & Solberg, B. (2013) 'Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?', *European Journal of Human Genetics,* 21(9); pp897–902, DOI: https://doi.org/10.1038/ejhg.2012.282

Stone, G.W., Kappetein, A.P.M, Sabik, J.F., Pockock, S. J., Morice, M.C., Puskas, J., Kandzari, D. E., Karmpaliotis D., Brown W.M., Lembo, N.J., Banning, A., Merkely, B., Horkay, F., Boonstra, P.W., van Boven, A.J., Ungi, I., Bogatas, G., Mansour, S., Noiseux, N., Sabate, M., Pomar, J., Hickey, M., Gershlick, A., Buszman, P.E., Bochenek, A., Schampaert, E., Page, P., Modolo, R., Gregson, J., Simonton, C.A., Mehran, R., Kosmidou, I., Genereux, P., Crowley, A., Dressler, O., Serruys, P.W. for the EXCEL Trial Investigators. (2019) 'Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease', *New England Journal of Medicine,* 381; pp1820-1830, DOI: https://doi.org/10.1056/NEJMoa1909406

Taylor, C. (1979) *Hegel and Modern Society*. Cambridge: Cambridge University Press

Taylor, C. (1985) *Philosophy and the Human Sciences: Philosophical Papers,* vol. 2, Cambridge: Cambridge University Press

Ter Meulen, R. (2017) *Solidarity and Justice in Health and Social Care*. Cambridge Books, Ch 3, 12

Thompson, C., Smith, D., Cummins, S. (2018) 'Understanding the Health and Wellbeing Challenges of the Food Banking System: A Qualitative Study of Food Bank Users, Providers and Referrers in London', *Social Science & Medicine*, 211; pp 95-101 DOI: https://doi.org/10.1016/j.socscimed.2018.05.030

Wakefield, A. J., Murch, S.H., Anthony, A., Linnell, J., Casson, D.M., Malik, M., Berelowitz, M., Dhillon, A.P., Thomson, M.A., Harvey, P., Valentine, A., es, S.E., Walker-Smith, J.A., (1998) Retracted: Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children. *The Lancet*, 351(9203); pp637-641, DOI: https://doi.org/10.1016/S0140-6736(97)11096-0

Walker, P. (2019) *'Hancock Compulsory Vaccinations Being Seriously Considered'*, 29 Sept. The Guardian. Available at https://www.theguardian.com/society/2019/sep/29/government-seriously-considering-compulsory-vaccinations-matt-hancock (Accessed on 15th October 2021)

Webster v Burton Hospitals NHS Foundation Trust [2017] EWCA Civ 62

Whitley EA, Kanellopoulou N, Kaye J. (2012) 'Consent and Research Governance in Biobanks: Evidence from Focus Groups with Medical Researchers', *Public Health Genomics*, 15(5); pp232-42. doi: https://doi.org/10.1159/000336544

Whittall, H. (2017). '*Foreword*' In Prainsack, B., Buyx, A. (eds) Solidarity in Biomedicine and Beyond. Cambridge University Press. DOI: https://doi.org/10.1017/9781139696593

Williamson, S. (1984) 'One Hundred Years Ago: Anti-Vaccination Leagues', *Archives of Disease in Childhood*, 59; pp 1195-6, DOI: https://doi.org/10.1136/adc.59.12.1195

World Health Organisation (WHO) (2019) 'Top Ten Threats to Global Health in 2019'. Available at https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019 (Accessed 15 October 2021).

World Medical Association (WMA) (2013 [1964]) 'Word Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects', *Journal of the American Medical Association*, 310(20; 2191-4 DOI: https://doi.org/10.1001/j

[1] A draft report in 2009 suggested that between 400 and 1200 deaths occurred in a 50-month period, however in the final report Sir Francis asserted that these mortality statistics could not be relied upon as a measure of avoidable deaths. See Francis, R (2010) Independent Inquiry into Care Provided by Mid-Staffordshire NHS Foundation Trust January 2005 – March 2009. Volume I. HC375-1https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279109/0375_i.pdf Section G p352

[2] The Cumberlege Report 2020 has the following definition of gaslighting (footnote, page 17): *"Gaslight (vb): To manipulate (a person) by psychological means into questioning his or her own sanity. Oxford English Dictionary. Etymology: title of George Cukor's 1944 film 'Gaslight' (based on a play by Patrick Hamilton first performed in 1938) in which a man psychologically manipulates his wife into believing that she is going insane".*

Section 2

Publications

Paper 1

I. Towards Conjoint Solidarity in Healthcare

Conflict of Interest Statement

No Conflict of Interest

Abstract

Solidarity remains an ambiguous concept despite the long political tradition pertaining to concepts of fraternity, togetherness and collective values or goals. In healthcare ethics, it has been under-explored, perhaps due to the perception that it opposes individual autonomy. However, even where autonomy is interpreted as a liberal construct, the solidaristic act may be borne out of free choice, rather than stand in opposition to it. To complement the existing scholarship, the concept of 'conjoint solidarity' in healthcare, is proposed. Conjoint solidarity may be defined as *'the shared goal of all healthcare stakeholders (encapsulating all healthcare professionals and service users) to accept or adopt a duty to assist one another to achieve improved healthcare outcomes.'* The practical application of both medical autonomy and conjoint solidarity is through the process of shared decision making. An epistemic approach may be applied to 'pool information' from healthcare professionals and patients to determine what improved healthcare outcomes are. This collective approach may also serve to address healthcare issues such exclusion, othering, paternalism, and conflict of interest. Furthermore, in extending this relational approach to justice, consideration may be given to how improved healthcare may be attained in a manner which allows patients to also play their part. To this end, medical autonomy, conjoint solidarity, and relational distributive justice may be considered inter-dependent constructs which, when fully utilised, may help improve healthcare.

TOWARDS CONJOINT SOLIDARITY IN HEALTHCARE

1. Introduction

There is little consensus upon a definition of solidarity which been described as a value[1], a principle of social morality[2] and a moral duty.[3] It may be a 'prescriptive' call to action or a 'descriptive' norm.[4] The various conceptualisations of solidarity do, however, incorporate similar features such as fellowship or shared bonds[5]; the shared goal or commitment; the commonality of purpose[6] and the idea of reciprocity which distinguishes the solidaristic act from one of charity or altruism. However, solidarity is not to be *confused* with reciprocity and its associated *expectation* of receiving in return.[7] Nor is it to be equated with purely emotive concepts such as empathy.[8] Instead, solidarity may be considered a *normative* moral obligation[9], or the *rational choice* to provide and receive support.[10] Interpretations of solidarity vary to such an extent that solidarity can be used to argue opposing sides of the same argument, yet irrespective of application there is often a preconception that solidarity refers to collective good in a way that is contrary to *individual* rights of autonomy.[11] Similarly, the pooling of collective resources through acts of solidarity may be considered to oppose the principle of distributive justice and *its* focus upon equality and individual rights in relation to subsequent resource allocation. This paper proposes a new concept of solidarity in healthcare to contribute to current scholarship and debate by tackling such misconceptions and by addressing concerns such as exclusion and othering that may arise from *exclusive* forms of solidarity as applied to the healthcare setting. This will be addressed through the proposed model of conjoint solidarity, defined as '*the shared goal of all healthcare stakeholders (encapsulating all healthcare practitioners and service users) to accept or adopt a duty to assist one another to achieve improved healthcare outcomes.'* It will be argued that the *inclusive* nature of conjoint solidarity, which is founded upon a shared

[1] Dawson A & Jennings B. (2012). The Place of Solidarity in Public Health Ethics. Public Health Rev. 34:65-79.
[2] Sass H.M. (1992). Introduction: The Principle of Solidarity in Health Care Policy. J Med Philos. 17, 367-370.
[3] Scholz SJ. (2015) Seeking Solidarity. Philos. Compass. 725-735, DOI: https://doi.org/10.1111/phc3.12255.
[4] Prainsack B. (2017) 'The 'We' in the 'Me': Solidarity and Healthcare in the Era of Personalised Medicine'. Sci Technol Human Val. 43(1), 21-44.
[5] Fullilove MT, Cantal-Dupart M. (2016). Medicine for the City: Perspective and Solidarity Tools for Making Urban Health. J Bioeth Inq. 13, 215-221.
[6] Davies B, Savulescu J. (2019) Solidarity and Responsibility in Health Care. Public Health Ethics.12(2),133-144.
[7] Prainsack B, Buxy A. (2011) Reflections on an emerging concept in bioethics. London: Nuffield Council on Bioethics.
[8] Ibid.
[9] Scholz, S. (2008). Political Solidarity. University Park, PA: University of Pennsylvania Press.
[10] Bayertz K. (1999) Four Uses of "Solidarity". In: Bayertz K. (eds) Solidarity. Philosophical Studies in Contemporary Culture, vol 5. Springer, Dordrecht. https://doi.org/10.1007/978-94-015-9245-1_1
[11] Prainsack & Buxy, op. cit. note 7.

common goal of improved healthcare, will serve to demonstrate how autonomy, solidarity and justice are, as relational constructs, not only intertwined but interdependent.

2. SOLIDARITY

2.1 Origins and Modern Conceptualisations of Solidarity

Solidarity can be traced back to antiquity when the basic social unit of Ancient Greece, the οἶκος,[12] came to signify the *bonds* that united those with a shared commitment to one another.[13] Aristotle's writing on φῖλία (friendship) also referred to early forms of solidarity whereby "…*citizens experience friendship with each other in that they wish each other well…and do things for each other even though they do not know each other*".[14] Notably, in this early guise of φῖλία, an interdependence between the shared interests of solidarity and the self-interested individual is recognised, which is pertinent to the modern debate on the compatibility of solidarity with individual autonomy as will be addressed later. According to Aristotle, man must first care for his own self-interest before he can care for the shared interests of the collective - an early nod to the interdependence of between individual autonomy and collective solidarity.[15] Etymologically, solidarity appears to stem from the Roman Law of obligations whereby rights held by common debtors to repay a shared obligation were characterised as *obligatio in solidum.*[16] This early notion of *in solidum* encapsulates a conjoint *legal* duty incumbent on individuals to repay debt and, whilst under Roman law *patria potestas* refers to patriarchal rather than autonomous rights, the concept of *in solidum* holds at least some pertinence to modern solidarity.[17] Solidarity has also been explored in theological ethics as a cohesiveness amongst believers. Whilst not expressly mentioned in Old or New Testament, it is a central form of Catholic virtue[18] pertaining to the moral obligation to assist others which recently formed the basis of Vatican guidance for the uptake of the COVID-19 vaccine as an expression of public health solidarity.[19] Solidarity has also been widely explored as a

[12] Roy J. (1999),'Polis' and 'Oikos' in Classical Athens. Greece Rome. 46(1), 1-18.
[13] Smith C., & Sorrell K. (2014) On Social Solidarity. In: Jeffries V. (eds) The Palgrave Handbook of Altruism, Morality, and Social Solidarity. New York: Palgrave Macmillan, p222.
[14] Jang M. (2018). Aristole's Political Friendship (Politike Philia) as Solidarity'. LAPS. 12, 417-433.
[15] Ibid.
[16] Bayertz. op. cit. note 10.
[17] Britannica Encyclopaedia. (2016) 'Patria potestas' Available at https://www.britannica.com/topic/patria-potestas. Accessed on 12 April 2021.
[18] Bārbat C. (2015) A Catholic view of the ethic principle of solidarity. Consequences at the ethic-social level. Procedia Soc Behav. Sci. 183, 135-140.
[19] Ibid; Holy See Press Office. (29 December 2020). Note of the Vatican COVID-19 Commission in Collaboration with the Pontifical Academy for Life "Vaccine for all. 20 points for a fairer and healthier world". Available at https://press.vatican.va/content/salastampa/en/bollettino/pubblico/2020/12/29/201229c.html Accessed on 10 April 2021

concept relating to political struggle.[20] Emerging in the 17th century during the French Revolution, notions of *fraternité*[21] and *solidarité*[22] were used to promote the national identity which bound citizens together. By the late 19th century, the term solidarity itself gained widespread traction and consideration, mainly by communitarians who considered the collective need of society as that which should take precedence.[23] [24] One communitarian variant was that of *ethnic* solidarity which arose alongside the rise of Nazism in the early 20th century[25] [26] - the atrocities of which led to greater importance subsequently being placed upon individual patient autonomy by way of the Nuremberg Code, which perhaps contributed to the neglect of solidarity in the field of bioethics.[27] It has also been suggested that communitarianism grew further still, in response to the liberalism of Rawls's influential publication '*A Theory of* Justice'.[28] Therein, Rawls considered that in fashioning an imaginary 'veil of ignorance' individuals would be unaware of any advantage or disadvantage they held, thus creating a theoretical equal platform known as the 'original position'. He hypothesised that from this original position the most likely collective rules which would be established were those that upheld principles of freedom, equal liberty, and opportunity. Rawls describes this theory as an *"abstraction [of] the familiar theory of social contract"*.[29] It has been suggested that whilst social contract theorists do not expressly mention solidarity, they treat it as both *"an empirical fact and a positive goal*".[30] Social contract theory is based upon the premise that modern society was borne out of the collective agreement of individuals to unite so as to overcome hardships encountered living independently in a 'State of Nature'. Accordingly, individuals voluntarily surrendered their liberty to a governing authority in return for benefits. Rosseau considered social contract theory to be based upon "*mutual assistance*" with equal individuals dependent upon the *collective* for protection[31] - a concept which arguably underpins the modern European

[20] Schmale W. (2017). European Solidarity: A Semantic History, European Review of History: The rise of European Solidarity in the Course of the Nineteenth Century. Eur Rev Hist. 24(6), 854-873. doi:10.1080/13507486.2017.1345869

[21] Gilbert J, Keane D. (2016) Equality Versus Fraternity? Rethinking France and its Minorities. Int J Const Law. 14(4), 883–905.

[22] Prainsack & Buxy, op.cit. note 7.

[23] Ibid.

[24] Schmale. op. cit. note 20.

[25] Russell, N. (2018) The Nazi Regime – Ideology, Ascendancy, and Consensus. In: Understanding Willing Participants. Vol 2. Palgrave Macmillan, Cham, 22-64.

[26] Schmale. op. cit. note 20.

[27] Nuremberg Military Tribunal. (1949). Trials of War Crimes Before the Nuremberg Military Tribunals. Vol 11. "The Medical Case" Control Council Law No.10. Nuremberg Oct 1946-April 1949. US Government Printing Office, Washington 25, D.C.

[28] Prainsack & Buxy. op.cit. note 7

[29] Rawls J. (1971). A Theory of Justice. Oxford: Oxford University Press.

[30] Prainsack & Buxy. op.cit. note 7

[31] Becker A, Reyelt M. (2001) Jacques Rousseau's Concept of Society and Government: A Study of the Social Contract. Seminar Paper. Wyoming: University of Wyoming.

welfare state whereby citizens are dependent upon the governing authority for protection in times of vulnerability.[32] Collectively, Locke[33], Hobbes[34] and Rousseau[35] proposed liberal interpretations of social contract theory. Locke, for example, proposed that benefits *deriving* from the social contract should include protection of individual rights of life, liberty, and property.[36] To this end Hobbes suggests that social contract theory incorporates themes of individualism, absolutism, and utilitarianism suggestive of compatibility between liberalism and rational solidarity. [37] [38] The premise is that where solidarity is borne out of individual, rational and deliberate choice to subscribe to a collective interest, rather than by way of presumption, solidarity cannot oppose liberalism. Indeed, it could even be considered a product of it. Hetcher also proposed that subscription to the solidaristic group ('groupness') should be derived from individual rational choice to consume shared goods and subsequent acceptance of associated rules and obligations. [39] More recently, Dean has proposed that individual rational choice to act in solidarity, or comradery, should instead align with the revival of communist ideals. Through acts of comradery, collective efforts are bound by the "*joy of committed struggle*" [40] to invoke individual discipline to undertake responsibilities otherwise avoided. This is not considered by Dean to represent a threat to individual liberty, as participation in comradeship is through voluntary choice which may have a *"liberating quality*" in freeing the individual from 'obligations' of independence.[41] In contrast to such contractualism, Durkheim – through a substantial contribution to the scholarship - considered solidarity as a principle extended to *all* humanity - a form of community cohesion that may be categorised as either 'mechanical' or 'organic' solidarity according to societal development. 'Mechanical solidarity' develops in societies whereby individuals are linked by a feeling of sameness in relation to their roles or status in society. In contrast, 'organic solidarity' - which is associated with more advanced societies - develops when individuals with specialised roles develop a mutual reliance upon one another.[42] This is perhaps most

[32] Gourevitch V. (Ed). (1997) Rousseau The Social Contract and Other Later Political Writings. In Cambridge Texts in the History of Political Thought. Cambridge: Cambridge University Press.
[33] Locke, J. (1948 [1632]). The Second Treatise of Civil Government and A Letter Concerning Toleration. Oxford: Blackwell, 1948.
[34] Shapiro I (Ed). (2010). Hobbes, T [1651]. Leviathan: Or the Matter, Forme, and Power of a Common-Wealth Ecclesiasticall and Civill. New Haven, CT: Yale University Press.
[35] Becker & Reyelt, op cit. note 31.
[36] Locke, op.cit. note 33.
[37] Shapiro, op. cit. note 34.
[38] Becker & Reyelt, op cit. note 31
[39] Hechter, M. (1987). Principles of Group Solidarity. Berkeley: University of California Press.
[40] Dean J. (nd). We Need Comrades. Jacobin [online]. Available at https://www.jacobinmag.com/2019/11/comrades-political-organizing-discipline-jodi-dean Accessed on 12 April 2021
[41] Ibid.
[42] Durkheim E. (1984 [1893]). The Division of Labour in Society. London: Macmillan

pertinent to the healthcare 'society' where a mutual reliance develops between specialised members of the multidisciplinary team and patients with their *own* the epistemic value.

2.2 Modern Concepts of Solidarity in Bioethics and Healthcare

Whilst the liberalism of countries such as the United States may favour the promotion of self-interested social models[43], the longstanding European solidaristic traditions of the 19th century gave rise to the European welfare state.[44] [45] The welfare state mandates national insurance contributions from its citizens in return for state support, such as the provision of public healthcare. Whilst it may be presumed that this would serve as a basis for subsequent development of solidarity in bioethics and healthcare, solidarity remains a neglected concept in this field[46], perhaps stifled by perceived difficulties in aligning solidarity with autonomy, justice, and the perceived obligation to take some form of positive action to be deemed solidaristic.[47] The Nuffield Council on Bioethics commissioned Prainsack and Buyx to undertake a systematic analysis of the literature pertaining to solidarity in bioethics in 2011 and they subsequently published the findings alongside their three-tier model of solidarity applicable to bioethics. Such solidarity develops through the manifestation of commitments across interpersonal, collective, and contractual levels. At the initial interpersonal level, *"…solidarity comprises manifestations of the willingness to carry costs to assist others with whom a person recognises sameness or similarity in at least one relevant respect".* Only once sufficiently strong levels of solidarity are established, can solidarity extend across subsequent tiers. The second tier of solidarity is founded upon the "*manifestations of a collective commitment to carry costs to assist others*" which may include acting in solidarity to *"help each other in times of need, support disease research or organise communal healthcare*" and may give rise to models of broad or presumed consent. The third tier relates to manifestations of solidarity at contractual level, whereby there may be a legal duty to share a collective burden - such as evidenced by the welfare state.[48] Arguably, however, models of solidarity which are founded upon recognition of "*sameness or similarity*"[49] may exclude those perceived as different. Prainsack and Buyx provide the example of an individual who may not support a gambler whereby they cannot recognise *that particular*

[43] Sass, HM (1992). Introduction: The principle of solidarity in health care policy. The Journal of Medicine and Philosophy 17: 367-370.
[44] Ter Meulen R, Arts W, Muffels, R (2010) (eds). Solidarity in Health and Social Care in Europe. Dordrecht: Kluwer Academic Publishers.
[45] Baylis F, Kenny, NP, Sherwin, S. (2008). A Relational Account of Public Health Care Ethics. Public Health Ethics 1/3: 196-209.
[46] Dawson & Jennings, op. cit. note 1.
[47] Bayertz. op. cit. note 10.
[48] Prainsack & Buxy. op.cit. note 7.
[49] Ibid.

vulnerability in their own psyche. In healthcare, however, such exclusion could potentially impede care. In a recent publication Prainsack sought to address this by asserting that "*…similarities [should] weigh more heavily than … differences*"[50]. However, solidarity that is *founded* upon principles of sameness or similarity continues to present the risk of exclusion of those who do not meet this pre-requisite.

Whilst a "*willingness to carry costs*" indicates an autonomous decision to engage in solidaristic acts, Dawson and Jennings argue that costs are an unnecessary requirement of solidarity. Instead, they propose solidarity should be a *value,* so entangled within our morality that it is an inherent component of ethical decision-making. Their model of solidarity calls us to 'stand up beside' one another - whether it be in sympathy or understanding – to rectify disadvantage or injustice.[51] Whilst there may be the *potential* for associated negative consequences resulting from the act of standing alongside, this should not equate to costs. The idea of costs – or obligations – is included in the model of healthcare solidarity described by Davies and Savulescu (2019). They use their 'rights and obligations' model to argue that, to enjoy the *right* of healthcare access, patients should be *obliged* to maintain a healthy lifestyle.[52] Whilst such active obligations would likely affect all members of society at some point, these are likely to disproportionately target the least healthy in society – and therefore those *most* in need of healthcare - by way of fine or exclusion. Such solidarity which penalises patients who fail to 'conform' may veer towards the paternalistic and so may serve to undermine autonomy.

2.3 Exclusive Solidarity in Healthcare and the Risk of Othering

It is pertinent to explore the manner in which solidarity based upon collective similarities can lead to exclusion before the case is made for conjoint solidarity that is *inclusive* of all healthcare stakeholders. Exclusive solidarity is that which "…*[restricts] the criteria for inclusion and therefore solidarity to certain groups in the population*".[53] In this way, those perceived as dissimilar are not included in the collective. Exclusion may therefore perpetuate othering, the process that "*serves to mark and name those thought to be different from oneself*"[54] and may be used to describe "*instances of perpetuating prejudice,*

[50] Prainsack B. (2020). Solidarity in Times of Pandemics. Democr Theory. 7(2), 134-133
[51] Dawson & Jennings, op. cit. note 1.
[52] Davies & Savulescu, op. cit. note 6.
[53] Hrast MF, Immergut EM, Rakar T, Boljka U, Burlacu D, Roescu A. (2018). Healthcare Futures: Visions of Solidarity and the Sustainability of European Healthcare Systems. In: Taylor-Gooby P., Leruth B. (eds) Attitudes, Aspirations and Welfare. Palgrave Macmillan, Cham. https://doi.org/10.1007/978-3-319-75783-4_7
[54] Weis L. (1995) Identity Formation and the Process of 'Othering': Unravelling Sexual Threads. EDFN. 9,17-33

discrimination, and injustice either through deliberate or ignorant means".[55] Othering is widely explored in medical literature as a vehicle for discrimination against those with actual or perceived dissimilarities, which may or may not include factors such as "*gender, ethnicity or age*".[56] Exclusive solidarity that is based upon similarity within a diverse healthcare setting can give rise to various forms of exclusion and othering which will create a fragmented approach to healthcare.

Patients may develop solidarity with all other patients through a shared vulnerability, yet this could mean that the healthy do not form strong bonds of solidarity with the sick – which is fundamental to the ongoing support of many European healthcare systems.[57] Othering that arises from specific patient demographics[58] may also promote intergenerational tensions and ageism, whereby the young fail to relate to elderly patient demographics, as described by Ayalon's commentary of the COVID-19 pandemic.[59] Othering may also be directed towards healthcare practitioners (HCPs) who are simply perceived as occupying a different role or it may be founded on the grounds of age[60] or race.[61]

Solidarity may also develop amongst HCPs themselves who may have shared experiences of the rigors of training. Yet *this* form of solidarity may exclude different specialities of HCP[62] or may lead to the othering of colleagues on the basis of sex or race.[63] Such solidarity may develop through the hardships of training, bringing the benefit of professional support networks and access to training opportunities. Indeed, many medical schools actively promote solidarity amongst their students through school-specific sports teams,[64] events[65]

---

[55] MacQuarrie C. (2010). Othering. In Mills AJ, Durepos D & Wiebe E (Eds.). Encyclopedia of Case Study Research. Thousand Oaks, CA: SAGE Publications, Inc, 636-639. doi: 10.4135/9781412957397.n238
[56] Kempenaar LE, Shanmugam S. (2018) Inclusionary Othering: A Key Threshold Concept for Healthcare Education. Med Teach. 40(9), 969-970 doi:10.1080/0142159X.2017.1403575
[57] Hrast *et al*., op. cit. note 53.
[58] Chrisler JC, Barney A, Palatino B. (2016). Ageism can be Hazardous to Women's Health: Ageism, Sexism, and Stereotypes of Older Women in the Healthcare System. J Soc Issues. 72, 86-104.
[59] Ayalon L. (2020) There is Nothing New Under the Sun: Ageism and Intergenerational Tension in the Age of the COVID-19 Outbreak. Int Psychoger. 1-4. doi: 10.1017/s1041610220000575
[60] Lasher T. (2013). Young Doctor, Nervous Patients. Anesthesiology. 119(1), 231-232
[61] Vogel L. (2018). Doctors On Their Own When Dealing with Racism from Patients. CMAJ. 190(37), E1118-1119.
[62] Kempenaar & Shanmugam, op. cit. note 56.
[63] Limb M. (2014). NHS Doctors Face Racism, Exclusion and Discrimination Report Finds. BMJ. 349 doi: https://doi.org.10.1135/bmj.g4960
[64] Babenko O, & Mosewich A. (2017). In Sport and Now in Medical School: Examining Students' Well-Being and Motivations for Learning. Int J Med Educ. 22(8), 336-342. Doi: 10.5116/ijme.59b7.8023.
[65] Shochet R, Colbert-Getz J, Levine R, Wright S (2013). Gauging Events That Influence Students' Perceptions of the Medical School Learning Environment: Findings from One Institution. Acad Med. 88(2), 246-252 doi: 10.1097/ACM.0b013e31827bfa14

and buddy schemes[66] with the intent of developing the aforementioned support networks.[67] [68] Fear of exclusion from the collective can also lead to de-individualization of those within it. As a result, members become less inclined to speak out[69] which can erode individual virtue, accountability, and empathy. It is in this way that whistle-blowers or those with differing views may be excluded, their actions or opinions viewed as different or as having failed to uphold their obligation to support colleagues.[70] [71] Zimbardo (2007) warns that in such circumstances individuals may be become subsumed within the collective.[72] This may also lead to the perpetuation of self-interest within the collective. When this concerns a subgroup – particularly a subgroup of HCPs - it could lead to conflict of interest. As a result, secondary interests, such as research interests or financial incentives, may supersede the primacy of *patient* interests. This raises further concern for care outcomes.

Solidarity amongst HCPs themselves may also exclude patients as they become subsumed within a collective that considers patients as dissimilar.[73] Kolers describes how "…*physicians are likely to identify with other doctors, even contrary to patients' interests…*" as they are "…*much more likely to project themselves into the shoes of other physicians than into those of patients or families…*".[74] This is often built upon the common misconception that patients are less knowledgeable or informed than doctors – a stance that fails to recognise the epistemic value of the patient. This may further promote the idea that patients represent a 'dissimilar' group.[75] [76] De Zulueta explains that "…*doctors [may become] immersed in the white-coated group of individuals…*"[77] that view patients as "…*not [being] one of us…*"[78] [79] - a process which can lead to disengagement and even de-humanization of

[66] Akinla O. (2108). A Systematic Review of the Literature Describing the Outcomes of Near-Peer Mentoring Programmes for First Year Medical Students. BMC Med Edu. 18(1),1-10. doi:10.1186/s12909-018-1195-1
[67] Babenko & Mosewich, op. cit. note 64.
[68] Shochet et al., op. cit. note 65.
[69] De Zulueta P(2013). Compassion in 21st Century Medicine: Is It Sustainable? Clin Ethics.8(4),119–128. https://doi.org/10.1177/1477750913502623
[70]Patrick K. Barriers to Whistleblowing in the NHS. BMJ. 2012;345:e6840. Doi:https://doi.org/10/1136/bmj.e6840
[71] Kempenaar & Shanmugam, op. cit. note 56.
[72] Zimbardo P. (2007) The Lucifer Effect. How Good People Turn Evil. Rider Random House. London.
[73] Kempenaar & Shanmugam, op. cit. note 56.
[74] Kolers A. (2020). What Does Solidarity Do for Bioethics? J Med Ethics. (online) doi:10.1136/medethics-2019-106040
[75] De Zulueta, op. cit. note 69.
[76] Dans PE.(2002). The Use of Pejorative Terms to Describe Patients: "Dirtball" Revisited'. Proc (Bayl Univ Med Cent). 15(1), 26-30
[77] De Zulueta, op. cit. note 69.
[78] Kempenaar & Shanmugam, op. cit. note 56.
[79] De Zulueta, op. cit. note 69.

patients which may inevitably fuel paternalism.[80] [81] Such de-humanization[82] may also be perpetuated by treatment of the disease rather than the patient which may be fueled by dehumanizing[83] descriptors such as '*the appendix in room 1*' or *'the oncology case from yesterday'*.[84] In addressing this worrying trend of subconscious dehumanization of the patient, Karan warned that it can lead to the erosion of empathy [85] - a value shown to correlate with improved outcomes including "…*more accurate diagnosis and better care…*"[86], improved patient engagement and overall job satisfaction.[87] The 2013 Francis Inquiry and subsequent report into the systematic failings of Mid-Staffordshire NHS Foundation Trust - whilst by no means representative of all healthcare – serves as an example of the effects of patient dehumanisation. [88] The report revealed that damaging culture had developed which put target-driven practice ahead of patient care.[89] The report described how "…*staff [had] treated patients…with callous indifference…*"[90] and, whilst it did not offer an ethical perspective as to the aetiology of such collective behaviour, it did identify a shared commitment to the achievement of Foundation Trust status. Arguably, this *could* have provided the foundations for exclusive solidarity which subsequently led to the exclusion and othering of those who did not share the commitment. The report suggests that HCPs who did not share this commitment were also excluded – by being "…*silenced, ignored or intimidated…*"[91] – as they sought to instead address poor care standards. The report recommends that "…*emphasis [should be put upon a] ... commitment to common values throughout the system by all within it…*".[92] By recognising that there should be *shared* commitment held by all those within the healthcare system, it stands to reason that solidarity in healthcare must *include* patients and healthcare professionals (HCPs) alike.

[80] Ibid.
[81] Zimbardo, op. cit. note 72.
[82] Kempenaar & Shanmugam, op. cit. note 56.
[83] Zimbardo, op. cit. note 72.
[84] Karan A. (2019) The Dehumanisation of The Patient. BMJ. 367, l6336.
[85] Ibid.
[86] Larson E, Yao X (2005). Clinical Empathy as Emotional Labour in the Patient-Physician Relationship. JAMA. 293, 1100–1106.
[87] Jeffrey D. (2016). 'Empathy, Sympathy and Compassion in Healthcare: Is There a Problem? Is There a Difference? Does it Matter?'. J R Soc Med. 109(12), 446–452. https://doi.org/10.1177/0141076816680120
[88] Francis, R QC. (2013). The Mid-Staffordshire NHS Foundation Public Inquiry (2013) 'Report of the Mid Staffordshire NHS Foundation Trust Inquiry. Executive Summary. HC 947
[89] Trueland, J. (2018). 'Target Driven, Fearful and Under Pressure – A Snapshot of Working in The NHS' BMA News. Accessed at https://www.bma.org.uk/news/2018/november/target-driven-fearful-and-under-pressure-a-snapshot-of-working-in-the-nhs
[90] Francis, R, op. cit. 88
[91] Ibid.
[92] Ibid.

2.4 Towards a Conceptualisation of Conjoint Solidarity

Dean also argues for an *inclusive* form of reflective solidarity, which concerns the "…*mutual expectation of a responsible orientation to relationship…".* [93] From such responsibility derives the 'accountability' to steer relationships towards inclusivity of others and to reconsider collective boundaries of 'us' and them' by incorporation of a third 'generalised other' in relation to concepts of 'we'.[94] In this way, a collective can give consideration to others in a way that may be lacking in traditional conceptualisations of solidarity. This, Dean proposes, creates the "…*openness…[and]… accountability…to grasp …solidarity no longer blocks us from difference, but instead provides a bridge between identity and universality…".*[95] Similarly, Honneth's 'societal solidarity' considers that individuals, although different, share a value horizon from which societal solidarity derives.[96] Differences of gender, religion or race are, therefore, recognised in such contemporary constricts of solidarity. Rorty goes further to suggest that solidarity should be a dynamic concept subject to continual self-renewal and reaction to overcome any differences by the *"…imaginative ability to see strangers, people as fellow sufferers…".*[97] Conjoint solidarity, as a descriptive norm, proposes an alternative form of inclusive solidarity that – rather than being based upon similarity or difference – is founded upon a shared goal. Central to the foundations of conjoint solidarity is a relational interpretation of individual autonomy.

2.5 Bridging the Gap Between Solidarity and Autonomy

The proposed concept of conjoint solidarity shares an interdependence with relational autonomy through the practical act of shared decision making. In healthcare, such shared decision making supports informed consent - the practical facilitation of individual medical autonomy. There is general consensus as to the *centrality*[98] of individual autonomy in Western healthcare and bioethics. Nonetheless, interpretations of autonomy are - in healthcare and beyond – so subjective that as a principle, it can be used to argue opposing sides of the same argument.[99] In legal philosophy, for example, liberal autonomy may be used to argue for individual rights of free speech, whilst relational autonomy is used to argue

[93] Dean J. (1996). Solidarity of Strangers: Feminism after identify politics. Berkeley: University of California Press.
[94] Ibid.
[95] Ibid.
[96] Honneth A. (1995). The Struggle for Recognition. The Moral Grammar of Self-Conflicts. Cambridge: MA Polity Press
[97] Rorty R. (1989). Contingency, Irony and Solidarity. Cambridge: Cambridge University Press.
[98] Vaerlius J. (2006). The Value of Autonomy in Medical Ethics. Med Health Care Philos. 377-388. doi:10.1007/s11019-006-9000-z
[99] Mackenzie, C., & Stoljar N. (2000). Relational autonomy: Feminist perspectives on autonomy, agency, and the social self. Oxford University Press.

against hate speech.[100] Autonomy, as etymologically interpreted from its Greek origins means self-law, which originally pertained to the self-governance of the Greek *polis* or state. It was Kant who first described moral autonomy in relation to *individual* self-governance and the self-imposition of universal moral law upon oneself.[101] Subsequently, some interpretations of autonomy have taken an individualistic approach whereby completely "*…self-sufficient, independent and …self-realizing individual[s]… direct [their] efforts towards maximising … personal gains…"*.[102] However, this represents an *atomistic* form of autonomy that considers the intrinsic metaphysical identity to be independent of, and isolated from external relationships, culture or society. It is to this end that individualism is refuted as a valid interpretation of autonomy by Baier, who holds the position that autonomy cannot possibly be truly independent as external influences shape individual development.[103] It is also important to distinguish between individualism and the concept of 'self-interest' in moral theory[104]. Individualism holds that individuals are the "*…ultimate point of reference of moral obligations…[whilst] collective entities such as nations, peoples [and] societies…cannot fulfil this function*".[105] Notably, self-interest need not necessarily exclude external considerations such as "*…nations, peoples and societies…*".[106] In Nicomachean Ethics, it was Aristotle's view that individuals should primarily pursue their own *eudaimonia*.[107] Often confused with 'happiness', the pursuit of *eudaimonia* is more in line with upholding one's own self-interest or well-being than the emotion of happiness. Such a form of normative egoism is, however, *"...a more sophisticated phenomenon than first meets the eye".*[108] It is not to be confused with the self-indulgence of hedonism, nor the self-absorption of *egotism.* By distinction, the safeguarding of individual self-interest in the pursuit of Aristotelian eudaimonia should incorporate virtue ethics.[109] A virtuous decision in pursuit of eudaimonia should, therefore, consider virtues such as friendship, justice and

[100] Ibid.
[101] Kant, I., (2005 [1785]), Groundwork for the Metaphysics of Morals (translated by Abbott, T revised and edited by Denis L). Peterborough: Broadview Press.
[102] Code, L. (1991). "Second persons," in What Can She Know? Feminist Theory and the Construction of Knowledge. Lanham, MD. Rowman and Littlefield.
[103] Baier A. (1985). Postures of the Mind. Essays on Mind and Morals. Minneapolis: University of Minnesota Press
[104] Smith T. (1998) Rights, Wrongs and Aristotelian Egoism: Illuminating the Rights/Care Dichotomy. J Soc Philos. 29(2), 5-14.
[105] Von der Pfordten D. (2012). Give Elements of Normative Ethics – A General Theory of Normative Individualism. Ethical Theory Moral Pract. 15, 449-471.
[106] Ibid.
[107] Aristotle. (2000). Aristotle: Nicomachean Ethics (Cambridge Texts in the History of Philosophy) (R. Crisp, Ed.). Cambridge: Cambridge University Press. doi:10.1017/CBO9780511802058 Chapter X, 183-204.
[108] Smith, op. cit. note 104.
[109] McKerlie E. (1998). Aristotle and Egoism. South J Philos. XXXVI, 36(4), 531-55.

prudence and in doing so, take the interests of others into account.[110] [111] McKerlie clarifies that "…*in acting to achieve my own eudaimonia [or self-interest] I will in fact be acting in ways that benefit other people…*".[112] Of the cardinal virtue of prudence, Aquinas described how the individual *"…first deliberates and consults others, seeking the best means and circumstances necessary to act honestly and correctly…*"[113] before reaching a decision. Ferrari also clarifies that;

> true individual prudence cannot exist in the mere pursuit of private interest but implies taking care of the social dimension as well…[therefore]...[m]ere egoistic behaviour is short-sighted rather than prudent, … it implies a wrong understanding of the individual himself/ herself, deprived of the network of relationships which permits him/her to flourish.[114]

The fulfilment of self-interests, therefore, *"....is not possible in isolation, but needs a community … [and in turn] the community … without the individual's active contribution … cannot maintain and improve itself"*.[115] Aristotle also goes further to consider that virtuous activity may also require "…*sacrifice for the sake of others…*" – a concept not dissimilar to that of solidarity.[116] To this end, the fulfilment of individual self-interest in healthcare through individual rights of autonomy can be said to align with solidarity, rather than to oppose it. However, as previously explored, self-interested *exclusive* forms of solidarity can pose problems in healthcare. It is for this reason that the inclusivity of conjoint solidarity presents a vehicle for the *collective* pursuit of *eudaimonia,* or well-being through the shared goal of improved healthcare outcomes.

Notably, liberals take a more fundamental view of atomistic autonomy that is *further* grounded in concepts of *'self*'. In political theory, liberal autonomy represents a negative right that should *not* be infringed upon by wider societal institutions. John Stuart Mill's '*On Liberty'*, considers autonomy to be "…*one of the central elements of well-being…*", upon

[110] Aristotle. (2000), op. cit. note 107.
[111] McKerlie E., op. cit. note 109.
[112] Ibid.
[113] Gardiner P. (2003). A Virtue Ethics Approach to Moral Dilemmas in Medicine. *J Med Ethics.* (29), 297-302.
[114] Ferrari G. (2017). The Relevance of Prudence to Environmental Ethics. *EJSTA.* 36(1), 126-164.
[115] Ibid.
[116]Aristotle (1984). Nichomachean Ethics. Translated by Ross WD. revised by Urmston JO. In the Complete Works of Aristotle. The Revised Oxford Translation LXXI: Princeton, New Jersey: Princeton University Press.

which the individual self can flourish.[117] [118] Both Kantian self-governance and Rawlsian liberalism are rooted in conceptualisations of autonomy pertaining to the rational, self-legislative capacity of persons. Kant aligns morality with rationality by recognising individuals as free moral agents – a requirement thought unnecessary by contemporaries such as Dworkin.[119] [120] For Kant, a moral action is not that which is influenced by human *"…desires, appetites, wants and interests…"* but the "…*higher authority*…" of rationality. He further asserts – by way of his Categorical Imperative - that individuals must act *"…only on that maxim which you can at the same time will be to a universal law…"* and in doing so adds the caveat that autonomous decisions should be reasonably applicable to all.[121] [122] According to Rehg, Kant portrays "... *a universal moral community*…", membership of which "...*constitutes a real social bond that enables harmonious cooperation in everyday life*".[123] Such 'membership' can promote a *"…commitment to…cooperation...[which is] grounded in the mutual recognition of the dignity of persons capable of autonomy*..".[124] In this way, autonomy that recognises the moral community can be both rational and relational.[125] Rawls takes a differing approach by considering *political* liberty to be subject to the requirement of 'endorsement'. According to Rawls, liberty is only justifiable, legitimate and valid, so long as it is acceptable to the individuals it affects, and institutions are only valid if endorsed by individuals subject to their power.[126] It may therefore be said that Rawlsian liberalism is also grounded in a relational 'social contract' that is also pertinent to Kantian self-governance.[127] Both Kant and Rawls acknowledge that interpretations of autonomy – and even liberalism – require a *social* dimension. Furthermore, the social dimension of autonomy can also apply when interpreted as a normative concept of self-realization. Whilst Aristotle considers the self-realisation of autonomy to be a normative concept, Meyers instead argues that autonomy is a *competency* encompassing various capacities that are required to achieve 'self-realization'. [128] [129] Such capacities are developed, reinforced or even inhibited by the social context or environment.[130]

[117] Mill JS. (1867) On Liberty. London: Longmans, Green and Co.
[118] Gray J. (2000). Mill's Liberalism and Liberalism's Posterity. J Ethics. 4 (1/2),137–165
[119] Dworkin G. (1988) The Theory and Practice of Autonomy. Cambridge: Cambridge University Press, 334-47.
[120] Campbell, L. (2017). Kant, Autonomy and Bioethics. Ethics Med Public Health. 3(3), 381-392
[121] Kant, I. (2005 [1785]), op. cit. note 101.
[122] Campbell, op. cit. note 120.
[123] Rehg W. (2007). Solidarity and the Common Good: An Analytical Framework. J Soc Philos.38(1),7-21
[124] Ibid.
[125] O'Neill O. (2009). Autonomy and Trust in Bioethics. Cambridge UK, Cambridge University Press
[126] Rawls J. (1993), Political Liberalism, New York: Columbia University Press; 144-50
[127] Hampton J. (1980). Contacts and Choices: Does Rawls Have a Social Contract Theory? J Philos. 77(6), 315-338
[128] Aristotle (1984), op. cit. note 107.
[129] Meyers DT. (1989). Self, Society, and Personal Choice, New York: Columbia University Press.
[130] Ibid.

Accordingly, Wolf – in building upon Kantian constructs of autonomy - considers normative competence, or capacity, to be a central requirement of autonomy.[131] Autonomy is also *"…understood as the capacity for rational self-regulation…"*[132] according to Korsgaard. Such capacity or competence to make decisions is, as Meyers proposed, influenced by social interaction.[133] This is reflected in the medico-legal interpretation of autonomy whereby the capable adult – or indeed, the competent child of sufficient maturity or understanding[134] - can exercise rights of medical autonomy through informed consent.

Relational autonomy as a concept in its own right has developed in the field of feminist ethics and may be defined as the *"…shared conviction…that persons are socially embedded and that agents' identities are formed within the context of social relationships…[and]…shaped by a complex of intersecting social determinants, such as race, class, gender and ethnicity…".* [135] This alternative, societal interpretation of selfhood and autonomy considers that relations with others actually *shape* our being, and therefore influence self-governance, rule or determination in relation to autonomy.[136] It proposes that the very values that individuals hold as their own are derived from their environment.[137] Links to society and societal identity - whether they relate to race, culture or religion - subsequently shape *individual* identity and so have a bearing upon autonomous decision-making.[138] In terms of medical autonomy, the patient's autonomous decision is *reliant* upon information they obtain from HCPs. Indeed, MacLean argues that *the way in which* information is given to patients can shape their views and subsequently influence 'autonomous decision making'. To this end, MacLean proposes that in order to *fully* facilitate patient autonomy a truly relational approach is required.[139] This involves an engaging *di*alogue rather than an advisory *mono*logue to afford patients and HCPs the opportunity to persuade and challenge one another so as to address misconceptions or misinformation.

[131] Wolf S. (1990). Freedom and Reason, New York: Oxford University Press.
[132] Korsgaard CM. (1996). The Sources of Normativity, New York: Cambridge University Press.
[133] Meyers DT. (1989). Self, Society, and Personal Choice, New York: Columbia University Press.
[134] Gillick v West Norfolk & Wisbeck Area Health Authority [1986] AC 112 HL
[135] Mackenzie & Stoljar, op. cit. note 99.
[136] Ibid.
[137] Taylor C. (1991). The Ethics of Authenticity, Cambridge, MA: Harvard University Press.
[138] Sandel MJ. (1999 [1982]). Liberalism and the Limits of Justice. Cambridge: Cambridge University Press. 2nd Ed
[139] MacLean, A. (2006). Autonomy, Consent and Persuasion. European Journal of Health Law, 13, 321-338

2.6 Conjoint Solidarity to Improve Healthcare Outcomes

The concept of conjoint solidarity builds upon existing theories such as Durkheim's *"community cohesion [that is] extended to all".* Durkheim's organic solidarity, founded upon the interdependence between individuals with specialised roles in society, could readily be applied to the interdependence between the specialised HCPs in the healthcare setting. However, conjoint solidarity - as an inclusive form of solidarity - recognises the epistemic value of all stakeholders, including those who are not 'specialised' in their roles, such as patients whose own epistemic value may derive from prior knowledge, or experience. [140] As aforementioned, this inclusive approach contrasts with potentially exclusive forms of solidarity which may be rooted in mutual recognition of similarity or vulnerability. [141] Dawson and Jennings's solidarity requires that one should 'positively identify with another' – such as through sympathy or understanding – so as to invoke the solidaristic act of 'standing up beside' them.[142] This applies in three main forms: the act of 'standing up for' (speaking on behalf of others), the act of 'standing up with' (mutuality and equality) and 'standing up as' (tolerance of difference or disagreement). [143] It is this final form that aims to ensure inclusivity. Yet whilst this represents an inclusive form of solidarity that is in the same vein as conjoint solidarity, there are key conceptual differences between Dawson and Jennings's solidarity and conjoint solidarity. According to Dawson and Jennings, the relationality of solidarity is rooted in the establishment of right – or just – recognition amongst individuals, which is considered an intrinsic moral good. [144] By contrast, conjoint solidarity looks positively ahead towards the shared interest that is improving healthcare outcomes. In this way, relationality is embedded in the shared aim or achievement, rather than the establishment of intrinsic moral good amongst individuals. Conjoint solidarity, therefore, forgoes the need for any form of mutual recognition. Its establishment is not dependent upon precursors such as sympathy or disadvantage – although they may exist. Instead, it is the shared interest that instils a sense of unity and togetherness. Arguably, in this way, conjoint solidarity holds the stronger ethical appeal, as the focus is upon overall attainment of those shared interests of improving healthcare outcomes, rather than purely the establishment of mutual recognition based upon some form of disadvantage or injustice, which is required to then prompt the solidaristic act of standing alongside another. Conjoint solidarity – like Dawson and Jennings's model – is one of mutuality and bidirectionality; however, its focus is upon a shared 'self' interest represents inclusivity, which incorporates

[140] Durkheim, op. cit. note 42.
[141] Prainsack & Buyx, op. cit. note 7
[142] Dawson & Jennings, op. cit. note 1.
[143] Ibid.
[144] Ibid.

all stakeholders within the diverse healthcare system they subscribe to. Naturally this position raises questions pertaining to *epistemic* solidarity and *who* decides what *improved* healthcare outcomes are. Whilst general conceptualisations of solidarity concern collective *action, epistemic* solidarity concerns consolidation of information to ascertain the "*true interest*" of the collective. [145]

As a political concept, Goodin and Speikermann describe how masses – often disadvantaged by less information and incompetence – can 'pool information' to redress balance with the informed, competent elites. Taking the Condorcet Jury Theorem (CJT) as an example, they assert that in democratic voting systems, the majority of voters are more likely to come to the 'right' decision pertaining to collective best interests, than individual voters. Notably, the power of the collective depends upon the *"…sufficiently independent and competent…"* individuals. [146] In this way, epistemic solidarity may be said to be *dependent* upon individual autonomy. However, epistemic solidarity with its focus upon 'elites' and 'masses' – which in healthcare may pertain to 'elite or specialised HCPs and 'patient masses' – may represent an *exclusive* model of solidarity. Furthermore, competent elites may also pool *their* knowledge and resources to 'over-come' the masses to determine best interests which, in healthcare, could promote paternalism over autonomy.[147] The investigative findings of the Independent Medicines and Medical Devices Safety Review (IMMDSR) offer a potential insight into how this could affect determination of collective interests. The review addressed, in part, the scandal surrounding implantable pelvic polypropylene mesh pelvic – or vaginal - mesh.[148] The prolonged use of mesh in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) was, for a considerable period of time, considered to be safe despite patient reports of harm suffered. Indeed, several patients asserted that their complications were often dismissed and not taken seriously. Instead, the 'knowledgeable healthcare elite' relied upon evidence-based practice – which was subsequently found to be subject to bias - to determine that this was a safe practice which could attain improved healthcare outcomes. Through decades of campaigning, the competent patient 'masses', facilitated by support groups such as *'Sling the Mesh!'* were

[145] Goodin B, Spierkermann K. (2015). Epistemic Solidarity as a political strategy. Episteme. 12, 4: 4239-457.
[146] Ibid.
[147] Goodin B, Spierkermann K, op. cite note 145
[148] Independent Medicines and Medical Devices Safety Review [Internet]. Cumberledge J, CBE. 2018, November 20. [Updated 2020, ,July 31; cited 2021, February 8]. Evidence. Available from https://www.immdsreview.org.uk/Evidence.html . See also the final report: Cumberlege J CBE. First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review. 2020 July 8 [cited 2021 February 8] United Kingdom. ISBN 978-1-5272-6567-7. Available at https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf Accessed 12 April 2021.

able to collectively pool information and demonstrate that mesh implantation was associated with significant morbidity and, even mortality.[149] In doing so, the patient 'masses' successfully challenged the views of the 'elite'. This, perhaps, illustrates that exclusive forms of epistemic solidarity are not conducive to improved healthcare outcomes. It is to this end that conjoint solidarity applies *inclusive* epistemic solidarity so the *collective* healthcare entity 'pool information' to better determine best interests and improve healthcare outcomes.

In healthcare, decision-making occurs at the micro, meso, macro and meta levels.[150] The micro level concerns decision-making between patients and HCPs whilst the meso-level concerns the "*…clinical decisions involved in the development of guidelines or protocols that can be used for the treatment of specific conditions…with the aim of [determining] optimal treatment policies…"*.[151] Subsequent macro and meta level decision-making tends to pertain more to distributive justice which will be considered later with macro-level decisions concerning "*…allocation and utilization of resources in a region, organization [or] hospital etc…*"[152] with the meta-level concerning healthcare budget as determined at governmental level. It is anticipated that application of an inclusive epistemic gloss to conjoint solidarity would enable determination of 'improved healthcare outcomes'. At the micro level conjoint solidarity can promote a two-way dialogue between patient and HCP through the medium of shared decision-making which will facilitate the initial 'pooling of information'. Such information can subsequently contribute to determination of best interests and improved healthcare outcomes. Conjoint solidarity is likely to promote trust and, in turn, greater patient disclosure which can improve diagnosis and promote better clinical outcomes.[153] Similarly, the HCP offers their specialised knowledge, and the patient discloses key information for diagnosis. Following treatment, this model can also provide a valuable source of information pertaining to patient experiences and their perspectives on treatment outcomes which can help shape future practice. Such an approach at both meso and macro levels could also enrichen the evidence-base for policymakers. Currently in the United Kingdom, the evaluation of efficacy, safety and cost-effectiveness of treatments is undertaken by the National Institute for Clinical Excellence (NICE) – a macro level organisation - which subsequently provides evidence-based guidance on available

[149] Ibid
[150] Guler S, Hurton S, Winn MC, Molinar M. (2015). Levels in Decision Making and Techniques for Clinicians. Int J Dig Dis. 1(1) 2
[151] Ibid.
[152] Ibid.
[153] Ibid.

treatments and how to improve outcomes. Such 'evidence-based practice' involves assimilation of the best research evidence.[154] However, the evidential hierarchy which currently favours quantitative data tends to disregard input such as patient-based qualitative evidence.[155] Patient-based evidence pertains to that which is collaboratively generated from patients and has been shown to improve healthcare outcomes.[156] Arguably the disregard for patient-based evidence may, inadvertently, promote a paternalistic approach to determining best interests and good healthcare outcomes. Recent studies also discuss how conflict of interest can bias clinical studies, unduly influence the medical literature, and therefore impair healthcare outcomes.[157] This was the case in the aforementioned IMMDSR, whereby mesh studies unduly influenced by conflict of interest dominated the literature and eclipsed smaller studies - and even NICE recommendations.[158] Indeed there was such a reliance upon quantitative data in the medical literature, that patient experiences were often discounted. Arguably the *lack* of epistemic conjoint solidarity could have contributed to the use of mesh for far longer than need have been the case. If the epistemic value of all stakeholders *had* been considered, better healthcare outcomes could have been achieved and increased morbidity avoided. In the United States, the regulatory body the Foods and Drug Administration (FDA) has outlined ways in which patients can be engaged during *their* decision-making to contribute qualitative input, stating "*…if our ultimate goal is…to improve patient outcomes, we must take a whole-system approach…*".[159] The Advancing Quality Alliance (AQUA) found that where patients were empowered, through shared decision making, to make decisions about their own health, there were "*…more favourable health outcomes…*".[160] In the UK, NICE will look to patient-based evidence only if there is

[154] Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS.(1996). Evidence based medicine: what it is and what it isn't. BMJ. 312(7023),71.
[155] Ibid.
[156] Staniszewska S. Werko S. (2017) Patient-Based Evidence in HTA. In: Facey K. Ploug Hansen H. Single A. (Eds) Patient Involvement in Health Technology Assessment. Adis, Singapore.
[157] Elder K, Turner KA, Cosgrove L, Lexchin J, Shnier A, Moore A, Straus S, Thombs BD. (2020) Reporting of financial conflicts of interest by Canadian clinical practice guideline producers: a descriptive study. CMAJ, 192(23) e617-625 https://doi.org/10.1503/cmaj.191737
[158] See Rowland, D. (2020) Some financial conflicts of interest in medicine cannot be managed and should be prohibited. BMJ Opinion. Available at https://blogs.bmj.com/bmj/2020/07/21/david-rowland-some-financial-conflicts-of-interest-in-medicine-cannot-be-managed-and-should-be-prohibited/ Last Accessed 11 March 2021 and also National Institute for Clinical Excellence (2003). Final appraisal determination. Tension-free vaginal tape (Gynecare TVT) for stress incontinence. Available at https://www.nice.org.uk/guidance/ta56/documents/final-appraisal-determination-tension-free-vaginal-tape-gynecare-tvt-for-stress-incontinence2 Last Accessed 11 March 2021
[159] Finnegan G. (2018). Patient Collaboration and Patient-Based Evidence – Closing the Infinite Loop to Connect the Dots. Patient Focused Medicines Development. Available at https://patientfocusedmedicine.org/patient-collaboration-and-patient-based-evidence-closing-the-infinite-loop-to-connect-the-dots/ Accessed on 12 April 2021
[160] NHS. Shared Decision Making to Improve Health Outcomes. https://www.england.nhs.uk/shared-decision-making/why-is-shared-decision-making-important/shared-decision-making-to-improve-health-outcomes/ Accessed on 12 April 2021

a corresponding *lack* of quantitative evidence. Whilst greater patient engagement may be considered burdensome, studies have shown that *overall* healthcare system burden is lowered, which in turn results in better outcomes.[161] It is not suggested that such patient-based evidence in any way *replace* existing evidence, but instead that it should, instead, support it. An epistemic interpretation of conjoint solidarity would call for collective pooling of information from *all* stakeholders to determine and then improve healthcare outcomes. In a manner similar to Goodin and Speikermann's example of CJT, the majority are more likely to reach the right outcome than individuals.[162] The determination of outcomes and what constitutes a 'good healthcare outcome' is complex as it must reflect public interest, societal preference and cost-benefit analyses. These further considerations tie into the principle of justice.

3. BRIDGING THE GAP BETWEEN SOLIDARITY AND JUSTICE?

3.1 Conjoint Solidarity and Justice

Justice has been described as a *virtue* associated with the intrinsic moral character of the individual, a prescriptive *norm* aimed at guiding conduct and a *moral practice* through which an externalised form of virtue may be attained. Modern theories of *distributive* justice in particular seek to ascertain which societal frameworks (such as laws and policies) should be implemented to determine the distribution of resources amongst a collective. It was the influence of Roman Jurisprudence upon Thomas Aquinas that saw the shift from the classical position of *virtuous* justice to a framework of moral guidance, rights and obligations incumbent upon individuals.[163] This apparent focus on 'the individual' may lead to the assumption that justice is a liberal construct that opposes the commonality of solidarity; however, just as there are liberal and social interpretations of both autonomy and solidarity, so too there are also liberal and social interpretations of justice.

One of the most rudimentary approaches to the matter of *distributive* justice is to apply a framework of strict equality amongst individuals in society. Such *egalitarianism* considers that individuals are morally equal and so there should be equal distribution of goods. Aristotle and John Stuart Mill both considered equality to be the foundation-stone of justice[164]. Indeed, Mill's philosophy was one of 'the greatest good for the greatest number',

[161] Finnegan, op. cit. note 159.
[162] Goodin & Spierkermann, op cit. note 145.
[163] St. Aquinas T. (1947). Summa Theologica of St Thomas Aquinas, 'Of Justice' [translated by Rathers of the English Dominican Province]. New York: Benziger Brothers Inc.
[164] Agnol D. D. (2005). Dworkin's Liberal Egalitarianism. Kriterion [online]. 46(111), 55-59 Translated by Tonette MC.

of the utilitarian kind. However, egalitarianism often does not take into account that, in the simplest of terms, there may not be equal contribution or *need* amongst the collective. So, somewhat paradoxically, equal allocation could result in actual or perceived inequality. Marxian views sought to eliminate inequality by distributing goods, first according to contribution and then - upon the subsequent establishment of a communist society - according to need.[165] By contrast, *liberal* theories of justice mirror liberal conceptualisations of autonomy in that they consider whether the act of a free individual is just.[166] Liberal theory, developed from philosophers such as John Locke, holds that every individual has equal basic moral or natural rights which relate to their claims on societal resources.[167] Kant prioritised liberty as the basis of justice, so that the state would redistribute very little in order to facilitate the greatest individual autonomy.[168]

Philosophers such as Rawls[169] and Dworkin[170], however, sought to bridge the gap between liberal and egalitarian theories of justice. Their theories of *liberal egalitarianism* combine equality with personal liberty and responsibility. Dworkin's liberal egalitarianism aimed to bridge a gap by considering liberalism and equality as complementary to one another. Equality - such as equal respect and equal opportunity amongst individuals – would provide a foundation upon which liberty would be established. Inequality is acceptable, according to Dworkin, if it derives from voluntary choice, rather than disadvantage. [171] [172] In this way, he seeks to make people responsible for their choices, but not matters beyond their control. Rawls's publication '*A Theory of Justice'* presents the one of most influential theories of liberal egalitarian justice.[173] Justice according to Rawls, should not "…*adopt for society as a whole the principle of choice for one man…*" as the utilitarian approach proposes, as this places broad limitations upon the rights and liberties of individuals. [174] Rawls acknowledges limitation in another way through his 'thin theory' which proposes an index of primary goods should be developed to identify the necessities individuals require to then go on and achieve their various *individual* goals. It is this primary index which can be used to determine

[165] Marx, K. (1978). Critique of the Gotha Program. In R. C. Tucker (Ed.), The Marx-Engels reader (pp. 525-541). W. W. Norton.
[166] Ter Mulen R. (2016). Solidarity, Justice and Recognition of the other. Theor. Med. Bioeth. 37, 517-529.
[167] Locke J. (1978) [1698]). Two Treatises of Government. New York: EP Dutton
[168] Kant, I. (1996 [1797]) in Gregor, M. (trans) *The Metaphysics of Morals*, Cambridge: Cambridge University Press
[169] Rawls (1971), op. cit. note 29.
[170] Dworkin R. (2000). Sovereign virtue: The theory and Practice of Equality. Cambridge. MA: Harvard University Press
[171] Agnol, op. cit. note 164.
[172] Dworkin, op. cit. note 170.
[173] Rawls (1971), op. cit. note 29.
[174] Ibid.

whether inequality is justified or not.[175] An example of a primary good could be that of 'opportunity', that is explored in more depth through the theory of opportunity egalitarianism whereby rights take the form of opportunity. The degree to which individuals then take advantage of such opportunities determines their degree of distribution. In this way, individual justice can be derived from social justice, as the individual is seen to effectively comply with societal principles of justice.[176] There are problems with such opportunity egalitarianism – which was described by Ter Meulen as a cold form justice - as not everyone will be able to take advantage of opportunities in the same way.[177] For example, some individuals may be less *able* to adopt a healthy lifestyle due to sedentary forms of employment. Yet under such opportunity egalitarianism they may be denied healthcare access or have it restricted. According to Ter Meulen, this is a form of humiliation, whereby those who do not take the opportunities afforded to them are considered, by society, to be 'underserving' of collective resources.[178] Such humiliation may lead to *"rejection, exclusion, paternalism and denial of rights*".[179] Schmidtz and Thrasher suggest that justice should *bridge* the gap between individual virtue and the virtue of the *polis* or society.[180] They recognise that as relational entities we rely upon community, therefore where justice promotes harmony in a community, compliance with justice will promote individual virtue. In a similar vein, Ter Meulen argues that *solidarity* should be applied *in addition* to theories of distributive justice to support relational aspects of personhood – as this can contribute to reciprocity, support and so ultimately perpetuate solidarity. [181]

3.2 Conjoint Solidarity to Support Relational Distributive Justice

According to Ter Meulen, justice as a theory of rights and obligations, lacks a normative framework for its practical application that exists in the practical application of solidarity. [182] Therefore, the incorporation of relational elements such as communication and "*reciprocal recognition of individuals"* amongst those who act in solidarity can *supplement* justice. In delivering healthcare, this would facilitate a relational approach to distributive justice that would allow participants to appreciate their "…*identities and responsibilities…*".

[175] Ibid.
[176] Ter Meulen R (2017). Solidarity and Justice in Health and Social Care. Cambridge: Cambridge Books. Ch 3, 12.
[177] Ibid.
[178] Ibid.
[179] Ibid.
[180] Schmidtz D, Thrasher J. (2014). "The Virtues of Justice," in K. Timpe and C. Boyd (eds.), Virtues and Their Vices, Oxford: Oxford University Press
[181] Ter Meulen R (2017), op. cit. note 176
[182] Ibid.

[183] Relational justice may be defined as *"…justice produced through cooperative behaviour, agreement, negotiation or dialogue amongst actors in a post-conflict situation…".*[184] It has also been described by Raines as a *"…connectedness of persons and groups in community and [the] basic obligations to look out for the relational good of others…".*[185] [186] Whilst Raines' definition relates to *restorative* justice, such reciprocal recognition amongst individuals is also pertinent to distributive justice as means of addressing the deficiencies in equality identified in liberal, liberal egalitarian and opportunity egalitarian views of justice.[187] To attain this goal, relational justice also requires "…*attentiveness and appropriateness of response…trust and loyalty…*" as well as reciprocity.[188] As with relational autonomy and conjoint solidarity, relational justice recognises that individuals are inextricably linked. It holds that where the individual is denied their voice, there is subsequent inequality and *lack* of justice. In this way, relational justice addresses the social collaboration that is often missing in alternate constructs of distributive justice. Conjoint solidarity could also support relational distributive justice as both concepts share the goal of improving healthcare outcomes. The collaborative nature of conjoint solidarity, founded upon the shared decision making of relational constructs of autonomy, can support distributive justice by involving patients in the matters of healthcare utilisation and allocation that currently do not include them. A collaborative approach could promote the responsible utilisation of healthcare resources which could - in turn - allow more efficient future allocation of resources to attain the goal of improved healthcare outcomes. It is not anticipated that patients would be able to participate in *all forms or levels* of distributive justice, however even at the micro level of care, collaboration and involvement could have a substantial impact. Consider, for example, that in 2017 the National Health Service (NHS) spent £70 million on paracetamol prescriptions alone. On prescription, paracetamol may cost £34 for 32 tablets,[189] whilst some retailers sell it "…*for pennies…*".[190] It is predicted that the NHS could save £190 million a year by reducing prescriptions for short term, or

[183] Ter Meulen R (2017)., op. cit. note 176.
[184] Casanovas P, Poblet M. (2008). Concepts and Fields of Relational Justice. In: Casanovas P, Sartor G, Casellas N, Rubino R (Eds). Computable Models of the Law. Lecture Notes in Computer Science. Vol 4884. Berlin: Springer. 323-339.
[185] Pillsbury SH. (2019). What Is Relational Justice? Loyola Law School, Los Angeles Legal Studies Research Paper No. 2019-09. doi:10.2139/ssrn.3338052
[186] Ibid.
[187] Raines JC. (1989). Toward a Relational Theory of justice. Cross Currents 39(2), 129-141, 160.
[188] Ibid. at 139
[189] NHS England. (2017). Prescription Curbs to Free up Hundreds of Millions of Pounds for Frontline Care. News. Available at https://www.england.nhs.uk/2017/11/prescription-curbs-to-free-up-hundreds-of-millions-of-pounds-for-frontline-care/ Accessed on 12 April 2021.
[190] Buchan L. (2017). Providing paracetamol to Patients in England Cost over £70m last year, official figures show. The Independent. 2 July. Available at https://www.independent.co.uk/news/uk/politics/nhs-70-million-paracetamol-last-year-figures-department-health-painkillers-prescriptions-a7819661.html

minor conditions that are alternatively available over-the-counter.[191] In UK law, the issue of distributive justice recently came to the fore in the legal case of *Bayer Plc v NHS Darlington CCG and Others* [2018] which considered the use of 'off-label' and 'off-licenced' medicines in NHS. The case explored whether the NHS could use cancer drug Avastin 'off-label' – beyond its licenced indication – in the treatment of ophthalmic condition macular degeneration.[192] Avastin cost £28 per dose whilst Bayer's EYLEA drug with specific marketing authorisation for the treatment of macular degeneration cost £816 per dose. The court, in establishing a legal precedent whereby the NHS could use 'off-label' medications to reduce cost, determined that Avastin was a safe and cost-effective treatment for macular degeneration.[193] The case also created a new legal duty for doctors to consider the wider issues of distributive justice and resource allocation when prescribing medical treatment. Justice Whipple said that "*…having regard to resources is an enduring requirement, which touches on every decision which a clinician makes…*"[194] and that it was a "*… a matter of professional conduct… [that doctors] be free to choose whichever medicine he or she considers to be most suitable, taking account of his obligations to the patient, and to patients more generally*".[195] Therefore, whilst doctors have legal obligations to act in the best interests of individual patients, they also have an obligation to consider the best interests of *all* patients when prescribing. Sutherland suggests that healthcare will face increasing difficulties in trying to satisfy both issues of patient autonomy and distributive justice in years to come.[196] However, Davies and Savulescu propose that in order to enjoy the right to free healthcare, patients should be obliged to *"...play their part..."* in terms of healthcare solidarity.[197] The UK healthcare system is based upon universal access at the point of need with distributive justice used to address such questions of 'need'. Yet relational justice in healthcare – whereby individuals acknowledge their "*…identities and responsibilities…*" as inextricably linked entities – could facilitate a form of collective collaboration, which is often missing constructs of distributive justice. Conjoint solidarity, which requires collaboration and collating of information, could also provide a means of supporting distributive justice by allowing patients to 'play their part' – albeit to a degree. As relational autonomy and conjoint, epistemic forms of solidarity all involve sharing and pooling

[191] NHS England, op. cit. note 189.
[192] Bayer Plc v NHS Darlington CCG and Others [2018] EWHC 2465 (Admin)
[193] Wolgast E. (1987). Wrong Rights, The Grammar of Justice. Ithaca: Cornell University Press, 30
[194] Bayer, op. cit. note 192.
[195] Ibid.
[196] Sutherland A. (2015). It is time to review how unlicensed medicines are used? S. Eur J Clin Pharmacol.71,1029 doi.org/10.1007/s00228-015-1886-z
[197]Davies B, & Savulescu J., op. cit. note 6.

information, then it is likely that healthcare literacy will be improved. Subsequently, through greater collaboration, a form of collective responsibility could be adopted, which would facilitate more conscientious use of the NHS and more efficient healthcare utilisation. This proposal does not intend to provide a single solution to these issues, but instead to serve as a reference point for future debate.

4. CONCLUSION

Solidarity in the field of healthcare ethics has been somewhat neglected, perhaps due to the assumption that it opposes concepts of individuality and autonomy. Yet where autonomy is interpreted as a *relational* concept, these principles can develop an inter-dependency – founded, in part, upon the process of shared decision-making - so that both individual and collective may benefit. In seeking to complement existing scholarship, conjoint solidarity proposes a new model that is inclusive of *all healthcare* stakeholders in diverse healthcare communities. In this way, with the focus upon the mutually held goal of improved healthcare outcomes, exclusion and othering can be avoided in our diverse healthcare communities. It is anticipated that such desirable healthcare outcomes can be determined by adopting an *epistemic* approach, which involves collective pooling of information. Furthermore, this may also help address some of the current problems in healthcare - such as exclusion, paternalism, and conflict of interest - so that they be mitigated. Such a conjoint and epistemic approach can also provide an opportunity to rethink distributive justice. As a *relational* concept it may afford patients the opportunity to 'play their part' in a small way – such as through responsible healthcare usage. This may help ensure efficient use of healthcare resources and more appropriate resource allocations - which can, in turn, improve healthcare outcomes.

Paper 2

II. Materiality of Conflict of Interest in Informed Consent to Medical Treatment in the United Kingdom

Abstract

The UK Supreme Court ruling of *Montgomery v Lanarkshire* [2015] clarified that in obtaining informed consent to treatment, practitioners are under a duty to inform patients of material risks. Traditionally such risk has pertained to the clinical risks inherent to treatment. In examining empirical and judicial evidence, this paper makes the case for disclosure of potent financial interests; with potency relating to those interests likely to have greatest influence over practice. The paper explores how financial interests may detrimentally influence practice patterns and how non-disclosure of such interests may be linked to the erosion of patient trust and subsequent disinclination to consent to treatment. Judicial notions of material risk are explored, and the conclusion reached that they offer a broader interpretation of disclosable risk compared to current UK GMC guidance. It is anticipated that empirical evidence could be used by the courts in determining questions of both materiality and causation in cases of negligent non-disclosure of potent financial interests. The paper concludes that there is sufficient reason to surmise that a test case could successfully apply the principles identified therein to establish the materiality of conflict of interest in informed consent to medical treatment.

Key Words: *Conflict of Interest, Materiality, Informed Consent, Medical Treatment, United Kingdom*

Introduction

The United Kingdom (UK) common law standard of informed consent - set out in the case of *Montgomery v Lanarkshire Health Board* - holds that in obtaining consent to medical treatment, medical practitioners must inform patients of *material* risks associated with treatment (*Montgomery v Lanarkshire Health Board* [2015]). The decision called for collaboration with patients through shared decision-making which marked a departure from the paternalism which had become embedded medical law following the *Bolam* ruling some sixty years earlier (*Bolam v Friern Hospital Management Committee* [1957]). The Cumberlege Report into the findings of the United Kingdom's (UK) Independent Medicines and Medical Devices Review (IMMDSR) exposed how conflict of interest can lead to poor treatment outcomes for patients, erosion of trust and the invalidation of informed consent (Cumberlege, 2020; IMMDSR, 2018). In addition, recent empirical studies have also demonstrated that practitioner's financial interests – and subsequent conflict of interest – can result in harmful changes to practice patterns (Robertson *et al*., 2012). The purpose of this paper is to explore the case for conflict of interest as a disclosable material risk required for valid informed consent. This manuscript will examine physicians' financial conflicts of interest, their potential influence upon patterns of practice and the subsequent harm that a failure to disclose such interests poses to patients. The case will then be made, through provision of empirical evidence, for including disclosure of certain financial interests as an essential element of informed consent post-*Montgomery*. These recommendations are subject to certain limitations: namely that only financial interest which can be demonstrated to be 'potent' or high-risk for patient harm should be disclosable to prevent a tide of information disclosure overwhelming the patient; that empirical evidence is likely to be required in proving materiality to the reasonable person and that a test case in the UK would likely be required to clarity the scope of materiality at common law. Finally, consideration will be given to future directions of research.

Practitioners' Conflict of Interest

In exercising professional judgement medical practitioners have a duty to *"…[m]ake the care of … patients [their] first concern…"* (GMC, 2019, p4) and so that patient interests take primacy over any secondary interests of the practitioner. Conflict of interest may arise when *"…professional judgement concerning a primary interest … [such as]… patient's welfare ….[is]… unduly influenced by a secondary interest [such as financial gain]…"* (Thompson, 1993, p573). These secondary interests may be broadly categorised as being

'non-financial' or 'financial' in nature (Wiersma *et al.*, 2017). Non-financial interests encompass a range of factors, such as "*…political, academic, ideological or religious…*" considerations which have the potential to influence professional judgement (PLoS Medicine Editors, 2008, e1299). In healthcare, such interests may derive from practitioner autonomy, such as a preference to undertake a particular type of surgery; practitioner paternalism, such as the influence derived from a perceived belief that an action is in the patient's best interests (Strauss & Merios, 2009) or even practitioner egotism, such as the preference to undertake innovative treatment so as to fulfil a personal *"…desire for prestige and career progression…"* (Wiersma *et al*., 2017, p319; Cumberlege, 2020).

Financial Conflict of Interest

Financial Interests Linked to Patient Referrals. Financial interests include monetary factors, such as payments or incentives, given to the practitioner in relation to their professional capacity. Montgomery and Lipworth (2019) describe financial interests as the financial *"…conflicts and quandaries…"* which are endemic across all levels of patient care; from the upper 'macro' level incorporating regulators, policy-makers and healthcare organisations, to the intermediary 'meso' level of care concerning those professional organisations, researchers, or academics with indirect influence over patient care (Montgomery & Lipworth, 2019, chpt. 1). Yet, it is the financial interests of the individual practitioner, affecting the micro level of patient care, which are most pertinent to the issue of informed consent (Montgomery & Lipworth, 2019). In a study which will be explored later, Spece and colleagues propose that practitioners should disclose "potent" financial interests to patients (Spece *et al*., 2014, p271). Potent may be defined as *"…having great power, influence, or effect…"* (Oxford Languages, 2021) therefore, for the purposes of this paper, financial interests are those likely to have great influence over treatment decisions. In a review of the empirical evidence relating to how financial interest can affect practitioner behaviours, Robertson and colleagues identified three main categories of financial interest in the United States (US) healthcare system; insurer-based financial interests, financial interests linked to patient referrals, and financial interests linked to pharmaceutical or medical device companies (Robertson *et al*., 2012). The latter two categories are most readily applicable to the UK healthcare system. Funded by a government mandated national insurance system, the UK public National Health Service (NHS) affords universal access to all UK citizens. Approximately ten percent of the population opt for supplementary cover by way of *"…duplicative private insurance…"* (Papanicolas *et al*., 2019, p369). Private insurance confers added benefits including choice of practitioner and improved access to services and specialist treatments (BMA, 2020). Any practitioner registered with the UK

medical regulator the General Medical Council (GMC) – in accordance with the Medical Act 1983 - is eligible to undertake such private work, including those whose primary contract is with the NHS (Medical Act 1983, s3). It is a practice which has rapidly increased in recent years with data from 2016 showing that approximately half of the 46,000 consultants employed by the NHS were involved in some form of private practice (Smyth, 2016). Full time NHS consultants with a pre-2003 contract can undertake private work so long as the gross private earnings do not exceed 10% of their gross NHS salary, however post-2003, there is no limit on consultant's private work – yet there is an expectation that they prioritise NHS overtime (BMA, 2020). The British Medical Association (BMA) recognise that such private work could create a conflict of interest and therefore advise their members not to initiate conversations about private care with their NHS patients. However, such discussions can take place if it is the patient who initiates the enquiry. Furthermore, where patients seek to be treated privately, there is nothing in the guidance to say that practitioners need disclose the *nature* of any associated financial interest they may have with the provision of such private healthcare (BMA, 2020). A study by Rowland (2019) for the Centre for Health and the Public Interest (CHPI) found that private hospitals in the UK provide consultants with "*substantial*" hospitality incentives for referring patients to them (Rowland, 2019, p4, p11). In the year 2017-18, a staggering £1.5 million was spent on corporate hospitality by seven private UK hospitals alone, including *"…numerous lavish trips to sporting events worth over £1000 a head…"* (Rowland, 2019, p4, p11). This, despite NHS guidance that employees should receive no more than £75 in hospitality or gifts (NHS England, 2017; Rowland 2020). Furthermore, Rowland identified that 546 NHS consultants owned shares, equipment or had pay-per-scan arrangements with private institutions (Rowland 2019, p4). At one NHS hospital – the Royal Surrey County NHS Foundation Trust - 50% of its consultant oncologists were found to hold shares, or own equipment, in private hospitals whilst the same could be said for 45% of orthopaedic surgeons at another NHS hospital in the city of York (Rowland 2019, p8). Whilst it is widely acknowledged that the private sector offers valuable support to the NHS, particularly when contracted to help tackle long waiting lists, it is clear that the ties between public and private sector healthcare in the UK create the potential for conflict of interest to arise. In 2020, the UK House of Commons published its Report of the Independent Inquiry into the Issues raised by Paterson, otherwise referred to as 'the Paterson Report' (James, 2020). The inquiry explored one of the largest known examples of patient overtreatment in the UK associated with conflict of interest between the NHS private healthcare sector (Rowland, 2019, s.5p5). "*Rogue*" NHS breast surgeon, Ian Paterson, was described was having "*significant*" financial incentives to preferentially treat patients in the private sector rather than the NHS (Dyer, 2017; Rowland, 2019 at s.25, p4;

James, 2020, p119). In the period between 1997 and 2011, Paterson harmed 750 patients by undertaking investigations or surgical procedures for ailments which patients did not have (Rowland, 2019, s.5, p5). This included mastectomies and surgeries for the removal of cancer in individuals not suffering from the disease. In one instance the inquiry heard that soon after a cancer diagnosis, Paterson had starkly told 'patient 162' that they faced a three year wait for treatment on the NHS or could pay £10,000 to undergo the surgery in the private sector within one week (James, 2020, p119). The Inquiry heard that patient 162 *"…[was] convinced she had unnecessary surgery that she didn't agree to…"* and that her medical records had since "*disappeared*" – thus removing any pathological evidence of the existence of the cancer (James, 2020, p52-53). Evidence from the CHPI presented to the Paterson Inquiry attested that whilst there was, as of yet, still no evaluation of Paterson's financial interests, the interests were estimated to be "*significant*" and *"…in the region of £3 million…"* (Rowland, 2019 at s.5, p5; CPHI, 2019 s.25, s.26, p4). Furthermore, the Paterson Inquiry heard how Paterson had, in turn, incentivised general practitioners (GPs) in his local area by providing hospitality so that they would preferentially refer patients to his private practice (James, 2020, p120).

Financial Interests Linked to Industry. Financial conflict of interest in the UK may also derive from the links with the pharmaceutical or medical device industries. Such links are often recognised as a necessity of medical advancement, yet Rowland cautions that it may be difficult to *"…distinguish payments that inappropriately influence clinical decision making from those which are made for contributing to scientific innovations…"* (Rowland, 2020, para 16). The pelvic (vaginal) mesh scandal exposed *"…the extent to which individual surgeons, researchers and professional bodies are reliant on device manufacturers for financial support…"* through its investigation into the use pharmaceuticals and medical devices (Gornall, 2018, para 18). It revealed how one medical device manufacturer, Ethicon, marketed its pelvic (vaginal) mesh as a solution for stress urinary incontinence (SUI) and, more recently, pelvic organ prolapse (POP) (Gornall, 2018). The company had *"…highly [and] aggressively marketed to gynaecologists …[through] the Ethicon 'buy a Lamborghini' and 'Surgery is the Cha-chin thing' campaigns'…"* which proved "*…highly lucrative for private surgeons…*" (Dr Vincent Argent, Clinicians etc. Evidence, IMMDSR, 2018, p15). Ethicon also influenced medical education through its sponsorship of the Royal Colleges' continuing professional development (CPD) programmes, thus extending its influence to individual practitioners (Cumberlege, 2020). The company also comprehensively marketed its product at conferences where it offered individual surgeons' financial incentives (Gornall, 2019). As a result, such financial

interests are often inextricable from the training which practitioners receive, making it difficult to identify the source of such influence. Therefore, as will be explored, it is likely that only financial interests which can be demonstrated to pose high risks to patients - ideally through the provision of empirical evidence - will be disclosable due to the difficulties in establishing legal causation.

Failure to Disclose Conflict of Interests

Interests Linked to Patient Referrals. Rowland (2020) describes UK patients as being "very poorly protected" from the influence of practitioner's financial interests under current voluntary disclosure arrangements (Rowland, 2020, para 6). In 2019, of approximately 300 NHS consultants who owned shares in private hospitals in the UK, only 19 had declared their interests via their NHS Trust - indicating wide-spread non-disclosure of financial interests (Rowland, 2019, p20). The Paterson Inquiry – which heard how the breast surgeon had preyed upon patient fears following cancer diagnoses by exaggerating NHS waiting times – had failed to provide independent information to patients to facilitate informed decision making, with a lack of valid informed consent obtained for one third of patients (James, 2020, p115,119). The CPHI considered that it was unlikely that Paterson's patients were informed or had knowledge of his financial interests as the information was either missing or difficult to find on the websites of private hospitals (CHPI, 2019 s.20, p3). Indeed, Rowlands describes a general *"…lack of willingness across parts of the profession to be open and transparent [about financial interests]…"* (Rowlands, 2020, para 21). This was reflected in the Private Healthcare Investigation (PHI) by the Competition and Markets Authority (CMA) which uncovered a widespread lack of disclosure and concluded that *"…clinicians should be required to disclose to their patients any equity interest they have in a facility to which they propose to refer the patient, or in any major item of equipment …which they propose to use to conduct tests on or to treat the patient…"* (Witcomb *et al*., 2014. para 11.463 p11-99 as cited in Rowlands, 2020, p76).

Interests Linked to Industry. Rowland also describes the large number of incentive schemes designed to influence practice which remained *"…largely hidden from patients and the public…"* (Rowland, 2019, p18). A recent report by McCartney in the British Medical Journal (BMJ) explored the difficulties associated with finding conflict of interest disclosures linked to pharmaceutical or medical device companies in the UK (McCartney, 2018). McCartney describes being caught in a time-consuming "*game*" of trying to find a practitioner's conflict of interest (McCartney, 2018, para 1). The most promising disclosure tool available in the UK is that which the Association of the British

Pharmaceutical Industry (ABPI) oversees. The ABPI publishes payments made by the pharmaceutical company to doctors on a voluntary basis (ABPI, 2021). However, only half of the £53million of payments made have thus far been declared (McCartney, 2018). Arguably, such disclosures could enable patients to make a truly informed treatment choice of whether to accept such treatment and facilitate greater patient autonomy. However, such disclosure databases place a burden on the patient, as described by McCartney, to source the relevant information which is likely to create a barrier. Such information does, however, appear to be valuable to patients. In patient testimony to the IMMDSR, one patient reflected upon the retrospective knowledge that conflict of interest had played a role in the promotion of pelvic (vaginal) mesh, stating that *"…[a]s patients, we allow the medical profession access to all manner of information [so they can determine] the best course of treatment. We, the patients, deserve the same […we should…] be aware of clinician's allegiances or […financial…] involvement…"* (Patient Written Evidence, IMMDSR, 2018, s5.7.2). The Cumberlege Report addressed the lack of disclosure in the UK by suggesting that the GMC medical register be extending to include the financial interests of its registrants, however, Rowland cautions that this is unlikely to fulfil the aim of making patients "aware of financial conflicts so that they can reach informed decisions about who is best to treat them" as currently on 11% of those who access the GMC Medical Register are patients (Cumberlege, 2020; Rowlands, 2020, para 17).

Changing Practice Patterns

Interests Linked to Patient Referrals. Practitioners' financial interests may be associated with changing patterns of practice. Robertson and colleagues describe a growing body of evidence which suggests that practitioner practice alters when influenced by conflict of interest (Robertson *et al*., 2012). The degree to which conflict of interest creates practitioner bias is largely dependent upon the nature of the secondary interest, such as whether it be derived from the private sector or industry (Robertson *et al*., 2012). This was a key finding of the Paterson Inquiry as, not only did his financial interests lead to self-referrals in the private sector, but there were also significant changes in his practice patterns. Paterson was involved in the provision of unnecessary, and often, disproportionate treatment which even included the non-indicated treatment of minors (CHPI, 2019, s.9 p2; James, 2020, p98-100). Paterson was also involved in undertaking unwarranted investigations, performing *"…unnecessary positron emission tomography (PET) scans, which exposed patients to radiation…"* the purpose of which was to afford Paterson further opportunity to misdiagnose disease so as to prompt further surgical intervention, such as biopsies (James, 2020, p106). Paterson even went so far as developing his own unproven 'cleavage sparing

mastectomy' (CSM) which the Paterson Inquiry describes as being driven by the financial gain derived from referring patients for such surgery in the private sector (James,2020, p100). Upon sentencing Paterson to a 15-year prison term for 17 counts of Wounding with Intent, Mr Justice Jeremy Baker described how Paterson had *"…carried out surgical procedures on…breasts, which [he] knew that no responsible body of duly qualified and experienced breast surgeons would have advised, because none of the procedures [were] necessary to maintain…health…"* (*Regina v Ian Stuart Paterson*, 2017 at s75). As will be explored later, the Inquiry also heard how Paterson's adjusted practice patterns resulted in physical and psychological harm of patients.

Interests Linked to Pharmaceutical or Medical Device Companies. Similar findings were revealed by the IMMDSR in its exploration of changing patterns of practice relating to the use of select medicines and medical devices. Evidence provided to the review showed that the Ethicon's influence upon the medical profession as a whole had led to an exponential rise in rates of transvaginal mesh implantation which corresponded with a sharp decline in the alternative, tried and tested, colposuspension surgery (IMMDSR, Clinician etc. written evidence, 2018, p15; 17-20; Gornall, 2018). Notably, as Robertson *et al* (2012) attest, the links to changing practice patterns can be difficult to precisely pinpoint. Indeed, Rowlands cautions that in relation to mesh, it may be difficult to illustrate the links between financial conflict of interest and the subsequent *harm* suffered by patients (Rowland, 2020). This is particularly true given the cost saving and perceived benefit mesh had, which was likely to have further fuelled its popularity amongst practitioners and healthcare providers (Gornall, 2018). However, even when the mesh was found to be associated with increased harm, the fact that its use continued could be indicative of financial interest continuing to influence practice (Patient Written Evidence, IMMDSR 2018, Annex 6)[1].

Potential Harm to Patients

Interests Linked to Patient Referrals. Changes in practice can be beneficial or harmful, depending upon the given circumstances. For example, where there is inherent *under* treatment, an increase in treatment could be representative of raising care standards to more optimal levels. However, any course of investigation or treatment must be appropriate and in the overall best interests of the patient. The concern, as Spece and colleagues attest,

[1] Note that the US Federal Drug and Food Administration (FDA) had given the first warning on mesh safety in 2008 – it was not until 2014 that transvaginal use was suspended in Scotland, though its use continued in England until 2017.

is that financial interests can *"…skew physician's advice and possibly lead to bad decisions…"* which can propagate these patterns of unnecessary or unsuitable treatment which may ultimately prove harmful to patients (Spece *et al*., 2014, p256). Such harmful practices were evident in the case of Paterson, who, adopted harmful and unnecessary breast augmentation procedures into his practice despite patients being at little to no risk of developing cancer (*Regina v Ian Stuart Paterson* [2017] at 6). Justice Baker heard that Paterson's victims had all been left with *"…physical scarring to their bodies, and those who underwent mastectomies … [had] had their breast tissues [permanently] removed…"* (*R v Ian Paterson*, 2107, at 60). For at least one patient this meant the inability to breastfeed her child, which Justice Baker described as having "*particularly pernicious*" long-term psychological effects (*Regina v Ian Stuart Paterson* [2017] at 44). This example, thus illustrating the individual impact that harm deriving from financial interests can have upon particular patients.

Interests Linked to Industry. Such psychological effects were also described in the patient testimony presented to the IMMDSR in relation to pelvic (vaginal) mesh. Evidence from a patient support group demonstrated that the majority of mesh-injured patients consulted had physical symptoms - including dysuria, dyspareunia, organ dysfunction and tissue erosion leading to chronic pain and morbidity – in addition to increased rates of depression, suicide and self-harm (Patient Written Evidence, IMMDSR, 2018, p14-16, s.2.3.3). One patient directly attributed the harm that many had suffered to practitioner conflict of interest, stating that *"…I am…tired of doctors inserting this product, …so many…know the harm that mesh is causing, but they still choose to implant it…[as]…it is much more lucrative to carry on…"* (Patient Written Evidence, IMMDSR, 2018, p29). A further concern raised by the IMMDSR was that influential practitioners - who are subject to conflict of interest - can adopt harmful practices which then have a detrimental 'knock-on' effect upon the practice of other practitioners. The modern practitioner-patient relationship is now consumed within wider multi-disciplinary teams which oversee the meso-level of patient care. It is at this level that guidelines and policies are often drafted which subsequently shape the practice of other practitioners when they come to select treatments for their own patients. (Montgomery & Lipworth, 2019). Therefore, the financial interests which affect an influential practitioner, can have an indirect impact upon a wider body of medical opinion; thus, shaping treatment choices for the patients of other practitioners. In 2019, influential cardiologist Dr Gregg Stone and his colleagues published findings of their EXCEL study in the New England Journal of Medicine. The study suggested that stents were a more effective and safer alternative to coronary artery bypass

grafts (CABG) for left main coronary artery disease (Stone *et al*., 2019). However, the clinicians involved had been sponsored by large American stent manufacturer Abbot and, as a result, the findings were subject to substantial conflict of interest (Cohen & Brown, 2019). Before the conflict of interest came to light, the guidelines were endorsed by the European Association for Cardio-Thoracic Surgery (EACTS) and subsequently formed the basis for the 2019 European Revascularisation Guidelines (Neumann *et al*., 2019; Stone *et al*., 2019). The conflict of interest had influenced the researchers to heavily manipulate the data so that it appeared that the stents were safer, when in fact they posed an 80% higher risk of heart attack (Cohen & Brown, 2020). This illustrates that the harm deriving from financial interest can radiate throughout medical practice to inflict harm on larger numbers of patients. Such harm is likely to be the most difficult to link to financial interests, as Rowlands attests, and so would be unlikely to concern issues of materiality in informed consent (Rowland, 2020). It is for this reason that the proposed expansion of disclosable risk be supported by further measures – such as a mandated financial interest register and more stringent adherence to journal codes of conduct – so as to mitigate against the wider harm derived from financial interests (Cumberlege Report, 2020 at 2.56, 2.67).

Erosion of Trust

Such conflict of interest and its potential to promote harmful practice patterns also carries the potential for eroding patient trust. In his sentencing of Paterson, Justice Baker explained that the surgeon had purposefully exaggerated the risk of cancer to gain patient trust and confidence to consent to the surgery, and in doing so had "*deceived*" patients (*Regina v Paterson*, 2017 at 45). A key theme throughout Justice Baker's sentencing of Ian Paterson was the absolute trust his patients had in him, due to his position as a consultant surgeon. In addition to the financial, physical, and psychological harm sustained by his patients, Justice Baker described how they had all experienced a loss of trust in the medical profession at large (*Regina v Ian Stuart Paterson* [2017]] at 61, 62). Justice Baker describes the victim impact statements as describing the "*profound*" physical and psychological effect from the overtreatment (*Regina v Ian Stuart Paterson* [2017] at 47) and that they were *"…left feeling violated and vulnerable…"* (*Regina v Ian Stuart Paterson* [2017] at 59) with psychological harm including *"…post-traumatic stress disorder, anxiety and depression…"* – all of which contributed to eroding trust in the profession (*Regina v Ian Stuart Paterson* [2017] at 59). In one impact statement patient Carole Johnson described how she had *"…lost a lot of trust in medical professionals…"* as a whole (Dyer, 2017, p1). The subsequent Inquiry heard that Paterson's incentivisation of local GPs had further contributed to the loss of trust in the medical profession (James, 2020 p120). There was a similar theme throughout the evidence

presented to the IMMDSR pertaining to mesh. Evidence presented to the IMMDSR considered that there had been "a gross abuse of trust" (Patient Written Evidence, IMMDSR, p172, s. 5.13.3). Such loss of trust has important implications for healthcare outcomes as the practitioner-patient relationship requires trust in order to facilitate open discussions for the purposes of both diagnosis and subsequent consent to medical treatment. Therefore, loss of trust can indirectly result in harm to patient care (Birkhäuer *et al*., 2017).

Empirical Evidence

Empirical Evidence for Financial Interests leading to Harmful Changes in Practice

Robertson and colleagues describe several studies which provide empirical evidence of practitioner practice changing "for the worse" (Robertson *et al*., 2012, p456) when subject to financial interests. In a study by Mitchell and Scott in JAMA, patient referrals to practitioner-owned centres were up to 45% higher compared to those of from practitioners holding no such financial interest (Mitchell & Scott, 1992 as cited in Robertson *et al*., 2012, p455). Studies also show that financial interests are associated with higher rates of diagnostic investigations. Swedlow and colleagues' study of a Californian employee compensation scheme found that almost 40% of Magnetic Resonance Imaging (MRI) scans ordered by self-referring practitioners who held a financial interest in the testing facility were *"medically inappropriate"*; indicating that practitioner behaviour had changed *"…for the worse…"* where financial interests were at play (Swedlow *et al*., 1992 p1504 in Robertson *et al*., 2012 at p455, 456). Shah and colleagues presented similar *"highly significant"* findings which indicate that where financial interests exist, rates of medically inappropriate and harmful investigations are heightened, despite being contrary to relevant clinical guidelines (Shah *et al*., 2011 in Robertson *et al*.,2012, p454). From a sample size of 17,847 patients, Shah *et al* found that rates of diagnostic cardiac nuclear stress test referrals were 2.3 times higher when practitioners had a financial interest in billing, compared to those practitioners who did not (Shah *et al*., 2011, p1997). Such tests are not routinely indicated for investigative purposes due to their poor specificity, risk of false positives – which can trigger further unnecessary investigations – and the risk of harm from ionizing radiation (Shah *et al*., 2011 in Robertson *et al*., 2012, p454). Even greater *"…disparity in practice patterns…"* was noted in relation to stress echocardiography – an investigation which is also not indicated for routine use - with rates of referral 12.8 times higher amongst practitioners with financial interest (Shah *et al*., 2011, p1997 in Robertson *et al*., 2012, p454). Empirical evidence of inappropriate investigations linked to financial interest even extended to invasive procedures such as biopsies. Mitchell demonstrated, through a regression analysis

of Medicare data, that amongst self-referring urologists the billing rate for prostate biopsies was 72% higher and was associated with lower rates of cancer detection (Mitchell, 2012 in Robertson *et al*., 2012, p455). This indicates that patients *"…unlikely to have prostate cancer…"* were undergoing prostate biopsies (Mitchell 2012, in Robertson 2012, p455). UK charity Prostate Cancer UK describe side effects of prostate biopsies as including pain, discomfort, bleeding, infection, acute urinary retention, and erectile dysfunction (Prostate Cancer UK, 2019). There are also likely to be psychological implications associated with undergoing investigations for cancer which could constitute harm. This indicates that patients were subject to unnecessary and harmful investigations (Mitchell, 2012, in Robertson 2012, p455). In another study from 2008, Mitchell also demonstrated that individual practitioner behaviour changed *following* acquisition of private medical facilities, stating that the "*relative odds*" that a patient would receive more complex – and costly - surgery was 65 times higher after a practitioner had taken ownership (Mitchell, 2008, at p735 in Robertson *et al*., 2012 at p456).

These findings add empirical value in support of the mostly observational findings of the UK's Paterson Inquiry and IMMDSR; both of which are likely indicative of more widespread issues in the UK (James, 2020; Patient Written Evidence, IMMDSR, 2018, p29). Such evidence can help bridge the connection between financial interests, detrimental changes in practice and patient harm. The Paterson Inquiry was subject to an overall lack of empirical evidence (James, 2020; Rowlands, 2019 s.5p5). The inquiry failed to expose the extent of Paterson's financial interest in the UK private sector - which would have strengthened the case for causal link between his interests and resultant harm – although the CHPI suggest the figure could run into millions of pounds (CHPI at s9, p.2; s26, p4). Furthermore, the true extent of Paterson's 'over-treatment' of patients remains unknown, however it is also likely that the 740 patients said to have been harmed from 1997-2011 represents a gross underestimation[2] due to the insufficiencies in patient recall (James, 2020, p1, para 2; Rowlands, 2019 s.5p5). By comparison, there is more evidence relating to the use of pelvic (vaginal) mesh, although data are still lacking. A 2018 study by Gornall offers some empirical evidence that the widespread use of transvaginal mesh in the UK *was* derived from financial interest. Gornall describes that from 1998-99 only 214 women in England were treated for SUI, yet in the subsequent decade rates rose dramatically so that by 2009 up to 12,000 mesh implantations were performed annually in England alone (Gornall, 2018).

[2] Note, James 2020, p1 para 2 describes the *"[t]housands of people …still living with the consequences of what happened."*

Notably, such findings correspond with a 1998 study by Ulmsten – which was subject to a $1 million Ethicon sponsorship in return for "favourable" results (Ulmsten, 1998; Gornall, 2018, p2). A recent class action trial found that Ethicon's parent company Johnson and Johnson had actively suppressed knowledge that their mesh maimed patients (*Emmett et al. v Ethicon women's Health & Urology,* 2019). Ethicon's widespread courting of the medical profession through conference and educational sponsorship, a practice which may be linked to brand loyalty, also correlates with UK surgeon's 'eagerly adopting' the practice (Hall & Jones 2007; Gornall, 2018, p1). Treatment bias in favour of mesh is evident and is suggestive of – at the very least - a tentative link between financial interests and changes in practice patterns. The studies collated by Robertson and colleagues provide a firm empirical foundation which further supports the link between financial interest and harmful changes in treatment practice.

Empirical Evidence for Erosion of Trust

The practitioner-patient relationship is fiduciary relationship founded upon trust, which may be undermined by conflict of interest. Spece and colleagues provide empirical evidence that financial interests, which promote harmful practice patterns, erode such patient trust in both the practitioner and in their treatment recommendations (Spece *et al*., 2014). The 2014 randomized vignette-based experiment undertaken enlisted 691 mock patients who were asked to put themselves into the position of a patient due to undergo a cardiac stent procedure upon the recommendation of a cardiologist. The researchers then controlled the information given to the participants relating to the appropriateness of the treatment - in terms of the risk of *not* undergoing the procedure - and, according to the degree of financial disclosure made by the fictional practitioner in relation to hospital ownership. Degrees of disclosure ranged from non-disclosure to standard and enhanced disclosure. Standard disclosure informed patients of the hospital ownership, whilst enhanced disclosure gave notice of links between such conflict of interest and treatment recommendation bias. Participants were asked whether they agreed or disagreed with the statement *"…the cardiologist has only my interests in mind in making this recommendation…"* which was an operationalisation of the notion of trust (Spece *et al*., 2014, p270). The study found that disclosure *"…significantly and substantially increased the probability…"* that simulated patients would refuse treatment, irrespective of whether the disclosure was standard or enhanced (Spece *et al*., 2014, p270). The findings indicate that the *"…existence of disclosure as opposed to the strength of disclosure…"* had *"swayed"* patients and that this was likely due to doubts as to whether the practitioner continued to uphold their best interests (Spece *et al*., 2014, p270). Notably, trust was only reduced when the patient had a low-risk condition therefore patients

at high risk are more likely to continue to trust their practitioner. One limitation of the study was that it lacked real-world context as mock patients may act differently to real patients whose own health is at stake (Spece *et al*., 2014 p268-269).

Another study by Rose and colleagues which did involve real-world context suggests that financial interest disclosure does not erode patient trust, but that failure to disclose conflict of interest could. Investigators mailed 'conflict of interest' disclosure notifications to 1903 patients alongside their appointment letters for Cleveland Clinic in 2015 (Rose *et al*., 2019). Twenty-seven practitioners participated, disclosing payments of $20,000 or more from companies whose products they used in their practice. The study demonstrated that the disclosure "*significantly*" improved patients' knowledge of practitioner financial conflict of interest with 56% of patients correctly acknowledging their practitioner's interest. Such knowledge was found to have a "*significant association*" with trust ($p < .003$). Trust was highest amongst patients who erroneously believed that their practitioner had no financial conflict of interest. In comparison with this cohort, trust was significantly lower amongst patients with uncertainty over a practitioner conflict of interest ($p = .001$). Most tellingly, the results also indicate that there was no statistical difference between patients who correctly believed their practitioner held a conflict of interest and those who falsely believed there was no conflict of interest ($p = .22$). The study was subject to some limitations, such as the acknowledgement that since patients already had appointments they may have been *"…motivated to continue to trust their physicians…"* rather than search for an alternative (Rose et al., 2019, p10). The authors also note that the findings may not be generalizable as trust in the sample hospital, for example, was particularly high. Nonetheless, whilst the study appears to contradict the findings of Spece and colleagues, the authors support the general premise that disclosure of information is important for *"…encourag[ing] patients to play a more active role in their healthcare decisions…"* through informed consent (Rose *et al*., 2019, p3). The findings indicate that knowledge of conflict of interest – rather than the disclosure – has a "*significant association*" with patient trust (Rose *et al*., 2019, p10). Therefore, we can surmise, that a *failure* to disclose information and, the associated lack of transparency, could erode trust.

For the purposes of this study, it is suggested that the study by Spece and colleagues most readily reflects the informed consent process in the UK, which usually involves a discussion with the practitioner rather than the provision of written information. Furthermore, the study by Spece relates directly to acceptance of treatment, whereas the study by Rose and colleagues does not specify whether patients subsequently accepted treatment or whether

they attended a consultation only (Spece *et al*., 2014; Rose *et al*., 2019). Nonetheless, it is preferrable that further research be undertaken in this area. One consideration could be whether the provision of a letter offers sufficient comparison to the verbal provision of information afforded in the study by Spece and colleagues (Spece *et al*., 2014). Spece and colleagues argue that *"…a substantial portion of patients appear likely to behave differently once given … information…"* about practitioners' financial interest and so patients appear to attach significance to such information (Spece *et al*., 2014 p271). Notably, Rose and colleagues also found patient *knowledge* of financial interest to have a significant association with trust (Rose *et al*., 2019). It is to this end that Spece and colleagues therefore assert that such information is *"…material to [patient's] decisions…"* and that disclosure of "*potent*" financial conflicts of interest should be *"…added to the list of presumptively required disclosures…"* or should be "interpreted as falling within the existing category of "*risks*" that presumptively must be required" (Spece et al., 2014, p271, 273). Accordingly, the case will be made that potent financial interests – namely those which are likely to have great influence over treatment decisions - would be disclosable under existing UK common law relating to disclosure of material risks (Spece *et al*., 2014, p271; *Montgomery v Lanarkshire* [2015]).

Physician Disclosure during Consent to Clinical Care

The law pertaining to consent to medical treatment in the UK more commonly lies in the tort of negligence than in the tort of battery, since the consent process has become a routine part of practice. Cases which concern pre-treatment advice tend to relate to whether the practitioner provided sufficient information to allow the patient to make an informed decision and whether causation can be established (see Table 1).

UK Case Law: Pre-Montgomery

Bolam [1957]

Responsible Body of Medical Opinion Standard. In the mid-1950s, the case of *Bolam v Friern Hospital Management Committee* explored the extent of the practitioner's duty of care at law. Mr Bolam had not been given muscle relaxants during a course of electro-convulsive therapy for treatment of mental illness, and subsequently suffered severe acetabular fractures. The court found that the practitioner had not failed in their duty of care owed to Mr. Bolam. The House of Lords recognised that whilst some practitioners offered muscle relaxants, the practice not to offer them was also accepted. Nair J stated that the

practitioner was not negligent because they had acted *"…in accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art…"* and that negligence is not established *"…merely because there is a body of opinion who would take a contrary view…"* (*Bolam v Friern Hospital Management Committee* [1957] at 587). To some extent, this was a policy decision which gave recognition to the existence of differences of opinion in medical science. Yet it was also reflective of the prevailing paternalism of the time with the case determining that a body of medical opinion would also decide what information on risk patients should be told, rather than giving consideration to what patients believe they need to know in order to fully exercise their rights of self-determination (*Bolam v Friern* [1957], at 583; Devaney & Holm, 2018). Legal academics have described the ruling as overtly deferential to the medical profession (Poole, 2019) and as one which facilitates a degree of self-regulation therein (Devaney & Holm, 2018).

Sidaway v Board of Governors [1985]

In *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] Mrs Sidaway, was unsuccessful in her claim for negligent pre-treatment advice. Her neurosurgeon had failed to warn her of a 1-2% risk of spinal cord damage arising from a surgical procedure to treat neck pain – a risk which subsequently materialised. The case was brought before the House of Lords where there were divergent views on whether *Bolam* remained the correct test to apply in determining the legal standard of pre-treatment advice.

The Prudent Patient. Lord Scarman contemplated that patient decision-making was reliant upon a broad range of considerations including *"…circumstances, objectives and values which [the patient] may not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion…"* (*Sidaway v Board of Governors* [1985] at 886). He therefore proposed a 'prudent patient test' be applied in order to recognise the patient's right to make their own decisions, stating that *"…[i]deally, the court should ask itself whether in the particular circumstances the risk was such that this particular patient would think it significant if he was told it existed…"* (*Sidaway v Board of Governors* [1985] at 888). This statement introduced early considerations of 'significance' and the 'particular patient'. Lord Scarman reasoned that if a patient could suffer harm resulting from an undisclosed risk, then such risk should have been disclosed by a doctor (or practitioner) exercising reasonable care in fulfilling their duty of care towards said patient.

The Responsible Doctor. Lord Diplock dissented and, in theorising that disclosure of unsolicited information could deter patients from undergoing treatments which

were in their best interests, asserted that the standard of information disclosure should be judged according to a body of medical opinion in line with the *Bolam* standard (*Sidaway v Board of Governors* [1985] at 891).

The Prudent Doctor, Prudent Patient. Lord Templeman proposed a midway solution by way of the 'prudent doctor, prudent patient' approach. An objective test of professional judgement according to the *Bolam* test, set alongside a subjective test which is applied to the individual patient. Accordingly, there may be greater disclosure if the patient *"…asks in vain for more information or…there is some danger which…requires to be taken into account…"* so as to ensure the practitioner provides *"…sufficient information to enable the patient to reach a balanced judgement…"* (*Sidaway v Board of Governors* [1985] at 902). This, however, placed the burden upon the patient to ask the relevant questions as Lord Templeman believed that *"…[a]n obligation to give a patient all the information… [would be] inconsistent with the doctor's contractual obligation to have regards to the patient's best interests…"* (*Sidaway v Board of Governors* [1985] at 904).

Reasonably Prudent Doctor. In offering judgement – and ultimately dismissing Mrs Sidaway's claim - Lord Bridge applied a 'qualified' *Bolam* test to establish that the standard of information required was a matter of clinical judgement, and so was reflective of a 'reasonably prudent doctor test'. Lord Bridge rejected the claim that patients should be warned of all risks (*Sidaway v Board of Governors* [1985] at 897). He did however accept that it was not necessary to *"…hand over to the medical profession the entire question of the scope of the duty of disclosure…"* and so a qualified *Bolam* Test should be applied with the stipulation that the court adopt an oversight role and that doctors must provide honest answers when asked specific questions pertaining to their treatment (*Sidaway v Board of Governors* [1985] at 900).

Bolitho v City and Hackney Health Authority [1998]

The case of *Bolitho v City and Hackney Health Authority* [1998] relates to negligent failure to treat and causation rather than negligent non-disclosure, yet its judgement is illustrative of the dominance *Bolam* maintained even some forty years later. The House of Lords considered the case concerning two-year-old Patrick Bolitho admitted to hospital with breathing difficulties. A doctor who was called via pager did not attend and the child subsequently died. His mother brought a claim in negligence against the practitioner claiming that had he been intubated his life would have been saved. It was established that the doctor failed in their duty of care by not attending Patrick, however the decision turned

on the issue of causation. The doctor argued that, but for the failure to attend, Patrick would still have died as she would not have intubated him. Such a decision was in line with practice considered acceptable by a responsible body of medical opinion as per *Bolam* the Standard (*Bolam* v *Friern* [1957] at 587). The Law Lords sought to address the apparent deficiencies in the *Bolam* standard by adding additional qualifications of logic and reasonableness. Lord Browne-Wilkinson stated *"…if…it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible…"* (*Bolitho v City* [1998] at 243). Nevertheless, the subsequent application of *Bolitho* qualification to the *Bolam* test has been inconsistent (Samanta & Samanta, 2003; *Bolitho v City* [1998]; *Bolam v Friern* [1957]).

Pearce v United Bristol Healthcare Trust [1998]

Shortly after the ruling in *Bolitho*, the first inkling that the sands were shifting away from the prevailing paternalistic standard of *Bolam* became evident in the case of *Pearce v United Bristol Healthcare NHS* Trust [1998]. The case was heard in the lower Court of Appeal where Lord Woolf first introduced the concept of a 'reasonable patient' and their right to be informed of 'significant' risk. The case concerned Mrs. Pearce, who had requested labour induction to advance the delivery of her overdue baby. She was instead advised to await a natural onset of labour and the baby was subsequently stillborn.

Towards the Reasonable Patient Standard. In bringing a claim for negligent pre-treatment advice, the court considered that the risk associated with the advice was in the region of 0.1-0.2%. In offering his judgement, Lord Woolf MR considered the 'reasonable patient' in stating that *"…if there is significant risk which would affect the judgement of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk…"* (*Pearce v United* [1998] at 124 as per Woolf MR). On the interpretation of 'significant risk' Woolf MR stated that *"…it is not possible to take in precise percentages…"* (*Pearce v United* [1998] at 124 as per Woolf MR) and that such risk would be determined by taking account of *"…all the relevant considerations…"* (*Pearce* v *United* [1998] at 125). The appeal was ultimately dismissed on the grounds that it could not be established that the risk posed by the additional passage of time represented a significant, and therefore disclosable risk. (*Pearce v United* [1998] at 125 as per Woolf MR).

Chester v Afshar [2004]

The case of *Chester v Afshar* [2004] explored the complexities of causation, a hurdle which many cases pertaining to information disclosure fail to overcome. On causation, the focus

shifts from examining the practitioner's standard of care to addressing what the patient would have done had they been in possession of the non-disclosed information. In this case, Miss Chester, a young woman suffering from lower back pain, was referred to neurologist Dr. Afshar. Surgical intervention was proposed however Miss Chester was not informed of a 1-2% risk of cauda equina syndrome, which materialised. She argued that had she known the risk; she would not have consented to undergo the treatment some three days later.

Causation in Medical Negligence. Lords Hoffman and Bingham powerfully rejected Miss Chester's claim. Lord Bingham argued that Miss Chester had not satisfied the court that, 'but for' the failure to inform, she would never had undergone the surgery, only that she would not have consented at that time and therefore undergone the surgery on the specified day. He explained that whilst the 'but for' test was an ordinary test of causation, it was *"…generally accepted that …[it] does not provide a comprehensive or exclusive test of causation in the law of tort [as too often] …it gives too expansive an answer…",* thus highlighting that additional tests of causation may be applied (*Chester v Afshar* [2004] at 8). Lord Hoffman also agreed that the ordinary test of causation was not satisfied and held that there were no grounds for a special rule to be applied in this case. However, the three remaining Law Lords disagreed, finding that a departure from the ordinary test was required on policy grounds so that a practitioner's duty to inform would not become a hollow one. Lord Steyn said

> I have come to the conclusion that, as a result of the surgeon's failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense. Her right to autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles (*Chester v Afshar* [2004] at 24).

The case illustrates that in some circumstances, the contextual difficulties associated with applying an ordinary test of causation will require adjustments be made to the test; such as by the application of a series of 'but for' tests or by applying a test of 'material contribution' (Poole, 2019 p129, 135).[3] However, the decision to depart from the ordinary test of causation in *Chester* was controversial. Mason and Laurie, 2011 suggest that whilst *Chester* sought to address the paternalism of *Bolam*, it perhaps "swings too far in the other direction"

[3] For example, in *Bailey v The Ministry of Defence & Anor* [2008] EWCA Civ 883, a question of 'material contribution' was applied instead

as the harm sustained was more in line with "hurt … feelings – than … actual physical injury" (Mason & Laurie, 2011, s4.138, p 120; *Chester v Afshar*, 2004; *Bolam v Friern Hospital* [1957]). Conversely, it may also be argued that the departure from the ordinary test which was applied in *Chester* offers broad consideration of the effect that non-disclosure of material information has on harm suffered. On such grounds, non-disclosure of potent – and therefore material – financial interests could arguably satisfy a test of causation under UK law.

Montgomery v Lanarkshire [2015]

The case of *Montgomery v Lanarkshire Health Board* [2015] marked a landmark departure from the paternalistic *Bolam* standard towards a more patient-centric approach to medical decision-making (*Bolam v Friern* [1957]). Mrs Montgomery brought a claim for negligent non-disclosure to the Supreme Court. The claim centred on the failure to disclose the 9-10% risk of shoulder dystocia associated with vaginal delivery that Mrs Montgomery was subject to as a type 1 diabetic mother (*Montgomery v Lanarkshire* [2015] at 13). The information had not been disclosed despite Mrs Montgomery raising explicit concerns relating to complications associated with her diabetes, nor had she been informed of the option of a caesarean section (*Montgomery v Lanarkshire* [2015] at 2; 17). The risk of shoulder dystocia materialised, resulting in a traumatic vaginal birth during which her son was starved of oxygen and suffered permanent brain damage. In bringing the case on his behalf, the mother argued that had she been advised of this risk, she would have elected for a caesarean section and the brain damage her son subsequently sustained would have been avoided.

The 'Prudent Patient' Standard. The Supreme Court Justices rejected the stance taken in *Sidaway* which placed the burden on the patient to ask the doctor the necessary questions so as to be informed, describing the proposition as "*profoundly unsatisfactory*" (*Montgomery v Lanarkshire* [2015] at 58). It was recognised that such a standard was deficient as the patient may not be aware of what questions they need to ask and thus be placed at a disadvantage. To this end, patients were no longer to be treated as placing themselves in doctors' hands but, instead, as autonomous adults capable of understanding that decision-making involves consideration of risk (*Montgomery v Lanarkshire* [2015] at 91). This set a new standard which recognised that doctors are under a duty to;

[t]ake reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatment. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in

the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it (*Montgomery v Lanarkshire* [2015] at 87).

The case established that a 'prudent patient' test – which gives consideration to materiality and significance – should be used in determining disclosable information for the purposes of informed consent (Lee A, 2017). The Supreme Court justices again emphasised that material risks "…*cannot be reduced to percentage…s*" as decision-making is often multi-factorial (*Montgomery v Lanarkshire* [2015] at 89). Baroness Hale asserted that patients are *"…entitled to take into account [their] own values, [their] own assessment of the comparative merits […of a treatment option…]…"* and in doing so make an assessment *"…of comparative merits…"* of treatment (*Montgomery v Lanarkshire* [2015] at 115). In order to establish the factors relevant to an individual patient there must be dialogue – a concept which has given rise to shared, or supported, decision-making models (*Montgomery v Lanarkshire* [2015] at 90; GMC, 2020; Royal College of Surgeons, 2018). This redefined legal duty sought to facilitate greater respect for patients' rights of self-determination and autonomy by enabling them to make informed choices about their treatment.

Causation. On the matter of causation, *Montgomery* successfully applied the ordinary rule of causation without need to adopt the approach in *Chester* (*Montgomery v Lanarkshire* [2015] at 105). The Supreme Court ruled that it would be wrong to determine the issue of causation according to the claimants *"…supposed reaction…if she had been advised of the minimal risk of a grave consequence…"* and instead causation should be determined according to her *"…likely reactions if she had been told of the risk of shoulder dystocia…"* (*Montgomery v Lanarkshire* [2015] *at* 103). The court considered that, had during discussion between patient and practitioner, the patient been informed of the risks, "*dispassionately*" and without coercion to adopt the practitioner's recommended course, then she *"…would probably have elected to be delivered of her baby by caesarean section [and upon those grounds] is not in dispute that the baby would then have been born unharmed…" (Montgomery v Lanarkshire* [2015] at 104) Evidence in support of this decision – namely that the doctor admitted that Mrs Montgomery would have elected for caesarean section – had been discounted in the lower courts (*Montgomery v Lanarkshire*, [2015] at 101-102). The Justices also considered the likely response from other *"…women in her position…"* would be to opt for a caesarean section. (*Montgomery v Lanarkshire* [2015] at 101; 104). This approach to causation was also adopted in case of *Webster v Burton Hospital* [2017]). The claimant's baby - delivered after 40 weeks' gestation -

suffered neurological harm which could have been avoided had the birth been induced at term. In applying the approach to causation adopted in *Montgomery*, the Court of Appeal asked whether the mother had been advised of the risks and benefits associated with managing the latter stages of pregnancy at the 34-week scan, including the option to induce labour. In finding that the harm sustained could have been avoided, the case re-affirmed the decision in *Montgomery* and successfully established causation (*Webster v Burton Hospital* [2017]; *Montgomery v Lanarkshire* [2015]).

Essential Elements of Informed Consent after Montgomery

The key outcomes of the Montgomery ruling (as outlined in Table 1) were considered in the subsequent case of *Duce v Worcestershire Acute NHS Trust* [2018]. The case explored the scope of *Montgomery's* prudent patient test and offered further clarification on the applicability of *Chester* in establishing causation in *"failure to war*n" cases (*Montgomery v Lanarkshire* [2015]; *Chester v Afshar*, [2004]). As evidenced by development of the current standard of informed consent, it is evident that the burden of proof in such cases remain high (see case law summary in Table 2).

Mrs. Duce brought a case for negligent non-disclosure of risk. The claimant, having suffered from dysmenorrhea and menorrhagia for several years, elected to undergo a total hysterectomy and bilateral salpingo-oophorectomy, yet claimed not to have been informed of the risk of nerve damage and subsequent chronic pain. The complication materialised and she brought her claim in negligence before the Court of Appeal. Hamblen LJ made the "*fundamental distinction*" between the doctor's role in considering suitable medical treatment and their subsequent role in disclosing information to the patient for the purposes of consent, so clarifying informed consent as a *two-stage test* (*Duce v Worcestershire* [2018] at 30, 33). The clarification acknowledged that, within medicine, there may be different schools of thought (*Montgomery v Lanarkshire Health Board* [2015]). As such, selection of investigations and treatment would be considered an exercise of *"…professional skill and judgement…"* for which the *Bolam* test should apply (*Duce v Worcestershire* [2018] at 33; *Bolam v Friern* [1957]). Subsequent information disclosure during pre-treatment advice would be considered according to Montgomery's Reasonable Person Standard (*Duce v Worcestershire* [2018] at 33). *Duce* further clarified additional factors relevant to materiality, such as *"…the odds of the risk materialising; the nature of the risk; the effect its occurrence would have on the life of the patient; the importance to the patient of the benefits sought by the treatment; the alternatives available and the risks associated with them…"* (*Duce v Worcestershire* [2018] at 35). This clarification of materiality includes 'the odds of

the risk materialising' which could expand the criteria for materially relevant, disclosable information.

Summary of Relevant UK Case Law

UK case law (as outlined in Table 2) demonstrates judicial precedence in setting a strict threshold for medical negligence cases pertaining to standards of treatment and pre-treatment advice. There are, however, signs that the tide is continuing to turn - albeit slowly - towards greater patient-centricity on matters of both materiality and causation. The clarification of materiality in *Duce* built upon *Montgomery* to suggest that where it can be proven that a risk is more likely to occur – such as through the provision of empirical evidence – then materiality can be confirmed (*Duce v Worcestershire* [2018]; *Montgomery v Lanarkshire*, [2015]). Such empirical evidence could be derived from studies such as those undertaken by Robertson and colleagues which demonstrate harmful changes to treatment patterns derive from financial interests and subsequently cause harm to patients (Robertson *et al*., 2012). To then establish causation in negligent pre-treatment advice, the question should turn *not* what the doctors would have decided to disclose, rather on the advice which *should* have been disclosed and what the patient would subsequently have decided to do (Poole, 2019). This affords greater consideration of the patient; however, the standard is often difficult for claimants to establish. The courts recognise that it is easy in hindsight to say one would not have made a certain decision and so they look for "*compelling evidence*" that the claimant would have refused such treatment (Poole 2019, p134). The aforementioned study by Spece and colleagues suggest that disclosure of conflict of interest changes the patient's likelihood of consenting, indicating that they attach significance to that information for the purposes of informed consent – a key argument which could help establish causation linked to non-disclosure of financial interests (Spece *et al*., 2014 at 273).

Comparison of Common Law Standard with GMC Guidance Post-Montgomery

Montgomery's test of materiality stipulates that the practitioner is under a legal duty to ensure that the patient is made aware of any material risks, with the test of such materiality being whether a reasonable person in that situation would attach significance to such risk or, whether the practitioner should reasonably have awareness that the 'particular patient' would attach significance to it (*Montgomery v Lanarkshire* [2015] at 87). However, recent GMC guidance, outlined in the publication 'Decision making and Consent', appears to be at odds with this legal standard, both in relation to the prudent patient test and the test of materiality (GMC, 2020).

Materiality in Relation to the Reasonable Person and the Particular Patient

The Reasonable Person. Recent guidance from the GMC could reflect a lower threshold for information disclosure than that which is set out in *Montgomery* (GMC, 2020; *Montgomery v Lanarkshire* [2015]). The GMC guidance refers to information which "*a patient*" or *"the patient"* would want to know, rather than *Montgomery's* specific reference to the "*reasonable person*" or "*particular patient*" (GMC, 2020; *Montgomery v Lanarkshire*, [2015] at 87). The GMC advise practitioners that, in providing information for the purposes of consent;

> 12. You should not rely on assumptions about
>   a. The information a patient might want or need
>   b. The factors a patient might consider significant
>   c. The importance a patient might attach to different outcomes" (GMC, 2020, page 12).

The contemplation of what "*a patient*" might want, need, or consider significant appears ambiguous. Under UK law, the 'reasonable person' standard is applied. It was first described during the libel case of *McQuire v Western Morning News* [1903] as relating to the "*man on the Clapham omnibus*"; a standard which has served as a point of reference in English law ever since (*McQuire v Western Morning News* [1903] at 109 as per Collins MR). The 'man on the Clapham omnibus' is the theoretical ordinary man, representative of the person on the street who is reasonable in his judgements and therefore provides a benchmark against which reasonable action can be measured. Lord Scarman likened his proposed 'prudent patient' to 'the man on the Clapham omnibus' in *Sidaway*, thus setting the reasonable standard of information as that which the reasonable person would expect to be given (*Sidaway v Board of Governors* [1985] AC at 889). However, Lord Kerr and Reed diverged from this approach in *Montgomery* when they asserted that in exercising reasonable care in determining which information pertaining to risk should be disclosed, it should be recognised that *"…no woman would, for example, … likely [be willing] to face the possibility of a fourth-degree tear, a Zavanelli manoeuvre or a symphysiotomy with equanimity…"* (*Montgomery v Lanarkshire* [2015], at 94). In considering the collective views of women, there was a subtle yet important evolution of the reasonable person standard. In continuing the analogy, the Supreme Court Justices appear to determine reasonableness according to the collective 'passengers on the Clapham omnibus' standard, rather than that of the individual 'man on the Clapham omnibus' (Dunn *et al*., 2019, p 117; *McQuire v Western Morning News* [1903] at 109; *Montgomery v Lanarkshire* [2015], at 94). This could

represent a majority assessment of reasonableness. Indeed, Baroness Hale also considers a majority view in stating that *"…[t]hese are risks that any reasonable mother would wish to take into account in [decision-making] …in order to balance said risks against benefits in relation to each eventuality…"*, highlighting a wider interpretation that goes beyond the individual (*Montgomery v Lanarkshire*, 2015, at 121). Such majority assessments could be determined according to empirical evidence of what information patients would expect to know in the given circumstances. Whilst such an approach has yet to be adopted by courts - as they remain cautious about retaining the right to go against 'unreasonable' popular opinion - Spece and colleagues argue that the use of empirical evidence could *"…shed light on the question of materiality…"* (Dunn *et al*., 2019, p117; Spece *et al*., 2014 at p273). Instead, the GMC's consideration of what 'a patient' might want, need, or consider significant could reflect the outdated 'man on the Clapham omnibus' standard, thus failing to encapsulate the intricacies of the current legal standard *its* potential to be interpreted in its broadest terms (GMC, 2020).

The Particular Patient. One may argue that the GMC's reference to 'a patient' could, instead, be interpreted as reflecting the 'particular patient' standard which was also referred to in *Montgomery* yet this too is a deficient interpretation of the legal standard (*Montgomery v Lanarkshire* [2015] at 87). The 'particular patient' caveat requires that practitioners tailor according to the particular patient. Such information would likely relate to the patient's own values and the impact such risk would have upon their life (*Montgomery v Lanarkshire* [2015] at 87). In a subsequent section, the GMC goes on to refer to 'the patient' in advising practitioners that;

> 23. You should usually include the following information when discussing benefits and harms;
> a. Recognised risks of harms that you believe anyone in the patient's position would want to know
> …
> c. Risks of harm and potential benefits that the patient would consider significant for any reason
> d. Any risk of serious harm, however unlikely it is to occur ….(GMC, 2020, p15).

This may give strength to the argument that the GMC's guidance be interpreted as reflecting *Montgomery's* 'particular patient' caveat. Yet, whilst this is undeniably an important aspect of the test of materiality – indeed, it was further emphasised in *Duce*, when the court asserted

that practitioners should consider the *"…effect… [that a risk] would have on the life of the patient…"* (*Duce v Worcestershire*, 2018 at 35) – it must also be noted that it may undermine patient autonomy (Dunn *et al*., 2019). Dunn and colleagues caution that the limitation that practitioners need only have a 'reasonable awareness of what a particular patient would attach significance to' could be interpreted as placing the onus on patients to make their practitioner aware of values or concerns that they consider significant (Dunn *et al*., 2019, p115). Relational constructs of autonomy call for dialogue and discussion whereas 'reasonable awareness' calls for no such duty to actively develop relationships with patients in order to determine their values (MacLean A, 2006, p328; Dunn *et al*., 2019, p115). The reasonableness caveat in represents a policy decision by the courts to protect practitioners from "limitless liability" for non-disclosures of apparently insignificant risk (King & Moutlon, 2006, p 452). Similarly, the 'reasonable awareness of the particular patient' caveat may also limit the patient's ability to receive the information they may need to make an informed decision. It is therefore pertinent that the Montgomery test be read in its entirety, giving recognition to the 'reasonable person' and 'particular patient' standards in their broadest forms (*Montgomery v Lanarkshire* [2015], p87). To this end, the GMC guidance represents an insufficient interpretation of the legal standard which leaves ample room for misinterpretation which could undermine the intent of *Montgomery*. Notably, there is a sharp contrast between the GMC's guidance and that from Royal College of Surgeons of England (RCS Eng.) which does reflect the legal standard (GMC, 2020; RCS Eng., 2018). The RCS Eng. guidance on 'Supported (or shared) Decision Making' emphasises the relational nature of informed consent. It asserts that surgeons are *"…no longer the sole arbiter of determining what risks are material to their patients…"*, instead, *"…what will constitute a material risk will vary from patient to patient …[therefore] consent has to be patient-specific…"* (RCS Eng., 2018, p3, p14). The guidance continues by stating that *"…the discussion has to be tailored to the individual patient…[which]…requires time to get to know the patient well enough to understand their views and values…"* (RCS Eng., 2018, p4). Ultimately, this guidance better reflects the focus of *Montgomery* which is to facilitate the exchange of information between patient and practitioner so that consent be truly informed and valid (*Montgomery v Lanarkshire* [2015])

The Reasonable Person-Particular Patient Standard. In appeasing the reasonable person-particular patient elements of consent, King and Moutlon 2006 suggest that a two-stage approach to materiality be adopted. Initially, the reasonable person standard could be used to define the 'base line' standard of information to be disclosed to patients relating to a particular risk (King & Moutlon, 2006). An empirical assessment could be used

to determine the nature of such base line of information. Following this disclosure, King and Moulton assert that practitioners should then engage in a discussion with the patient which would allow them to identify and *"…satisfy [their] subjective needs…"* (King & Moulton, 2006, p 452). Such an approach is supported by the results of a patient survey conducted by Feldman-Stewart and colleagues. The findings demonstrate that, within a collective of 'reasonable people', there were diverging views which are likely attributable to differences in personal values and in perception and acceptability of risk (Feldman-Stewart *et al*., 2000). Therefore, both aspects of the test are required to ensure individual patients are sufficiently informed; and empirical evidence could play an important role in facilitating this.

From Material Risk Back to Significant Risk?

The GMC's reference to 'significant factors' and the 'importance of outcomes' rather than materiality, may also be at odds with the legal standard (GMC 2020, p12, p15) (*Montgomery v Lanarkshire* [2015], 87). Whilst terminology such as 'significant', 'important' and 'material' may be interchangeable in general linguistical terms, at law a careful distinction must be made, as demonstrated by the case law whereby the courts have considered 'substantial', 'significant' and 'material' harm (see Table 2) (GMC, 2020 p12; 15). 'Material' may be defined in non-legal terms as that which is "*significant*" (Oxford English Dictionary, 2021) or has *"an important effect"* (Cambridge English Dictionary, 2021). In legal terms it may defined as *"…important…having influence...[or]… [of being] …relevant…"* (Black's Law Dictionary). By comparison, the definition of 'significant' tends to align with empirical factors. Definitions include that which *"…[is] likely to have a major effect…",* is *"…fairly large in amount of quantity…"* or that which describes the *"…statistics of, or relating to, observations or occurrences…"* (The Free Dictionary, n.d.). In exploring the tautology of materiality and significance, Madden 2015 describes a spectrum of legal interpretations of 'significance' which ranges from *"…degree or amount, [to] probability, and even near certainty…"* (Madden, 2015, p233). Therefore, 'significance' may be interpreted as a form of measurement which distinguishes it from materiality and its incorporation of additional factors such as importance and relevance. The uncertainty surrounding the term 'significance' has been cause for extensive judicial consideration as is summarised in Table 2.

In *Sidaway* the court described a disclosable risk as that which was *"…so great that the doctor should have appreciated that it would be considered a significant risk…"* (*Sidaway v Board of Governors*, 1985 at 900 as per Lord Bridge). Lord Bridge preferred the adjective

'substantial', instructing practitioners to inform patients of *"...substantial risk of grave and adverse consequence..."*, such as that which fell in the region of 10% (*Sidaway v Board of Governors*, 1985 at 900). Current GMC guidance - that patient should be informed of *"...[r]ecognised risks of harms that you [the practitioner] believe anyone in the patient's position would want to know..."* (GMC, 2020 at p15) - could be interpreted as reflecting the *Sidaway* standard. The guidance creates ambiguity on two fronts. Firstly, it relates to 'recognised risk' rather than 'material' or 'significant' risk – which could arguably be interpreted as risks which are 'recognised' as important by the surgeon. Secondly, it relates back to the aforementioned 'reasonable person' (in the patient's position) standard which does not consider the 'particular patient'. This appears to set a standard which is determined by the practitioner and therefore may promote a standardised form of disclosure. Notably this position is no longer considered good law as practitioners and patients may diverge on what is considered a substantial, or even significant, risk. In *Wyatt v Curtis* [2003], it was Sedley LJ recognised that:

> what is substantial and what is grave are questions on which the doctor's and the patient's perception may differ. To the doctor… [a 1% chance that] …the patient's chickenpox may produce an abnormality in the foetus may…be [neither substantial nor grave]. To the patient…[such] risk of a potentially catastrophic abnormality may…be both substantial and grave (*Wyatt v Curtis* [2003] at 16).

This acknowledgement that a disclosable risk should not be that which is determined by according to the practitioner's interpretation of significance marked a judicial shift from *Sidaway (Sidaway v Board of Governors* [1985]). The Supreme Court justices in *Montgomery* built upon this concept in asserting that risk is not purely related to a patient's perception of magnitude nor a *doctor's* assessment of significance (*Montgomery v Lanarkshire* [2015]). In addressing the relevant standard, the Supreme Court recognised that 'significant' and 'substantial' have *"...different shades of meaning..."* (*Montgomery v Lanarkshire* [2015], at 66). Ultimately rejecting the adjective 'substantial', 'significant' was considered to be the more fitting adjective when subsumed within the wider concept of 'materiality'. Material risk considers that *"...a reasonable person in the patient's position [or the particular patient] would be likely to attach significance to the risk..."* (*Montgomery v Lanarkshire* [2015] at 87). Therefore, the GMC guidance to disclose that which the practitioner *believes* the patient would want to know also reflects an inadequate interpretation of the prevailing legal standard (GMC, 2020 p15). In a subsequent subsection of GMC guidance, it appears that greater consideration of the patient is afforded. However,

in instructing that that information should usually include *"…[r]isks of harm…that the patient would consider significant for any reason…",* the GMC fails to mention disclosure of material risk, thus maintaining a narrow interpretation of risk which fails to reflect the legal standard (GMC, 2020, p15). The Supreme Justices in *Montgomery* distinguished materiality as that which *"…cannot be reduced to percentages…"* in the way which significance has in the past (*Montgomery v Lanarkshire*, 2015, at 89). This conclusion reflects earlier judicial consideration of Lord Scarman's speech in *Sidaway* whereby he explained that patient decision-making goes beyond medical fact – and therefore beyond empirical considerations of 'significance'. Instead, it incorporates broader *"…circumstances, objectives, and values [which may not be] … known to the doctor but which may lead [the patient] to a different decision…"* than one which is based upon clinical considerations alone (*Sidaway v Board of Governors* [1985] at 886; *Montgomery v Lanarkshire* [2015] at 45). Accordingly, material risk is both *"…fact-sensitive, and sensitive to the characteristics of the patient…"* (*Montgomery v Lanarkshire* [2015] at 89). Material risk affords consideration of the "…*significance of a given ris*k…", in terms of *"…the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives…"* (*Montgomery v Lanarkshire* [2015], at 89). Therefore, the GMC's reference to 'significant risk' alone fails to incorporate those wider patient-sensitive factors which are required for medical decision-making. Ultimately, the language employed throughout the GMC guidance fails to reflect the patient-centric approach which *Montgomery* sought to promote through considerations such as the 'reasonable person', the 'particular patient', 'materiality' and 'significance.' Legal materiality reflects an umbrella term which incorporates factors such as the importance or relevance information has to a patient, in addition to significance as interpreted in its broadest form (GMC 2020 p12, 15). Whilst the legal standard has been re-defined in favour of greater patient-centricity; the GMC guidance suggests this has not yet fully descended into practice. The GMC's failure to articulate the current legal standard leaves practitioners with the erroneous impression that paternalism continues to prevail. The GMC's reference to 'significant' factors and the 'recognised risks' of harm which the *practitioner* believes the patient would want to know stands in direct contrast to *Montgomery's* materiality rule which requires consideration of the risks that the particular *patient* would want to know (Montgomery v Lanarkshire [2015]). To this end, the current GMC guidelines are insufficient and require strengthening, particularly since the legal standard is unlikely to be sufficient in solving this problem alone (GMC 2020).

Summary

Financial Interests as Significant and Material

In the UK. informed consent to medical treatment remains focused upon disclosure of clinical information despite increasing evidence that many non-clinical factors influence patient decision-making (Sawicki, 2016). Indeed, financial interests, which are not of a clinical nature, have been shown to impact upon clinical decision making and clinical outcomes (Robertson *et al*., 2012). It is upon these grounds that Berg and colleagues argue that it would be *"…fundamentally unfair to deprive patients of information concerning the financial pressures that may influence their physician's treatment decisions…"* (Berg, *et al*., 2001, at 212). If the 'reasonable person' standard in *Montgomery* is interpreted as adopting a majority view of materiality, then empirical evidence could be assumed in cases of non-disclosure (*Montgomery v Lanarkshire* [2015]). Existing empirical evidence presents a strong case for 'potent' financial interests representing a disclosable material risk under current UK common law standards. Evidence has shown that financial interests influence practitioners' patterns of behaviour "…*for the worse…*" (Robertson *et al*., 2012, p456). This includes the provision of inappropriate and unnecessary treatments. Further evidence suggests that a "*substantial portion*" of patients change their behaviour when in receipt of such information and so may be said to attach significance to it (Spece *et al*., 2014, p271). On these grounds, such evidence could be interpreted as representing a majority view that potent financial interests are material to decision-making. As per King & Moutlon 2006, such a majority view – in satisfying the reasonable person standard of Montgomery – could then form the core information required for disclosure. Building upon this, practitioners should then tailor information to the 'particular patient', bearing in mind that materiality goes beyond percentages – and therefore empirical evidence alone. Such dialogue requires the practitioner acquire patient-sensitive knowledge to evaluate any additional disclosable information, which would be facilitated by shared decision-making. Notably, since the non-disclosure of financial interests was found to be associated with erosion of trust, it may be argued that increased disclosure of financial interest could potentially re-build trust in the medical profession (Rose *et al*., 2019).

Directions for Future Research

The conflicting findings relating to patient behaviour following disclosure of financial interests indicate that further research is required in this area. Such research would be critical in enhancing arguments pertaining to both materiality and causation. Spece and colleagues suggest that a substantial proportion of patients will refuse treatment following a potent financial interest disclosure, whereas Rose and colleagues found that in the real-world

setting, patients retained their appointments (Spece *et al*., 2014; Rose *et al*., 2019). On the matter of causation, if the findings by Spece and colleagues were accepted they could provide "*compelling evidence*" (Poole 2019, p134) for an ordinary test of causation (Poole, 2019). It could then be argued that 'but for' the failure to disclose potent financial interests, the patient would not have been likely to consent to treatment and the harm would not have been sustained. As previously explored, in negligent non-disclosure cases, the question of causation often turns on what information should have been disclosed, yet in *Montgomery* causation was determined according to the *"…likely reactions [of the claimant] if she had been told of the risk…"* which was determined by giving consideration to the reaction of women in general (*Montgomery v Lanarkshire*, 2015 at 103). This approach could, similarly, reflect a majority approach to causation. The experimental vignette adopted by Spece and colleagues could be adapted to the given case in order to support causation by offering an estimation of whether disclosure would have changed the patient's decision to accept treatment (Spece *et al*., 2014, p272). Spece and colleagues suggest employing the expert witnesses to conduct experimental vignettes which reflect the individual decision the patient was presented with could represent a "…*promising reform…*" (Spece *et al*., 2014, p 273). UK cases such as *Chester* and *Montgomery* have demonstrated that causation often turns on whether disclosure would have avoided the harm sustained (*Chester v Afshar* [2004]; *Montgomery v Lanarkshire* [2015]). If the patient could successfully demonstrate that the disclosure of financial risk would have led them to delay treatment, seek a second opinion or an alternative treatment, then causation may be established (*Chester v Afshar*, [2004]; *Montgomery v Lanarkshire* [2015]). Such empirical evidence could support the claim of causation, rather than setting the burden of proof purely at the patient's door. Whilst *in lieu* of a test case, uncertainty remains as to how the courts would view such cases, in the US the courts have recognised a practitioner's duty to disclosure information which is not strictly medical-related whereby it represents a factor which may influence the practitioner's medical judgement (*Moore v Regents* [1990] as cited in Sawicki, 2016 p25). However, it is pertinent to note that the data from Rose and colleagues suggest that in the real-world context patient behaviour does not change – at least in terms of appointment attendance - following disclosure. Yet whilst their data suggests that patients continued to trust that their hospital would *"…give [them] all the information [they] need about treatment…",* there is no evidence to suggest that patients actually elected to then undergo treatment following their consultations (Rose *et al*., 2019, p5). Expanding this research to consider whether patients then underwent treatment would be beneficial. Of further interest is whether patient's behaviour changes if information is disclosed verbally compared to receiving the

information in a letter, thus comparing the findings of the two studies (Spece *et al*., 2014; Rose *et al*. 2019).

It must also be considered as to how far informed consent can be relied upon as a 'risk-management mechanism'. On one hand, it may be argued that once practitioners disclose financial interests and obtain consent in light of a heightened risk that there may, in practice, be a lowering of the standard of care to which the practitioner is held. Arguably, however, the *Bolam* standard – which holds that the standard of care should be that which is in line with a body of medical opinion – should mitigate against instances whereby care deviates beyond the norm, such was the case with *Paterson* and his cleavage-saving mastectomies (*Regina v Paterson* [2017]; *Bolam* [1957]; James, 2020). It is suggested that should financial interests be accepted as disclosable material risks, then future empirical research be directed towards establishing whether, or to what extent, such disclosures mitigate against potential harms. One further limitation of this study lies in the diverse nature of financial interests. As outlined, it is likely that only those deemed 'potent' would be disclosable, with potency relating to those interests which are likely to have most influence over patterns of practice. It is likely that, even with such a definition, uncertainty will remain and therefore future research should also aim to clarify which financial interests which should be directly disclosed for the purposes of informed consent. However, caution must be employed in defining potency as, if interpreted too widely, therein lies the risk that patients could be bombarded with irrelevant information. Lord Templeman's cautioned that the standard of information disclosure should not transcend into a deluge of information for the purposes of discharging a duty (*Sidaway v Board of Governors* [1985] at 904). Ultimately, a balance must be struck so as not to overwhelm the decision-making process and undermine the intent of informed consent.

Finally**,** as Rose and colleagues highlight, when patients are in the process of arranging or attending an appointment the 'cost' of making alternative arrangements may prove influential (Rose *et al*., 2019). In the UK, many patients already face long waiting times for NHS treatment, therefore patients may feel they have little choice to accept treatment from the practitioner they are assigned. However, the impact of the recent scandals which have hit UK healthcare should not be discounted. Therein lies a strong argument in favour of greater transparency through enhanced information disclosure for informed consent. At the very least, such transparency may help to rebuild trust, which has been shown to improve healthcare outcomes (Birkhäuer *et al*., 2017). Furthermore, it is not anticipated that informed consent is the cure-all solution for the harmful influence of financial interests in healthcare.

It should, instead, be read alongside the recommended mandatory disclosure and device registries outlined by the Cumberlege Report (Cumberlege, 2020). Since such practitioner registries in the US have failed to sufficiently inform patients of financial interests, it is anticipated that the recognition of potent financial interests as disclosable material risks would strengthen any legislative provisions introduced into the UK (Cumberlege, 2020)

Conclusion

The current common law standard pertaining to informed consent, as set out in the case of *Montgomery v Lanarkshire* [2015], holds that patients must be informed of the material risks of treatment. The *Montgomery* test of materiality - which asks whether in the circumstances, a reasonable person in the patient's position would attach significance to the risk - incorporates consideration of various factors, including the magnitude of the risk. This test of materiality is considered appropriate and should be followed by practitioners, medical authorities, and future courts however its applicability may be broader than is currently appreciated. Traditionally, only the risks which are inherent to the treatment are considered disclosable for the purposes of informed consent yet, evidence suggests that potent financial interests may also be considered material – and therefore disclosable – under current common law provisions. Whilst practitioners should uphold the patient's best interest as their primary concern in discharging their professional duties, secondary financial interests have been shown to take precedence in some cases. Empirical evidence supports the theory that financial interests can change practice patterns for the worse and result in harm to the patient.

It is also anticipated that the *Montgomery* materiality rule will bolster the case for causation in a court of law by considering whether the patient would have reacted differently if they had been in possession of this information. There is evidence to suggest that patients *would* consider such information to be significant for the purposes of informed consent to treatment and would refuse treatment which was subject to the influence of potent financial interests – a crucial consideration in establishing causation. A test case is likely required on several points; to determine whether UK courts would interpret the law as such; to explore whether the courts would be willing to adopt empirical evidence to support their reasoning on matters of materiality and causation and, to consider whether the expert witness role could be expanded to incorporate the undertaking of experimental vignettes. It may be surmised that, since the courts have demonstrated an evolution towards greater patient-centricity in recent years, that such an approach may be adopted in future to determine the materiality of conflict of interest in informed consent to medical treatment.

Supplementary Tables

Table 1: Summary of *Montgomery v Lanarkshire* [2015] UKSC 11

Summary of *Montgomery v Lanarkshire* [2015] UKSC 11	
Roles	
The Doctor	To take into account medical considerations and exercise professional skill and judgement in choice of investigatory or treatment options. (p.27)
The Patient	To enact the "entitlement to decide on the risks" (p.27)
The Court	Takes "responsibility for determining the nature of a person's rights" (p.27)
Duty	"The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments" (p.28)
Materiality	"The test of materiality is whether in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it." (p.28) (See also p.89; significance includes "magnitude" plus additional factors).
Causation	"If the patient had been informed of all material risks…if she had known the probability and magnitude (Severity) of the risks …, would she have made a difference choice, thereby avoiding harm?" (p.105)

Table 2: Summary of Relevant UK Case Law on Medical Negligence Relating to Treatment and Pre-Treatment Advice

Summary of Relevant UK Case Law on Medical Negligence	
***Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582**	
Facts	Claim of negligent non-disclosure of information pertaining to risk and treatment options
Ruling	To adopt a 'Responsible body of medical opinion' standard in relation to duty of care.
Key Points	• A practitioner is *"not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that art"* (at p585) • Standard of care and information disclosure determined by body of medical opinion and not consideration of the patient.
***Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] A.C. 871**	
Facts	Claim of negligent non-disclosure of information pertaining to 1-2% risk from surgery
Ruling	To adopt a 'qualified' *Bolam* standard
Key Points	• Lord Scarman dissented, preferring a prudent patient standard be applied (p888, 889) • However, Lord Bridge delivered the judgement of a *"reasonably prudent doctor"* standard (p900) • Burden upon patients to ask the right questions pertaining to risk • Disclosable risk is that which is considered to be a substantial risk of grave and adverse consequence (at p898)
***Bolitho v City and Hackney Health Authority* [1998] 2 AC 232**	
Facts	Claim of negligent failure to treat linked to causation
Ruling	To maintain the *Bolam* Standard with qualifications of reason and logic. Link between the failure to act and harm sustained could not be established, so case failed on causation (p243)

Key Points	• The *Bolam* standard prevails with qualification as to whether a body of opinion is logical and reasonable. • Ordinary test for causation applied.
***Pearce v United Bristol Healthcare NHS Trust* [1998] 48 BMLR 118**	
Facts	Claim of negligent non-disclosure of information pertaining to 0.1-0.2% risk of harm
Ruling	The case was unsuccessful however the concept of significant risk and the reasonable patient were introduced. Significant risk cannot be determined according to precise percentages (p124)
Key Points	Lord Woolf reconsidered the qualified *Bolam* Test asserting that *"…if there is a significant risk which would affect the judgement of a reasonable patient, then it is…the responsibility of a doctor to inform the patient…"* (p124)
***Chester v Afshar* [2004] UKHL 41**	
Facts	Claim of negligent non-disclosure of information pertaining to 1-2% risk which was linked to causation
Ruling	To adapt the ordinary test for causation
Key Points	The ordinary 'but for' test of causation can be adapted to meet the complexities of the circumstances
Montgomery v Lanarkshire Health Board [2015] UKSC 11	
Facts	Claim of negligent non-disclosure of information pertaining risk and treatment options
Ruling	**New precedence:** To adopt the "*reasonable person*" and "*particular patient*" standard in determining materiality of risk in informed consent (p87)
Key Points	• Patients to be informed of material risks • Materiality is that which a reasonable person would attach significance to or what the doctor should reasonably be aware that a particular patient attaches significance to • Reasonable person and particular patient standard • Material and significant risk (p87) **Causation**: considered that had the patient been aware of the risk, and not the minimal risk of grave consequence would she have reacted differently

***Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307**	
Facts	Claim of negligent non-disclosure of risk
Ruling	Clarified the extent of *Montgomery's* reach; to be applied only to information disclosure and not treatment selection
Key Points	Established a **two-part test to informed consent.** • Standard of care in treatment (and alternative treatment) selection is to be determined according to *Bolam* • Information disclosure to be determined in accordance with *Montgomery* (p33) **Causation** the court suggests that the departure from the original test of causation in *Chester* would be the exception rather than the rule – the ordinary test should prevail.

References

Association of the British Pharmaceutical Industry (ABPI) (2020). Our Ethics: Disclosure UK. https://www.abpi.org.uk/our-ethics/disclosure-uk/#2108bb8f

Bailey v The Ministry of Defence & Anor [2008] EWCA Civ 883 (Eng.)

Birkäuer, J., Gaab, J., Kossowsky, J., Hasler, S., Krummenacher, P., Werner, C., Gerger, H. (2017) Trust in the Health Care Professional and Health Outcome: A Meta-Analysis. *PLoS One*. 12(2), e0170988 https://doi.org/ 10.1371/journal.pone.0170988

Berg, J.W., Appelbaum, P.S., Lidz, C.W., Parker, L.S., Informed Consent: Legal Theory and Clinical Practice. (2nd Edition) (Oxford University Press, 2001) at p212 https://doi.org/10.1093/oso/9780195126778.001.0001

British Medical Association (BMA). (2020). Advice and Support: S https://www.bma.org.uk/advice-and-support/private-practice/setting-up-in-private-practice/setting-up-in-private-practice-overview

Black's Law Dictionary [online] (2021). Material. https://thelawdictionary.org/material/

Bolam v Friern Hospital Management Committee (1957) 1 WLR 582 (Eng.)

Bolitho v City and Hackney Health Authority [1998] 2 AC 232 (Eng.)

British Medical Association (BMA). (2020, September). Setting up in Private Practice – Overview. https://www.bma.org.uk/advice-and-support/private-practice/setting-up-in-private-practice/setting-up-in-private-practice-overview

Cambridge Dictionary [online] (2021). Material (adjective)(important). https://dictionary.cambridge.org/dictionary/english/material

Centre for Health and the Public Interest (CHPI). (2019, August). CHPI Evidence to the Inquiry into Ian Paterson. https://chpi.org.uk/wp-content/uploads/2019/08/CHPI-Evidence-to-the-Inquiry-into-Ian-Paterson-Inquiry-10-August-2019.pdf

Chester v Afshar (2004) UKHL 41 (Eng.)

Cohen, D., & Brown, E. (2019, December). Surgeons Withdraw support for heart disease advice. *BBC Newsnight*. Available at https://www.bbc.co.uk/news/health-50715156

Cohen, D., & Brown, E. (2020). New England Journal of Medicine Reviews Controversial Stent Study. *British Medical Journal*, 368: m878 https://doi.org/10.1136/bmj.m878

Cumberlege, J. (2020). First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review. Jul 8 https://www.immdsreview.org.uk/Report/html

Devaney, S., & Holm, S. (2018). The Transmutation of Deference in Medicine: A Medico-Legal Perspective. *Medical Law Review*, 26(2), 202-206. https://doi.org/10.1093/medlaw/fwy013

Duce v Worcestershire Acute Hospitals NHS Trust [2018] EWCA Civ 1307 (Eng.)

Dunn, M., Fulford, K.W.M., Herring, J., Handa, A. (2019) Between the Reasonable and the Particular: Deflating Autonomy in the Legal Regulation of Informed Consent to Medical Treatment. *Health Care Analysis*. 27, 100-127 https://doi.org/10.1007/s10728-018-0358-x

Dyer, C. (2017) Rogue Surgeon Paterson is sentenced to 15 years after performing unnecessary operations. *British Medical Journal*. 357, j2678 https://doi.org/10.1136/bmj.j2678

Emmett et al v Ethicon Women's Health & Urology. Case ID: 130701495 in Koutouzos GD. Pennsylvania woman awarded $41M pelvic mesh verdict. Wolters Kluwer; 2019 [cited 2021 Feb 8] Available from https://lrus.wolterskluwer.com/news/products-liability-law-daily/pennsylvania-woman-awarded-41m-pelvic-mesh-verdict-3/72205/.

Feldman-Stewart, D., Brundage M.D., McConnell, B.A., Mackillop, W.J. (2000). Practical Issues in Assisting Shared Decision-Making. Health Expect. *3*(1), 46-54 at 46-49 https://dx.doi.org/10.1046%2Fj.1369-6513.2000.00082.x

General Medical Council (2019). Good Medical Practice. Implemented 22 April 2013, Updated 29 April 2019. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/duties-of-a-doctor

General Medical Council (2020). Decision Making and Consent. Published 30 September 2020, in effect from 9 November 2020. https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA

Gornall J. (2018). How Mesh became a four-letter word. *British Medical Journal*, 362, K4137 https://doi.org/10.1136/bmj.k4137

Hall, D., V. Jones, S., C. (2007). Branding of Prescription Medicines to Australian Consumers. *Australasian Marketing Journal*. 15(2), 97-107.

Independent Medicines and Medical Device Safety Review. Patient Written Evidence https://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20Patient%20Groups%20-%20Pelvic%20Mesh.pdf; Clinicians, Academics and Other Individuals https://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20Clinicians,%20academics%20and%20other%20individuals%20-%20Pelvic%20Mesh.pdf p. 15

James, G. (2020). Report of the Independent Inquiry into the Issues Raised by Paterson. February 2020. United Kingdom Government. HC31 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/863211/issues-raised-by-paterson-independent-inquiry-report-web-accessible.pdf

King, J.S., Moulton, B.,W. (2006). Rethinking Informed Consent: The Case for Shared Medical Decision-Making. *American Journal of Law & Medicine*. *32*(4),429-501 https://doi.org/10.1177/009885880603200401

Lee, A. (2017).'Bolam' to 'Montgomery' is result of evolutionary change of medical practice towards 'patient-centred care'. *Postgraduate Medical Journal.* 93, 46-50. http://dx.doi.org/10.1136/postgradmedj-2016-134236

MacLean, A. (2006) Autonomy, Consent and Persuasion. *European Journal of Health Law*. 13, 321-338 https://doi.org/10.1163/157180906779160274

Madden, T.M. (2015) Significance and the Materiality Tautology. Journal of Business & Technology Law. 10, 217 http://digitalcommons.law.umaryland.edu/jbtl/vol10/iss2/3

Mason, J.K., Laurie, G.T. (2011). Mason and McCall Smith's Law and Medical Ethics. (8th Ed) Oxford University Press, Oxford.

McCartney, M. (2018) Hiding and Seeking Doctors' Conflicts of Interest. *British Medical Journal.* 360,k135 https://doi.org/10.1136/bmj.k135

McQuire v Western Morning News [1903] 2 KB 100 (Eng.)

Medical Act 1983 (U.K.)

Mitchell, J. (2012). Urologists' Self-Referral for Pathology of Biopsy Specimens Linked to Increased Use and Lower Prostate Cancer Detection. *Health Affairs*. 31(7), 741. https://doi.org/10.1377/hlthaff.2011.1372

Mitchell, J.M. (2008). Do Financial Incentives Linked to Ownership of Speciality Hospitals Affect Physicians' Practice Patterns? *Medical Care.* 46(7); 732-737 https://doi.org/10.1097/MLR.0b013e31817892a7

Mitchell, J.M., Scott, E. (1992) Physician Ownership of Physical Therapy Services on Charges, Utilization, Profits and Service Characteristics. *Journal of the American Medical Association. 268*(15): 2055-2059 https://doi.org/10.1001/jama.1992.03490150107033

Montgomery v Lanarkshire Health Board (2015) UKSC 11 (Eng.)

Montgomery, K., & Lipworth, W. (2019). Medical Professionals: Conflicts and Quandaries in Medical Practice. Routledge Studies in Health Management. New York, First ed.

Moore v Regents of Univ. of California, 793 P.2d 479, 485 (Cal. 1990) (USA)

Moore, A., Strause, S., Lexchin, J., & Thombs, B.D. (2020) Financial conflict of interest among clinical practice guideline-producing organisations. *British Journal of General Practice,* 70(700), 530-531 https://doi.org/10.3399/bjgp20X713177

National Health Service (NHS) England (2017). Managing Conflict of Interest: Revised Statutory Guidance for CCGs 2017. https://www.england.nhs.uk/wp-content/uploads/2017/06/revised-ccg-conflict-of-interest-guidance-v7.pdf

Neumann, F.J., Sousa-Uva, M., Ahlsson, A., Alfonso, F., Banning, A.P., Benedetto, U., Byrne, R.A., Collet, J.P., Falk, V., Head, S.J., Juni, P., Kastrati, A., Koller, A., Kristensen, S.D., Niebauer, J., Richter, D.J., Seferovic, P.M., Sibbing, D., Stefanini, G.G., Windecker, S., Yadav, R., Zembala, M.O., & ESC Scientific Document Group. (2018). ESC/ EACTS Guidelines on Myocardial Revascularization. *European Heart Journal*. 40(2), 87-165 https://doi.org/10.1093/eurheartj/ehy394

Oxford English Dictionary [online] (2021). Material. [Adjective 1(1.2)]. https://www.lexico.com/definition/Material

Papanicolas, I., Mossialos, E., Gundersen, A., Woskie, L., Jha, A.K. Performance of UK National Health Service Compared with other High Income Countires: observational study. BMJ 2019; 367: 166326 DOI: 10.1136/BMJ.16326 https://doi.org/10.1136/bmj.l6326

James, G. (2020) Paterson Inquiry Report. UK House of Commons. HC 31 https://www.gov.uk/government/publications/paterson-inquiry-report

Pearce v United Bristol Healthcare NHS Trust [1998] 48 BMLR 118 (Eng.)

PLoS Medicine Editors. (2008) Making Sense of Non-Financial Competing Interests. PLoS Medicine. 5(9) e199 https://doi.org/10.1371/journal.pmed.0050199

Poole, N. (2019). Clinical Negligence Made Clear: A Guide for Patients and Professionals: With a foreword by Sir Robert Francis QC. 2019 Bath Publishing, Bath.

Prostate Cancer UK. (2019, January). Prostate Tests: Prostate Biopsy. https://prostatecanceruk.org/prostate-information/prostate-tests/prostate-biopsy

Re W (A Minor)(Medical Treatment: Court's Jurisdication)(1992) 3 W.L.R 758 at 78 (Eng.)

Regina v Ian Stuart Paterson [2017] WLR(D) 743 (Engl. Wal.) https://www.judiciary.uk/wp-content/uploads/2017/05/r-v-paterson-sentencing-remarks-mr-justice-jeremy-baker-20170531.pdf

Robertson, C., Rose, S., & Kesselheim, A. (2012). Effect of Financial Relationships on the Behaviors of Health Care Professionals. A Review of the Evidence. *Journal of Law, Medicine and Ethics*, 40(3), 452- 466. https://doi.10.1111/j.1748-720X.2012.00678.x

Rose, S.L., Sah, S., Dweik, R., Schmidt, C., Mercer, M., Mitchum, A., Kattan, M., Karafa, M., & Robertson, C. (2019). Patient responses to physician disclosures of industry conflicts of interests: a randomised field experiment. *Organizational Behavior and Human Decision Processes.* Article in Press. https://doi.org/10.1016/j.obhdp.2019.03.005

Rowland, D. (2019). Pounds for Patients? How private hospitals use financial incentives tow in the business of medical consultants. *Centre for Health and the Public Interest (CHPI),* Available at https://chpi.org.uk/wp-content/uploads/2019/06/FINAL-REPORT-POUNDS-4-PATIENTS-070619.pdf

Rowland, D. (2020). Some financial conflicts of interest in medicine cannot be managed and should be prohibited. *British Medical Journal Opinion.* https://blogs.bmj.com/bmj/2020/07/21/david-rowland-some-financial-conflicts-of-interest-in-medicine-cannot-be-managed-and-should-be-prohibited/

Royal College of Surgeons. (2018, November). Consent: Supported Decision-Making: A Guide to Good Practice. RCS Professional and Clinical Standards. https://www.rcseng.ac.uk/-/media/files/rcs/standards-and-research/standards-and-policy/good-practice-guides/new-docs-may-2019/rcs-_consent-supported-decision-making.pdf

Samanta, A., & Samanta, J. (2003) Legal Standard of Care a shift from the traditional Bolam Test. *Clinical Medicine*. 3, 443-6 https://doi.org/10.7861/clinmedicine.3-5-443

Sawicki, N.N. (2016). Modernizing Informed Consent: Expanding the Boundaries of Materiality. *University of Illinois Law Review,* (3), 821-872. http://dx.doi.org/10.2139/ssrn.2610766

Shah, B.R., Cowper, P.A., O'Brien, S.M., Jensen, N., Patel, M.R., Douglas, P.S., Peterson, E.D. (2011) Association Between Physician Billing and Cardiac Stress Testing Patterns Following Coronary Revascularization. *Journal of the American Medical Association*. 18, 1993-2000. https://doi.org/10.1001/jama.2011.1604

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] A.C. 871 (Eng.)

Smyth, C. Doctors told to reveal all income from private work. The Sunday Times. 20 September 2015. https://www.thetimes.co.uk/article/doctors-told-to-reveal-all-income-from-private-work-p08p53g57

Spece, R., Yokum, D., Okoro, A.G., & Robertson, C. (2014). An Empirical Method for Materiality: Would Conflict of Interest Disclosures Change Patient Decisions. *American Journal of Lifestyle Medicine,* 40, 253-274 PMID: 27530047.

Stone, G.W., Kappetein, A.P.M, Sabik, J.F., Pockock, S. J., Morice, M.C., Puskas, J., Kandzari, D. E., Karmpaliotis D., Brown W.M., Lembo, N.J., Banning, A., Merkely, B., et al for the EXCEL Trial Investigators. (2019) Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease. New England Journal of Medicine. 381; 1820-1830 https://doi.org/10.1056/NEJMoa1909406

Strauss, D.C., & Merios, T.H. (2009). What does the medical profession mean by 'standard of care?' *Journal of Clinical Oncology*, 27(32) https://doi.org/10.1200/JCO.2009.24.6678

Swedlow, A., Johnson, G., Smithline, N., Milstein, A. (1992). Increased Costs and Rates of Use in the Californian Workers' Compensation System as a Result of Self-Referral by Physicians. *New England Journal of Medicine*. 327, 1502-1506 https://doi.org/10.1056/NEJM199211193272107

The Free Dictionary [online] (2021). Significant. https://www.thefreedictionary.com/significant

Thompson, D.F. (1993). Understanding Financial Conflicts of Interests. *New England Journal of Medicine,* 329(8), 573-576 https://doi.org/10.1056/NEJM199308193290812

Ulmsten, U., Falconer, C., Johnson, P., Jomaa, M., Lanner, L., Nilsson, C.G., Olsson, I. (1998). A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *International Urogynecological Journal of Pelvic Floor Dysfunction*. 9, 210-3 DOI: 10.1007/BF01901606

Webster v Burton Hospital NHS Foundation Trust (2017) EWCA Civ 62 (Eng.)

Wiersma, M., Kerridge, I., Lipworth, W. (2017) The Dangers of neglecting non-financial conflicts of interest in health and medicine. *Journal of Medical Ethics*, 44:319-322. https://doi.org/10.1136/medethics-2017-104530

Witcomb, R., Almond, J., Morris, T., Peat, J., Whiticar, J., Saunders, D., Chisholm, A. (2014, April) Private Healthcare Market Investigation Final Report. *Competition and Markets Authority (CMA). CMA25. https://assets.publishing.service.gov.uk/media/533af065e5274a5660000023/Private_healthcare_main_report.pdf* Para 8.51, 11.463

Wyatt v Curtis [2003] EWCA 1779 (Eng.)

Paper 3

III. Lessons from the Vaginal Mesh Scandal; Enhancing the Patient-Centric Approach to Informed Consent for Medical Device Implantation.

Abstract

The vaginal mesh scandal, in which thousands of women were irreversibly maimed by polypropylene mesh, revealed multi-level failures in medical device regulation and implantation, demonstrating that patient-centric care has not yet fully transcended from policy into practice. In law, informed consent is considered by a two-stage test; reasonable treatment and patient information disclosure. The standard of reasonable treatment is determined according to that which is deemed acceptable in accordance with a body of medical opinion. However, such bodies of medical opinion were vulnerable to external influence from device manufactures. Vaginal mesh manufacturers were found to have had financial links to research, royal colleges and influential clinicians which then influenced the basis of the evidence-based practice which often guides such bodies of medical opinion. According to the Independent Medicines and Medical Device Safety Report, patients' mesh complications were also frequently under-reported and patient-based evidence of harm disregarded. Patients were also not sufficiently informed of the material risks or reasonable alternatives to mesh, which is required of the second stage of informed consent pertaining to information disclosure. This paper makes the following recommendations; that conflict of interest disclosure be mandated; that greater value be afforded to patient-based evidence to improve evaluation of treatments; and that information disclosure for informed consent should relate to the risks, benefits and alternatives to the surgical procedure *and* medical device. This will ensure that patients can evaluate whether surgeons are offering unbiased treatment options and are also informed of the potential long-term risks associated with device implantation.

Introduction

In 2012, the United Kingdom Department of Health published the new policy document *No Decision About Me, Without Me* which acknowledged a new era of patient-centric care [1]. The aim was to promote such patient-centric care and improve patient involvement in healthcare through shared decision-making [1]. It was anticipated that this would improve care strategies [1]. Such intent was echoed by the General Medical Council's (GMC) publication Good Medical Practice which directed doctors to work with patients to attain better clinical outcomes [2]. However recent high-profile medical device scandals, in which

patients were harmed by implantable devices, demonstrate that patient-centric care has not yet fully transcended into practice [3]. The Independent Medicines and Medical Device Safety Review (IMMDSR) and its subsequent Report "First Do No Harm" revealed that surgeons frequently failed to listen to patients' life-altering experiences of mesh implantation and often under-reported adverse effects [4][5]. Affected patients also claimed to have been misled or misinformed during the informed consent process [4][5]. This suggests that there are two main barriers to patient-centric care and informed consent in device implantation surgery. Firstly, that patient-based evidence of treatment outcomes is often over-looked despite being a potentially valuable resource for improving healthcare outcomes. Secondly, that standards of information disclosure for informed consent as per the *Montgomery v Lanarkshire* case of March 2015 [6] have yet to fully transcend into practice. The landmark medical consent case changed legal standards of consent to treatment by recognising that patients should be told what *they* want to know about a treatment rather than what a doctor thinks they should know. It created a new legal duty upon doctors to fully inform patients of the material risks of treatment, benefits and any viable alternatives when gaining consent for medical treatment. It is proposed that disclosure of material risks should not be restricted to risks directly associated with the surgical procedure but should also reference long-term risks associated with device implantation, such as erosion or toxicity.

Implantable Devices: Lessons from the Vaginal Mesh Scandal

A medical device may be defined as *"…an instrument, apparatus, appliance, material or other article…which is intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease...*" [7]. Pharmaceutical drugs and implantable medical devices share a commonality in that they are designed to work within the human body. In the European Union (EU), pharmaceuticals undergo rigorous clinical trials, stringent regulation, and strict post-marketing surveillance. By comparison, medical devices are often insufficiently tested and may be awarded CE certification by Notified Bodies with insufficient medical knowledge [8]. Despite the intention that it address the shortcomings of current EU Medical Device Directives, Bowers suggests that the anticipated EU Regulation 2017/745 will merely allow manufacturers to *"…specify and justify the level of clinical evidence necessary to demonstrate … general safety...*" [9][10]. This requirement to submit minimal information will likely maintain the status-quo of self-regulation amongst device manufacturers and allow unproven and potentially unsafe devices to be used inside patients [3]. Pharmaceutical manufacturers must include clinical trial evidence, including risks, on the Summary of Product Characteristics (SmPC). Yet there is no specification that device manufacturers need disclose all risks in

corresponding Information for Use (IFU) leaflets. It is also not uncommon for manufacturers to forego clinical trials altogether if an equivalent device is already on the market [3]. This was the case for toxic metal-on-metal hip implants and mutilating transvaginal mesh made from polypropylene [3]. In the 1950s polypropylene was proclaimed to be the first man-made plastic deemed suitable for implantable medical devices [11]. Experts have since testified that it is, in fact, an unstable material that never should have been used inside the human body [3].

Initially used to treat abdominal herniae [4], Johnson & Johnson's subsidiary company Ethicon sponsored the research, development, and safety studies into the use of polypropylene mesh (also known as transvaginal tape) as a treatment for stress urinary incontinence in 1997 [12]. Having sponsored the research, Ethicon heavily influenced researchers to report favourable findings [12] Those findings, which were likely subject to bias, formed the basis of the evidence-based practice which promoted mesh as a treatment for stress urinary incontinence [12]. Polypropylene mesh was also subsequently indicated for the treatment of pelvic organ prolapse (POP) [4][12]. Ethicon played an instrumental role in the promotion of mesh for uro-gynaecological indications [4], yet in 2019 the company was found guilty of withholding knowledge that their mesh could leave women in chronic pain [13]. The $41 million Penn State lawsuit heard that the company had considered suppressing studies showing unfavourable data or those highlighting the potential for chronic pelvic pain and increased morbidity [13]. Further complications included urinary and intestinal dysfunction, dyspareunia and mesh-induced-injury of sexual partners [4][14]. Evidence showed that Ethicon also extensively marketed mesh at conferences and provided surgeons and Royal Colleges with financial incentives [4] [15]. Patient testimony pertaining to the harm they had suffered was often disregarded by the National Health Service (NHS) surgeons whose practice was based upon literature which favoured the intervention [4]. In some cases, women were even referred for psychiatric treatment instead of receiving an acknowledgement of their symptoms [4]. This is indicative of how a body of medical opinion may be unduly influenced by industry, conflict of interest or unreliable scientific evidence.

CLINICAL JUDGEMENT

Conflict of Interest within a Body of Medical Opinion

The General Medical Council publication '*Good Medical Practice'* advises doctors to provide efficacious treatments according to existing evidence [2]. This guidance upholds principles of evidence-based practice which are intended to mitigate paternalism by ensuring

that treatment options are not based upon outdated or unproven surgical preference but are instead proven to be safe and efficacious [16]. Evidence-based practice may be defined as the "*…conscientious, explicit and judicious use of current best evidence to inform decisions about the care of individual patients…*" [17]. In practice, the credibility of evidence is evaluated according to the source, with quantifiable research considered more credible than other forms of evidence [17]. However, as will be addressed later, such a pecking-order of evidence often fails to recognise the value of patient-based evidence, such as treatment evaluation, patient experience or opinion [17]. As a result, evidence-based practice is a predominant factor in the treatment patients receive.

Under UK law, informed consent is a two-staged test [18]. The first stage test recognises that surgeons should exercise professional judgement in evaluating potential treatment options [19] and the second stage applies the *Montgomery* test to address the subsequent information which should be disclosed to patients in seeking their consent [7].

The first test of professional judgement is determined according to the *Bolam* Test which states that the standard of care should be in "*...accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.."* [19]. Surgeons are therefore under a legal duty to propose treatments which are accepted as proper by a responsible body of similarly qualified surgeons. Nair J cautioned that this "…. *does not mean that a medical man can obstinately and pig-headedly carry on with some old technique if it has been proved to be contrary to what is really substantially the whole of informed medical opinion…*" [19]. Such a caveat recognises that whilst differences in medical opinion exist, there is an expectation that surgeons should keep up-to-date through evidence based practice. Since it is not possible to read every relevant published article, clinical guidelines can provide surgeons with valuable overview of standardised best practice [20]. Notably, the courts may also look to retain some judicial authority over the degree of professional self-regulation afforded by *Bolam*, by considering whether a practice is responsible, reasonable and logical so as to give greater consideration to external opinion [19] [20]. Yet the application of this is rare, and reliance upon the paternalistic *Bolam* Test and evidence-based practice continues [19] [21]. Caution must be applied when assessing care according to standards of professional judgement, as conflict of interest or external influence could create confirmation bias. Conflict of interest may be defined as "*...a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest"* [22]. The Evidence from the IMMDSR strongly suggests that professional medical judgement relating to vaginal mesh

may have been clouded by financial ties to industry and biased studies [12][15]. On this basis, greater priority needs to be given to the interests of patients and their experiences.

Gornall (2018) describes how influential clinicians involved in drafting mesh guidelines may have been subject to conflict of interest in this way, having received industry funding, sponsorship and incentives which could have then prejudiced their recommendations [15]. Similarly, Hurwitz (2004) argues that a high percentage of guidelines follow poor quality information and should not influence legal standards [16]. The IMMDSR also reported that over the last ten years industry-sponsored studies with conflict of interests dominated the literature creating a false narrative of vaginal mesh efficacy [4]. Ethicon was just one of many mesh manufacturers found to have sponsored the influential Royal Colleges and conferences which are traditionally forums of research dissemination [15]. Such widespread industry influence can fuel bias and skew judgement of which patients are often unaware. To this end, Hampton warns that "…*guidelines are evidence filtered through opinion…*" [23]. It must be recognised therefore, that external influence may lead to inappropriate treatments being considered appropriate by a body of medical opinion [19].

Patient-Based Evidence as a Valuable Component of Evidence-Based Practice

A key argument in the UK class action case in 2018 of *AH verses various Health Boards and Manufacturers*, was that surgeons had not been aware of the risks associated with mesh [4][24]. However, patient testimony to the IMMDSR suggests that complications had largely been ignored [4] and so the use of mesh continued in subsequent patients. Whilst patient-based evidence is increasingly recognised by the National Iinstitute for Clinical Excellence (NICE) [25] and some select areas of practice [26] it has yet to be fully embraced in surgical practice. Accordingly, there are only three sources of treatment information available to surgeons; information from the manufacturer; their "…*skill and expertise as a reasonably competent doctor…"* and their obligation to "…*keep abreast of the developments in the field of medicine in which he practices by, for example, reading articles relating to treatments…*" [24]. Surgeons have a duty to keep up to date, attend meetings and read the literature to keep abreast of current developments [27]. Yet, as aforementioned, such information sources may be subject to bias or conflict of interest. A 2015 Cochrane Review identified a high potential for bias in mesh literature [28]. Arguably, such biased literature could have eclipsed studies highlighting the risks of mesh. Safety concerns were voiced as early as as 2007 with reports of erosion and pelvic organ damage yet mesh continued to be used surgically in England until 2017 [4][14]. Some five years earlier in 2012, the United States regulator - the Food and Drug Administration (FDA) - had raised concerns over the

lack of mesh efficacy weighed against significantly increased complications rates compared to non-mesh alternatives [29]. Such complications included chronic pelvic and vaginal pain, vaginal constriction and associated dyspareunia which could have severe impact upon quality of life [14]. Greater emphasis on conflict of interest could ensure a more balanced playing field for unbiased literature, however the scandal also illustrates the need to recognise the value of patient-based evidence as *integral in improving healthcare outcomes.*

New European Regulation 2017/745 aims to ensure patients *are* heard, and protected, by creating a device registry to record adverse events [9]. This gives recognition to patient experience as a form of evidence which is often undervalued in evidence-based practice [17]. In fact, the IMMDSR heard that valuable patient evidence of harm from mesh was often disregarded by surgeons in favour of the literature [17]. Had greater credibility been afforded to patient testimony, arguably, change could have come sooner. Wider incorporation of patient-based evidence could not only help mitigate bias but may also help to shape professional judgement through the adoption of a truly patient-centric approach to treatment. In adopting such an approach, patients can potentially *inform doctors* of their treatment experiences to reflect a model of mutual respect.

Samanta *et al.,* (2006) suggest that the increasing use of guidelines in litigation could mark a departure from the professional opinion standard of *Bolam* towards greater recognition of external sources of evidence, such as that from patient experience [19] [20]. Patient-based evidence, which has been shown to correlate with improved healthcare outcomes, could also be incorporated into the evidence-based practice framework to offer greater appreciation of what constitutes effective care [30]. Browne *et al*., (2010) found patient-based evidence can help to expose problems so that practice can be improved [31]. A systematic review conducted in 2012 urged clinicians to recognise patient experience rather than to dismiss it as too subjective or as being non-scientific and without credence [30]. Patient-based evidence is also increasingly used by the NICE when there is a lack of scientific literature [25]. Arguably, incorporation of patient-based evidence within evidence-based practice could safeguard against conflicts of interests by alerting practitioners to poor patient experience, as was the case with vaginal mesh. One survey found that 71% of women in a mesh support group required long term analgesia and nearly half had considered suicide as a direct result of mesh surgery [4]. If such evidence had been incorporated into evidence-based practice perhaps other women need not have suffered in the same way. Patient-based evidence may also help rebuild trust. If other patients' experiences are referred to, at least in

part, during the informed consent process, patients may feel better equipped to make treatment decisions.

PATIENT INFORMATION DISCLOSURE

Information Disclosure for Implantable Devices

Campell *et al*., (2018) describe informed consent as "…*perhaps the most important ethical issue associated with the use of vaginal mesh in prolapse surgery…*" [32]. In law, the second stage of informed consent is that of information disclosure. According to the Supreme Court ruling in *Montgomery*, the surgeon is "…*under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments…*" [6]. This places a duty upon surgeons to inform patients of the material risks, which for these purposes, are those which a reasonable patient in the same circumstance would attach significance to [6]. The intention of the court was to rebalance the scales in favour of a more patient-centric model to informed consent. However, patient testimony suggests that this did not transcend into practice when obtaining consent for mesh implantation [4]. In the aforementioned 2018 class action, the Court of Session heard four related cases brought by patients claiming to have suffered harm as the result of pelvic (vaginal) mesh implantation [24]. The claimants asserted that they had not adequately been informed of the risks listed on the Prolift IFU [24]. Those risks include the formation of adhesions, erosion caused by movement of the device and subsequent laceration of anatomical structures within the pelvic including nerves, blood vessels and pelvic organs [24]. Rather patients claimed only to have been advised of a *"…small risk of infection…*" which is common to most forms of surgery [24]. Considering the risks listed in the Proflit IFU raises the question of what patient *would* consent to that level of risk for a single surgery. The claimants also stated concerns that they were not informed of potentially life-changing longer-term risks, such as chronic pain, or the still undetermined risk implanted plastic may have upon fertility or pregnancy in women of reproductive age [24]. Many women, instead of being warned of the risks, were encouraged by reassurances that mesh implantation was the 'gold standard' treatment; a quick solution for incontinence that was actually *popular* with other patients [4]. The court found that Ethicon had failed in its duty of care relating to the design and manufacture of the product and so the case and subsequent class action was settled for an undisclosed sum [24]. Yet as Campell *et al*., (2018) attest, the scandal highlights ongoing deficiencies in informed consent which should be recognised and used to improve clinical practice [32]. Whilst the issues pertaining to the available evidence and conflict of interest have already been described, it is pertinent to take this opportunity to reflect upon issues specific to consent for device

implantation, particularly disclosure of longer-term risks including foreseeable unknown risk [33].

The Proflift IFU described risks which may result during implantation of the device and gives recognition to complications such as inflammation, infection and scarring which can occur in the days and weeks after any surgical procedure [24]. However, the most common risk of mesh, that of erosion [14], often developed years after surgery was performed, creating a dormant period [4]. Whilst the IMMDSR heard that some patients had been informed that perforation could occur *during* surgery there was little mention of this being a longer-term risk [4]. Whilst it may be argued that the patient consented to the known risk of perforation, it is important to differentiate between the *modality* of such perforation. A patient may, for example, anticipate that a surgical perforation could be immediately repaired, or addressed, during the surgery. However, perforation caused by mesh erosion is likely to create chronic pain and be extremely difficult to repair. The removal of mesh has been compared to "…*getting chewing gum out of hair…*" [7].

It is important, therefore, to recognise that information disclosure for consent to surgical device implantation should include two distinct categories of information. The first category should include information relating any risks, benefits, and reasonable alternatives to the surgical procedure itself [12]. The second category should include information relating to the risks, benefits, and reasonable alternatives to the implantable device. This will give recognition to the fact that a separate form of risk is linked to the implantable device itself. Such risk of harm was also evidenced in similar scandals involving metal-on-metal hip implants and PIP breast implants, both of which caused systemic toxicity in patients [3]. Information relating to the recommended device should include an explanation of the nature of the device, and any potential benefits relating to that product. The IMMDSR heard that surgeons had not routinely shown patients device samples which could have supported shared decision-making by helping patients better understand the nature of the device and implantation procedure they are consenting to [4]. A crucial part of informed consent is ensuring patients understand *what* they are consenting to. Even if risks are unknown due to lack of long-term studies, patients must be made aware of this so that they can decide whether, or not, to incur such risk. Cockburn and Faye (2019) propose that disclosure of material risks for innovative treatment should include unknown or unforeseeable risks, conflict of interest and potentials for bias [33]. Whilst under UK law surgeons cannot be expected to warm of unforeseeable unknown risks [18], the authors argue that unknown harm *is foreseeable* in the case of innovative medical treatment [33]. Arguably unknown risk

is foreseeable in the long-term when medical devices – which are essentially foreign bodies - are implanted into the body. Therefore, disclosure of unknown risks *and* conflict of interest can serve to reduce paternalism and simultaneously mitigate against bias. Whilst links with industry are important for device development, a surgeon's primary interest should be the patients. The GMC advise doctors to disclose such conflicts of interest with device manufacturers, however there is no corresponding legal duty [2]. Patients need to be aware of conflict of interest so that they themselves can determine whether a doctor's recommendations are subject to secondary influence. Arguably, conflict of interest disclosure should also be a key component of informed consent, allowing patients to evaluate whether information disclosed to them, particularly relating to risk and benefit, is likely to have been objectively evaluated by their surgeon.

Conclusion

It is important that in upholding patient-centric care, patients be more fully involved in shared, or supported, decision making. However, in the selection of reasonable treatments, a doctor-centric approach endures. The pelvic (vaginal) mesh scandal has revealed that a body of medical opinion can be influenced by conflict of interest or bias which can cloud judgements of what is truly in patients' best interests. Whilst it is unlikely that the courts will move away from the current *Bolam* standard, it is proposed that a greater recognition of patient-based evidence within evidence-based practice could provide a more patient-centric approach to determining the risks and efficacy of treatments. Furthermore, it is recommended that information disclosure for medical device implantation relate to any conflict of interest, the surgical procedure, *and* the long-term implications of an implanted device.

References

1. Department of Health. Liberating the NHS: No Decision about me without me – Government response to the consultation. 2012, December 13 [cited 2021 February 8] United Kingdom Accessed. Gateway Reference 18444 Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216980/Liberating-the-NHS-No-decision-about-me-without-me-Government-response.pdf

2. General Medical Council. Good Medical Practice. 2013, April 22. Updated 2020, November [cited 2021, February 8]. United Kingdom. Code: GMC/GMP/1120. ISBN: 978-0-901458-73-5. Available at https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

3. Heneghan C, Thompson M. Rethinking medical device regulation. J Roc Soc Med 2012; 105:186-8

4. Independent Medicines and Medical Devices Safety Review [Internet]. Cumberlege J, CBE. 2018, November 20. [Updated 2020, July 31; cited 2021, February 8]. Evidence. Available from https://www.immdsreview.org.uk/Evidence.html Particularly from 'Patient Groups-Pelvic Mesh' s.2.1.2, 3.1.8, 5.1.1, 5.1.2,6.1; Evidence of Properties of Mesh; Evidence from Clinicians, Academics and Other Individuals p15-31, Manufacturer Evidence: Ethicon.

5. Cumberlege J CBE. First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review. 2020 July 8 [cited 2021 February 8] United Kingdom. ISBN 978-1-5272-6567-7. Available at https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

6. *Montgomery v Lanarkshire* [2015] UKSC 11 available at https://www.supremecourt.uk/cases/uksc-2013-0136.html [cited 2021 February 8]

7. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0047&from=en [cited 2021 February 8]

8. Heneghan C. Updated EU medical Device Regulations: do they make a difference? 2018 November, 25 [cited 2021, February 8] In: BMJ EBM Spotlight [Internet] United Kingdom. Available at https://blogs.bmj.com/bmjebmspotlight/2018/11/25/carl-heneghan-why-eu-medical-device-regulations-are-a-smokescreen/

9. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

10. Bowers S. How lobbying blocked European safety checks for dangerous medical implants: Confidential injury and malfunction reports have tripled in less than 10 years in many countries [Internet] ICJI. 2018 Nov 25 [cited 2021 February 8] Available at https://www.icij.org/investigations/implant-files/how-lobbying-blocked-european-safety-checks-for-dangerous-medical-implants/

11. Busico V. Guilio Natta and the development of stereoselective propene polymerization. Adv Polym Sci. 2013; 257:37-8

12. Gornall J. The trial that launched millions of mesh implant procedures: did money compromise the outcome? BMJ 2018; 363:k4155

13. *Emmett et al v Ethicon Women's Health & Urology A.* 2019 January 31, Case ID 130701495 in Koutouzos GD. Pennsylvania woman awarded $41M pelvic mesh verdict. [Internet] 2019, February 1 [cited 2021 February 8] Wolters Kluwer. Available at https://lrus.wolterskluwer.com/news/products-liability-law-daily/pennsylvania-woman-awarded-41m-pelvic-mesh-verdict-3/72205/

14. Swift SE. 'First do no harm' and the emerging story of the vaginal reconstructive mesh implant. IUJ 2007; 18; 983-984

15. Gornall J. Vaginal mesh implants: putting the relations between UK doctors and industry in plain sight. BMJ 2018; 363: k4164

16. Hurwtiz B. How does evidence-based guidance influence determination of medical negligence? BMJ 2004; 329:1024

17. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312(7023):71.

18. *Duce v Worcester Acute Hospitals NHS Trust* [2018] EWCA Civ 1307 2018, June 7. Available at https://www.bailii.org/ew/cases/EWCA/Civ/2018/1307.html

19. *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 available at https://www.lexisnexis.com/uk/legal/results/enhdocview.do?docLinkInd=true&ersKey=23_T134318055&format=GNBFULL&startDocNo=0&resultsUrlKey=0_T134318057&backKey=20_T134318058&csi=417192&docNo=1&scrollToPosition=307 [Cited 2021 February 8]

20. Samanta S, Mello MM, Foster C, Tingle J, Samanta J. The role of clinical guidelines in medical negligence litigation: A shift from the Bolam standard? Med L Rev 2006; 14(3): 321-366

21. Mulheron R. Trumping Bolam: A critical analysis of Bolitho's "gloss". Camb Law J 2010; 69(3): 609-638

22. Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Washington (DC): National Academies Press (US); 2009 [cited 2021, February 8] 2, Principles for Identifying and Assessing Conflicts of Interest. Available from: https://www.ncbi.nlm.nih.gov/books/NBK22937

23. Hampton JR. Guidelines-for the obedience of fools and the guidance of wise men*?* Clin Med. 2003; 3: 279–84

24. *AH v Greater Glasgow Health Board; and (second) Johnson & Johnson Medical Limited and others* [2018] CSOH 57 Available at https://www.scotcourts.gov.uk/docs/default-source/cos-general-docs/pdf-docs-for-opinions/2018csoh57.pdf?sfvrsn=0

25. Sharma T, Choudhury M, Kaur B Naidoo B, Garner S, Littlejohns P, Staniszewska S. Evidence informed decision making: the use of "colloquial evidence" at NICE. Int J Technol Assess Health Care. 2015; 31(3):138-146.

26. Bradshaw A. Listening to the Patient's self-reported testimony: the authentic hermeneutical witness to the compassionate nurse? J Adv Nurs. 2013; 70(1): 60-67

27. Kennedy v Frankel [2019] EWHC 106 (QB) Available at https://www.bailii.org/ew/cases/EWHC/QB/2019/106.html [cited 2021, February 8]

28. Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral Sling Operations for Stress Urinary Incontinence in Women. *Cochrane Database Syst. Rev.* 2015, Jul 1;(7):CD006375.

29. United States Food and Drug Administration (FDA). Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. July 2011 [cited 2021, February 8] Accessed at https://www.fda.gov/files/medical%20devices/published/Urogynecologic-Surgical-Mesh--Update-on-the-Safety-and-Effectiveness-of-Transvaginal-Placement-for-Pelvic-Organ-Prolapse-%28July-2011%29.pdf

30. Doyle C, Lennox L, Bell D. A systematic Review of the evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open*. 2013. 3:e001570

31. Brown K, Roseman D, Shaller D, Edgman-Levitan S. Measuring Patient Experience as a Strategy for Improving Primary Care. Health Aff: Millwood; 2010; 29(5): 921-925

32. Campbell, P, Jha, S, Cutner, A. Vaginal mesh in prolapse surgery. Obstet. Gynecol. 2018; 20: 49–56.

33. Cockburn T, Fay M. Consent to Innovative Treatment. Law Innov Technol. 2019 3 Jan; 11(1): 34-54

Paper Four

IV. The Case for Persuasion in Parental Informed Consent to Promote Rational Vaccine Choices

Abstract

There have been calls for mandatory vaccination legislation to be introduced into the United Kingdom in order to tackle the national and international rise of vaccine-preventable disease. Whilst some countries have had some success associated with mandatory vaccination programmes, the Royal College of Paediatrics and Child Health (RCPCH) insist this is not a suitable option for the United Kingdom, a country which has seen historical opposition to vaccine mandates. There is a lack of comprehensive data to demonstrate a direct link between mandatory vaccination legislation and increased uptake. Whilst there are examples whereby there has been an improvement, some studies suggest that comparable results can be obtained by strongly recommending vaccinations instead. The RCPCH insist that Healthcare Workers (HCW) are ideally placed to engage and inform parents to make every interaction a "*vaccine opportunity*". This paper calls for a principled, rational approach to interpretations of autonomy which underpin parental informed consent. MacLean's concept of mutual persuasion could be a vehicle to ensuring parents are suitably informed of both the material risks associated with vaccine choices and to consider the rationality of their decisions, whilst ultimately upholding parental autonomy. It is argued that this, alongside infrastructural improvement, could create a more sustainable, long-term improvement in childhood vaccination rates in the United Kingdom than mandatory vaccination.

Introduction

Whilst Health Secretary Matt Hancock recently called for the "*bold action"* of mandatory vaccination in the United Kingdom [1], there is a lack of comprehensive data to demonstrate a direct link between mandatory vaccination legislation and increased uptake. Although there are examples whereby there has been an improvement, some studies suggest that comparable results can be achieved by strongly recommending vaccinations instead [2][3]. The House of Lords voiced their opposition by stating that *"…mandatory vaccination is not the way forward…*" [4] and instead recommended that healthcare workers [HCW] facilitate improved vaccine uptake through improved communication with parents [4] [5]. This mirrors the stance of the Royal College of Paediatrics and Child Health (RCPCH) in calling

for a "…*coordinated approach…*" so that *"…every contact between a child and healthcare worker ... be a vaccine opportunity…*" [6]. The RCPCH have warned that mandatory legislation fails to address the underlying cause of poor vaccine-uptake, namely poor accessibility, and parental anxieties [4] [7] and would likely back-fire to create "…*determined vaccine-refusers...*". The RCPCH have also warned that whilst "…*compulsion may work for some countries, it's not for us…*" [8].

Healthcare workers [HCW] have an opportunity to engage parents on the issue of vaccination when gaining consent. Informed consent is a fluid, ongoing process and early discussions about vaccination may commence long before appointments are made. In the informed consent process, those with capacity consider information to make an autonomous decision relating to medical intervention. There is no legal requirement for that decision to be rational [9]. Yet principled interpretations of autonomy concede that autonomous decisions *should* also be rational. Whilst irrationality may be acceptable for adult patients willing to bear the consequences of their own decisions [10], in the case of parental decision-making on behalf of a child, it is reasonable to argue that a legal duty should exist to facilitate rationality in parental informed consent. Parental decision-making exists on the premise that the child's best interest takes precedence, yet in the case of vaccinations, parents may struggle to determine those best interests amid the myriad of information and misinformation. As US Judge Mr. Justice Rutledge once said - *"...parents may be free to become martyrs themselves, but it does not follow that they are free ... to make martyrs of their children…*" [11]. This paper considers a new legal standard, incorporating MacLean's model of mutual-persuasion in informed consent, as a way to facilitate rationality in parental decision-making in issues such as vaccination [9]. When combined with infrastructural improvement, this could present a more sustainable alternative to mandatory vaccination whilst upholding parental autonomy [4][12].

The Re-emergence of Vaccine-Preventable Disease

There has been parental suspicion of vaccination ever since Edward Jenner made his contribution to medical science over 220 years ago. In the mid-to-late 1800s, the original "*anti-vaxxers*" - the Anti-Vaccination Leagues - were created to protest against compulsory vaccination provisions held under the Vaccination Acts of 1853 and 1867. Their right to conscientious objection – or exemption - was finally recognized in the subsequent Act of 1898 [13] [14]. Such exemption clauses, which are often still incorporated into vaccine mandates to this day, can threaten to undermine the entire vaccine mandate strategy. Measles illustrates this point particularly well. Falling confidence in the Measles vaccine,

and subsequent reduction in uptake, contributed to a 30% global resurgence in Measles cases in 2018 [15]. In New York State, where the vaccine is mandatory, a community with high levels of exemption was the source of an outbreak in the Spring of that year, which led to the declaration of a State of Emergency [16] [17].

When a population acquires a level of immunisation, whether that be through prior exposure to the pathogen or through immunisation programmes, it reduces the pool of hosts available to the pathogen. This can reduce transmission and indirectly protect unimmunised members of society through what is known as 'herd immunity'. Unimmunised members of society often include vulnerable groups such as; the immunocompromised, or those who cannot be vaccinated due to allergy or on account of their age, such as very young children. Measles is one of the leading causes of global child mortality in the under 5s and can cause severe, long-term and debilitating complications [7]. In some areas of the UK, coverage with the first dose of the Measles Mumps and Rubella (MMR-1) triple vaccine plummeted to as low as 74.3% in 2018-19 [18]. This is of particular concern, as in 2017 when coverage of MMR-1 fell to 86% in Romania, it was soon followed by deadly measles epidemic which bore witness to 50,000 cases and 59 deaths [7][19]. Whilst Measles serves as a strong representation of the consequences of low vaccination coverage, last year uptake across all routine child vaccines fell in the UK [20]. This included reduced rates of immunisation with DTaP/IPV/Hib/HepB, also known as the '6-in-1' vaccine, leaving children exposed to the risk of contracting diphtheria, pertussis, tetanus, polio, hepatitis B and disease caused by Hameophilus Influenzae (Type b) [20].

Parental Rights of Autonomy

For each childhood vaccination to be administered, informed consent must be obtained. Where a child lacks the requisite capacity, such consent must be sought from those with parental responsibility [21][22]. The moral authority for parental responsibility "*…depends …[upon] the entirely reasonable supposition that parents will act in the best interests of their children…"* [23]. The legal authority, arising from the Children act 1989 Part 2(2), upholds such *"...rights, duties, powers, responsibilities and authority..."* [24] which should be used the child's best interests only. These rights are supported by the European Convention of Human Rights (ECHR) through Article 8 which upholds *"...the right to respect for private and family life..."* [25]. As a qualified right this can be limited *"...such as is in accordance with the law and is necessary…for the protection of health…or ..the rights and freedoms of others…"* [26] such as the child, or others in society. The provisions of Article 8 of the European Convention on Human Rights (ECHR) recognise individual

rights of autonomy in medical decision-making, yet crucially interpret autonomy in a manner which must give due consideration to others in society. This reflects a principled, rational interpretation of autonomy which will be addressed later.

The current legal standard for medical consent, established in *Montgomery v Lanarkshire* [2015][27], focuses upon information disclosure with an emphasis upon disclosure of material risks. Whilst undeniably important, such duty is purely informative. There is no corresponding duty to ensure decisions are rational. MacLean argues that in order to *truly* respect autonomy, decision-makers *must* consider the rationality of their decisions [9]. On that basis, MacLean proposes that the decision-making process should include a legal duty placed upon HCWs to persuade patients to make rational decisions, whilst the patient ultimately makes the final decision. This, he says, can ensure patients have both fully understood the material risks and are aware of the rationality of their decision; and that by doing so offers better protection of autonomy.

Autonomy (*'Auto' is Greek for 'self' and 'nomous' is law*) is a principle of self-governance. It is central to decision-making, yet its interpretation is subjective. Liberal views of autonomy, such as presented by Locke, hold that we should be afforded the *"...freedom to order [our] actions…as [we] think fit…without asking leave, or depending on the Will of any other Man…"* [28]. This uninhibited right to freedom considers only self-interests in decision-making [29], describing the patient's right to pursue their own ends without medical interference, or question, even if it seems irrational. Liberal parents will hold their freedom of thought in highest regard, often considering their parental instinct to be superior to medical knowledge [29]. Yet such reasoning is fundamentally flawed as it fails to consider the impact one's decision may have upon others. We do not exist in isolation, just as disease does not exist in isolation. Stirrat *et al.* argue that liberalism fails to recognise bonds of society and community [30], whilst Mill's example of a dangerous bridge further illustrates that we are duty-bound by humanity to at least challenge irrational decisions. He states *"…it would be a great misunderstanding of this doctrine to suppose [that we] should not concern [ourselves with].. the well-doing or well-being of one another…"* [31] . Ultimately a liberal parent's decision not to vaccinate their child also does not exist in isolation as it could eventually impact upon the health of another parent's immunocompromised child [29] [32]. Under European Law, such liberal constructs of autonomy are also rejected. Parental rights and those of medical autonomy held under ECHR Article 8 may be limited where they interfere with the rights of others [26].

Even Kant's classical liberalism, which upholds that one is autonomous when their actions are free from external influence, has a caveat to recognise that individuals are inextricably bound into the fabric of greater society. Kant's test of rationality, the categorical imperative [33], requires one to "*...act only according to that maxim by which you can at the same time will that it should become a universal law…*" [34]. This requires the individual decision to be one which could be intended to be applicable to all, so that we hold ourselves to the same standards as others. If we therefore accept autonomy as a principled, relational concept which gives consideration to society, then, as argued by Maclean it *"…seems reasonable that the decision-maker should depend on others for support and assistance...[p]rovided the responsibility remains with the patient…*" [9]. This would enable autonomous parents to seek support from HCWs in their decision-making. On that basis, it would also be reasonable to assume that HCWs could support *rational* autonomous parental decision-making by offering advice which gives consideration to the universal law. On the issue of vaccination, HCWs should be able to offer information relating to wider societal impacts of decisions and in doing so promote rationality. On this basis, informed consent, therefore, should be more educationally intensive for all involved. For example, in applying Kant's maxim; if one parent refused child vaccination, then in applying the test of universal law, all parents could refuse vaccinations. As a result, diseases could re-emerge in an era of ever-growing drug resistance, which could put the whole of society at risk.

Maclean goes further to argue that if we are to truly support a principled, rational construct of autonomy, HCWs should be under a *legal* duty to go further and *persuade* patients, or in this case the parent, on how best to meet a child's best interests. Persuasion can refer to influences upon decision making which *"…appeal to...self-interest ..[or a]…sense of social obligation...or both…"* which can lead to the achievement of a *"…collectively valued goal…*" [35]. Such a collectively valued goal would be the health of all children in our society

Importantly, Anderson *et al.*, recognize that there is a spectrum of treatment pressures from persuasion to coercion, and the fine line must be recognized in practice [40]. However, at an individual *and* public health level, persuasion may be more acceptable, as it recognizes individual autonomy and concerns whilst putting the case forward for the overall benefits of a course of action [40]. Furthermore, such supportive persuasion would not amount to external influence as the parent would retain ultimate responsibility and could, according to MacLean similarly engage in persuading the HCW [9]. Persuasion should be a 'two-way street', whereby the patient, in demonstrating understanding and rationality could also

persuade the HCW to consider their perspective. This somewhat reflects the court's approach in cases of parental dispute over vaccination whereby the courts have welcomed the chance to be persuaded by the dissenting parent [41].

Information Disclosure in Informed Consent to Facilitate Best Interests Decisions

The common law standard pertaining to consent focuses upon whether a doctor adequately informs the patient [27]. Maclean argues that as a result, the doctor's duty is to simply bestow information without influencing by way of professional opinion and so the patient is left "*...to their fate…*" [9]. He argues that it is unrealistic to expect information to be relayed in a way that does not hold some bias; the order of words, the tone of voice and the doctor's own research influences and experiences are all likely to combine to influence how the patient receives and therefore process that information. In *Mills v Oxford University Hospitals NHS Trust* [2019] Steyn J accepted that *"…there should be a dialogue between the doctor and the patient, and it is important the advice should be comprehensible…"* [42]. One could, therefore, argue that to ensure a patient has understood the information provided requires a dialogue – one which goes beyond simple disclosure. This amounts to a duty to ensure the patient has awareness of risk [43]. In accepting the proposition that material risks are subjective to each patient an open dialogue is key to determining which risks are material. Such a dialogue should be subject to persuasion from either party.

When confronted with negative information, it is an evolutionary instinct to focus upon risk, rather than benefits [44]. This is where dialogue and HCW communication skills are vital. Research has shown that parents do not feel they have enough time to fully discuss their vaccine concerns [45] and even pro-vaccine parents do not feel they received sufficient information and often question their choices [46]. Those for whom dialogues with HCWs are insufficient are more likely to seek their own information, usually from internet sources or other parents [46]. NHS England chief recently condemned the school gates as the "*…breeding grounds…"* for "*…vaccine myth…s*" [47]. This is the kind of '*willful disinformation*' [47] which should be addressed directly through informed consent dialogues by recognising parental concerns and providing evidence-based information. For those parents who are complacent [48] engaging in early discussions could be an opportunity for engagement.

MPs have discussed the need for *"…better training of health professionals on what vaccines are, what they do, how they work and what is in them so that those professionals are ably*

equipped to answer parents' questions…" [49]. These recommendations reflect the need for improved information disclosure and trust to reach the Montgomery standard, and beyond. In the case of vaccination, it is reasonable to conclude that upon a test of materiality - namely that a reasonable person in that parent's position would attach significance to that risk – that the HCW should inform the parent as to the risk of side effects and the risk that non-vaccination poses in terms of disease and its associated complications. Whilst, in reflecting a rationalized approach to autonomy, the parent would be informed of the wider risk of disease in the community, such as that concerning immunocompromised groups, the loss of herd immunity and the consequential rise of disease re-emergence which could be resistant to treatments. By providing such information the parent should consider the impact individual vaccine choices have upon others, which may then induce – not coerce – not only better determination of their child's best interests, but a sense of civic duty amongst parents to have their children vaccinated. Whilst the law recognises that decision making should be free from coercion, Anderson *et al*. (2016) consider that persuasion is a more socially acceptable construct which assists the patient in determining the best course of action to meet their best interests, whilst retaining the right to decide [40]. This could greatly assist parents in determining their child's best interests as vaccine hesitancy often arises from an uncertainty over the best course of action in order to best serve those best interests of the child.

Working Together to Determine Best Interests

The GMC advises that "…*[d]octors should always act in the best interests of children and young people…*[therefore] *assessment of best interests will include…the views of the child...so far as they can express them,* [and]*…the views of parents…"* [50]. This indicates that the GMC hold that the determination of the child's best interests may be determined by parental opinions, which requires active dialogue and a degree of persuasion from the parents. Yet, as research has shown many parents remain uncertain over whether they hold the correct views in relation to vaccination. This further raises the issue of whether there should be an additional legal duty placed upon doctors to persuade parents as to why vaccination is in the child's best interests. The State and those employed by it, are duty-bound to uphold the child's right to the *"…enjoyment of the highest attainable standard of health…"* which includes the duty to "…*combat disease…"* and *"...develop preventive health care…*" according to Article 24 of the United Nations Convention on the Rights of the Child (UNCRC) [51]. In practice, such a legal duty of persuasion would reflect current GMC guidance that consent is a "…*process of discussion and decision-making..."* [36] rather than the end result of information disclosure alone, which MacLean argues can

"…*abandon ..[patients].. to their choices…*" [9]. Enhanced engagement with parents, during the consent process, can facilitate greater understanding of parents' values and beliefs. This will allow HCWs to better support treatment choices and may help avoid the pitfall of defensive medicine by enhancing, rather than eroding, the practitioner-patient relationship. At law, there is no obligation for patients to explain irrational treatment choices [10] yet it may arguably be justifiable for such a new legal duty to require engagement with parents on irrational choices which may affect a child's health. Where parents adamantly refuse to engage, MacLean suggests that the legal duty upon HCWs to support decision-making in this way, would then be discharged [9]. Whilst determined parental refusal may be a potential barrier to this approach, recent statistics suggest that the percentage of parents refusing vaccines fell from 11% in 2015 to 8% in 2019, which could indicate an openness to persuasion within that demographic [37].

As parents may hold concerns relating to vaccinations, so too may HCWs. This may affect their ability to meet the legal standard of persuasion. However, existing GMC guidance advises HCWs not to burden vulnerable patients with personal beliefs. One option may be to utilize existing guidance for professional conscientious objection. This would enable HCWs to refer patients on to alternative, more suitable, practitioners when they feel unable to provide such treatment or evidence-based information [38]. In practice, the legal duty of persuasion would expand upon the current standards of disclosure in informed consent and time spent engaging with parents viewed as an investment in both the future health of the child and wider public health. Such discussions will require HCWs to have more specialist knowledge of vaccines, their safety and ongoing post-marketing surveillance. In recognizing that *a "...high level of knowledge and a positive attitude to immunization in [HCWs] are …important determinants in achieving and maintaining high vaccine update…".* Public Health England (PHE) have already developed a Core Curriculum for Immunisation Training which ensures *"…immunisers are confident, knowledgeable and up-to-date…"* through a process of continuing professional development, evidence-based practice and revalidation [39].

Where the domestic courts have taken the role of judicial parent on the issue of vaccination, the priority has been to fulfil the child's *welfare* interests [41]. The courts have been clear they are not there to make judgement as to whether *vaccination* is a good or bad concept [41]. However, through careful examination of expert witness testimony [52] and evidence-based information [53], the judiciary support the *normative* medical opinion that vaccination best fulfils the child's welfare needs by preventing disease. In *Re C and F(Children)*[2003],

Sumner J emphasised that *"…over 20 million doses of MMR have been delivered in the United States alone...if there were any real problems they would have emerged…*" [52]. The current precedent, therefore, illustrates that by allowing the child to enjoy the highest attainable level of health, vaccination meets the best interests of the child [54]. As judicial parent, the court has access to expert testimony and evidence-based information which many parents do not. By incorporating a legal duty of persuasion into parental decision-making, parents are likely to be better informed and educated about vaccine safety and efficacy so that they too can make decisions which meets their child's best-interests.

The European countries which have, thus far, implemented mandatory vaccination have witnessed associated rises in coverage rates. France, which has one of the highest levels of mistrust in vaccines, witnessed a rise in non-mandatory vaccination uptake following mandatory vaccination legislation [55]. Whilst it can be difficult to disentangle the effects of mandatory vaccination from the accompanying persuasive information campaigns, Lévy-Bruhl *et al*. (2018) suggest success may stem, not from the mandate itself, but from better informing parents [55]. This could further support the premise that better communication with parents could yield the desired results without the need for mandatory vaccine legislation. A policy of mandatory vaccination may not offer up the same educational opportunities that informed consent does and could miss the chance for engagement with parents on these key issues.

Infrastructure to support Vaccine Uptake

Whilst vaccination is voluntary, the aforementioned strategies rely upon engagement opportunities with parents which will depend upon improved infrastructure. The RCPHC recommends improvements be made to appointment and reminder systems alongside the implementation of adequate numbers of well-trained staff to discuss vaccinations with parents [56]. The necessity for these recommendations were also emphasized in a survey from the Royal Society for Public Health (RSPH) which recognised appointment issues as some of the biggest barriers to vaccination [57]. Current NHS IT systems are not robust enough to manage records and prompt reminders for the complex array of vaccines which make up the UK vaccination schedule [4][5]. For families with multiple children this current system represents a logistical barrier to vaccination which is further perpetuated by difficulty in aligning appointments with time off work and school. Whilst a system of mandatory vaccination could potentially see unvaccinated children excluded from school, the House of Lords argue that instead, schools should represent a positive opportunity to trigger vaccine reminders and catch children who might otherwise fall through the net [4].

As part of the NHS's *"…wider commitment to digitally transform…"* communication with patients, social media can be used to *"empower the public to take charge of their own health and care*" [58]. This could positively engage parents in order to address vaccine hesitancy. A recent NHS Digital scheme successfully addressed breast screening hesitancy in a community through a Facebook group. HCWs used the group to prompt reminders, offer advice on accessing services and to provide "*quality information*" to alleviate anxieties. The scheme resulted in a 12.9% increase in screening [59]. The importance of engaging parents early was highlighted by Enkel et al (2018) who argue that *"…clear, accurate and concise information backed by quality evidence, must be provided to parents, ideally as early as pregnancy…"* [44]. Frequent visits to HCWs during antenatal and post-natal periods present early opportunities for vaccine discussion [60].

The Department for Health and Social Care (DHSC) and PHE, tasked with developing a specific strategy to tackle falling MMR coverage, may consider "…*other settings outside of the GP for vaccinations…*" [61]. A study by Anderson et al (2014) also showed that patients want more convenient access to vaccine services and prefer to visit community-based pharmacies than GP practices [62]. NHS Community Pharmacist Consultation Service aims to create *"…same-day, booked private consultations…*" with pharmacists which could provide convenient and effective access to information and vaccination, saving around 20 million annual GP appointments per year [63] [64]. Further access could be improved through the creation of specialized consent clinics [65] or utilization of previously successful mobile screening units [66].

Conclusion

Falling vaccination rates must be addressed if we are to avoid a harmful re-emergence of devastating childhood diseases. Mandatory vaccination legislation is not a sustainable solution as it is likely to be undermined by parental mistrust and exemption. Healthcare Workers are key in the frontline battle of improving vaccine confidence amongst parents through informed consent. Yet we must consider whether a parental decision-making ought to be rational. Liberalist constructs of autonomy have falsely led to the belief that decision-making should be self-serving, whilst principled autonomy requires rational decision-making, with consideration of others. The law of informed consent should too reflect a more principled construct of autonomy by including a legal duty to facilitate rationality by persuading patients to make rational decisions. Such a duty would expand upon the existing legal duty of information disclosure in informed consent by ensuring consent is a process of

dialogue with parents, rather than the end result of information sharing. For parents, whose upmost consideration must be the best interests of their child, such persuasion would facilitate rational decision-making whilst upholding parental autonomy. Statistics suggest that the demographic of parental refusers may be falling, however, mandatory vaccination has the potential to damage parental trust and create more determined vaccine refusers. Conversely, persuasion is likely to enhance the practitioner-parent relationship, build confidence and is also likely invoke a sense of civic duty in favour of vaccination to create sustainable improvements. Supported by recommended infrastructural changes, HCWs could draw upon existing training opportunities and guidance to develop the skills and knowledge necessary to meet this new legal standard.

References

1 Walker, P ‘Hancock: Compulsory vaccinations beings seriously considered’ 29 Sept 2019. The Guardian. Accessed at https://www.theguardian.com/society/2019/sep/29/government-seriously-considering-compulsory-vaccinations-matt-hancock on 22 Dec 2019

2 Lee C, Robinson JL. 'Systematic review of the effect of immunization mandates on uptake of routine childhood immunizations. J Infect. 2016; 72, 659-666

3 Giard DZ. "Recommended or mandatory pertussis vaccination policy in developed countries: Does the choice matter? Public Health 2012; 126(2):117-22

4 HL Deb | 14 May 2019 | vol 797 | col 70CG

5 HC Deb | 12 June 2019 | vol 661 | col 354WH

6 Royal College of Paediatrics and Child Health: RCPCH Responds to Prime Minister’s Announcement on Immunisation, 19 August 2019. Accessed at https://www.rcpch.ac.uk/news-events/news/rcpch-responds-prime-ministers-announcement-immunisation-uptake on 9 November 2019

7 Dascalu S. Measles Epidemics in Romania: Lessons for Public Health and Future Policy; Front. Public Health (2019)

8 Royal College of Paediatrics and Child Health: Vaccinations important and highly effective, says child health experts, 27 March 2019 accessed at https://www.rcpch.ac.uk/news-events/news/vaccinations-important-highly-effective-says-child-health-expert on 9 November 2019

9 MacLean A. Autonomy, Consent and Persuasion. European Journal of Health Law 2006; 13:321-338

10 *Re T (Adult: Refusal of Treatment)* [1993] Fam 95 at [102], [1992] 3 WLR 782, 786.

11 *Prince v Massachusetts* [1944] 321 US 150 at [170]

12 MacDonald NE, Harmon S, Dube E, Steenbeek A, Crowcroft N, Douglas JO, Faour D, Leask J, Butler R. Mandatory infant & Childhooh immunization: Rationales, issues and knowledge gaps; Vaccine 2018; 36(39):5811-5818 https://doi.org/10.1016/j.vaccine.2018.08.042

13 Williamson S. 'One hundred years ago: Anti-vaccination leagues' Arch Dis Child 1984; 59; 1195-1196

14 Vaccination Acts of 1853, 1867, 1898

15 World Health Organisation Newsroom: Detail 'Measles cases spike globally due to gaps in vaccination coverage 29 November 2018 at https://www.who.int/news-room/detail/29-11-2018-measles-cases-spike-globally-due-to-gaps-in-vaccination-coverage Accessed on 22 Dec 2019

16 Hopkins Tanne, J. 'New York City Mayor declares measles public health emergency' BMJ 2019; 365 :l1724

17 Clarke S, Giubili A, Walker M J. Conscientious Objection to Vaccination. Bioethics 2017;31(3): 155-161

18 NHS Digital Childhood Vaccination Coverage Statistics - Hackney and City of London, MMR I at 24 months update was 74.3%. Accessed at NHS Digital Child Vaccination Coverage Statistics Interactive Resource available at https://app.powerbi.com/view?r=eyJrIjoiZTI3NWZhNzItMTIyZS00OWM2LTg0MzMtOGY5YTJjMGY0MjI1IiwidCI6IjUwZjYwNzFmLWJiZmUtNDAxYS04ODAzLTY3Mzc0OGU2MjllMiIsImMiOjh9 on 23 December 2019

19 Romanian National Centre for the Surveillance and Control of Communicable Diseases (CNSCBT) Weekly Report on Measles, Dec 21 2018 in Dascalu S. Measles Epidemics in Romania: Lessons for Public Health and Future Policy; Front. Public Health (2019)

20 NHS Digital Childhood Vaccination Coverage Statistics - England 2018-19. 26 Sept 2019 accessed at https://digital.nhs.uk/data-and-information/publications/statistical/nhs-immunisation-statistics/england-2018-19

21 Family Law Reform Act 1969

22 European Convention on Human Rights and Biomedicine 1997, Article 6(2)

23 British Medical Association Ethics Department: Parental Responsibility. Guidance from the BMA, October 2008 - states that "the moral authority behind parental responsibility depends in large part on the entirely reasonable supposition that parents will act in the best interests of their children".

24 Children Act 1989

25 European Convention on Human Rights, Article 8 (1) 'The Right to Private and Family Life'

26 European Convention on Human Rights, Article 8 (2) 'The Right to Private and Family Life'

27 *Montgomery v Lanarkshire* [2015] UKSC 11

28 Locke, 1960 [1689]: 287

29 Reich, J A. Neoliberal mothering and vaccination refusal: Imagined gated communities and the privilege of choice. Gender & Society. 2014, *28*(5), 679–704

30 Stirrat G M, R Gill. Autonomy in Medical Ethics after O'Neill. J Med Ethics 2005;31:127–130. doi: 10.1136/jme.2004.008292

31 Mill J S. 'On Liberty' (1859) in 'On Liberty and other Essays' (1998) Oxford University Press, Oxford, 84

32 Ikonomidis S, Singer P A. Autonomy, Liberalism and Advance Care Planning. J Med Ethics. 1999;25: 522-527

33 O'Neill O. Autonomy and Trust in Bioethics. Cambridge. Cambridge University Press, 2002, 30, 83–5.

34 Kant I. (1785) Grounding for the Metaphysics of Morals. In Ellington J W. (1981) 'On a Supposed Right to Lie Because of Philanthropic Concern' (3rd Ed) Indianapolis, Indiana, Hackett Publishing Company

35 Bell S, Hindmoor A, Mols F. Persuasion as Governance: A State-centric Relational Perspective. *Public Administration* 2010;88(3):851-870

36 General Medical Council (2008) '*Consent: patients and doctors making decisions together'*. Accessed at https://www.gmc-uk.org/static/documents/content/Consent_-_English_0617.pdf on 13 April 2020

37 National Audit Office 2019. *Investigation into pre-school vaccinations*. (HC 100, 2019-20), London: NAO External Relations

38 General Medical Council, 'Personal Beliefs and Medical Practice'. Accessed at "https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/personal-beliefs-and-medical-practice/personal-beliefs-and-medical-practice"on 13 April 2020

39 Public Health England, 'National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners' Revised February 2018 Accessed at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/679824/Training_standards_and_core_curriculum_immunisation.pdf on 13 April 2020

40 Anderson L. From Persuasion to Coersion: Responding to the Reluctant Patient in Rehabilitation. Phys Ther 2016; 96(8):1234-40

41 *Re B(A Child: Immunisation)[*2018] whereby Belamy LJ asserted that if the objecting parent was to provide evidence of an equivalent quality, which demonstrated that vaccines were *not* to be in the child's best interests, that would be considered.

42 *Mills v Oxford University Hospitals NHS Trust* [2019] WL 01574774 2019 at [202] in considering Montgomery at [90]

43 Hendrix K S, Strum L A, Gregory D Z, Meslin E M. Ethics and Childhood Vaccination Policy in the United States. Am J Public Health 2016;106(2):273-278

44 Enkel S L, Attwell K, Snelling T L, Christian H E. Hesitant compliers': Qualitative analysis of concerned fully-vaccinating parents. Vaccine 2018;36(44)

45 McKee C. Exploring the Reasons Behind Parental Refusal of Vaccines. J Pediatr Pharmacol Ther. 2016; 21(2):104-109

46 Downs J S, de Bruine W B, Fischoff B. Parents' Vaccination Comprehension and Decisions. Vaccine 2008;26:1595-1607

47 Gayle D 'School Gates Breeding Grounds for Vaccine Myths, Skas NHS Chief' The Guardian, 12 October 2019

48 Hornez Z, Powell D, Hummel J E, Holyoak K J. Countering Antivaccination Attitudes. Proc Natt Ac Sci USA 2015;112(33) 10321-10324

49 HC Deb |12 June 2019 | Col 342

50 GMC: 0-18 years: Guidance for all Doctors: Assessing Best Interests accessed at https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/0-18-years/assessing-best-interests

51 United Nations Convention on the Rights of the Child, Article 24 s.s 1, 2c, 2f

52 *Re C and F(Children)* [2003] EWHC 1376 (Fam) as per Sumner J at [194] *"…over 20 million doses of MMR have been delivered in the United States alone..if there were any real problems they would have emerged"*

53 *Re B (A Child)* [2003] EWCA Civ 1148 as per Thorpe LJ at [20]

54 London Borough of Barrett v SL [2017] EWHC 125 (Fam)

55 Lévy-Bruhl D, Fonteneau L, Vaux S, Barret A, Antona D, Bonmarin I, et al. Assessment of the impact of the extension of vaccination mandates on vaccine coverage after 1 year, France, 2019. Euro Surveill. 2019;24(26):1900301

56 Royal College of Paediatrics and Child Health: Response to Research on Compulsory Vaccination. 17 May 2019

57 Royal Society for Public Health Report: 'Moving the Needle, Promoting Vaccination Uptake Across the Life Course' January 2019. Accessed at https://www.rsph.org.uk/uploads/assets/uploaded/3b82db00-a7ef-494c-85451e78ce18a779.pdf on 23 Dec 2019.

58 NHS Digital Press Release. 'More women attend for Breast screening thanks to success of digital inclusion project.' 30 October 2018. Accessed at https://digital.nhs.uk/news-and-events/latest-news/more-women-attend-for-breast-screening-thanks-to-success-of-digital-inclusion-project On 12 November 2019

59 Information Services Division Scotland (ISD Scotland): Scottish Breast Screening Programme Accessed at http://www.isdscotland.org/Health-Topics/Cancer/Breast-Screening/ on 12 November 2019

60 NHS England. The Atlas of Shared Learning Case Study: Improving Vaccination Uptake by Changing the Way Pregnant Women Were Offered and Accessed Services, 18 July 2018. Accessed at https://www.england.nhs.uk/atlas_case_study/improving-vaccination-uptake-by-changing-the-way-pregnant-women-were-offered-and-accessed-services/ on 9 November 2019

61 Wickware C. News & Analysis: NHS England to look at childhood vaccinations in healthcare settings other than general practice' The Pharmaceutical Journal online, 19 Aug 2019. | DOI: 10.1211/PJ.2019.20206968 Accessed at https://www.pharmaceutical-journal.com/news-and-analysis/news/nhs-england-to-look-at-offering-childhood-vaccinations-in-healthcare-settings-other-than-general-practice/20206968.article

62 Anderson C, Thornley T. "It's easier in pharmacy": Why some patients prefer to pay for flu jabs rather than use the National Health Service. BMC Health Services Research 2014;14: 35

63 NHS England and NHS Improvement North East and Yorkshire: News: Community Pharmacy Pilot to Increase access to General Practice (24 July 2019). Accessed at https://www.england.nhs.uk/north-east-yorkshire/2019/07/24/community-pharmacy-pilot-to-increase-access-to-general-practice/ on 23 Dec 2019

64 Wickware C. Flu Vaccine Uptake Lower than 2017 for GPs while vaccination Numbers Surge for Pharmacists, *The Pharmaceutical Journal* 2019 DOI: 10.1211/PJ.2018.20205885 https://www.pharmaceutical-journal.com/news-and-analysis/news/flu-vaccine-uptake-lower-than-2017-for-gps-while-vaccination-numbers-surge-for-pharmacists/20205885.article Accessed on 9 November 2019

65 NHS Wales. Good Practice in Consent Implementation Guide: Consent to Examination or Treatment: Seeking Consent for Anaesthesia (7). (2002) accessed at http://www.wales.nhs.uk/publications/impguide-e.pdf on 9 November 2019

66 Greenwald Z R, El-Zein M, Bouten S, Ensha H, Vazquez Franco E L. Mobile Screening Unit for the Early Detection of Cancer: A Systematic Review. Cancer Epidomiol Biomarkers Prev 2017;26(12):1679-1694 DOI: 10.1158/1055-9965.EPI-17-0454.