While this book certainly provides a valuable practical resource for those seeking to get to grips with the practical implications of medico-legal case law, would benefit from greater recognition that the socio-cultural context within which obstetric and gynaecological healthcare is delivered has a very real impact on clinical care. Improving clinical practice, and therefore reducing litigation necessarily, involves more than just ensuring that healthcare practitioners have the relevant technical competencies and that they know what the law says. Meaningful and sustainable improvement also requires an understanding of potentially harmful attitudes and assumptions which continue to pervade both society and medical practice—and a commitment to actively tackle these. The conspicuous absence of such considerations in this book serves to illustrate the value of engaging with socio-legal perspectives when writing about medical law, even when writing with a very practical focus.

CONCLUSION

This book offers a valuable resource for healthcare professionals looking to understand, and learn from, clinical negligence case law. In its goal of making (often complex) areas of the law accessible to non-legal professionals, this book unquestionably succeeds. It provides clear insights into how the law on negligence operates in the context of obstetrics and gynaecology, and practical suggestions on how clinical practice can be improved to avoid future litigation. However, in its attempt to facilitate broader improvements in clinical practice it would benefit from greater engagement with the socio-cultural realities against which obstetric and gynaecological healthcare are delivered—as this has an inevitable impact on the way that healthcare is experienced.

Anna Nelson
University of Manchester, UK

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Carolyn Adams, Judy Allen, and Felicity Flack, *Sharing Linked Data for Health Research: Toward Better Decision Making*, Cambridge University Press, 2022, Hardback, 300 pp, £85, ISBN 9781108426640.

Every health lawyer is aware of the importance of using data to better understand health and drive medical and scientific innovation. Fewer may be aware, however, of the importance of *linking* various sets of data to each other—in other words, bringing together sets of data from various sources relating to the same individual or event into a single file—as a primary means of accomplishing better understanding of health and driving innovation. These sources may comprise not only health data (eg cancer registries, births and deaths registries, immunisation registries, midwifery summary reports), but also other personal information gleaned from education, justice, housing, and social welfare data sets. Even fewer still, I reckon, may be aware that more often than not, the most valuable data collections are held by governments, and may contain individual-level data on whole populations. These collections are often termed government administrative data. Bland term aside, they offer incredible value for research.

As Carolyn Adams, Judy Allen, and Felicity Flack demonstrate in this new superb new addition to Cambridge University Press's *Cambridge Bioethics and Law* series, access to and use of population-level linked data provide evidence-based findings that can guide and improve

decision-making across governments and foster health prevention and improvement. One close-to-home example they cite is the finding from Kavanagh and others in Scotland that human papillomavirus (HPV) vaccination leads to a massive reduction in HPV infections in girls vaccinated at the age of twelve to thirteen years, in turn likely leading to a huge reduction (upwards of 90%) in cervical cancer.[1] As Adams and others opine, 'linking data from different sources is the future of population health research',[2] although one can say it is very much at the forefront of present-day population health research, too, albeit with a number of challenges, which I will proceed to discuss below.

Adams and others note that government administrative data within these registries are sensitive and must be used in ways that respect and protect the values, interests, and rights of individuals and their communities. This is particularly pertinent given that these data are often accessed and used without the explicit consent of individuals. How access to and use of data for linkage can be done well is a matter of good decision-making by key sets of actors, namely researchers, data custodians, data privacy committees, and ethics committees. Adams and others' book, which is set out in eight chapters divided into three parts, delineates the theoretical and practical issues at play regarding the decision-making processes for granting access to data and enabling linkage of different data sets; they also, more valuably, set out a number of practical suggestions for reform to improve those decision-making processes. Their motivation for undertaking the book project was to determine whether it was possible '. . .to achieve these great benefits [of using government administrative data for research] while minimising the risks? What were the roadblocks, and could we help to clear the way?'[3] In what follows, I highlight what I consider to be the particularly significant contributions their book makes to the field of health research and medical law more broadly.

First, Adams and others come at this project from an on-the-ground experience and expertise of working with key actors in managing access to government administrative data for research. This means not only having significant knowledge of what data linkage is and the various approaches used to address privacy risks, but it also means explicating with rigour the relevant legal and ethical issues at play, and demonstrating a thorough understanding of the tremendous potential data research has for public health and well-being. This enables Adams and others to display in Chapter 1 a keen awareness of the *problems* associated with data linkage for health research. These include concerns from researchers of unjustified delays in getting access to data for research that is in the public interest; concerns from data custodians about difficulty in navigating the complex array of law, regulation, and policy regarding disclosures of identifiable data; concerns from ethics committees about the complexity in assessing the ethical issues associated with data linkage projects; and concerns from community groups about privacy, transparency, and public engagement.[4] This experience and expertise enable the authors to identify the various individual, collective, and public interests at play in data linkage and the challenge of accounting for all these interests (Chapter 2), and to develop practical *solutions* to these problems faced by key stakeholders and to focus the book on improved *decision-making itself*. After all, as the authors note:

[1] Kimberley Kavanagh and others, 'Changes in the Prevalence of Human Papillomavirus Following a National Bivalent Human Papillomavirus Vaccination Programme in Scotland: A 7-Year Cross-Sectional Study' (2017) 17 The Lancet Infectious Diseases 1293.

[2] Carolyn Adams, Judy Allen, and Felicity Flack, *Sharing Linked Data for Health Research: Toward Better Decision Making* (CUP 2022) 3.

[3] ibid 1.

[4] Adams and others also note wider problems with data linkage, including data quality and standards; the large number of governments, agencies, and private sector organisations involved; differences in legal and privacy regimes; and lack of public trust in data linkage beyond national borders.

> Access to government administrative data for research is based on a series of decisions by data custodians, ethics committees, and others that seek to balance the risks and benefits associated with the use of this data for research. These decisions operate as keys that unlock access for researchers to a well-guarded and extremely valuable community resource. It is critical that each key works well and is fit for purpose.[5]

Recent developments, including the emergence of Big Data and advances in information technology and data science mean that '[i]f linked data is to continue to be used for health and medical research without consent, the terms and conditions under which this occurs needs renegotiation.'[6] This argument is unpacked over the ensuing chapters and brings me to the second significant contribution worth highlighting.

Adams and others focus their analysis on three common law countries with advanced data linkage programmes: Australia (specifically Western Australia), Canada (specifically Manitoba), and the UK (specifically Scotland). This not only allows them to draw out with great specificity the data linkage programmes that run in these countries. It also enables them to analyse how well existing laws, regulations, and policies address data access decision-making within a framework of good decision-making, in turn enabling them to identify what Professor Fiona Stanley AC in her Foreword calls 'essential ingredients'[7] for good decision-making by governments in using and linking data for health research. This is first illustrated in their chapter on the legal bases on which linked data are used and disclosed in the three jurisdictions under consideration (Chapter 6) and then in Chapter 7, which analyses existing practice and processes in these jurisdictions. I was impressed with Adams and others' meticulous analysis of constitutional law; the common law duty of confidentiality; the misuse of private information tort; as well as data protection law. Their general argument is that, from a legal perspective, the use of data for research is 'unjustifiably restricted by complex, overlapping, and poorly designed regulation',[8] not to mention a proliferation of a bewildering number of statutes authorising and regulating the use and sharing of data for research. Their sub-argument, however, that the linkage and use of data for research ultimately should be regulated by statute alone and the operation of the common law excluded entirely[9] is understandable yet seems to me a bold, provocative (if not idealistic) proposal that requires much fuller consideration of the consequences, both intended and incidental, and the limitations in turn this may create for the stakeholders involved. The common law, in my view, should continue to play an important gap-filling role where statutory authority is absent *and* where statutory authority necessitates interpretation in changing social contexts—which almost invariably will be the case. Sometimes too much legal certainty, and reliance on statutory rules for answers, creates its own risks and impediments.

This small criticism aside, the jurisdictional analysis is excellent. Focusing on the Scottish context as an example, over several pages,[10] Adams and others present a precise analysis of how decisions about linking data for research would be made in a hypothetical research study (involving evaluation of vaccine compliance before and after the introduction of new mandatory childhood vaccination legislation), noting the importance of the Public Benefit and

[5] Adams and others (n 2) 3.
[6] ibid 27.
[7] ibid xiv.
[8] ibid 133. There is no space here for me to engage with all of the arguments raised in the ch 6 ('Law'), but I would echo the criticisms they raise regarding data protection law's weaknesses, including the outdated notice and consent model, regulatory complexity, and the false binary between identifiable and 'de-identified' personal data and the failure to protect 'de-identified' data. I endorse their call for a new approach in which data protection legislation extends protection to *all* individual-level level.
[9] ibid 171.
[10] ibid 189–97.

Privacy Panel for Health and Social Care (PBPP),[11] which acts as a centralised governance and partial-ethics review body[12] for access to national health data in Scotland, and which adopts a proportionate approach to its review. One comes away thoroughly impressed by the authors knowledge of the relevant decision-makers; law, policies, and guidelines governing the release of data for linkage and research without consent; and the operation of ethics review (ie is ethics review required and what guidelines are considered?). One also comes away agreeing with their view that classic paradigms operating in this field, such as the 'consent or anonymise' paradigm (viz obtain consent from individuals to use their data for secondary uses such as data linkage or sufficiently anonymise data such that they are no longer reasonably re-identifiable and consequently privacy risks are eliminated), is simply no longer fit for purpose with respect to using linked data for research. This is because (i) consent is 'no longer effective in protecting autonomy and choice about risks and preferences' and reliance on consent 'as the moral justification for using linked data is misplaced' and 'is no longer able to bear the moral weight it is given',[13] and (ii) anonymisation is hardly infallible, with re-identification easier than previously assumed, de-identification potentially adversely impacting the utility of data, and potential harms arising to individuals that are unrelated to re-identification.

A third and final significant contribution worth highlighting is that Adams and others set their jurisdictional analysis and good (or better) decision-making framework within three core regulatory frameworks for making decisions about whether linked data can be used for research: human rights, research ethics, and law. Spread across Part II of their book (Chapters 4–6), Adams and others advance several significant arguments here. Most broadly, they argue that 'the existing legal and research ethics frameworks—developed originally in relation to research involving direct contact with participants—do not adequately reflect the range of rights and interests at play in the context of research using linked data'.[14] They make the case for why an overly individualistic paradigm in law and research ethics frameworks is problematic in the context of research using linked data, and that there are often-overlooked collective interests of groups recognised or created by linked data research. For example, in Chapter 5,[15] they are critical of the international guidelines on genomic and genetic data that seem to rely on individual consent and do not permit much, if any, scope for waivers of consent—which as mentioned above, are crucial in research using linked data. They are also critical of the lack of guidance and inconsistency on consideration of collective interests in research using linked data, and how collective interests should be balanced with protection of individual interests. Yet rather than dismissing and replacing the core ethical values common to existing ethics guidelines, being research merit and integrity; justice; beneficence; and respect, instead, Adams and others propose that these can be re-envisaged and made fit for purpose. In the chapter, they suggest that greater recognition of the differences between interventional and observational research can help make core ethical values more applicable to data-intensive research and offer astute suggestions for how these could be applied to research using linked data (eg research without consent can be ethical in

[11] Public Benefit and Privacy Panel for Health and Social Care <https://www.informationgovernance.scot.nhs.uk/pbpphsc/> accessed 6 January 2023.
[12] The PBPP focuses its review on privacy and public benefit-related matters.
[13] Adams and others (n 2) 38. This does beg the question as to what is meant by 'no longer'. The recentness of linked data research is not so fully fleshed out as to make a persuasive case for why consent is 'no longer' effective in protecting autonomy and choice about risks and preferences and 'no longer' serves (and yet once did) as bearing the moral weight it is given.
[14] ibid 28–9.
[15] 'Research Ethics'.

certain circumstances; value of respect should be broadened to include respect for rights, interests, and values of the relevant individuals and groups).[16]

Specifically in relation to their case for more nuanced recognition of rights, interests, and values, and as one example, Adams and others argue in Chapter 4 that human rights are relevant to research using linked data without consent, and that these rights might conflict or otherwise come into tension with each other and other relevant interests. As they note, 'Taking a rights-based approach to using government-held data for research is necessary to ensure that law, policy, and practice in this area do not infringe human rights and that progress continues to serve human needs and interests.'[17] Notably, Adams and others emphasise not only the human right to privacy, which is understandably a key human right in this area and often the only right explicitly referenced in regulatory frameworks, they also emphasise the importance of the human right to health (the highest attainable standard of health) and the human right to science (to enjoy the benefits of scientific progress and its applications), the latter of which has often been overlooked in the medical law literature.[18] They rightly observe that the Western focus on civil and political rights (eg the right to privacy) rather than economic, social, and cultural rights (eg the right to health, the right to science) 'has resulted in an unbalanced approach to the regulation of research'[19] and that the lack of due recognition of the right to health (and the right to science) across the three jurisdictions under their microscope is problematic and merits much more consideration than it currently receives. Given the increasing scholarly valorisation of the right to science, it would have been welcome if the authors dedicated more analytical coverage to it (as it is, only one page addresses this right).[20]

As another example, the authors benchmark their analysis of existing decision-making processes against aspects of what they consider to be 'good governance', defined as four principles comprising efficiency (including proportionality, timeliness, and minimisation of duplication); transparency; accountability; and community participation. This last principle of community participation is particularly emphasised throughout the book and linked with the authors' prominent weight given to public health ethics values of reciprocity and solidarity, as well as the need for '*social licence*', that is, ongoing community acceptance and support for an activity (indeed, all of Chapter 3 is dedicated to unpacking the concept of social licence). In their words:

> Social licence can play a role in clarifying the social dimensions of research using linked data and in bringing together the scientific and the social considerations. The world of data analysis, of numbers, codes, and algorithms, can appear devoid of human beings and deceptively value-free. The social licence framework draws attention to the social impact of research using linked data and invites consideration of the wider cultural and moral norms of the community.[21]

[16] Interestingly, Adams and others suggest that many existing ethics committees may not have the necessary skills and experience in data science, data management, and community involvement to assess applications for data-intensive research with appropriate rigour and oversight. They openly question whether specialist data ethics committees may be appropriate. See also Agata Ferretti and others, 'The Challenges of Big Data for Research Ethics Committees: A Qualitative Swiss Study' (2022) 17 Journal of Empirical Research on Human Research Ethics 129.

[17] Adams and others (n 2) 105.

[18] This is beginning to change. See, for example, Helle Porsdam and Sebastian Porsdam Mann (eds), *The Right to Science: Then and Now* (CUP 2022).

[19] Adams and others (n 2) 85.

[20] ibid 100–1.

[21] ibid 59.

Social licence is more than an abstract concept; it is 'an essential analytical tool for developing and evaluating the decision-making framework for linking data and approving research using linked data'.[22] Adams and others rightly recognise that data linkage for health research implicates not only the individuals whose data are used (so-called data donors), but also groups and communities in which those individuals are situated—including the taxpayers who support the government (and public universities) that build and maintain data linkage infrastructure. They argue that the interests of groups need to be given serious consideration in decision-making in this space as they can be harmed by, for example, poor public health outcomes and discrimination and stigmatisation based on public health research results. So, compliance with existing regulatory and ethical frameworks is necessary but not sufficient to ensure trust and legitimacy in the research enterprise (these being the foundations of social licence). Researchers, data custodians, ethics committees, and other stakeholders must ensure that security standards are upheld and that confidentiality and privacy norms are upheld. They must also ensure that community acceptance and support is in place. This is achieved by ensuring research involving data linkage is set up to yield tangible benefits for the community or for particular groups; non-discriminatory outcomes; and acceptable uses (collectively what the authors term substantive conditions for social licence). Thus, the book offers several astute recommendations for how current regulatory systems can be enhanced to build and maintain social licence. That said, at times one wishes for even more practical suggestions in working through challenges that can seem intractable. For instance, Adams and others write:

> The decision-making frameworks, principles, and policies should support the transparent consideration of these multiple, divergent, and sometimes conflicting interests and values. There are two minimal requirements to achieve this. First, there should be explicit and transparent consideration of the conflicting interests, concerns, and consequences. This includes the contribution of the project to the welfare of the community and the impact on individuals and groups. Second, decisions should be made in consultation with those with a morally relevant interest.[23]

This recommendation of community participation and consultation rings clear and would be hard to dispute. But what happens when participation and consultation yield even further multiple, divergent, and sometimes conflicting interests and values? Whose voices are representative? Whose voice ought to prevail or (over)rule? Adams and others acknowledge that 'Most communities will not have clear representatives or structures, so the authenticity of representation is challenging, but this does not preclude a consultative and advisory process'.[24] While undoubtedly true, this does leave one wondering about the ability to work through divergent voices that yield knowledge and insight rather than discordant cacophony.

Adams and others' final chapter (Chapter 8) is their most original and significant; it alone is worth the value of the book. The authors explain how a decision-making framework of clear and transparent criteria can be developed that includes an evaluation of all the relevant interests, values, and rights. They set out the relevant decision-making criteria and some of the considerations that must or may be examined to establish each criterion. In so doing, they ably demonstrate that it is possible to have decision-making practices and processes that

[22] ibid.
[23] ibid 56.
[24] ibid 237.

establish and sustain social licence for the enterprise of research using linked data. One is hard-pressed to disagree with their suggestion that:

> The processes to decide whether or not to share data should be designed to encourage scientific progress while recognising that the benefits of conducting as much research as possible as quickly as possible must be weighed against the risks of spending insufficient time reflecting on the potential impact and consequences of each research project.[25]

Two detailed tables in the chapter provide (i) a list of ethical values, criteria, and considerations for decision-makers; and (ii) a list of the relevant governance criteria for decision-makers. The authors suggest that the evaluation of the ethical criteria should be the responsibility of an ethics committee (and perhaps a specialist data ethics committee), and that the evaluation of the governance criteria should be statutory criteria and should be the responsibility of the data custodian. They further argue (rightly in my view) that *all* projects involving individual-level data should be reviewed by an ethics committee, and that triaging projects to ethics review based on identifiability ought not to be supported. Their book concludes with six recommendations for improving decision-making in relation to use of linked data for research.[26]

Overall, despite some instances of minor repetition and a few areas where further elucidation would have been welcome, *Sharing Linked Data for Health Research* is an outstanding academic achievement and worthy of purchase and study by all involved in data-intensive research, within and outwith the health context. The value of Adams and others' work lies not so much in their analysis of existing law, policies, and guidelines, astute as it is, but rather in their practical, nuanced recommendations for how decision-making processes can be done better and contribute to more consistent frameworks for cross-jurisdictional data sharing, and in a way that advances the public good. Their recommendations for good governance, comprising principles of efficiency (including proportionality, timeliness, and minimisation of duplication), transparency, accountability, and community participation, provide plenty of intellectual substance for governments, data custodians, ethics committees, and other stakeholders to engage with for years to come. In the UK, and specifically the English context, where in early 2023 we witnessed the integration of NHS Digital into NHS England,[27] raising justifiable concerns about the independence and oversight of data access decisions regarding NHS patient data,[28] Adams and others' book is a timely reminder of the importance of government bodies demonstrating how they can be a trusted custodian of health and care data that enable research that is in the public interest and constructed on sound ethical, rights-based, and lawful foundations.

Edward S. Dove
School of Law, University of Edinburgh, UK

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[25] ibid 208.
[26] ibid 239–40.
[27] NHS Digital, 'NHS Digital Merger with NHS England' (25 January 2023) <https://digital.nhs.uk/about-nhs-digital/nhs-digital-merger-with-nhs-england> accessed 28 January 2023.
[28] Kingsley Manning, 'Rapid Response: Doing Away with NHS Digital: Why It Matters' (2022) 376 BMJ o361 <https://www.bmj.com/content/376/bmj.o361/rr-0> accessed 6 January 2023.