

Institution: University College London		
Unit of Assessment: 30 - Philosophy		
Title of case study: Shaping NHS policy on confidential patient data through ethics advice		
Period when the underpinning research was undertaken: 2009–2019		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
James Wilson	Lecturer (until 2014); Senior Lecturer (2014-19); Professor of Philosophy (2019 onwards).	2008 to present
Period when the claimed impact occurred: 2013–20		
Is this case study continued from a case study submitted in 2014? No		
1. Summary of the impact (indicative maximum 100 words)		
<p>Wilson's research has been instrumental in maintaining trust in the use of confidential patient information in the NHS. It has led to changes in the way that core concepts such as confidentiality, implied consent, and public interest are interpreted by healthcare professionals, national-level committees, and the National Data Guardian. Wilson's research-based ethical advice contributed materially to: the prevention of the implementation of the care.data project, thereby helping to protect the privacy of all English GP patients (2014); an Information Commissioner's Office (ICO) finding that Google DeepMind and Royal Free had breached the Data Protection Act (2017); the withdrawal of an MoU between the Home Office and NHS Digital, preventing the mis-use of patient data for immigration control purposes (2018); and the adoption across the NHS of a new principle for the use of data (2020).</p>		
2. Underpinning research (indicative maximum 500 words)		
<p>In a series of papers, Wilson rigorously analysed how health data can be used more effectively for the purposes of delivering care to patients, and to improve population health, while respecting duties of privacy and confidentiality [R1, R2, R3, R4]. He argued that the state's duties to protect and promote health should be articulated through the right to public health, and that this is the best way to reconcile the value of health with other values such as liberty and autonomy. [R1] On this view, states which fail to take easy steps to reduce socially controllable threats to health violate their citizens' rights. Ways that states can violate this right include failing to collect the data necessary to facilitate public health planning. Wilson also argued that citizens' reasonable expectations play a significantly larger role in justifying the shape and limits of state activity than has often been appreciated. In line with this account, Wilson developed a Public Value account for the NHS, which provides a reconciliation of the public interest in maintaining confidentiality and public trust, with the benefits that can come through commercial partnerships and sale of data. [R5]</p> <p>Underpinning research was supported by grants from EPSRC [ii], NHS Digital [iii], and a secondment to the Royal Society's Science Policy Centre [i]. Wilson was PI for [ii], which provided an ethics framework for the GBP11,000,000 i-sense Agile Early Warning Sensing Systems for Infectious Diseases and Antimicrobial Resistance collaboration. Wilson's project examined how to build and maintain public trust in the context of novel mechanisms of disease surveillance such as the ethics of the use of Twitter data for disease detection. The project showed that much of the philosophical discussion so far has presupposed some implausible assumptions about what it is to waive a right, and that the concept of reasonable expectations is crucial for clarifying what counts as a violation of the right to privacy in a range of crucial cases involving inferring private information from public information. [R3]</p> <p>This account of privacy and reasonable expectations was crucial for advice Wilson provided to the National Data Guardian for Health and Social Care (NDG), Dame Fiona Caldicott, in a high-profile case about the nature and limits of implied consent. Resolving the case made clear that a</p>		

theoretical clarification of the nature of implied consent was necessary. With the NDG's encouragement, Wilson fundamentally rethought the normative underpinnings of medical confidentiality [R4], arguing that much of the role that had previously been assigned within guidance to implied consent should be assigned to reasonable expectations.

3. References to the research (indicative maximum of six references)

Key Publications

[R1] Wilson J. (2016). "The Right to Public Health", *Journal of Medical Ethics* **42**: pp.367–375. Journal article. doi.org/10.1136/medethics-2015-103263. Peer reviewed.

[R2] Wilson J. and Hunter D. (2010). "Research Exceptionalism", *American Journal of Bioethics* **10**(8): pp. 45–54. Journal article. doi.org/10.1080/15265161.2010.482630. Peer reviewed.

[R3] Rumbold B. and Wilson J. (2019). "Privacy Rights and Public Information", *Journal of Political Philosophy*, **27**(1): pp.3-25. Journal article. doi.org/10.1111/jopp.12158. Peer reviewed.

[R4] Taylor, M. and Wilson J. (2019). "Reasonable Expectations of Privacy and Disclosure of Health Data", *Medical Law Review* **27**(3): pp.432–460. doi.org/10.1093/medlaw/fwz009. Peer reviewed.

[R5] Wilson J., Herron D., McNally N., Nachev P., Rees G., (2020). "The value of data: a public value model", *Journal of Medical Internet Research* **22**(3): e15816. doi.org/10.2196/15816. Peer reviewed.

Key Grants

[i] James Wilson. Secondment to Royal Society as co-leader of Science as an Open Enterprise project, 2011–12. Royal Society. GBP45,594.

[ii] James Wilson (PI). Building and Maintaining Public Trust in Early Warning Sensing Systems for Influenza. IRC in Early-Warning Sensing Systems for Infectious Diseases exploratory projects grant 2015–16. EPSRC, GBP81,576.

[iii] James Wilson (Co-I). *Machine Learning and Predictive Analytic Data Usage for Adult Social Care Prevention and Intervention*. (2018–19) NHS Digital. GBP76,500.

[iv] James Wilson (Co-I). UK Ethics Accelerator: Coordinating and Mobilising Ethics Research Excellence to Inform Key Challenges in a Pandemic Crisis. (2020–22). UKRI. GBP1,405,807.

4. Details of the impact (indicative maximum 750 words)

Patient data is essential for the effective functioning of the NHS. All users of NHS services, and all health professionals benefit from a system of governance that ensures patient data is used only in ways that appropriately balance the need for confidentiality against the benefits to be obtained from wider usage of data for research and service planning. Wilson's research based ethical advice has been instrumental in maintaining trust in the use of confidential patient information in the NHS, contributing materially to: the prevention of the implementation of the NHS care.data project, thereby helping to protect the privacy of all English GP patients (2014); an Information Commissioner's Office (ICO) finding that Google DeepMind and Royal Free had breached the Data Protection Act (2017); the withdrawal of an MoU between the Home Office and NHS Digital, thus preventing the mis-use of patient data for immigration control purposes (2018); and the adoption across the NHS of a reasonable expectations principle for the use of data (2020).

Maintaining Public Trust in NHS Digital's Data Disseminations. Wilson's research was a key resource in preventing the implementation of the care.data project. Care.data was proposed to harvest data on every individual patient from English GP practices into a central database, without either anonymisation or allowing patients to opt out. Wilson was the ethicist for NHSD's General Practice Extraction Service Independent Advisory Group (GPES IAG), which was tasked with providing independent advice on whether the project was in the public interest. Drawing on his work on the ethics of risk imposition [R2], Wilson "led the development of the GPES IAG Public Interest Model". [A] As the then Chair of GPES IAG explains, this model "underpinned GPES IAG processes and recommendations" and "was instrumental in the group articulating its concerns about why care.data did not appear to be in the public interest." [A] GPES IAG's role in opposing

the policy was recognised by the Parliamentary Office of Science and Technology's POSTNote 474, the subsequent Health Select Committee inquiry, and by the medical privacy NGO medConfidential, which described GPES IAG as "The one single body that stood up to care.data". [B] Care.data was "paused" in February 2014, and then finally abandoned in 2016. Wilson's expertise was further recognised when in 2015 he was invited to become an independent member of NHSD's Data Access Advisory Group (DAAG), which advised NHSD on how to maintain public trust in their data disseminations. The then Chair of GPES IAG, who also served as Chair of DAAG, states that Wilson's contribution was "consistently valuable" [A], bringing "increased rigour", and "greater attention to the achievement of public benefits". The committee's advice contributed to a "wholesale move away from the use of confidential patient information for the routine planning, monitoring, and reimbursement of health and care services", which "improved the protection of the confidentiality and privacy of millions of NHS patients' records, without detriment to services." [A] In 2016, he was chosen as "a leading academic in the ethics of data sharing" [C] to help NHSD to transition DAAG into a fully independent oversight group, the Independent Group Advising on the Release of Data (IGARD), and was IGARD's ethicist (2017–18). NHSD's Chief Medical Officer estimates that the work Wilson did with IGARD to maintain public trust and improve the ability of NHS data to improve patient outcomes benefited "hundreds of thousands of patients." [C]

Advice to NDG on ethics, confidentiality, consent, and maintaining public trust in the NHS.

Wilson was appointed to the NDG's Panel in 2016, "principally in virtue of his experience and contributions as an academic philosopher and ethicist" [NDG for Health and Care, in D]. Wilson was the first philosopher to be appointed to the NDG Panel, and as NDG relates, she "soon came to recognise that we had made an excellent decision in deciding, in general, to have an academic ethicist and philosopher on the panel and specifically, to recruit Wilson, due to the contributions that he has made individually." [D]. In 2018 Wilson joined the NDG's Steering Group, which is a smaller group of closer advisers. Wilson has regularly represented NDG in national level meetings, and occasionally at Ministerial level meetings such as a roundtable on Artificial Intelligence on 28 February 2018, and the Global Digital Health Partnership (with Directors General and ministers from twenty different countries) on AI and Health in September 2018. [D]

Specifying the limits of implied consent through the concept of reasonable expectations.

Wilson was key to the formation of the NDG position on implied consent and the common law duty of confidence from 2016 onwards. In one crucial case, Royal Free London NHS Foundation Trust shared the records of 1.6 million NHS patients with Google DeepMind for the development and testing of an App for detecting acute kidney injury. Royal Free claimed to have done so on the basis of patients' implied consent, despite the fact that at the time that the data was shared, no steps were taken to make patients aware of this fact. The case was complex, and raised an important point of principle about the circumstances in which it is legitimate to infer that a patient has consented to disclosure of information. Wilson, as a member of the NDG Panel, met senior representatives from Royal Free and DeepMind on three occasions, in order to come to a considered judgement. NDG was subsequently asked by the Information Commissioner to give advice as part of a formal investigation into whether the Data Protection Act had been breached. [D] Wilson, together with fellow NDG panel member Mark Taylor, argued that reasonable expectations are crucial in distinguishing between legitimate and illegitimate uses of implied consent. [R3, R4] As NDG explains, "Wilson significantly influenced the emphasis that I laid on the relevance of the legal concept of 'reasonable expectations' in this case and in later work". [D] Wilson's advice was crucial for shaping the NDG's response to the Information Commissioner—namely that as the data usage by Royal Free was not in line with patients' reasonable expectations, it therefore could not plausibly be claimed that patients had consented to it. [D] This advice led directly to the finding by the Information Commissioner's Office that the Royal Free had breached the Data Protection Act. [E] As the Chair of the Health Research Authority explains, Wilson's analysis was also deeply influential with the Health Research Authority (HRA): "The HRA accepted the conclusions of his work and built its regulatory response upon it. I chaired a multi-agency meeting in which the implications were worked through, all predicated on the analysis that Professor Wilson had developed. Professor Wilson's work on this specific issue has had a very wide impact on data governance in the NHS." [F]

New reasonable expectations principle for information use in the NHS. Wilson published [R4], which provided NDG with the “intellectual underpinning” [D] for the introduction of a new reasonable expectations principle for data use within the NHS. In a 2019 press release, the NDG praised [R4] as “a very convincing article which outlines the importance of reasonable expectations and explores how this principle might be used to support appropriate information sharing.” [G] NDG undertook a national consultation in 2020 on whether a new reasonable expectations principle should be adopted across the NHS. The consultation document explicitly mentions how [R4] influenced the NDG position. [H] Consultation respondents were overwhelmingly in favour, and the new principle published in December 2020. [H]

Change to Government Policy on the use of NHS Data for Immigration Enforcement. Wilson’s contribution was important for shaping the line taken by the NDG for the Health Select Committee inquiry on the Memorandum of Understanding (MoU) between NHSD and the Home Office (2017–18), and through that changing government policy. The MoU allowed demographic information held by NHSD to be used for the purposes of tracing immigration offenders. While it was not illegal for NHSD to share patient information in this way, doing so was thought to be incompatible with the General Medical Council’s (GMC) confidentiality guidance. GMC is the regulatory body for doctors, and so any doctor who was involved with decision-making about individual cases under the MoU would potentially be subject to censure and even to being struck off. It was nonetheless a policy that the Home Office, and NHSD claimed to be in the public interest. Wilson argued that NHSD’s public interest test was deeply flawed. Both NHSD’s most senior advisers on ethics and confidentiality—its Caldicott Guardian and Deputy Caldicott Guardian—were doctors. Thus, neither could be involved in the decision-making about individual cases required under the MoU, because of the risk of their breaching the GMC Confidentiality Code. NHSD’s solution was to remove the Caldicott Guardian and his Deputy from its processes for determining the public interest in individual cases. Wilson argued this amounted to excluding the very persons who through institutional role and expertise would be best placed to determine the balance of public interest from making their contribution. As NDG explains, Wilson’s argument “became a central plank of the view I provided to the committee” [D] and proved influential. Wilson’s argument was quoted prominently in the letter sent by the chair of the Health Select Committee to the CEO of NHSD on 29 January 2018, requesting that NHSD immediately withdraw from the MoU. [I] It is quoted again on p. 23 of the subsequent Health and Social Care committee report. [I] On 9 May 2018, the Government announced that the memorandum would be withdrawn and revised, reducing the number of cases that would fall under it by over 90%. [I] Wilson was then asked to address a private meeting of NHSD’s Board on 5 June 2018, which focused on how the organisation might respond to the ethical criticisms made against it. As NHSD’s then Chief Medical Officer and Caldicott Guardian explains, NHSD’s Board “wanted a renowned expert in the field to advise them” and that Wilson’s name “came up from multiple sources as someone whose body of work had the potential to educate and advise the Board of a national body on the way forward... The impact was a change in organisational structure and adherence to [Wilson’s] advice.” [C]

NHS Covid-19 App Ethics Advisory Board. Wilson was a member of the Ethics Advisory Board (EAB) for the NHS Covid-19 App in 2020. The project was extremely high-profile, as it was initially envisaged in the government’s strategy that the App would play the leading role in controlling the spread of coronavirus. The Board’s advice and challenge was widely discussed, including in parliament, on the Radio 4 *Today Programme*, and was covered extensively in *The Telegraph* and *The Guardian* and other newspapers. EAB’s main formal output was a letter to the Secretary of State for Health on 24 April 2020, which laid out six principles and a framework for meeting the objectives of effective control of the epidemic and protecting privacy. The EAB Chair confirms that “Wilson was the most influential member in crafting the ethical principles that we established”, and explicitly recognises how Wilson’s work on public value and on public health ethics shaped the principles. [F] EAB’s principles were warmly welcomed by the government, which committed to follow them [J], and that these principles would be “the basis by which any future change requests for the app will be assessed.” [J] Wilson continued to advise on behalf of NDG in the lead up to the launch of the second iteration of the App. A number of changes were made to the privacy

information provided for App users on the basis of his advice, including making clear that “despite the anonymity of the alerts delivered through the app, users might sometimes be able to infer who among their contacts had tested positive for Covid”. [G] As NDG makes clear, his advice “significantly influenced” her decision to endorse the App [G] which had been downloaded over 20 million times by the end of 2020. [F]

5. Sources to corroborate the impact (indicative maximum of 10 references)

[A] Letter from Chair of GPES IAG, and DAAG, 6 November 2020

[B] POSTNOTE no. 474 July 2014, “Big Data and Public Health”, <https://bit.ly/3aqs9e>; Written Evidence by Chief Executive, Health and Social Care Information Centre, to Health Select Committee enquiry (26 March 2015) <https://bit.ly/3nbAtnF>; medConfidential bulletin (18 July 2015), <https://bit.ly/3dACJ4E>

[C] Letter from Medical Director of NHS Digital to JW, 27 Feb 2019

[D] Letter from National Data Guardian for Health and Care, to James Wilson, 5 November 2020

[E] Letter from Elizabeth Denham, Information Commissioner to Royal Free NHS Trust, 3 July 2017 <https://bit.ly/2QnLmXF>

[F] Letter from Chair of the Health Research Authority (HRA) to UCL Provost, 14 December 2020

[G] National Data Guardian for Health and Care, “Data driven innovation and meeting patients’ reasonable expectations about data use”, 23 August 2019, <https://bit.ly/3dCkr3b>

[H] National Data Guardian for Health and Care, “Consultation background document. Caldicott Principles: a consultation about revising, expanding and upholding the principles”, <https://bit.ly/3arhKil>; NDG announces new Caldicott Principle and guidance on Caldicott Guardians [press release, 8 Dec 2020]: <https://bit.ly/3avj6cn>

[I] Quotations of Wilson’s argument on the MoU between NHS Digital and The Home Office in: Letter to the CEO of NHS Digital from Health Select Committee Chair [29 Jan 2018, pp. 2-3] <https://bit.ly/2RO5FxF>; Health and Social Care Committee Report [HC677, 15 April 2018, p.23] <https://bit.ly/32wfm62>; Margot James, Minister of State for Digital and Creative Industries, Data Protection Bill [Lords] Hansard, [9 May 2018] <http://bit.ly/2PeEdHn>

[J] Report on the work of the Ethics Advisory Group to NHSx on the COVID19 Contact Tracing App [25 August 2020] <https://bit.ly/32A89ly>; NHS Covid-19 App: privacy information, Department of Health [13th August 2020] <https://bit.ly/3tlVsRi>