Institution: University of Sheffield		
Unit of Assessment: C-18 Law		
Title of case study: Confidentiality and privacy: influencing policy and practice in the use of health data		
Period when the underpinning research was undertaken: 2011–2020		
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:**
Mark Taylor	Senior Lecturer	2002–2017
Victoria Chico	Lecturer	2006–present
Period when the claimed impact occurred: 2014–2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact (indicative maximum 100 words)

Effective use of health data for research is crucial for innovations in health and wellbeing. There are significant gaps in the legal regimes and policy positions governing the use of identifiable patient data for research. Inconsistent interpretation creates complex and confusing barriers for researchers. Chico and Taylor's research identified the gaps and contradictions in the legal and governance frameworks. Their work provided clarity on the legal position that has been directly relied on in drawing common policy lines and guidance nationally, internationally and in support of the research response to the COVID-19 pandemic. This clarity has enabled a change in governance facilitating innovations in healthcare to patients in a way that is transparent and maximises public trust.

2. Underpinning research (indicative maximum 500 words)

Chico and Taylor have both been seconded to the UK healthcare research regulator, the Health Research Authority (HRA), whilst also continuing to develop their research. This dual focus has allowed them to identify and respond to gaps in the regulatory and policy landscape that prevent innovative research. Addressing these gaps is key for the HRA to be able to facilitate health research and innovation in a way that maximises public trust.

Chico and Taylor's research to understand, map and resolve gaps and inconsistencies in healthcare information governance comprises empirical, mixed methods and theoretical research.

Determining the conditions to fulfil the duty of confidentiality

The absence of a legal standard determining when a consent is sufficient to negate an action for breach of confidence can result in risk-averse researchers avoiding beneficial research that requires the use of identifiable patient data. Chico and Taylor investigated the detailed and varied English jurisprudence on valid consent, misuse of health data and conditions to assess adequate consent that negates an action for breach of confidence. They argue the application of a clear legal principle of 'real' consent, coupled with an established standard for setting relevant information levels needed to achieve the 'broad awareness' required for this. They also provide

greater clarity concerning the kind of information that is required to support a valid consent to the use of health data [R1].

A reasonable expectation of privacy as an alternative legal basis for the disclosure of health data

The National Data Guardian (NDG) is the body that advises and challenges the health and care system to help ensure that citizens' confidential information is safeguarded securely. It has recognised that developments in data-driven technology and the adoption of machine learning in healthcare are putting stress on the traditional concepts for negating a breach of confidence in the use of health data for innovation. Chico and Taylor argued that conformity with a reasonable expectation of privacy could provide an alternative account for the lawful disclosure of confidential patient information for health innovations [R2], and that the role of the independent advisors (HRA Confidentiality Advisory Group) should contribute to these decisions so disclosure for the purposes of public health improvement is transparent and maintains public trust [R3].

Empirical investigation of public attitudes on secondary uses of health data

The public is cautious about the use of confidential patient information outside the provision of care, especially when commercial organisations are involved. However, there was a lack of nuanced consideration of the multiple factors that might impinge on public acceptability of secondary uses of health data. To provide more granular evidence, Chico and Taylor conducted empirical investigation into what influences people's attitudes towards sharing health data with commercial organisations, where there is both a public and a private benefit. A key finding of the work showed substantial shifts (18%-45%) in the acceptability of sharing with a commercial organisation when people were exposed to further information about the public benefits of commercial use [R4].

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

R1. Chico, V., & Taylor, M. J. (2017). Using and Disclosing Confidential Patient Information and The English Common Law: What are the Information Requirements of a Valid Consent? *Medical Law Review*, *26*(1), 51–72. https://doi.org/10.1093/medlaw/fwx038

R2. Chico, V. (2019). Reasonable expectations of privacy in non-disclosure of familial genetic risk: What is it reasonable to expect? *European* Journal *of Medical Genetics*, *62*(5), 308–315. https://doi.org/10.1016/j.ejmg.2018.11.013

R3. Taylor, M. J. (2015). Legal Bases for Disclosing Confidential Patient Information for Public Health: Distinguishing between health protection and health improvement. *Medical Law Review*, *23*(3), 348–374. https://doi.org/10.1093/medlaw/fwv018

R4. Chico V., Hunn, A. and Taylor, M. (2019). *Public views on sharing anonymised patient-level data where there is a mixed public and private benefit*. NHS Health Research Authority. https://bit.ly/3rKs5Nt

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

Chico and Taylor's research has provided evidence which has been directly relied on to inform legal and policy positions in national and international health information governance.

Impact on the policy and guidance for determining the conditions to fulfil the duty of confidentiality

NHS Digital (NHSD) is the national information and technology partner to the UK health and care system. It has a statutory duty to collect, analyse, publish, and disseminate national health and social care data and issue related guidance. NHSD had no reference point to determine whether a patient's consent to share their health record was sufficient for NHSD to meet their obligations under common law. The NHSD Research Advisory Group worked with Taylor and Chico using their research [R1] in the guidance document Data Sharing Standard 7b – Duty of confidentiality. The NHSD guidance explicitly directs applicants to [R1] to help them determine when consent is considered sufficient by NHSD to modify the obligation of confidence and enable the use of confidential patient information **[S1].**

NHSD holds significant health and social care data sets. It also provides a reference point for all other NHS organisations on data protection and confidentiality. Thus, Sheffield research has affected all organisations comprising the health and social care system and anyone who is or will be an NHS patient.

[Text removed for publication].

Eighth Caldicott principle - reasonable expectations of privacy and a disclosure of health data

The Caldicott Principles are guidelines used across health and social care information governance to safeguard people's data. The increasing use of data-driven technology in health and social care requires access to significant amounts of confidential data. The legal bases for setting aside confidentially are limited, and new practice is stretching current legal bases beyond their authentic interpretation. As the common law cannot act to address this directly, the research **[R2, R3]** proposed the policy development of a reasonable expectation of privacy as a legal basis for modifying the obligation of confidence. According to the Head of the Office of the National Data Guardian "*The most significant and longstanding impact from Vicky Chico and Mark Taylor's work on the National Data Guardian (NDG) is on the development of a new Caldicott Principle*" **[S2]**.

In December 2020, the NDG published Caldicott - Principle 8: Inform patients and service users about how their confidential information is used **[S3].** "*Her [Chico's] research on the common law duty of confidentiality and the concept of a reasonable expectation of privacy has allowed her to lead engagement with stakeholders to progress an agreed policy position*" (Director of Policy and Partnerships, HRA **[S4]**). Chico worked closely with the NDG on the development of the recognition of the importance of reasonable expectations where confidential health and social care data is used and shared. She "*influenced the wording of the new (eighth) Caldicott Principle, recognising the importance of creating clear expectations, which formed part of a public consultation about revising, expanding and upholding the principles*" **[S2].**

All NHS organisations and local authorities must ensure that staff act in accordance with the Caldicott Principles.

Confidence of patient consent in health research

HRA Confidentiality Advisory Group (CAG) provides independent expert advice on the appropriate use of confidential patient information. All applications to use confidential patient information where consent is impossible or impractical in research must apply to this group. Applications are approved based on whether the study is potentially in the public interest. Taylor, as CAG Chair (2012-2017), used R1 when writing the 2017 paper which sets out CAG's understanding of the public interest **[S5].**

In response to the COVID-19 pandemic the Secretary of State for Health and Social Care issued notices that require health and care organisations to share confidential patient information for the purpose of responding to the pandemic. Chico was asked to work with the Department of Health and Social Care (DHSC) and the NHS to enable healthcare researchers to access data under this notice. Alongside NHSX colleagues, Chico wrote step-by-step guidance to accessing data on COVID-19 for research purposes. *"This guidance was published promptly and continues to be supportive to applicants so that they have access to data to support the pandemic",* Head of Stakeholder Engagement NHSX **[S6].** Up to 31 December 2020, CAG had approved 203 applications involving research in response to COVID-19, utilising the notice and CAG's understanding of public interest **[S7]**.

Impact on the underpinning public trust in policy on secondary uses of health data

Chico and Taylor's research into the public's views on sharing patient data with third parties including commercial organisations **[R4]** has informed policy development and practice across health and social care organisations and the technology sector regarding uses of health data for research.

It has shaped CAG's advice to NHSD on sharing anonymised data outside of the NHS where there is a public benefit but consent is not possible. "*These principles have been applied throughout the CAG advice and continue to underpin CAG considerations when advising on non-consented developing and innovative uses of patient information*" (Head of Confidentiality Advice Service, HRA [**S8**]).

The research has also had a significant impact on the NDG's work to fulfil the statutory role to publish guidance about the processing of health and adult social care data in England. The NDG, Sciencewise, the Wellcome Trust and UKRI have used it as a key piece of evidence for the 2020 consultation on how the public understand the benefit of sharing health and social care data for research **[S9]**.

Public attitudes on secondary uses of health data is a barrier to medical innovation globally. As the specialist adviser to the OECD Advisory Expert Groups for health and the digital economy recommendations, Taylor "*helped steer the Group towards a draft Recommendation that treats making personal health information available to serve the public interest and the protection of privacy as twin aims that can be progressed together rather than traded off against each other*", Group Member and Deputy Commissioner, ICO, UK **[S10]**. The recommendation was adopted by the OECD Council in 2016 to enable more countries to benefit from research uses of data in which there is a public interest **[S11]**.

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

S1. Data sharing standard 7b – Duty of Confidentiality. This standard is part of a series of guidance documents to support the various stages of a Data Access Request Service (DARS) application. https://digital.nhs.uk/services/data-access-request-service-dars/dars-guidance/data-sharing-standard-7b---duty-of-confidentiality

S2. Letter from Head of the Office of the National Data Guardian coming Chico and Taylor's contribution to the NDG on the formulation of eighth Caldicott principle on reasonable expectations

S3. Launch of the eighth Caldicott principle (https://www.gov.uk/government/news/ndg-announces-new-caldicott-principle-and-guidance-on-caldicott-guardians).

S4. Letter from Director of Policy and Partners, HRA describing Chico's research contribution to public consultation and Caldicott principles.

S5. Confidentiality Advisory Group: understanding public views on using personal data 2017 (https://www.hra.nhs.uk/about-us/news-updates/confidentiality-advisory-group-understanding-public-views-using-personal-data/).

S6. Letter from Head of NHSX Engagement confirming Chico's role in the creation of guidance for access for confidential patient data applications in response to the COVID-19 pandemic.

S7. HRA research summaries of COVID-19 application to CAG (https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/).

S8. Confirmation by Head of Confidentiality Advice Service HRA of use of Sheffield research by CAG when advising on non-consent uses of patient information.

S9. Launch of the National Data Guardian public consultation to explore how people weigh up the benefits and disadvantages of health and social care data sharing for research. (https://www.gov.uk/government/speeches/our-new-dialogue-with-the-public-about-data-for-public-benefit).

S10. Deputy Commissioner, ICO, UK and Advisory Expert Group member statement on contribution to Recommendation on Health Data Governance.

S11. OECD Recommendation on Health Data Governance (https://www.oecd.org/health/health-systems/health-data-governance.htm).