In response to Ballantyne and Schaefer's 'Consent and the ethical duty to participate in health data research'

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ABSTRACT

We welcome Ballantyne & Schaefer's discussion of the issues concerning consent and use of health data for research. In response to their acknowledgement of the need for public debate and discussion, we provide evidence from our own public consultation on this topic.

Ballantyne and Schaefer outline some of the debates around the use of personal health information for the purposes of research.[1] Specifically, they discuss whether '*citizens have an ethical obligation to share their health information for research purposes*', and propose a model for rethinking traditional research ethics frameworks with a shift to focussing on the public good of the research, public engagement and transparency. We wish to contribute a crucial missing part of the argument: patient and public attitudes toward the use of health information for research.

In recent years, there have been huge technological advances for using the wealth of information contained within health records, and specifically electronic health records (EHRs), for research. As Ballantyne and Schaefer highlight, the secondary use of health data has a number of advantages over traditional research in producing meaningful health knowledge that is of public benefit. While the potential for the use of health data for research is clear, addressing the legal and ethical challenges in accessing and analysing large amounts of patient data is complex. The advancement of technologies allowing for the de-identification or pseudonymisation of EHRs have helped to address some of these issues and led to waivers of consent in some jurisdictions but not all.

Debates around consent and confidentiality have often made assumptions about what patients may find acceptable, but there has been limited engagement with patients and the public to explore these complex issues.[2 3] We agree with Ballantyne and Schaefer that progress in this area requires engagement with patients and the public to ensure ongoing trust and to develop the best models of security. We undertook a small public consultation to inform and support the ethical approval and governance process for the use of a new information retrieval platform[4] to use local EHRs for research. The consultation was advertised through existing patient and public involvement groups, volunteer lists and the hospital's member bulletin. Interested patients and family members were invited to attend one of two focus groups each lasting 2 hours. A total of 13 individuals attended the two focus groups with representation across 10 different clinical specialties and a range of services within the local hospital. Patients were invited to discuss: their views towards the use of de-identified data; the potential benefits of using hospital records for research; what might concern and what might reassure them; what information would be important for them to know if their data were to be used for research; what consent means to them; and how they feel about being approached to participate in research.

Overall, there was support for the use of EHRs for the purposes of research and a clear recognition of the benefits and opportunities provided they were used in a de-identified format. All participants agreed on the importance of research for the development of new treatments and for improving direct patient care. Many patients spoke about a desire to 'give something back' for the care received and saw the use of their de-identified health records for research as a way to do this. Patients discussed some important areas of concern which echo the considerations raised and discussed by Ballantyne and Schaefer. In particular, the patients in our consultation expressed concerns about data handling, security and access (especially by external agencies such as pharmaceutical companies). Regardless of anonymisation or de-identification, patients were unanimously against the use of their data for commercial gains. This reflects previous studies demonstrating that the recipient of data is the most important factor in determining willingness for allowing data to be shared.[5 6] The discussion highlighted the importance of having adequate information governance arrangements and effective information technology safeguards, while recognising that such policies will be complex. Patients were enthusiastic about a patient-led committee or advisory group which would review requests to obtain access to data in order to ensure patient safety as well as assess the value of proposed research, which is in keeping with Ballantyne and Schaefer's suggestion on preresearch consultation as well as ongoing partnership and/or patient involvement in research governance.

Related to autonomy and public trust, patients expressed a common wish to be informed of the use of their data for research and clear instructions on how to opt-out if desired. Ballantyne and Schaefer state that the violation of autonomy is kept relatively minimal if restricting their proposed model to secondary data research. Based on patient and public views, we would add that the provision of opt-out processes where possible would minimise this even further. Patients also want know to how their data are being used. Attitudes toward the use of personal information for the purposes of research are influenced by the nature of the information itself, what it will be used for and who might see it.[7] Echoing some of the 'transparency mechanisms' discussed, patients advocated for waiting room posters and short videos informing patients of both the use of de-identified data for research and the subsequent results of such research. Importantly, it was agreed that this information should come from and be promoted by a wide range of interested parties, not just researchers. Ongoing discussion, education, communication and collaboration with patients, as well as other stakeholders, are vital.

There is also the potential to use EHRs for the identification of potential

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participants for future interventional research. While we agree with Ballantyne and Schaefer that conscription into interventional research should not be advocated, the opportunities for voluntary participation of targeted groups can be enhanced. In this regard, a process called 'consent for contact' (C4C) has been developed whereby individuals can give generic consent, which is recorded on their EHR, to be contacted about suitable research opportunities, before considering whether they consent to take part in any given interventional research.[8] This provides a flexible and autonomous way of obtaining consent to be contacted, without any obligations for actual participation. Patients were willing to consider a C4C arrangement allowing researchers access to their contact details in order to be approached for active engagement in studies. However, in this instance, they were explicit that this must be an opt-in process discussed with them by someone trusted and familiar (eg, a known clinician). They were happy for this consent, once given, to be ongoing and valid across their spectrum of care provided they were given the appropriate time and information to allow them to make an informed choice to opt-in or not, and that the option of opting-out is available and the process for this made clear. C4C (or similar) initiatives using such an opt-in process have been successfully implemented in different secondary and tertiary care settings.[9 10]

We strongly agree that service user and stakeholder consultation is key for the future development and management of any model using health data for research. It is reassuring that the perspectives and considerations raised by Ballantyne and Schaefer and the wider research community are on the whole reflective of those raised by patients and the public in our consultation. Framing the use of health data in research as an obligation neglects the reality that some patients view the use of their data as positive and have a desire to give back. We hope that further public engagement is prompted by these debates.

Acknowledgements The authors thank all the patient representatives who took part in the consultation.

Contributors NH, AMF and AJ: conducted the patient consultation. NH: prepared the initial draft and subsequent versions of this manuscript. All authors contributed to the conception of the work, commented on the initial draft and approved the final version of the manuscript.

Funding This work was supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South London (NIHR CLAHRC South London) at King's College Hospital NHS Foundation Trust and the NIHR Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London . The views expressed in this article are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Competing interests None declared.

Provenance and peer review Not commissioned; internally peer reviewed.

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/medethics-2018-105271).

To cite Hepgul N, Sleeman KE, Firth AM, *et al*. *J Med Ethics* 2019;**45**:351–352.

Received 23 November 2018
Revised 4 December 2018
Accepted 12 December 2018
Published Online First 7 January 2019

► http://dx.doi.org/10.1136/medethics-2018-105318

J Med Ethics 2019;**45**:351–352.
doi:10.1136/medethics-2018-105271

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