Data donation after death

A proposal to prevent the waste of medical research data

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What happens to your personal data after you die? Most of the discussion on this topic has focused on whether and how relatives should be given access to the media accounts and music libraries of deceased loved ones (<http://www.theguardian.com/money/2012/sep/03/do-you-own-your-digital-content>; accessed 30 October 2015). However, an important issue—namely, of posthumous data use in research—has been mostly neglected. When they are alive, many people are willing to be involved in research projects and have their medical records used for medical and epidemiological studies, subject to the relevant safeguards. But few consider what will happen to their medical data after they die. Many will undoubtedly assume that this information will no longer be accessible once they are dead and that confidentiality automatically persists where life does not. Depending on the jurisdiction, these assumptions might be wrong: researchers can in fact access the medical data of deceased patients under certain circumstances as part of ethically approved research projects—for example, if the data is anonymized. However, in most countries, it is much more difficult to use “deceased data” than it is to use data from living individuals, as deceased persons cannot be asked to provide informed consent. We believe that there should be greater transparency regarding the use of medical data after death and that patients and other research participants should be encouraged to donate data after death—just as people donate organs posthumously [1]—as was once suggested in relation to brain researcher’s personal data [2].

Data protection is a significant issue in modern society, and most developed countries have sophisticated laws and regulations

to safeguard citizens’ private and sensitive data from abuse. (Sidebar A). However, in most countries, the focus is predominantly on protecting the data of those who are still alive. This is perhaps understandable, as these citizens have justified expectations of privacy and confidentiality that need to be met. But it would be a mistake to think that the dead do not also deserve protection or that they cannot be harmed by disclosure of their data. Medical confidentiality normally persists even after a person is dead. Conversely, it would also be an error to assume that everyone wants all their data to remain dormant after they die. The wishes of the deceased regarding their estate are always observed by law; similarly, registered organ donors’ intentions are generally respected. The same should be true of data.

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In the UK, a deceased patient’s records of physical or mental health cannot be accessed until 100 years after his or her death, but data concerning deceased patients can be used by medical researchers (without consent) subject to approval by the Public Records Office (<https://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/>; accessed October 30, 2015). In other jurisdictions, such as Germany, difficulties in accessing deceased persons’ data have a chilling effect on various

research enterprises such as epidemiological studies. For instance, to have a historical cohort study ethically cleared without the explicit consent of study individuals can be very challenging: researchers have to prove that public interest in the study’s results outweighs an individual’s right for privacy. Wherever possible, anonymized data has to be used—otherwise, it has to be shown why anonymized data would not be useful for the study. Furthermore, it must be demonstrated that there is no alternative way to answer the study question and that the deceased person could not be asked for informed consent (http://www.gesetze-im-internet.de/englisch_bdsch/englisch_bdsch.html; accessed 30 October 2015). But how can a deceased person have consented to a study that was not even contemplated during their lifetime? In many countries, elaborate

Sidebar A: Legislation and debate about data sharing and protection

Europe: In the European Union, the sharing of medical data and research data is governed by the Data Protection Directive. It allows some latitude in terms of future use of data, although several countries have more stringent requirements. The Directive will soon be replaced by a Data Protection Regulation, which has been the focus of many drafts and much debate concerning researchers’ access to medical and genetic data.

USA: In the United States, the COMPETE Act (“America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act”) actively encourages researchers to share data openly. However, the Act mainly concerns existing research data and not the private medical records of citizens. Medical records are normally kept confidential after death.

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zregulation impedes important research whose quality would be improved by easier access to deceased person's data.

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Going beyond regulations at the national level, we are in the midst of a harmonization process as the European Union prepares for the implementation of the General Data Protection Regulation. According to a recent editorial [3], while politicians do their best to protect individual's privacy rights in a digital world, such pan-European rules could become a burden for medical research.

The German National Cohort [GNC] [4] provides a good example to illustrate how our proposal of “data donation” could address possible problems for research associated with “data overprotection” (http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053205.pdf; accessed 30 October 2015). Scientists from the Helmholtz Association, the Leibniz Association, German universities and other research institutes intend to explore the causes of major chronic diseases and to understand their pre-clinical stages and functional health impairments. A total of 100,000 women and 100,000 men aged between 20 and 69 years old will provide a random sample of the general population across Germany. Baseline assessments will include interviews and questionnaires, extensive medical examinations and the collection of diverse biomaterials. Random subgroups will undergo an intensified examination programme. All study participants will be re-invited for reassessments after 4–5 years. Throughout the study, the scientists will collect data on chronic disease endpoints. The GNC is planned to last for 25–30 years and promises to yield a rich database for population-based epidemiology in Germany. Its explicit purpose is to generate novel strategies and tools to detect, predict and prevent major chronic diseases. However, the above mentioned current data protection

laws could prevent the use of key research data in Germany. Indeed, the German National Cohort has been generated as a research resource, which scientists can use exclusively for the specified purpose and within clearly defined rules [5]. This treasure trove of data could be a highly valuable resource for studying individuals who may die during and after the planned decades-long follow-up.

Let us assume the following scenario as an example of research that could benefit from the GNC data, including data from deceased persons. Shift work that involves circadian disruption has been classified by the International Agency for Research on Cancer [IARC] as a probable cancer risk for humans [6,7]. The GNC could provide data to pursue associations between various facets of shift work, chronobiology in humans or impaired sleep and chronic processes such as cancer development or premature ageing [8]. This could be used to identify individuals with differential susceptibility to inform them about individual risks.

However, unless individuals know what the research questions are and consent to them while alive, the data could end up in a grave together with the deceased. Obviously, not all research questions are evident today, and new questions may only come up during or even after the envisaged follow-up period. Unless study individuals have provided informed consent to using their data and stored specimens in a specific way before they die, this could put a stop to using these rich and expensive data during the planned duration of the GNC. According to the GNC website (<http://nationale-kohorte.de/allgemeines/basisinformationen-zur-nako/>), informed consent to participation is valid for 5 years and extends automatically for another 5 years and beyond death unless the participant opts out. However, access to health data, reporting data and secondary data from medical files and registries requires individuals to provide active re-consent every 5 years (<http://nationale-kohorte.de/allgemeines/basisinformationen-zur-nako/datenschutz-in-der-nako/>). Further details of the mortality follow-up are supposed to be developed together with the German federal data protection officer. Clearly, one objective must be to reconcile the apparent contradiction between broad consent and requiring individual consent every 5 years to access a

host of important data. More importantly, though, patients' consent to “data donation after death” could enable researchers to conduct studies like this much more easily than is possible under the current regulatory regime.

We are not suggesting that existing safeguards should simply be abandoned. Data must be protected during and after life. But current—and conceivably future—data protection systems in various countries do a disservice to individuals by failing to inform them about what may happen to their data before and, in particular, after their death—a scenario not mentioned in [3]—and by failing to give them more control over what is done with that data. Moreover, while data needs to be protected, we equally need research protection.

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In the case of posthumous organ donation, people can choose to donate all their organs or specific ones. Some persons even donate their whole bodies for research in anatomy institutes. We think that the same should apply to data. All citizens should be encouraged to sign up to a data donor register and perhaps carry an associated data donor card, which states whether their data can be used for research after their death. While people are alive, they can be asked for either consent to individual projects, or broad consent to using their data. Given the presumption that data of deceased persons is normally confidential, a register of those willing to share data after death is the logical solution to the current problem. The existence of such a register would also avoid the need to approach families to give consent to the use of their relative's medical data for research. Just as for organ donation, or for donating tissue to a research biobank, people should be able to indicate which data can be shared, as research has shown patients are less likely to consent to sharing of data concerning sensitive topics such as mental health issues or sexually transmitted diseases

(http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053205.pdf; July 2013; accessed 17 March 2014). They could also indicate whether only anonymized or pseudo-anonymized research should be permitted. Furthermore, they could be asked whether their relatives could be contacted for further information. These measures would streamline research that uses the data of deceased persons and perhaps comfort donors with the knowledge that they will leave behind a legacy that will help future patients in their own countries and abroad. Simply forbidding access to the data of deceased patients or putting barriers in the way of researchers is unethical because it assumes that patients would want that to happen, and because it places privacy concerns above avoiding diseases and helping sick people now and in the future.

Let us assume that the above “shift work—cancer” studies were conducted early during the planned GNC time window of 30 years. In that case, the living study individuals could be asked to consent to specific studies. However, as noted in the editorial [3], evidence suggests that individuals who consent in principle to supporting medical research with their personal data may become more and more reluctant to do so if asked for re-consent (possibly again and again). Would data donation before death avoid these issues?

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Whether data donation should ultimately be used more generally to govern the use of living patients’ data is an important question. While alive, patients are frequently asked to join particular research projects, each with its own governance mechanism, including ethics committee oversight. Patients can decide on a case-by-case basis which projects they wish to be involved in. This model is changing in the UK with the error-ridden introduction of care.data, which automatically shares patients’ data with NHS, academic and industry researchers unless

patients opt out entirely. Many commentators have criticized this approach, as it imposes a simple binary choice upon sensitive types of data [9]. Because of the complications of current governance of medical data sharing in clinical care and research, we would suggest that data donation is used only posthumously in the first instance. Just as people are too attached to their organs to donate them until after death, citizens will find it easier to donate data after death than while alive. Furthermore, the introduction of a posthumous data sharing system would also proactively address potential problems with access to a deceased person’s data in countries with permissive broad consent systems, which tend to be limited to the living with little thought given to how to handle the data of the deceased. Data donation after death would thereby both introduce and conclude a new era of broad consent to sharing medical data while alive.

Are there any potential downsides to data donation? Provided that information is anonymized, there appears to be little cause for concern. However, genetic information and big data analysis raise concerns that a would-be data donor would do well to consider. Even if data is anonymized, careful analysis of large data sets of genetic information and other data may enable unethical researchers or companies to generate data about family members of deceased donors. There is another clear distinction from organ donation: when someone becomes an organ donor, there is no long-term harm to the family, though the process of donation may be initially distressing. But donation of one person’s genetic data could lead to the disclosure of confidential information about family members’ genetic makeup and disease risk. To safeguard their relatives, data donors may wish to donate all data except specific genetic information, which would have the unfortunate effect of limiting genetic research substantially if many people took this option. The issue of sharing genetic data after death also raises the possibility that family members themselves might want a veto, even if a deceased person was happy to share. Any system of data donation after death would have to be carefully designed to warn and safeguard about the potential effect of donating genetic data on the families of donors.

Another interesting distinction between data donation and organ donation lies in the possibility to choose the users of deceased data. Organ donors cannot make any stipulations regarding who should receive their organs, but data donors might want their data shared only with NHS researchers and academics but not with industry, for example. As in current discussions regarding clinical trials, questions arise with regard to data donation: should data donated by the deceased also be open to all, or should they be able to limit access to particular entities? This can only be settled by careful analysis and public and professional debate.

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Our proposal is not a response to any problem with abuses of data under the current regimes in different countries; rather, our concern is that the policies and regulations designed to prevent abuse have gone too far and the balance needs to be redressed. Any such change raises the possibility that errors will occur; the attempted introduction of care.data in England is a prime example (http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053205.pdf; July 2013; accessed 17 March 2014). It uses an overly simplistic binary consent system, but patients were not adequately informed. Worse, those who did opt out did not have their refusal respected owing to logistic issues (<http://www.pulsetoday.co.uk/your-practice/practice-topics/it/caredata-paused-yet-again-due-to-confidentiality-review/20020042.fullarticle>; accessed 30 October 2015). This example shows that great care must be taken in designing any data sharing regime, whether for living or deceased patients and research participants.

Data overprotection [3] currently creates a difficult climate for research in some countries, and concerns remain that pan-European rules will hinder the use of necessary data for biomedical research without explicit consent. Our data donation proposal could provide an option to prevent the waste

of key medical research data. Many people sign up as organ donors because organs are of no use to them once they are dead, and each donation can save and improve lives. Data can also save lives: information about disease processes and the effect that different treatments have had on patients provides invaluable information that could facilitate the development of new lifesaving medicines and therapies. Although the benefits to individuals are not as immediate as in the case of organ donation, the cumulative impact on society of data donation after death could be substantial. Most people on the organ donor register do not actually end up donating their organs because the circumstances of their death do not make donation possible; in contrast, those registered as data donors will know that their decision will definitely contribute to future research, no matter how they die.

Thus, we would encourage governments to create and citizens to embrace a *Data Donor Card* scheme, and would further encourage citizens to consent to donating their data for open use before and after their

death, in order to help present and future generations live longer and better lives. We are convinced that necessary details including data donation agreements and establishing appropriate data donor banks and registers on the basis of respective laws can be successfully worked out. But regardless of the merits of our own particular initiative, how to handle data concerning deceased individuals deserves widespread discussion, as posthumous medical data is an extremely valuable legacy that should not be left untapped.

Conflict of interest

The authors declare that they have no conflict of interest.

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