Eur J Epidemiol (2010) 25:65–68
DOI 10.1007/s10654-009-9413-0

COMMENTARY

Changing defaults in biobank research could save lives too

**Joanna Stjernschantz Forsberg · Stefan Eriksson ·
Mats G. Hansson**

Received: 8 September 2009 / Accepted: 24 November 2009 / Published online: 3 December 2009

Abstract In an effort to increase the amount of organs available for transplantation, many countries have implemented presumed consent for organ donation. Presuming a wish to contribute to medical advances through biobank research on previously taken tissue samples could similarly improve health and wellbeing. In this article we analyze common arguments for and against presumed consent for organ donation and assess their relevance in the context of biobank research. In spite of obvious differences between biobank research and organ transplantation the cases for implementing presumption of a positive attitude appear quite analogous. It has repeatedly been shown that a majority of the general population supports these projects and selecting informed consent as the default position decreases the amount of organs and samples available and thus reduces the prospect of promoting health. We conclude that instead of presuming that individuals do not wish to contribute to the advancement of healthcare through biobank research on previously taken samples, ethics committees should presume that they do.

Keywords Biobank · Consent · Ethics · Organ donation

Introduction

In the illuminating article "Do defaults save lives?" Johnson and Goldstein argue that changing defaults from informed consent to presumed consent for organ donation could save lives. They state that: "…every policy must have a no-action default, and defaults impose physical, cognitive, and, in the case of donation, emotional costs on those who must change their status." They further note that since most people favor organ donation, selecting informed consent as default imposes the cost of switching on the majority [1].

Presuming that individuals wish to donate organs respects the standpoint of the majority, relieves suffering and saves lives. The same could be achieved by presuming a wish to contribute to the advancement of medicine through research on stored tissue samples. In the case of organ donation presuming a positive view has lead to implementation of presumed consent. Ethics committees could analogously presume a positive attitude toward research on previously taken material and evaluate the need for consent from this perspective.

Currently however, informed consent is generally deemed necessary for research on stored samples (unless they have been completely anonymized, in which case the WHO, CIOMS, HUGO and UNESCO all have adopted approaches that allow for research without consent [2]). The default position is that individuals do *not* wish to contribute by allowing leftover samples to be used for biobank research. Many of the arguments put forward in favor of presumed consent for organ donation also seem applicable to consent for biobank research, yet there is an apparent lack of debate on the issue.

In this article we will analyze common arguments for and against presumed consent for organ donation and

---

J. Stjernschantz Forsberg (✉) · S. Eriksson · M. G. Hansson
Centre for Research Ethics and Bioethics, Uppsala University,
Box 564, 751 22 Uppsala, Sweden
e-mail: joanna.forsberg@crb.uu.se

assess their relevance in the context of biobank research on stored leftover material.

Presumed consent in organ donation and implications for biobank research

Presumed consent as a way to increase the amount of organs and samples available

Many potential organ donors, that in fact do not oppose donating, have neither consented nor dissented when the issue of donation must be addressed. Presuming their consent may be both appropriate and correct, and numerous countries (e.g. Spain, Austria, Belgium, Israel, France, and Sweden) have implemented this strategy in an effort to overcome organ shortage. It has repeatedly been shown that presumed consent legislation has a positive effect on organ donation [1, 3–6]. However, the debate on the policy of presumed consent has been heated and many countries (e.g. the USA and UK) require informed consent for donation.

While demanding informed consent for organ donation seems to result in fewer organs being available, selecting informed consent as the default for biobank research risks generating collections of samples that are not representative of the population. If, for instance, samples from dead individuals cannot be used without prior consent, obviously, milder cases (that have not been lethal) will be overrepresented when studying a disease. Similarly, living individuals who do not consent to research on their samples may not be a random population, but rather have characteristics in common that can cause selection bias [7–10]. Furthermore, routinely obtaining informed consent for research on previously taken materials imposes practical and financial difficulties.

In the context of organ donation it is often argued that educational campaigns, more transplant coordinators, specialist teams and financial incentives could be alternative solutions to the organ shortage problem. Although they would all likely increase donation rates, it can hardly be denied that imposing them *and* presuming consent would save an even greater number of lives. From the perspective of biobank research it is equally evident that similar approaches could be effective but that even more good could be done if the default position of ethics committees was changed as well.

Presumed consent and the risk of mistakes being made

Both presumed consent and informed consent for organ donation are default rules, the former presuming a wish to donate and the latter a wish not to. In both cases deviation from the rule is possible, but active steps must be taken in order to do so [11]. Consequently, the same argument can be used against both: mistakes will sometimes be made. Those in favor of presumed consent argue that, since it has repeatedly been shown that a large majority of the population are willing to donate organs, presuming consent would be doing the right thing most of the time. It has also been claimed that individuals who do not want to donate organs are more inclined to opt-out under presumed consent than individuals who wish to donate are inclined to opt-in under informed consent [12]. While proponents of presumed consent argue that it leads to fewer mistakes being made, opponents claim that mistaken removals are morally much worse than mistaken non-removals [12]. Individuals may have special ties to specific organs or view the body as sacred making it wrong to mutilate it after death, for religious or psychological reasons [13].

In the case of biobank research it has analogously been shown that a majority of the population support research being done on their leftover samples [14–17]. What is more, there seems to be no reason why it would be worse to use a leftover sample for research if the individual from whom it was taken opposes it, than not to do research on a sample from a person who wishes for it to be done, given that almost no risks are involved and the potential benefit is great (approval in an ethics committee should ensure that samples are appropriately coded [18] and that possible negative effects on groups of people are obviated). Using samples in research is clearly not as sensitive an issue as is removing and transplanting organs.

Presumed consent and the burden of changing status

According to Johnsson and Goldstein, default rules impose the costs on those who wish to change their status. Experiments have shown that defaults have a significant role in determining what is chosen. Defaults can influence choices in three ways: First, they can be viewed as implying a recommended action, second, accepting a default is effortless and, third, changes involve trade-offs and losses appear larger than equivalent gains, making defaults seem more attractive [19]. Since it is in the interest of the public good that as many individuals as possible consent to donating their organs (and leftover tissue samples), it makes no sense to impose extra burdens or costs on the individuals who wish to be donors.

Presuming consent for organ donation has been claimed to wrongly imply that society has a right to interfere with our bodies after death [12]. While not requiring any consent could be viewed in this way, presuming consent cannot, since the possibility to opt-out exists. Presuming a wish to contribute to the advancement of medicine through research on leftover material does not imply that society has a right to use the bodies of individuals either. These samples have already been taken to benefit the individual, and will be discarded if not used for research. Instead, it should be regarded as a way of respecting the majority by not imposing extra burdens on them and respecting all people by doing what can be done to relieve suffering and save lives in a manner that optimizes the chances of success.

Presumed consent and the culture and meaning of giving

As noted previously, defaults can be viewed as implying a recommended action. English and Sommerville argue that presumed consent represents a positive endorsement of organ donation as a good thing to do, and that formal acceptance would lead to donation becoming the norm, thus increasing donation rates further [20]. Presuming that individuals favor research on leftover samples could similarly lead to a genuine change in positions. Changing defaults could have implications for the way in which medical research and healthcare are viewed in general, thereby facilitating a debate on individual-social relations and possible rights and duties of both parties in promoting health and wellbeing.

Against this, it has been claimed that presumed consent changes the meaning of organ donation, so that instead of being an act of altruism it becomes a routine procedure [11]. Although this might, but need not, be true, it seems to be a rather weak argument when weighed against the benefit of saving lives. Donors of leftover material may likewise benefit in some way from the notion that their donations are not taken for granted, but the cost of obtaining informed consent arguably outweighs this putative benefit. Moreover, it is not clear that “routinized” donations are morally less significant than supererogatory ones. Impersonal gifts honor important human values and express solidarity [21], regardless of whether an opt-in or opt-out system is employed.

Discussion: an argument for changing the default position of ethics committees

Although donating organs and donating leftover tissue samples share many characteristics, some differences must also be acknowledged. First, organ donation tangibly saves lives while biobank research may seem not to, i.e., the benefit of research may appear vague. However, awareness of the need for organ donation is a result of information campaigns and public education, and people could similarly be informed about the continuous need for medical research. Epidemiological research on existing data and samples could thus come to be viewed as a natural part of healthcare that is endorsed and facilitated, not because research on a specific sample will necessarily produce great benefit or save lives, but because in the absence of risks, no possible benefit should be disregarded. Second, in the case of organ donation, the donors are dead and cannot be harmed, while individuals that have donated leftover samples may be alive, and can be harmed if research is not carried out properly. Research on stored samples should therefore be carefully regulated and subject to ethical review. However, under these conditions, routinely obtaining informed consent arguably does more harm than good. Changing the *default* position of ethics committees notably does not hinder them from requiring informed consent if it is considered necessary. Third, the opposite stands true as well, organ donors cannot benefit from donating, while sample donors can. Fourth, it is not possible to ask dead potential organ donors whether they consent to donation, but potential donors of leftover tissue samples can be asked to consent if alive.

In spite of these differences, the cases for implementing presumption of a positive attitude appear quite analogous. In both instances more of the valued material would be available at a lower cost and in biobank research the collections of samples would likely also be more representative of the population. Some individuals who wish to opt-out may fail to do so under presumed consent, but a majority of the population has repeatedly been shown to support these projects, and individuals fail to opt-in under informed consent as well. Moreover, presuming a positive attitude does not impose the cost of changing status on the majority and could result in donation becoming the norm, additionally facilitating procurement.

Two important aspects of our analysis are worth noting. First, the suggested policy does not justify taking new samples without consent. Second, presumption of a positive attitude toward research on previously taken samples does not imply acceptance of presumed consent for organ donation. Although the arguments in favor appear similar in the two cases, some of the arguments against may bear more weight in the context of organ donation.

Limitations

A limitation of our analysis is that it cannot predict how individuals would react to the proposed change in policy. The willingness to contribute to medical research might be influenced, as people might come to distrust the healthcare system and research enterprise, thinking that they have no say. In a recent report from the organ donation taskforce in the UK, this argument was used against changing to an opt-out system, and it was claimed that presuming consent could actually lead to a lower donation rate [22]. Notably though, when Belgium changed donation policy from informed to presumed consent in 1986, no more than 2% of the population registered as non-donors and the donation rate increased greatly [23]. However, providing accurate information and education in order to maintain trust in research would clearly be an important task if the suggested policy change were to be implemented.

Conclusion

We conclude that instead of presuming that individuals do not wish to contribute to the advancement of healthcare through biobank research, ethics committees should presume that they do, and evaluate the need for consent accordingly. If consent is considered necessary, an opt-out system should be selected, imposing the cost of changing status on those who, although they have taken advantage of the healthcare system, do not wish to contribute to further advances.

Acknowledgments The research for this publication was supported by the EU sixth framework programmes AutoCure and CCPRB, and by Pfizer's Research Foundation. The funders had no role in the research process and the publication reflects only the authors' views. The funders are not liable for any use that may be made of the information herein.

References

1. Johnson EJ, Goldstein D. Do defaults save lives? Science. 2003;302:1338–9.
2. Knoppers BM. Biobanking: international norms. J Law Med Ethics. 2005;33:7–14.
3. Abadie A, Gay S. The impact of presumed consent legislation on cadaveric organ donation: a cross-country study. J Health Econ. 2006;25:599–620.
4. Mossialos E, Costa-Font J, Rudisill C. Does organ donation legislation affect individuals' willingness to donate their own or their relative's organs? Evidence from European Union survey data. BMC Health Serv Res. 2008;8:48.
5. McCunn M, Mauritz W, Dutton RP, Alexander C, Handley C, Scalea TM. Impact of culture and policy on organ donation: a comparison between two urban trauma centers in developed nations. J Trauma. 2003;54:995–9.
6. Low HC, Da Costa M, Prabhakaran K, et al. Impact of new legislation on presumed consent on organ donation on liver transplant in Singapore: a preliminary analysis. Transplantation. 2006;82:1234–7.
7. Jousilahti P, Salomaa V, Kuulasmaa K, Niemelä M, Vartiainen E. Total and cause specific mortality among participants and non-participants of population-based health surveys: a comprehensive follow-up of 54,372 Finnish men and women. J Epidemiol Community Health. 2005;59:310–5.
8. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. Heart. 2007;93:1116–20.
9. Helgesson G, Dillner J, Carlson J, Bartram CR, Hansson MG. Ethical framework for previously collected biobank samples. Nature Biotechnol. 2007;25:973–6.
10. Kaijser M. Examples from Swedish biobank research. In: Hansson MG, Levin M, editors. Biobanks as resources for health. Uppsala, Sweden: Universitetstryckeriet; 2003. p. 33–48.
11. Jacob M. Another look at the presumed-versus-informed consent dichotomy in postmortem organ procurement. Bioethics. 2006;20:293–300.
12. Gill MB. Presumed consent, autonomy and organ donation. J Med Philos. 2004;29:37–59.
13. Sanner MA. Two perspectives on organ donation: experiences of potential donor families and intensive care physicians of the same event. J Crit Care. 2007;22:296–304.
14. Kettis-Lindblad Å, Ring L, Viberth E, Hansson MG. Perceptions of potential donors in the Swedish public towards information and consent procedures in relation to use of human tissue samples in biobanks: a population-based study. Scand J Public Health. 2007;35:148–56.
15. Johnsson L, Hansson MG, Eriksson S, Helgesson G. Patients' refusal to consent to storage and use of samples in Swedish biobanks: a cross-sectional study. BMJ. 2008;337:a345.
16. Hoeyer K, Olofsson B, Mjörndal T, Lynöe N. Informed consent and biobanks: a population-based study of attitudes toward tissue donation for genetic research. Scand J Public Health. 2004;32:224–9.
17. Wendler D. One-time general consent for research on biological samples. BMJ. 2006;332:544–7.
18. Hansson MG. Ethics and biobanks. Br J Cancer. 2009;100:8–12.
19. Johnson EJ, Goldstein DG. Defaults and donation decisions. Transplantation. 2004;78:1713–6.
20. English V, Sommerville A. Presumed consent for transplantation: a dead issue after Alder Hey? J Med Ethics. 2003;29:147–52.
21. Murray TH. Gifts of the body and the needs of strangers. Hastings Cent Rep. 1987;17:30–8.
22. Department of Health. Organs for transplants: a report from the organ donation taskforce. London: Department of Health, 2008. Available from: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122.
23. Gundle K. Presumed consent: an international comparison and possibilities for change in the United States. Camb Q Healthc Ethics. 2005;14:113–8.