Author Manuscript
Author Manuscript
Author Manuscript
Author Manuscript

HHS Public Access
Author manuscript
J Med Ethics. Author manuscript; available in PMC 2021 December 22.

Pros and cons of prosent as an alternative to traditional consent in medical research

Vasiliki Nataly Rahimzadeh
Center for Biomedical Ethics, Stanford University, Stanford, California, USA

Abstract

In their recent article, Porsdam Mann *et al* propose to share biomedical research data more widely, securely and efficiently using blockchain technologies.[1] They present compelling arguments for how the blockchain presents both a technological innovation, and a deontologically grounded policy innovation to traditional research consent. Their proposal can be read in conversation with a rich body of evidence to suggest current consent processes are problematic on at least one of tripartite bases in biomedical research: that it be fully informed. This response attempts to further the author's discussion of social justice discourse in, and of their proposed prosent model to enhance engagement among under-represented and vulnerable populations in research, specifically. Motivating this response is the view that advancing technological capabilities is no doubt necessary, but on its own insufficient to reinvigorate distributive, procedural and social justice as guiding principles for con/prosent processes. I offer three pros and cons to consider in effort to deepen the model's commitments to social justice to historically marginalised groups in the biomedical research enterprise.

INTRODUCTION

In their recent article, Porsdam Mann *et al* propose to share biomedical research data more widely, securely and efficiently using blockchain technologies.[1] They present compelling arguments for how these technologies represent a technological innovation, and a deontologically supported policy innovation to traditional research consent. Prosent, the authors propose, offers comparative advantages for research stakeholders wishing to 'exercise their autonomy by sharing other data or sharing data with other trusted research or healthcare entities' through leveraging blockchain technologies.

Their proposal can be read in conversation with a rich body of evidence to suggest current consent processes are problematic on at least one of tripartite bases in biomedical research: that it be fully informed. That consent is more frequently followed in popular vernacular by 'form,' as opposed to 'process' outside the bioethics academe is indicative of the

Correspondence to Dr Vasiliki Nataly Rahimzadeh, Center for Biomedical Ethics, Stanford University, Stanford, CA 94305, USA; vrahim@stanford.edu, @VNRahimzadeh.
Contributors VNR is the sole author of this response, and takes full responsibility for the ideas and writings articulated in the manuscript.

Competing interests None declared.

Provenance and peer review Not commissioned; internally peer reviewed.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

reductionist light in which the principle of respect for persons is now largely seen. What follows is a reflection on the authors' new paradigm for data sharing and biomedical research participation they aptly term 'prosent.' A preface to my thoughts is merited here. I fully support, and have previously written about,[2] cross-sectoral adaptations of blockchain technologies to address systemic healthcare and research challenges, not the least of which include protecting patient data privacy. Blockchains and other distributed ledger technologies hold immense promise in disrupting isolationist practices in science which, as the authors rightly criticise, privilege the lone researcher at the expense of potentially greater returns on participant investments, contributions to new knowledge and better health outcomes.[3–5]

This reflection attempts to further the author's discussion of social justice discourse in, and of prosent to enhance engagement among under-represented and vulnerable populations in research. Motivating these reflections is the view that advancing technological capabilities is no doubt necessary, but on its own insufficient to reinvigorate distributive, procedural and social justice as guiding principles for con/prosent processes. I offer three pros and cons to consider in the prosent model proposed by Porsdam Mann *et al* in effort to deepen the model's commitments to social justice within institutional data sharing practices.

PROSENT AND THE ETHIC OF CARE

To care about the negative effects of under-representation or over-representation of marginalised communities in research, you have to know these communities; to know them, you must interact them. With blockchain-enabled prosent, there may be fewer opportunities to interact directly with study personnel traditionally charged with answering study-related questions, explaining overall aims of the research, and describing study procedures when needed. Concerning still, interactions between prospective data contributors and users may be reduced to smartly executed contracts of underinformed preferences.

In order to 'offer a novel and potentially powerful means of re-engaging individuals in these communities', as the authors note, prosent would need to redress the endemic mistrust in the biomedical research enterprise sowed over many years by its regulatory godparent, consent. Ultimately, how will prosent alter the care dynamic, or historically the lack thereof, between marginalised communities and researchers? Without recalibrating this dynamic—a primary reason why biomedical research engineers mistrust among many social, racial and ethnic groups—prosent will do little to enhance engagement among such communities in research. Likewise, unless prosent mechanisms invite opportunities for exercising advisory power, it is hardly an engagement innovation; indeed, it may even be status-quo preserving. To be the truly innovative instrument of public engagement the authors tout, prosent should aim to make explicit an unwritten social contract that the research will yield a just distribution of benefits for the informational risks assumed.

DEMANDING EXPERTISE IN ONE'S OWN DATA SHARING PREFERENCES

Of its many technological virtues, blockchain's immutable, time-stamped record of informational transactions is perhaps one of the most advantageous for ensuring downstream

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

data uses are compliant with the terms under which the data were originally contributed. The authors assert that with blockchain technologies 'we trace if, and when consent was given,' but what of its quality? Implied in the authors' arguments is that greater locus of control via prosent is synonymous with more meaningful engagement with prospective data generators. Two general assumptions frustrate the authors' position on this point. First, the benefits of ownership and direct access controls over one's data assumes the data contributor is fully informed of the menu of contractable data sharing options afforded to them by smart contracts on the blockchain.

Second, the concept of individually owned and controlled data may be incompatible with the view that data and biospecimens are communal resources, which are shared sources of biological identities as with genetic data, and which may carry sociocultural significance. The latter is particularly relevant to indigenous communities, where data and biospecimens are ancestral legacies and which decisions regarding how it can be shared are made collectively.[6] Prosent requires that prospective data contributors are literate in the technicalities of data security and protection and have contextualised the anticipated benefits and risks of the subsequent data uses each time they authorise their permissions. Although the blockchain effectively makes all data uses on the ledger transparent to both the authorising and authorised parties, the prosent process does not itself confirm that data contributors understand the short and long-term implications of their permissions. Previous studies, for example, evidence a wide range of public knowledge and understanding of the effectiveness of data protection methods, and how their health data are ultimately shared as well as with whom.[7–9] Concurrent to building blockchain infrastructure, prosent proponents could consider stakeholder education and outreach to guide prospective data contributors and users on making the most responsible data sharing decisions for themselves and their communities. They might also consult with diverse communities for whom traditional research consent has proven either culturally inappropriate or harmful, to ensure prosent respects diverse normative and cultural values.

FUTURES OF FUTURE PERSONS VIA PROSENT

Future orientedness is a key feature of the proposed prosent model, and enables sharing health data with stakeholders both within, and outside the academic research or medical contexts. Alas, prosent, as discussed in the article, seems to relate to prospective authorisation of research participants with capacity now. It begs the question how prosent accommodates for prospective authorisation of future data uses among participants who are not yet competent to do so but may be in the future. In short, can there be such thing as substituted prosent? This is particularly salient for research with children, who represent another similarly marginalised population in biomedical research with a tragic history of human rights abuses. Like traditional consent, prosent to research participation extended by parents on behalf of their children can impinge on the child's right to an open future even if the research involves minimal risk. It has long been debated, therefore, if parents have the authority to enroll children in research not expressly meant to benefit them directly, or to similar groups. The blockchain provides an immutable record of all research data permissions and uses, a welcomed improvement to current reconsent practices that often leave children, now adults, unaware that their data were in the past or are currently being

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

used in research. Prosent mechanisms executed using blockchain technologies will need to build infrastructures that enable authorisation transfer from parents to their children, akin to dynamic consent or recontact at the age of majority.[10]

CONCLUSION

Blockchain-enabled prosent affords both a technical, and principled supplement to traditional informed consent for sharing health-related data for biomedical research. Increased participation among historically marginalised groups is imperative if all populations are to benefit fairly from the fruits of scientific progress. Indeed, this right to benefit from science is codified in the United Nations Declaration of Human Rights under Article 27. Porsdam Mann *et al* have provided the data governance community with a rare opportunity to reflect deeply on practices that meaningfully advance social justice commitments in research, among other bioethical principles, while leveraging disruptive technologies to innovate others. Paying attention to the above ways that prosent can be more equity-enhancing for traditionally marginalised groups, Porsdam Mann *et al* invite us to imagine a future in which blockchain technologies catalyzethe immutability of social justice in scientific collaborationand participant engagement inbiomedical data sharing.

Funding

The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

REFERENCES

1. Mann SP, Savulescu J, Ravaud P, et al. Consent and prosent for medical research. J Med Ethics 2020:1–7.
2. Rahimzadeh V. Ethics governance outside the bo Reimagining blockchain as a policy tool to facilitate single institutional review and data sharing in the data-intensive sciences. BHTY 2018;1(1):1–10.
3. Shrier AA, Chang A, Diakun-Thibault N. Blockchain and health it: algorithms, privacy and data, 2016.
4. Benchoufi M, Porcher R, Ravaud P. Blockchain protocols in clinical trials: transparency and traceability of consent. F1000Research 2017;6.
5. Gordon W, Wright A, Landman A. Blockchain in health care: decoding the hype. New Engl J Med Catal 2017.
6. Moodie S Power, rights, respect and data ownership in academic research with Indigenous peoples. Environ Res 2010;110(8):818–20. [PubMed: 20817150]
7. Shen N, Bernier T, Sequeira L, et al. Understanding the patient privacy perspective on health information exchange: a systematic review. Int J Med Inform 2018;2019(125):1–12.
8. Kalkman S, van Delden J, Banerjee A, et al. Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence. J Med Ethics 2019:1–11. [PubMed: 30545901]
9. Skovgaard LL, Wadmann S, Hoeyer K. A review of attitudes towards the reuse of health data among people in the European Union: the Primacy of purpose and the common good. Health Policy 2019;123(6):564–71. [PubMed: 30961905]
10. Kaye J, Whitley EA, Lund D, et al. Dynamic consent: a patient interface for twenty-first century research networks. Eur J Hum Genet 2015;23(2):141–6. [PubMed: 24801761]