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Different types of health data should be governed differently

Submission to the UN Special Rapporteur on the Right to Privacy as part of the International Consultation on Health Data

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This submission is in response to the release by the UN Special Rapporteur on the Right to Privacy of a draft recommendation on the protection and use of health-related data.[1] An International Consultation on Health Data is to be held in Strasbourg in June as part of the consideration of the draft. The draft recommendation has clearly been informed by the Council of Europe's draft recommendations on the same topic.[2]

Issue for clarification

The current draft does not acknowledge the different roles for the state and for the private (economic) sector in data use and privacy. Without delving too deeply into political theory, it is surely clear that 'democratically authorised' use of data differs from data uses that are proprietary or designed to yield economic benefits to for-profit entities. Of course, not all governments are democratic, and not all for-profit entities are exploitative.

At minimum, the document should distinguish state uses of health data for the common good (epidemiological research, health services management and evaluation) from health data surreptitiously gleaned for marketing purposes from devices covered by unread commercial 'terms and conditions'.

State uses need to meet standards of privacy and not transgress on human rights, but there are different considerations in the use of data for the public good and for commercial purposes.

The need to consider different types of health data differently

The document reflects a very old and static understanding of 'health data'. To clarify privacy challenges with new forms of data collection, it might be useful to consider different types of data and the different privacy concerns with each type of data. This is done in the table on the next page.

The document acknowledges the burgeoning market for data from personally-owned mobile applications and from online activities related to an individual's health (Chapter VI of the Draft). There are few privacy issues that arise when owners of the devices or respondents to online health questionnaires explicitly authorise information use by sponsors or transfer of data to third parties (see #1 in Table 1 on next page). When such authorisation is buried in 'terms and conditions' that are routinely ignored by consumers, however, privacy issues common to other commercial uses of personal health data arise.

[1] https://rm.coe.int/draft-recommendation-on-the-protection-and-use-of-health-related-data/1680943bea, accessed 10 May 2019; the references to the paragraphs refer to the document as circulated to attendees at the Strasbourg workshop on 11 and 12 June.

[2] https://rm.coe.int/draft-recommendation-on-the-protection-of-health-related-data/16808b1e80, accessed 10 May 2019

Table 1: Categories of health data and associated privacy concerns

	Character of data	***Ownership/consent processes***	***Privacy concerns***
1	Patient-collected/ citizen scientist data	Data generated by personally-owned devices to measure physiological phenomena (eg, Fitbit), or online survey information voluntarily 'donated' for research.	Privacy determined by individual owner of data unless 'harvested' without knowledge or consent (see 3-5 below)
2	Randomised control trial (RCT) participant data	Data 'owned' by investigators, but use granted by patients as part of the 'consent to treatment' protocol	Prospective consent, although data-use authorisation may be considered coercive as a condition of acceptance into the trial
3	Data generated in the course of treatment	As above, but generally no explicit consent to data use;	Electronic medical records expand the scope of such data collection; as above, treatment may be seen as conditional on consent to data-use.
4	Secondary use of data previously collected for research	Consent not explicitly sought; no direct benefit to patient; distinguished from (5) by non-commercial uses	Data generally de-identified or anonymised; commonly used in research or public health surveillance.
5	Secondary use of data for marketing, insurance or other commercial or legal purposes	Consent not explicitly sought, no direct benefit to patient, and may be detrimental (eg, insurance coverage)	Data may/may not be de-identified; information may be to the detriment of individual patients.
6	Any of above	Consent may be sought from patient but have implications (generally genetic) for others (usually relatives)	Consent from unknown but related others difficult to ascertain.

The Draft seems to have adopted its model for consent procedures (see especially sections 11 and 12) from clinical randomised control trials (# 2 in the table above). These consent processes are an important safeguard for patients offered experimental treatments. Data fields are pre-specified by researchers, and thus, can be incorporated into 'consent to data use' protocols. Patients have a face-to-face relationship with the investigators and can individually withdraw from the trial (and thus data collection) at any point in their treatment. But this is no longer typical of most health data collection processes, and even less so, as electronic patient records become ubiquitous.

Secondary use of health data (# 3-5 in the table above) has grown in parallel with the use of computers in many aspects of health care. Research using such data has provided important clinical, management and policy insights into how to improve health care in many countries in the world. While explicit consent is not sought for these uses, the implicit bargain, at least for publicly funded health care, is that data generated by an individual's treatment (with exceptions, perhaps, for still stigmatised care such as drug and alcohol or psychiatric services) should be used to advance the common good. This implicit bargain is predicated on the patient's privacy being strongly protected and that there can be no detriment to the patient.

This case is not so clear when data are used for commercial purposes (#5 above), but even here, for-profit health insurers in the United States have significantly improved the care of patients using the data they collect. Use of health related data for marketing of other products is a growing field, for example, the targeting of online drug advertising to patients belonging to self-help groups for a specific chronic condition, or nappies/diapers to individuals ordering online pregnancy tests. Section 38.1 of the Draft proposes to deal only with individuals' online search histories being used in this way, but any type of identifiable health-related data can and will be used if not prohibited by law.

Genetic data is subject to privacy issues whether personally held, collected as part of a Randomised Control Trial, or collected in the course of patient care. The Draft gives particular attention to its use in insurance coverage, but what is unique to genetic data (#6 above) are the ethical issues arising from its potential to harm related, non-consenting individuals. As genetic profiling becomes more common in genealogy, and in clinical research, these issues will warrant closer examination, as proposed in Chapter IX of the Draft.

In summary, reliance on a model of Randomised Control Trial prospective data collection with explicit consent to data use would slow the commercial exploitation of health-related data, but ignores the considerable public benefit of responsible secondary uses of health data.

The Kommentiert at A28 notes the US Institute of Medicine's Rapid Learning Healthcare initiative, and it is recommended that the Taskforce examine this work.[3]

Data privacy and research governance

A third key issue raised by the Draft is an apparent confusion of data privacy protection with more general research governance. Section 5g, for example, suggests a long list of conditions relating to the use of archived health data that includes issues normally assessed by editors and peer reviewers of scientific publications (e.g, 'quality standards including use of scientific methodology'). In my view this exceeds the scope of Taskforce.

It is not appropriate to incorporate this detail in the taskforce Report.

Support for or dissent from Taskforce comments on Draft

It is a privilege to be able to comment on the Draft at this early stage. It is clear the Taskforce has many issues still to resolve. Table 2 below documents my support or dissent from 'Kommentiert' in the draft document.

Table 2: Response to Kommentiert

Strongly support:	Support:	Dissent/requires further discussion:
A13, A15, A19, A21, A23, A26, A28	A1, A4, A5, A6, A8, A10, A11, A12, A17, A18, A22, A24, A27	A3 requires acknowledgement of commercial or for-profit entities; A7 requires further consideration of 'boundaries' of the two sectors A9 'many wrongs' unclear A14 unclear what 'lower the protection level' might mean A16 requires answers to questions raised A20 for further discussion A29 for further discussion A30 unclear

[3] Etheredge (2007); Institute of Medicine. Committee on the Learning Healthcare System in America (2012); Institute of Medicine. Roundtable on Evidence-Based Medicine (2007)

References

Etheredge, L. M. (2007) 'A Rapid-Learning Health System', *Health Affairs*, 26(2), p w107-118

Institute of Medicine. Committee on the Learning Healthcare System in America (2012) *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*, The National Academies Press

Institute of Medicine. Roundtable on Evidence-Based Medicine (2007) *The Learning Healthcare System: Workshop Summary*, The National Academies Press