

Digital Health Society Task Force 3: Legal Framework facilitating the free-flow & 2nd use of health data

2 October 2017



1. Why? (Background)

- EU has no power to harmonise national health laws.
 - Data is very important for:
 - Patient safety and quality of services;
 - the development of new health and care services & products;
 - academic research, understanding, policy & innovation;
 - whole population management & sustainable healthcare systems;
 - Health data must include both health and social care data.
 - Truly integrated care (both health (primary and secondary) and social care) is facilitated and enabled by data.
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2. Nature of proposed legal framework

- Outside of/separate from the EU legal framework.
- "European Health and Care Data Convention".
- 9 Principles.
- Each region/country signatory agrees (voluntarily) to pass any required national laws to the extent necessary to adopt the Principles.
- Recommendation: The Digital Health Society (DHS) considers whether the Health and Care Data Convention should be binding or non binding on signatories.

Objectives

- Create common legal rights and obligations for Citizens and Patients to:
 - underpin and enable the flow of health and care data for treatment and research ;
 - strengthen Citizen trust by increasing transparency and confidentiality;
 - facilitate greater use and flow of health and care data in regions/country and between regions /countries for the tangible benefit of individuals and society driven by practical positive use cases;
 - Recommendation: DHS should review exactly what information/data should constitute a health and care record and create a priority list of use cases both for individuals and society.
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Principle 1 – Duty to create and maintain electronic health and care record(the "Record")

- In State funded systems there should be an obligation to create a single [aggregated] integrated Record for every Citizen/Patient underpin and enable the flow of health and care data and 2nd use;
 - Every Record should be able to note:
 - any consents or refusals (from time to time) to share information for treatment or research;
 - permissions to share information with family;
 - Powers of Attorney given by the citizen/patient;
 - Recommendation: DHS propose exactly what information/data constitutes a "Record".
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Principle 2 – Comply with the Law & Ethics

- All access to Records must be lawful and specifically comply with all EU (e.g. GDPR) and national laws.
 - Citizens and Patients have the right to privacy and confidentiality and for health and care systems to keep their confidential information safe and secure.
 - Health and Care workers must comply with applicable professional ethical obligations.
 - Consent needs to be freely given and 'informed'.
 - Recommendation: DHS considers whether "informed" needs a clear standard definition.
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Principle 3 – Access for citizens & patients

- The right for Citizens & Patients (including authorised family) to access their health and care Records created by health and care providers (whether paper and/or electronic) free of charge.
- Recommendation: DHS considers how Principle 2 may apply to private health and care providers or insurance based systems.

Principle 4 – Control of the Record

- The right for Citizens and Patients to control access to their Record by anyone including health and care professionals who will need consent to access the Record.
- Right for health and care professionals to access a Record in an emergency to treat a Patient.
- Recommendation: DHS should clarify the extent to which "implied consent" should apply, if at all, for the treatment of Patients and the provision of care services to Citizens.

Principle 5 – Communication and transparency

- The benefits of health data both for individuals and society need to be clearly and regularly communicated to all Citizens and health and care workers.
 - The use of data by health and care providers, researchers and public health organisations need to be clearly explained to Citizens and Patients.
 - There should be ongoing education and training for health and care workers and information for Citizens and Patients on the use and benefits of data and Records as well as information governance and compliance.
 - Improved communication, knowledge and transparency will assist obtaining lawful consents especially for GDPR purposes.
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Principle 6 – Research Consent

- All use of Patient or Citizen identifiable health and care data requires explicit consent .
- The use of anonymised data does not require consent.
- Recommendation: DHS considers whether Citizens and Patients should be able to sell access to their Record if they wish.

Principle 7 – Research uses

- Do not use personal confidential information unless it is absolutely necessary.
- Use the minimum necessary personal information.
- All use of identifiable personal health and care data requires consent.
- When research is completed publish simple summaries for Patients and Citizens to show how their data was used and the benefits the research achieved.

Principle 8 – Duty to share health and care data.

- Maximise use of the Record for the treatment of Patients or the provision of care services to Citizens.
 - Health and Care workers have a duty to share information in the Record where appropriate for treatment of Patients or the provision of care to Citizens. This duty can be as important as the duty to protect Patient and Citizen confidentiality.
 - Recommendation: DHS considers what guidelines are needed to permit the sharing of data in the Record by Health and Care workers. Allow/require clinicians to share if it is in their judgement in the patients best interest to do so?
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Principle 9 – Safe havens

- Accredited Safe Havens should be established for cross border European population based research and statistical analysis, audit and service improvement.
- Safe Havens might be national health and care organisations or research institutions.
- Safe Havens could be used for data donations by Patients and Citizens.
- Recommendation: DHS considers technical solutions for Safe Havens such as federated data bases where data never leaves national data bases or cloud solutions.

Conclusions

- It is important to remember the Terms of Reference where to utilise existing work and the Principles draw heavily from the UK Electronic Patients Records (Continuity of Care) Bill 2013 and the Caldicott Principles.
- The Principles will need to be reviewed against the work of the other 3 Task Forces to see if they need revising.
- The Principles are intended to be high level and to form the basis of more detailed work in order to create a coherent proposal for a European Health and Care Data Convention.
- Use should be made of relevant EU work (e.g. definition of patient summaries/eprescribing) and other organisations such as WHO.

Bleddyn Rees
