medConfidential comments on the "Governance and regulatory requirements for decision supporting and *making* software in the NHS and Adult Social Care"

medConfidential is disappointed that the [guidance](#) was published without any opportunity to comment or a meaningful consultation. It contains a number of mistakes as a result, which were clearly not picked up by the "industry and academic partners" who the document acknowledges helped write the rules published under the MHRA/DH/NHSD/HRA logos:

> "We are grateful to the Wellcome Trust for developing the checklist below in consultation with industry and academic partners." (page 5)

The checklist encourages an uninformed free-for-all around patient data with questions that solicit techbro platitudes rather than a demonstrable understanding of patient data - as we show in the Annex. For an alternate view of the checklist, the forthcoming update[1] to the Open Data Institute's Data Ethics Canvas may be a useful comparator.

The guidance entirely fails to recognise that the "purpose of this document" to build **"decision making software applications, or devices incorporating such technology"** (page 3) is in practice a multi-step process, which, for example, should demonstrate predictability based on past cases (which can be properly anonymised in line with the ICO code), before it moves to higher sensitivity data.

The document goes on to say:

> "When sharing data about patients, you need to ensure that you are doing so on the correct legal basis.
> The new national data opt-out, effective from May 2018, **allows patients to say if they do not want their identifiable data to be used beyond their direct care**. The opt-out does not apply to data that is anonymised in line with ICO's Code of Practice on Anonymisation"

Was it a deliberate inference that the opt out only applies to 'identifiable data'? Is that what the opt out will actually say? We note that this document was the first formal statement that the new national data opt-out does not start in practice until May 2018.

The FAQ asks:
> "Is there a presumption against sharing data for research?
> No. Guidance makes the point (the seventh Caldicott principle) that the duty to share information can be as important as the duty to protect patient confidentiality"

medConfidential is unclear why document seeks to equate data for the development of a decision making AI with provision of direct care. This question seems as carelessly worded as other areas of the document, and is entirely inconsistent with the guidance on page 4 around CAG.

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[1] As of February 2018

This document would benefit from a fundamental rewrite, likely with some exemplars, and clear signposting about when it is necessary to use patient identifiable information, and the steps that must have been completed in order to demonstrate "necessity"; and also the other work that does not require patient identifiable data - which, in the first instance, may be a vast amount of "decision supporting" software. All likely decision "making" software should be "decision supporting" software in the first instance, despite any consequence that may have for take up of press releases or interest from profit seeking entities.

Patients should come before the interests of the AI companies.

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