Draft: A modern Disease Register?

If they were to be commenced today, no one would expect the disease registers to look like they currently do.

The disease registers often get undeservedly forgotten. They are an important, if underutilised, resource to allow legitimate research from the perspective of the condition, not the hospital. The contain data on (almost) everyone who has had a particular disease - cancer, or diabetes, or many other conditions. This is a good overview as it was in 2002.

All too often, they are a backwater of the data culture because of the way they have evolved - to help a condition, or a temporary priority, rather than part of a designed whole. They have good intent, but it is far from clear whether every disease register is fulfilling their legal obligations around fair processing and consent any better than the NHS was before care.data. The luxury of inconspicuity is unlikely to last, although sitting outside the HSCIC and HES framework seemed like an entirely wise decision in 2014.

Times change, and as a comprehensive consent offer to patients comes into operation, the disease registers can benefit from being part of that. Previously, such a change would have required extra effort across the NHS; now, it will require extra effort for them to remain outside the NHS-wide consent cleanup that the Caldicott Review requires. The choice is theirs.

If the disease registers wish to have their own opt out, they must still follow the law, and also meet the transparency and consent standards of the rest of the NHS. Outside of the framework proposed by Dame Fiona, there will be no support, resource, or incentives for NHS care bodies to assist. Yet again, the registries will be neglected, and they can not succeed at fair processing alone. More problematically for their mission, it will become extremely difficult for them to merge back into the mainstream of the NHS data landscape, as linking data between the registers and other NHS data will get increasingly difficult, as NHS data requires a properly consented model, and the registers are covered by a different kind. Merging those two is not going to be a trivial act, and one which will also require systematic change on the part of the NHS, which while necessary now, it is unlikely to wish to perform a second time.

Patients should not have to learn how the NHS works. If the disease registers do wish their own opt out, as the Review has offered, then the opt out for them must be offered on the same basis and process as for the rest of the NHS. Patients will wonder why it is a separate box, but there will be a significant loss of trust if it is required to be a separate process and an entirely different form.[1] Confidence is not inspired by first requiring patients to learn how the bureaucracy separates itself out.

[1] Had this been considered for care.data, medconfidential would simply have added the disease registers to the opt out form that we produced, which ended up being used by 1.2 million people. While the material difference in opt out counts would likely have been negligible, the damage to public confidence would have been far more significant.

Having the disease registers under the broad NHS opt out brings them fully into the NHS family. They are each a type of deep expertise in their chosen fields, covering data for a condition. The disease registers deserve to be a first class data pool for research, not silos of subsets of data copied into corners and barely acknowledged.

What should a modern Disease Register look like?

A modern disease register should be a centre of knowledge and data for the relevant topic. It should have access to all data within the NHS that has not been dissented from linkage and sharing, with a commitment to transparency on projects and outputs, be they academic publications, new treatments, or cures.

Broader research access to linked data will require the use of safe settings for the analysis,[2] as there should be no expectation that the data is "safe" to release, or anonymised in any way, beyond basic pseudonymisation.

The need for accurate denominators

For some conditions, there is a legitimate need for accurate denominators to establish prevalence and calculate confidence intervals (including the effect of dissent) - in short, to calculate accurate population pyramids for the broad sub-populations, which was a primary reason for exclusion from the Caldicott Consent model.

While this may be a superficial argument in favour of a "collect it all" strategy, it is flawed by the fact that such data is already collected by other means to produce official statistics. As an example, data on tumours is collected by ONS for the Vital Statistics, and such data should be the basis for the sub-populations (which also simplifies analysis by ensuring all population bases are synchronised). This may require harmonisation of definitions, or the production of additional entries in the Vital Statistics, rather than simply entirely ignoring their existence.

A mandatory notification of a description of the tumour, but not the medical history of the patient, via the existing tight ONS legislative framework mandating publication, does not raise novel privacy concerns.[3] Requiring non-consented data for the Vital Statistics only also resolves the issue of the HSCIC mixing consented and non-consented purposes within the same flows - the separation is robust, standard, and used across Government for a variety of reasons.

A high quality culture of disease registers is possible with consented data, if there is a willingness to deliver it for the research community.

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[2] http://www.bmj.com/content/354/bmj.i3636 and responses

[3] There will need to be a discussion of the content of the mandatory notification, however the principle already stands for notifiable diseases and food poisoning, etc.

A test of Confidence in NHS Consent

In a fully Caldicott Compliant world, all data used for research would be consented, and it should all be linked and available to the disease registries. Doing anything else would be a failure of vision at this opportunity for change - the NHS has to upgrade its consent model, and the disease registries can take their rightful place at the same time. Whether they wish to take this opportunity or not is up to them.

The disease registry community has been given the option of excluding itself from the broad opt out that Dame Fiona proposed. Whether it chooses to take it or not says relatively little about the disease registers themselves, but it says a great deal about the registry's perception of the offer that DH is making to the public. The registries have been offered the escape route of creating their own opt out and fair processing methods. But, if they choose to take it, if they do not have confidence in the NHS and the Department, then we have to ask: if the disease experts don't trust the DH offer, why should anyone else?

medConfidential
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