medConfidential response to the Blood spot screening consultation on lowering standards

Summary

The use of blood spot samples for purposes beyond direct care is currently neither consensual nor transparent; and this consultation proposes to reduce the safety and integrity of the sample/data handling below reasonable levels.

This consultation does not reflect the spirit, principles or practice of the recent Caldicott Review, for an area that requires the broad consent of the public. As part of any legal changes from that process, the legal basis for the use of blood spot samples should be made explicit and specific.

Responding to this consultation, PHE must state that the next iteration will uphold the Caldicott guidance in its entirety, and should also do so in practice as soon as is possible.

Consent

While verbal consent is acceptable for direct care purposes - the testing for particular conditions - the consent that is requested is extremely broad.

Blood spots are used in a wide range of areas, including research.[1] The scope for use and reuse of “residual blood spots” has changed dramatically over the last few years, and the rules and governance has not kept pace.

It is unreasonable to expect for a fully informed consent decision about secondary uses of a blood spot to be made at the current time and manner, and to rely on verbal consent for such a wide range of secondary uses. Given the interest from researchers in using blood spots for purposes beyond direct care, this must be addressed. It may be that the broad secondary uses dissent choice for this case is inherited from the mother, rather than reflecting the newborn baby (which will not have made any choices as yet[2]).

In 2014, the Information Standards Board expressed concern over the neonatal consent leaflet for national collection:[3]

> 5.3 Upon examination of the outstanding risks and issues concern was expressed at the lack of clarity about information governance and patient consent, e.g. the suitability of the patient consent leaflet; the length of data retention within the

[1] http://www.farrinstitute.org/centre/London/117_Discovery.html

[2] Given the long term nature of reuse, it may be that the spots, and data derived from them, may be subject to re-consent when the individual reaches 16; alternatively, following the Calidcott model may be significantly simpler. Taking blood spots for direct care, sequencing the DNA, and deriving that into a wide set of secondary uses is unlikely to be appropriate or receive public acceptance, and may clearly undermine many claims from PHE in other aspects of their work.

[3] http://webarchive.nationalarchives.gov.uk/+/http://www.isb.nhs.uk/about/meetings/2013/isbmins1310.pdf

neonatal unit; the basis of section 251 approval provided by the Confidentiality Advisory Group (CAG)

The use of leaflets alone has since proved especially troublesome for care.data.

Given no meaningful action has been taken, the opportunity of broader changes following the Caldicott Review of Consent should be utilised. The legal basis for indefinite retention and secondary use of (genetic) data that is collected for direct care should be explicit. The legal basis for dissemination of such data should be clearly defined.

Safety

Laboratories should continue to be accredited within these standards. That the standard is identical to the code of practice is not a concern. However, the enforcement of these standards is simpler and higher than the enforcement, or otherwise, of a Code of Practice. If the laboratories do not wish duplication, despite it not being extra work, the Code of Practice should simply refer to these standards due to enforcement and measurement.

Commercial pressures on the laboratories will lead to potential risks, as has been seen elsewhere.[4] Given the interest and scope of this data, a "handbook" is insufficient, and the application of good practice must be mandated, inspected, and enforced.

Transparency

The secondary use of samples, must be transparent to the responsible guardian of the patient for whom they are taken, especially as regards commercial use of such samples or data based thereon.

Commercial use?

In 2005, the Newborn Screening Guidelines explicitly said commercial use was barred. The 2013 Amended Guidelines removed that statement. This 2016 Amendment broadens who can do the testing and some degree of oversight, if the testing sites need no longer be accredited. The implications of this continual reduction in accountability are of concern.

Public Health England should, as a matter of urgency clarify the state of commercial reuse of this data. With the proposed abolition of a rigorous and enforceable inspection regime, these issues are likely to interact badly in the public perception.

[4] https://en.wikipedia.org/wiki/Theranos

Other notes

- Information from Standard 3 should be published as formal statistics about the care providers from which samples are received.

medConfidential
September 2016
coordinator@medconfidential.org

About medConfidential

medConfidential is an independent non-partisan organisation campaigning for confidentiality and consent in health and social care, which seeks to ensure that every flow of data into, across and out of the NHS and care system is *consensual, safe and transparent*.

Founded in January 2013, medConfidential works with patients and medics, service users and care professionals; draws advice from a network of experts in the fields of health informatics, computer security, law/ethics and privacy; and believes there need be no conflict between good research, good ethics and good medical care.

-ends-