Response to the Consultation:
NHS Newborn Blood Spot Screening Programme 2017-18

About defenddigitalme

Defenddigitalme is a volunteer non-profit campaign group for children's privacy rights formed in 2015 in response to concerns from parents and privacy advocates about increasingly invasive uses of children's personal data. More information: http://defenddigitalme.com/

Summary

1. As 2005 guidelines[1] said, '*research and surveillance based on residual newborn blood spots has answered important public health questions and led to advances in antenatal and newborn screening which are to the benefit of children and their families. It is important to enable this to continue.'*

2. However current poor consent practices around newborn screening jeopardise Public Health research and population-wide good healthcare with it. The recent consultation, *New data security standards and opt-out models for health and social care*, is an opportunity to get flaws fixed and get future models of practice right across health in England. Whether this consultation, Newborn Blood Spot Screening Programme 2017-18, is taking that into account or running separately and in parallel is unclear.

3. Future plans for use of population wide healthcare data, are both intended to benefit direct population health and the British economy and a new children's digital health strategy[2] plays a significant role.

4. As care.data showed, to date only 2% were sufficiently informed and concerned that their health data are being used commercially, or are insufficiently secure, or for their own reasons have opted out of primary care data collection. How much more sensitive would the public be to find their newborn babies' data being used without their consent?

5. A national consent programme well managed, in line with the March 2013 Information Governance Review[3] *Information: To share or not to share?* will enable secure, trusted use of direct care, and secure stable continued use in public interest research. Consent must be informed, affirmative and consensual with the opportunity to change one's mind. This is supported by the Caldicott recommendation: *"You only have to state your preference once, and it will be applied across the health and social care system. You can change your mind, and this new preference will be honoured."*

6. Public Health England and NHS England must get consent models right to ensure direct care comes first. Secondary uses should be that, secondary, in all our policies and practice, and ensure third-party use is not compulsory and clearly separated. Any other model of consent, which continues the poor practices in newborn screening or school health collection (NCMP), or would propose to revoke the 2014 care.data opt out, would be calamitous for public trust[4]. The outcome of this consultation will determine how well or how badly the public and professionals will perceive the State's promise keeping, trustworthiness, and any plans for future uses of our data.

7. This consultation must therefore logically also respect the recommendations of the Caldicott review.

8. The autonomy of new mothers and the rights of our children are removed at birth and we never even know about it, never mind get asked. This is inadequate as the foundation of any children's digital health strategy, and needs replaced with an ethical based consent model with built-in opt out of secondary uses.

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[1] http://jenpersson.com/wp-content/uploads/2016/09/Code_of_Practice_for_the_Retention_and_Storage_of_Residual_Spots_2005.pdf

[2] https://www.england.nhs.uk/digitaltechnology/info-revolution/digital-primary-care/child-health/

[3] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

[4] Royal Statistical Society Data Trust Deficit with Lessons for Policymakers https://www.statslife.org.uk/news/1672-new-rss-research-finds-data-trust-deficit-with-lessons-for-policymakers

The 2016 Caldicott consultation: New data security standards and opt-out

9. The outcome of the broad NHS consultation[5] will affect what happens to our children's data in perpetuity. Once data are handed over it's impossible to get back after it's been copied, passed on, linked, or used by third parties.

10. The 2016 Review recommended (11) "*There should be a new consent/opt-out model to allow people to opt out of their personal confidential data being used for purposes beyond their direct care. This would apply unless there is a mandatory legal requirement or an overriding public interest.*"

11. While this wording is open to interpretation public trust will continue to be insecure. There must be a statutory footing for opt out, and it must be possible to opt out of any use that is not anonymous public interest research in safe settings. We support the principle that truly anonymised data need not have consent for sharing. However, conflating anonymous with deidentified and pseudonymous data gives the feeling 'how much can they get away with and be legal' and is not enough to safeguard public trust.

Case study: NHS Newborn Blood Spot Screening Programme

12. As the consultation on 'new consent' asks questions on consent and this screening consultation runs in parallel[6], we ask are they joined up? Public trust depends on truthful communication and consistency. It is untenable for one position and policy to support patients yet another in practice does the opposite. What kind of foundation is that to build upon for public and professional trust?

13. It is collected based on 'verbal consent' (pp9 table 1.4).[7] New plans 1a and 1b do not intend to improve this model.[8] As consent goes, it is meaningless because you can't choose to not have the secondary uses from your direct care tests. Meaningless because you don't have any written explanation of what will be done who will use the results or the sample and for what purposes beyond direct care, or any chance to revoke it with future reference contact information or a mechanism to do so. Meaningless because as a new mother, you say yes to everything and have little clue what a heel prick test is, or what secondary uses are, or what genomics research could use the bodily material and personal data for in perpetuity.

14. The only choice parents have is to opt out of being *contacted* about research, but secondary uses are compulsorily wrapped into a blanket package of consent if you say yes to the newborn health checks.

15. We must continue to secure the importance of these tests and public trust in them, because for the wellbeing of individuals and society, the dozen or so treatable conditions need to be acted on quickly. However, these data are not being collected and processed properly today.

16. There is limited information and documentation for newborn parents seem to have vanished on .gov sites. Hospital websites[9] like this, point here[10], but there is no booklet *Screening tests for you and your Baby* to be found. The NICE guidelines[11] link in the July 2016 MCDS specification[12] is 'not found'.

17. What happens to the samples and data? We understand that data fed into CHIS, the Child Information System, for example, from last November 2015, the part of care.data that *did* go ahead; The Maternity and Child Dataset (MCDS)[13]. The MCDS consists of 3 sub datasets. One of which contains the heel prick test results and sends the data flows from collection to the Health and Social Care Information

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[5] https://consultations.dh.gov.uk/information/ndg-review-of-data-security-consent-and-opt-outs/consult_view

[6] http://jenpersson.com/wp-content/uploads/2016/09/Revised_NBS_standards_for_consultation_220816.pdf

[7] http://jenpersson.com/wp-content/uploads/2016/09/Guidelines_for_Newborn_Blood_Spot_Sampling_January_2016.pdf

[8] http://jenpersson.com/wp-content/uploads/2016/09/Revised_NBS_standards_for_consultation_220816.pdf Standard 1a & 1b pp13-15

[9] http://www.gosh.nhs.uk/health-professionals/clinical-guidelines/newborn-blood-spot-screening

[10] https://www.gov.uk/government/collections/newborn-blood-spot-screening-programme-supporting-publications

[11] https://www.nice.org.uk/nicemedia/live/11837/36275/36275.pdf

[12] http://jenpersson.com/wp-content/uploads/2016/09/Maternity_Services_Data_Set_User_Guidance.pdf

[13] http://jenpersson.com/wp-content/uploads/2016/09/Maternity_Services_Data_Set_Data_Model_v1.5.pdf

centre national databases, now called NHS Digital, the arms length body that stores and manages the distribution and use of all these sensitive confidential data. This is not explained in any consent process.

18. NHS Digital has a document[14] on their site which appears to contradict the national screening staff handbooks and comments on parent communications. Mothers can, it says, object to secondary uses of data. How are these discrepancies to be rectified? Public Health England must ensure this is communicated and choice given.

19. In 2013 the ISCG felt there were problems to resolve, that *"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 neonatal unit; the basis of section 251 approval provided by the Confidentiality Advisory Group (CAG)".*

20. In 2012 the new guidelines for staff [section 4[15]] were changed and compared with the 2005 guidelines[16], Newborn blood spot screening in the UK – Policies and standards, April 2005 ISBN 0955013801 – the no commercial use statement that "newborn screening laboratories may not sell, or grant exclusive access to, residual newborn blood spots to commercial organisations", had been removed.

21. Children are not State commodities. This must be respected. Children's consent models must be revisited at Public Health England today. Their use and ethical practices must become properly embedded.

The Views of Young People on use of their Health data

22. Measures of public acceptance for data use in bona fide academic research in the public interest, and differences in the levels of trust that people attribute to different settings and organisations, were made in The Royal Statistical Society's Data Trust Deficit, with Lessons for Policy Makers (2014). This included views from people aged 16-75 on the use of their personal data in datasets within government. These findings were similar to those from the ESRC Public Dialogues on Using Administrative Data in 2013[17]; and young people, age 14-19 asked in 2010 by The Royal Academy of Engineering (Paterson, L. and Grant, L. eds., Privacy and Prejudice). Few have high trust that government has their best interests at heart using personal data. This improves for anonymous data (statistics) and non-commercial use.

23. Young people asked in the 2010 study conducted by The Royal Academy of Engineering (Paterson, L. and Grant, L. (eds) supported by three Research Councils and Wellcome, discussed attitudes towards the use of medical records. Questions centred on privacy, and data getting into 'the wrong hands'.

24. The report concluded: *"These questions and concerns must be addressed by policy makers, regulators, developers and engineers before progressing with the design, development and implementation of EPR record keeping systems and the linking of any databases."(p40)*[18]

25. Trust in use of their confidential health data was affected by understanding data security, anonymisation, having autonomy and control, knowing who will have access, maintaining records accuracy, how will people be kept informed of changes, who will maintain and regulate the database, and how people will be protected from prejudice and discrimination [through use of their data].

26. Our children repeatedly express the wish to have consent and control over their personal data. They also have the right to have data used well and safely to benefit them as a member of society that will experience scientific breakthroughs we cannot predict. This must be balanced with respect of their dignity, and rights, and needs to protect their future digital identity and autonomy from decisions made beyond their control, by people who may not have to live with the consequences as our children will.

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[14] http://jenpersson.com/wp-content/uploads/2016/09/Patient_Information_Leaflet_for_Mothers.pdf

[15] http://jenpersson.com/wp-content/uploads/2016/09/Health_Professional_Handbook_2012_v1.0_December_2012.pdf

[16] http://jenpersson.com/wp-content/uploads/2016/09/Code_of_Practice_for_the_Retention_and_Storage_of_Residual_Spots_2005.pdf

[17] http://www.esrc.ac.uk/public-engagement/public-dialogues/public-dialogues-on-using-administrative-data/

[18] http://jenpersson.com/wp-content/uploads/2016/08/Privacy_and_Prejudice.pdf

27. Separation of purposes by being able to differentiate between uses should be clear what kind of data is being used and for what. All secondary uses of data at the HSCIC should be covered under opt out 9Nu4 How is this being communicated to new parents effectively, and so that they can change their mind?

28. The current blanket consent to secondary uses under the guise of direct care purposes is untenable.

Legislation - anonymisation, and the right to revoke consent

29. The lack of distinct clarity using the term anonymised[19] inappropriately to mean deidentitied or pseudonymous data is important if you are to respect the EUGDPR and consent. While 'research' and 'economic interest' are open ended, these programmes using data are only done so with population wide and professional support, regardless of legislation. What the public understand may be legal may still be seen to be wrong. The responsibility to do the right thing and respect individuals rights cannot rely on legislation alone but must also underpin the underlying principles and common purpose of their intent.

30. The General Data Protection Regulation is explicit that pseudonymised data are identifiable and that all data not truly anonymous under the GDPR will need to have active consent for secondary purposes, especially from children. The GDPR reiterates the fundamental freedoms of the Charter of Fundamental Rights[20], and requires accountability and adequacy of data protection aligned with those Principles. The requirements for collection of children's data for processing by third parties and particularly with predictive scoring and stratification, may well not be met in screening and school health data collections.

31. The consent document should be laid out in simple terms. Silence or inactivity does not constitute consent; clear and affirmative consent to the processing of private data must be provided, it should not be open-ended or be a blanket consent to cover future processing.

32. Article 7(3) of the GDPR gives data subjects the right to withdraw consent at any time and "*it shall be as easy to withdraw consent as to give it."*

33. The Caldicott 2016, recommendation supports this principle and should therefore be implemented in any new model: *You only have to state your preference once, and it will be applied across the health and social care system. You can change your mind, and this new preference will be honoured.* This right to revoke consent whether it is identifiable or pseudonymous of anonymous, is important but cannot stand alone as a right, it must also be possible to enact.

34. It is currently impossible to revoke consent of the use of patient level data in NHS Digital databases, such as the Bloodspot screening or National Child Measurement Programme, not only technically, but in practice, as most people whose children's data are stored, do not know it exists at all at national level.

35. Providing the public ways to access copies of their own data (Subject Access Request) are needed to meet current legislation[21] and the publication of Transparency Registers or personal reports (showing how data have been used) can also demonstrate how data are used and promote the public benefit derived from that use. Academic public interest applications for data used in safe settings are published from some research organisations (For example, the Administrative Data Research Network (ADRN).[22]

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[19] http://ukanon.net/ukan-resources/ukan-decision-making-framework/

[20] http://www.europarl.europa.eu/charter/pdf/text_en.pdf Article 8 (2) Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

[21] http://www.legislation.gov.uk/ukpga/1998/29/contents

[22] https://adrn.ac.uk/research-projects/approved-projects/

Conclusion

36. The new children's digital health strategy[23] says "we must think differently."

37. Doing this in an approach towards children's health data at Public Health England must be transparent and honest. The consent and communication issues of the ISCG in 2013 *"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 neonatal unit,"* have not gone away and have not been resolved.

38. For collection a consensual, trusted relationship needs built between data subjects and controllers, the public and the State, to ensure the reliable flow of quality data available for public interest research.

39. For uses across the data spectrum to best serve our public interest needs, then consistent legal, safe and transparent policy and practice are needed across the data infrastructure, underpinned by accountability.

40. Scrapping accreditation of the processing, storage and retention at providers would seem a step that has potential to reduce trust and accountability in the collection system and infrastructure. We suggest this infrastructure must be publicly accountable, have transparent and accessible safety and data security processes and operate for non-profit from the handling, storage and management of babies bodily material and individual level data.

41. Policy must support a strong, simple and trusted consent model. The EUGDPR is enforceable in 2018. Recent data handing in the UK has taken a short-term approach in political policy, focussed on economic gain and based on outdated technology and attitudes to consent. The question is whether there is sufficient vision to manage citizens' data for the long-term. Policy must look beyond meeting the minimum 2018 legal requirements and instead look at why data should be managed to take future technologies and children's digital identities into account. Aiming for second rate solutions that are simply legal, is not good enough to safeguard children with the best solutions which are right.

42. A consent model that enables people to refuse secondary uses separately from direct care, to deny commercial exploitation but say yes to public interest scientific and academic research, will be meaningful.

43. The consultation offers an opportunity for change, to better secure both our children's future underpinned with practices that meet public expectation, as well as administrative datasets' access for public interest.

25th September 2016

[23] https://www.england.nhs.uk/digitaltechnology/wp-content/uploads/sites/31/2015/12/CHIS-Digital-Strategy-2016-v6-FS-edit-with-alt-txt-2.pdf