Introduction

1. The Medical Research Council (MRC) is one of the main agencies through which the UK Government supports biomedical and clinical research. It is dedicated to improving human health through the best scientific research. The MRC's work ranges from molecular level science to public health medicine and has led to pioneering discoveries in our understanding of the human body and the diseases which affect us all. This submission aims to address the areas within the consultation document which are directly related to the work of the MRC

2. The MRC is supportive of the Scottish Government's ambition to establish a framework for administrative data linkage that will facilitate research in an environment that safeguards the rights and confidentiality of patients and the public. The overarching aims of the Scottish Framework have the appropriate balance of maintaining privacy and utilising data for research that will result in public and patient good.

3. Unprecedented opportunities exist to utilise the wealth of administrative data and research data in the UK to develop more effective and targeted treatments, rapidly detect risks to public health, improve drug safety and audit of health services, and identify mechanisms of causes of diseases and conditions.

4. Scotland has an international reputation for conducting research linking medical data. Good examples include research linking the Scottish diabetes patients register to hospital admissions data to ensure patients are being correctly identified and treated, and cost effective follow up of patients who participated in a large trial of cholesterol lowering drugs, for long-term monitoring of drug efficacy and safety.

5. The MRC plays a leading role in supporting research in methodological development, longitudinal cohort studies and record linkage in Scotland and elsewhere in the UK involving Scottish participants via investment in MRC units, centres, hubs, and cohorts, such as UK Biobank and individual grants including through our needs-led programme.

6. In recognition of the vast research opportunities offered by electronic data linkage, the MRC is leading a £15m 10 funding partner call to establish centres of excellence in e-health research informatics across the UK. Applications are currently under review. The aim of the centres will be to:

    - Carry out high quality cutting-edge research using electronic health records
    - Undertake innovative data linkage and methodological development involving large health-related data sets
    - Build capacity in electronic health informatics research in the UK.

    The Centres will be networked to increase their translational impact and reach including providing advice and training on data linkage to the wider research community, public engagement and providing an interface for industry, policy-makers and the NHS.

7. CONSULTATION QUESTIONS

Are you responding *primarily* as a data custodian, data user or data subject? *(We recognise all people are data subjects and many organisations act as data guardians and data users, but please tick only one box)*

Data Custodian ☐

Data User (e.g. researcher) ☐

Data Subject (e.g. member of the public or group representing citizens) ☐

1. Are there any benefits of data linkage for statistical and research purposes that are not sufficiently described here?

Yes, there are further benefits ☐ No, the benefits are described fully X

If you ticked 'yes', please describe the further benefits of data linkage for statistical and research purposes.

Comments

2. Are there challenges or barriers preventing more effective and efficient data linkages for statistical and research purposes taking place that are not sufficiently described here?

Yes, there are further challenges X No, the challenges have been identified ☐

If you ticked 'yes', please describe the challenges or barriers.

- As well as being time-consuming a complex framework can also increase the cost of research due to extra and possible unnecessary steps to address concerns about data sharing and linkage.

- The legal and governance environment is currently changing in England and this will have impact on cross-border research. Examples include access to the ONS and other central registries in England via NHS Information Centre, changes to National Information Governance Board and the current Caldicott review. The new EU Data Protection Regulation currently under consideration will also have direct impact on research involving personal data in Scotland.

3. Are the guiding principles sufficient and appropriate? Please explain your answer fully and make suggestions for improvement.

Yes, they are sufficient and appropriate ☐ No, they are not X

Please explain your answer fully and make suggestions for improvement.

A general comment is that the principles are all reasonable, however in places they read more like a set of detailed requirements rather than a set of guiding principles. Ideally the principles should leave more latitude for proportionality rather than be too detailed and prescriptive.

Specific comments
Principle 9 - as written this reflects the current situation but highlights that by involving multiple overseers there may be a risk of conflicting requirements, delays and duplications. The principle should be extended from simultaneous oversight to combined oversight.

Principle 16 - Storage of linked data sets. It is important that this is worded in such a way so it doesn't promote the assumption that datasets derived from data linkage should be destroyed, as could be interpreted as currently written. Sharing of data derived from linkage should be on the same terms (according to risks and benefits) as unlinked data.

Removal of names and direct identifiers
A direct identifier definition would help here as de-identifying a dataset is complex. Obvious identifiers can be stripped out but this doesn't render a dataset unidentifiable. Content and context are important. The risk of re-identification is great if the dataset is not truly anonymous. Given this, not attempting to identify should be the overriding point in this section.

Principle 18 - Clarity is needed about the role of the data controller versus the Caldicott Guardian. Also clarification between personal data and identifiable data is needed. A coded dataset can be personal data if the data controller has access to the code. In the future the definition of personal data could potentially expand with the new EU Data Protection Regulation to include all linked anonymised datasets, regardless of who holds the code.

Principle 20 - For linkage via safe havens or other approaches resulting in anonymised data, there should be consideration of the nature of consent required and whether these options such as opt-out or an opt-in for a wider range of purposes might be appropriate. Explicit consent can be interpreted very narrowly.

Principle 21 - The Data Protection Act requires fair processing so people should be informed about what data held about them and what may be done with their data, not only where this is possible.

Principle 23 - There is a question as to whether an appropriate body can authorise use of data without consent as this conflicts with the Data Protection Act. It would be clearer if this was about setting aside the duty of confidence as permitted in Scotland by approval from a Caldicott Guardian.

Determining how appropriate the security measures are in a new system is likely to incur another set of approvals, as is the case for England, where system level security policies are approved and organisations are required to satisfactorily complete the IG Tool Kit before data access.

Principle 30 - The vetting and approval of researchers should be a joined up system to avoid repeated scrutiny of the same team once suitability has been established.

Principle 36 - Improved data linkage is likely to increase the need for re-contact of individuals who have participated in a clinical trial. This guiding principle is very strict and may limit future research if it strictly stipulates that no re-contact is permitted if no prior consent to be contacted was obtained.

4a. Are the objectives set out for a Privacy Advisory Service in Section 3c the right ones?

Yes, the objectives are right X No, they are not ☐

Please explain your answer fully and make suggestions for improvement.

Clarity about the role of the Service is important – would it be to facilitate research through advice or would it function to provide approvals? The role of an additional approvals body would need to be very clear and it would need not to be overly bureaucratic.

A Privacy Advisory Service could be very helpful if its purpose was to support risk-based, proportionate good practice, delivered by experts with the aim of advising and facilitate researchers. It would be less helpful if is was a service about form-filling and box-ticking. A wide range of expertise and skills would be needed to deliver all of the proposed functions and this would need to be well co-ordinated.

4b. Do you wish to be consulted on firmer proposals for a Privacy Advisory service as and when they are developed?

Yes X No ☐

5a. Are the functions that will be led by the National Data Linkage Centre set out in section 3d the right ones?

Yes, they are the right functions ☐ No, they are not ☐

Please explain your answer fully and make suggestions for improvement.

An emphasis on coordination of all bodies involved in the Centre is essential so as to avoid the pitfalls of multiple organisations not being joined up eg access to national registries elsewhere in the UK. It would be important for the National Data Linkage Centre to contribute to, and be informed by, other UK leading data linkage centres including work to share technical standards and good practices. A harmonised approach to linking to other UK bodies is to be encouraged and pointing out similarities with other UK systems would give confidence that cross-border research is being facilitated.

5b. Do you wish to be consulted on firmer proposals for a National Data Linkage Centre as and when they are developed?

Yes X No ☐