

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 | <input checked="" type="checkbox"/> |
| Data User (e.g. researcher) | <input checked="" type="checkbox"/> |
| Data Subject (e.g. member of the public or group representing citizens) | <input type="checkbox"/> |

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

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

NHS National Services Scotland (NSS) welcomes the development of the National Data Linkage Framework; in particular the way in which it builds upon the Scottish Health Informatics Programme (SHIP) and NSS's current Privacy Advisory Committee arrangements.

The NSS Privacy Advisory Committee (PAC) is an advisory committee to the Board of NHS National Services Scotland (NSS) and to the Registrar General. The committee was originally set up as an independent body in 1990 to provide advice on requests for the release of patient identifiable information by the Information Services Division (ISD), or by the General Register Office for Scotland (GROS) now part of the National Records of Scotland (NRS).

PAC meets twice a year and has non-medical/NHS membership. At these meetings PAC members review recent applications and discuss matters of precedent and principle. Between meetings, routine work of the committee is by mail or email. PAC advises ISD and GROS on the correct balance between protecting personal data and making data available for research, audit and other important uses. It ensures that any information releases are carefully controlled. Further details, including membership, are available on the website :http://www.nhsnss.org/pages/corporate/about_pac.php

The framework is helpful in raising the visibility and potential benefits of record linkage at a national level and showing clear commitment to increasing capacity and capability at a Scottish level moving forward. The comments contained herein are intended to support the Data Linkage Framework and the subsequent further development of a Data Linkage Centre for Scotland of which NSS's ISD is a partner.

The Scottish Health Informatics Programme (SHIP) is a Scotland-wide

research collaboration that was established in 2008 to enhance the safe and secure collation, management, dissemination and analysis of electronic patient records for research. The programme brings together the Universities of Dundee, Edinburgh, Glasgow and St Andrews with ISD and was funded initially (2009-2013) by the Wellcome Trust, the Medical Research Council and the Economic and Social Research Council. SHIP aims to create a secure and efficient infrastructure for the linkage of health and relevant non-health records, which encourages research use while maintaining the highest standards of governance and data security. It supports a key strand of the Scottish Government's Research Strategy for health and care, which aims to deliver benefit, improve population health and keep Scotland at the international forefront of clinical translational research

NSS have been a key partner in the development of SHIP and contributed, in particular, to the development of secure methods for linking data and the Information Governance Guiding Principles. ISD will provide a national 'safe haven' for use by academics (and potentially other collaborators) to enable indexing, linkage and analysis of any dataset for which identifiers are known, whilst simultaneously protecting patient/participant confidentiality within a wider proportionate governance framework. We are pleased to see these contributions to SHIP reflected within the Data Linkage Framework.

We suggest that the benefits outlined in the document are valid. In particular, our experience (in ISD over the past 3 decades or more) of the use of linked data confirms the benefits 1, 2, 4, 5 and 6. However, we believe that there is an additional benefit of enabling linkage to plan health and care provision, monitor performance and undertake wider epidemiological work to protect the health of the population of Scotland. The consultation document states that the "framework is concerned exclusively with data linkage for research and statistical purposes" and we suggest that this might be seen as overly restrictive and not inclusive of all potentially beneficial data linkages.

NSS's uses linked data for many purposes which are neither research nor statistical. For example, by analysing linked datasets NSS now has an enhanced knowledge of the epidemiology of conditions, including:

- the demographics of those at risk (i.e. age, sex, geographical location, socioeconomic factors)
- the outcomes of these conditions for individuals
- the use of resources in managing these conditions
- risk markers (including other disease conditions which may increase risks of developing the conditions, or leading to worse outcomes)

PAC members also noted that the consultation does not extend to service development and audit. We suggest that it is this bigger picture view which a national approach should be striving towards. In particular, there are opportunities for:

- Ascertainment of people with particular diseases to give fully representative population-based data for research and audit.

- Validation of other large national datasets for clinical audit and epidemiological research.

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 No, the challenges have been identified

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

Members of the PAC feel that complexity and unnecessary regulatory burden are relatively well-understood, but what is less clear is how to proceed in a coordinated cross sector way. PAC has been coordinating efforts with Scottish A Research Ethics Committee (REC) to identify improved ways of working between the two bodies, but uncertainties remain about spheres of influence and competence as between PAC, RECs, Caldicott Guardians etc. The Scottish Health Informatics Programme (SHIP) provides a Good Governance Framework that represents a single statement of principles that a range of actors can agree to adopt and it is encouraging that the Scottish Data Linkage framework initiative builds on these principles. However, any new developments will need more governance to ensure coordinated and streamlined action across all governance entities.

We suggest that privacy risks should be identified separately as a challenging area which requires a dedicated workstream to build cross sector understandings and alliances. Linking data from different sources may lead to increased risk of identifying an individual and then revealing information previously unknown to the user, whether a legitimate user or a motivated intruder. Mitigation relies heavily on robust information security.

The Framework suggests that data linkage should only be undertaken on an ad-hoc basis for specific projects and this is in line with the SHIP proposals for academic uses of linked data. However, as noted in our response to Question 1, we suggest that there are legitimate and sound uses of linked data beyond research and statistics which require the regular linking and holding of data. There are precedents for this; for example, ISD has since the 1990's been routinely linking different hospital activity and GRO datasets to allow effective service planning and monitoring of performance, patient safety etc. This approach needs to be extended for data systems which span different organisations and sectors – where there are clear justifications for undertaking the linkage of data. The framework could be a route to support this innovative approach.

The document highlights the difficulty of the multiplicity of 'citizen' identifiers in use across Scotland, both within and across the different sectors. It should be noted that the use of personal identifiers such as the CHI (Community

Health Index) Number in Scotland must be in compliance with the Data Protection Act (DPA), and there is currently a requirement that the CHI Number must not be used as a prime identifier for other than health and social care related purposes. ISD's Indexing Service provides a potential solution to this by replacing the CHI number with a 'study number' which contains no personal identifiable information.

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

Please explain your answer fully and make suggestions for improvement.

PAC endorses and already employs a principled-approach to its deliberations. These are starting points for interaction and discussion within the Committee and a common framework within which to formulate advice. It represents a well-understood basis for PAC to assess applications and also for ISD/NRS to justify outcomes even where there is room for reasonable disagreement. We believe it is an appropriate system to adopt for any new initiative. The principles as outlined in the consultation seem more than adequate so long as decision-makers see them as tools to assist reflection and deliberation and not as some sort of pseudo-set of rules. Principles are not rules. Sensitive judgments in this area must be made and these must be defensible. Principles assist in this.

As we have stated above, we believe that any new initiative should be a system both of principled *and* proportionate governance. Proportionate governance identifies the most appropriate research governance pathway for each research application. It is principled in its design by building the principles into its fabric to assist decision-making and as a common framework of reference to discuss and decide whether linkages or access should take place. Thus principled proportionate governance engages the right people and the right principles at a timely and effective moment in the governance process and reduces regulatory burden without diluting appropriate scrutiny.

PAC has employed a principled approach to decision-making for a number of years, and its relevant principles are available on the website:

http://www.nhsnss.org/uploads/pac/090806_updated%20policy%20and%20principles.pdf

More recently, PAC has adopted the concept of proportionate governance as advanced in the Scottish Health Informatics Programme (SHIP) – these are similar to the principles contained in this consultation. PAC are developing a bespoke risk assessment mechanism to uncover the benefits and burdens of risks of each application and using this to determine *how* the principles might be deployed in any given situation to decide *whether* data linkage should take place and if so on which terms and conditions. This means, for example, that some low risk applications might not require full PAC scrutiny and could be dealt with by Chairman's action or on the basis of precedents identified from past experiences. With other applications deemed to be higher risk these will always receive full Committee scrutiny. We are currently developing risk-assessment mechanisms to allocate certain types of application to the most appropriate pathway.

PAC is not sure that a one-size-fits-all model is appropriate or proportionate to support the wide range of research and other uses of linked data in Scotland. PAC can envisage, and have received, applications where the case for data travel is well made. In such circumstances, PAC would expect applicants to demonstrate that this is both necessary and proportionate use of data and would always require full Committee scrutiny. Any new system that is designed must have these flexibilities and also be adaptable for change of future circumstance. Getting the principles right is the first crucial step.

In Principles 1 and 2 we suggest it may be helpful to avoid drawing a dichotomy between 'public interest in worthwhile research' and 'individual interests in privacy'. In reality this is a complex area and often 'the public interest' benefits an 'individual', while protection of 'individual' rights to privacy is in the 'public interest'. This is seen most obviously in relation to communicable diseases, which threaten whole communities if not adequately managed at an individual level, but it is also relevant to many aspects of the public health. Furthermore, the interest in privacy is not just an individual one, it is a public one. The public interest in adequate data for service planning is defeated if the data are insufficient due to failure to come forward for treatment due to privacy concerns. Indeed, experience shows that where privacy is adequately protected individuals have confidence coming forward for treatment of sensitive conditions.

Taking such a strategic step forward as described in the document provides the opportunity to eradicate this false dialectic, and put good research and the protection of privacy 'on the same page' viz both are worthwhile objectives that are ought to be pursued in pursuit of the public interest. One suggestion would be to recast both of these principles more simply as: 'The pursuit of scientifically sound and ethically robust research and the adequate protection of the privacy of individuals are both in the interest of the public.'

Principle 15: This, or relevant supporting information, should contain a clear statement about the extent and nature of Privacy Impact Assessments (PIAs) required; e.g. as part of a current cross sectoral data linkage work with which NSS is involved, a PIA of over 100 pages has been produced. By contrast, this is not the sort of PIA that has previously been required of academic researchers prior to granting access to de-identified linked data. NSS require researchers to conduct a PIA in the sense that they must minimise the number of potentially identifiable variables within the requested data extract, and where any potentially identifiable variables are included, a clear justification is given for their inclusion, i.e. the 'data minimisation' principle which is so core to privacy.

Principle 16: This needs to align better with the DPA Section 33 exemption which permits the indefinite retention of data (linked or otherwise) where it is for statistical and research purposes.

Principle 17: Researcher access to data containing identifiers must also be lawful (the principle only mentions 'justified' and 'risk assessed').

Principles 17-19: These do not highlight the particular challenge of indirectly identifying variables. These, referred to in NSS as 'potentially disclosive' are particularly challenging to risk-assess, and we suggest that they are at least alluded from within this particular set of principles.

Principle 20: This sets explicit consent as the standard 'where practicable' and this is an important caveat. It is often impossible to obtain explicit consent for the whole population involved in studies that use administrative data. In the Summary on pages 3-4, an example is given to illustrate the use of linkages. It might be seen as misleading as it is one that used consented data. Most of ISD's datasets do not have consent (opt-in), however, if the reader did not know that, he/she might think from reading the example in the summary that the consultation was about consented data (especially as many people might not read beyond the summary).

Principle 30: 'Vetting' is a verb which will have particular connotations for some, e.g. as in vetting as part of recruitment to certain security-sensitive public services. In relation to current research applicants to our linkage service, we seek evidence that they work for a reputable organisation, and are trained and authorised. We do not regard this as 'vetting', but equally, view it as a proportionate safeguard.

Principle 35: Clarity is needed on who will have the responsibility for setting out these responsibilities, e.g. the Clinical Trial lead, the relevant clinician(s) or the Data Controller whose data are to be used.

Principle 37: We would assume that the need for, and the type of MoU, will be shaped by the type of proposed data linkage.

Principles 37-40: Perhaps these could be reduced in number and reference made to ICO Data Sharing Code of Practice which should be highly influential in this area.

We note that the Steering Group for the development of the Data Linkage Centre does not appear to have any public involvement. The ICO is the regulator of the DPA, and not representative of the views of the public. This simply may be an omission from the document.

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.

Most public authorities already benefit from an advice service on these matters from information governance staff, Caldicott Guardians, legal advisors etc, employed for these purposes. NSS is a leader in this area, having had a Privacy Advisory Committee to refer to for advice on privacy and linkages of national health datasets for more than 20 years. We would envisage that NSS would be involved in developing firmer proposals for a Privacy Advisory Service, bringing experience from its Privacy Advisory Committee.

PAC would welcome more detail on how Scottish Government proposes to establish and maintain the Analytical Privacy Advisory Service. The word

'service' suggests more of a department/directorate and full-time body. This may require a dedicated Secretariat and some degree of management. The economic and transaction costs could be considerable and this is very different from the working practices in PAC.

In addition, we are unsure what is meant by 'Analytical' in the Service's title?

We suggest that creating an additional 'advice service' would likely only add value if it could also take some of the burden, rather than add in additional waiting time for an opinion. One means would be for all participating Data Controllers to agree to authorise the 'service' to make decisions on their behalf, by means of a binding agreement, with all the relevant standards and safeguards built in. To sign such an agreement, the public authorities would have to have a high degree of confidence in the 'service's' decision-making, as, in the current legal environment, they would retain the risks and be accountable for any poor decision-making which resulted in data breaches, hence the need for engagement.

Alternatively, it may be beneficial to consider a stronger legal mandate. As long as Data Controllorship, and therefore legal accountability for use of personal data for linkage purposes resides at the level of the public authorities, public authorities are free to seek their own advice and make their own decisions on the use of personal data. (And rightly so, as it is their Chief Executive who would be asked to pay any fines (of up to £0.5M) for any data breaches.)

By way of a postscript, note should be taken that the 'statutory' Committee for health and social care in England in this area, the Ethics and Confidentiality Committee, is not necessarily the only model for consideration. In particular, and again due to Data Controllorship residing at the level of public authorities, even when the ECC considers and 'approves' a proposal, this does not require the public authority to release data. It is simply a (hopefully reassuring) statement that the ECC believes all is well with a proposal, and it will hopefully be highly persuasive to encouraging a public authority to release. It is not however a mandate.

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

Yes No

NSS wish to be actively involved in supporting the development of a National Data Linkage Centre, consolidating and building upon our previous work in this area.

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.

However, PAC points out that there is a crucial advisory role that happens in current local arrangements prior to submissions to the committee. The Caldicott Guardian who works with PAC (and colleagues) provides a very important filter & feedback service to applicants before applications reach PAC. This not only results in higher quality applications, but also raises the chances of a successful outcome. The research coordinator in SHIP is envisaged to have a similar role, but it is not clear who will perform this for the Data Linkage Centre. We cannot stress enough how useful this is to all parties from our experience of PAC.

We suggest that further clarity is needed around how long or whether the Data Linkage Centre will hold all linked datasets. Perhaps a pragmatic response is to leave this decision to the data controllers as part of their deliberations during the decision to link datasets depending on criteria such as the sensitivity and users of the linked datasets?

Regarding the response to the question 'If I don't want my personal data used in any data linkage will I be able to opt out?' - the answer is not currently clear and we suggest that this requires further consideration. This is an important issue which any proposals need to clarify.

There is also a question about commercial interest and there is a clear statement that data will not be sold for commercial gain. However, the potential value of partnerships with e.g. pharma, should not be overlooked. Data generated through routine care and prescriptions can provide an important resource for pharma when developing new drugs to address serious health problems. It benefits patients as well as the commercial organisation. It is true that the NHS Scotland are not planning to sell data to pharma, but the benefits of partnership working should also be recognised because they can be of value to both the public and individual. Chief Medical Officer and Chief Scientist's Office are working hard to develop partnerships that can bring benefit to Scotland's population. These initiatives should not be ignored or obscured in communications or public engagement.

We reiterate and endorse the recommendation of CSAGS a decade ago – Scottish Government needs to undertake robust public engagement on these issues.

In relation to the 'Development and maintenance of a population spine', it is assumed that this would be done only after a full PIA process. The ICO has in the past expressed a preference for avoiding the creation of national collections of data, in favour of a decentralised approach involving dynamic linkages of data called together only for required and specific purposes.

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

Yes No