NHS European Office: Response to the Ministry of Justice Call for Evidence on the Review of the Balance of Competences between the United Kingdom and the European Union: Information Rights

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The NHS European Office is hosted by the NHS Confederation and has been representing the concerns of the NHS at European level since 2007. The NHS European Office aims to influence EU legislation that impacts the NHS, to promote EU funding opportunities to NHS bodies, and to promote collaboration with European counterparts.

In terms of information rights, we have been following in particular the proposed changes in European legislation on data protection. This is a crucial area of work for us, as it will have a direct impact on how NHS organisations manage and use their data. This not only has cost implications, but also implications for the service as a whole and how data is processed in the direct care of patients, but also for secondary purposes, such as medical research and management/financing of heath care services. There could also be a direct impact on system wide data sharing programmes such as care.data. This is why our response to the call for evidence is also very much focussed on the three questions referring to Data Protection legislation.

What evidence is there that the EU's competence and the way it has used it (principally the Data Protection Directive) has been advantageous or disadvantageous to individuals, business, the public sector or any other groups in the UK?

The Data Protection Directive sets a basis and standards for data protection in Europe that were enshrined in the Data Protection Act in the UK in 1998. In principle, a clear legislative text can be useful in order to give legal clarity to common law duty of confidentiality and ensures that patient data and health data is protected across Europe. Protecting data, particularly data of a sensitive nature (such as health data) is of vital importance and patients should feel confident that their data is being treated with confidentially and with respect. This is important in terms of building trust between the professional delivering care and the patient.

Caldicott 2, the second information governance review of health and social care services by Dame Fiona Caldicott, revealed that 'Information Governance' was often cited as an impediment to sharing information, even when sharing would have been in the patient's best interests. This cannot only be attributed to the Data Protection Directive, but it is clear that rules and legislation on Information Governance can impact on data being shared, even in the patient's best interest. The balance also needs to be struck between confidentiality of the patient's personal data and accountability in terms of delivery of services. Transparency and accountability is an essential part of an efficient and sustainable health system.

One of the most delicate issues regarding the current Directive, and Data Protection Act is the different provisions for professions that may process data for health purposes. While regulated medical professions have the right to access personal data on people in their care, social service professionals do not have the same allowance, and are often reliant on consent as their legal basis for processing personal data. As the traditional health care model (primary and secondary care) is currently shifting to a more integrated system between health and social care settings, in particular to face the challenge of demographic change with an increasingly elderly population, it is important that data can lawfully be shared with any professional that is involved in caring for the individual.

What evidence is there that the EU's competence and the way it has used it (principally the Data Protection Directive) is meeting the challenges posed by the increasing international flow of data, technological developments, and the growth of online commerce and social networks?

We believe the current EU Directive, which has set principles and standards to be implemented by national legislation has proved to be an efficient way of setting minimum data protection standards across Europe. In principle, it is helpful to have a common, shared set of standards and principles in dealing with data protection to facilitate clinical trials and medical and scientific research across international boundaries, thus European legislation on Data Protection can be helpful. We believe the current Directive sets clear standards and allows for the level of flexibility at Member State level to cope with the complexities of this issue.

What evidence is there that proposals for a new EU Data Protection Regulation will be advantageous or disadvantageous to individuals, business, the public sector or any other groups in the UK?

We are concerned that the proposal for a new Data Protection Regulation, especially as amended by the European Parliament in first reading, could have a negative impact on the NHS and the health care sector if a number of provisions are not amended:

- **Scope**

Pseudonymisation

We believe that it is preferential to maintain the European Commission's (EC) original proposed text (COM(2012)0011), which leaves pseudonymised data or pseudonymisation out of the definitions in Article 4. This is because it is very difficult to create a definition that works across all sectors.

Codes of conduct

In recital 23 of the EC's proposal we would welcome a reference to guidance or codes of conduct as instruments for providing guidance as to the ways in which data may be rendered anonymous and retained in a form in which identification of the data subject is no longer possible. This provision is included in recital 26 of the current European Data Protection Directive (95/46/EC) and the ICO anonymisation code of practice has become a practical guide for the UK context. In light of this, it could also be appropriate to reference codes of conduct on pseudonymisation and anonymisation in Article 38 of the current proposal (COM(2012)0011).

Measured, risk based approach

We also would strongly support the EC's original definition of 'data subject'. From our perspective, it is crucial to ensure that the final text maintains the wording "**by means reasonably likely to be used**". The European Parliament (EP) has proposed deleting this phrase from the definition. We think this text is extremely important as it recognises the necessity to take into account the context when defining whether data are at risk of being identifiable. This wording ensures that anonymisation does not have to be completely risk free. It is clear that the risk of identification must be remote (particularly for the special categories of data the NHS processes), but 100% anonymisation is not the legal test.

- **Free access to data (Article 12)**

Article 12.4 (COM(2012)0011) states that information provided to the data subject should be free of charge, 'unless where requests are manifestly excessive, in particular because of their repetitive character'. In Department of Health guidance issued to the NHS, a maximum charge of £10 for electronic records, and a maximum of £50 for records held in another format has been imposed. Guidance is very

clear that no profit should be made from the activity. In the case of a service like the NHS, the customer/patient always has to pay for this service either directly or indirectly. A medium sized district trust can receive approximately 50 requests every week. While the NHS in general, and many trusts are moving to electronic records, in most cases, a significant part of a data subject's health record remains mostly paper-based, and rather voluminous. It can be time consuming and costly to go through the archives to find a complete record and for this reason many trusts still charge the maximum £50 charge, in order to cover costs. If that information had to be provided free of charge, it could cost an average sized district trust approximately £100 000 per annum, which would need to be taken from other services. A number of years ago an audit of access to health record requests was conducted by a Health Board in Scotland. As a medium sized NHS Board, they calculated the real cost to the NHS Board was approx. £400,000 per year. These costs take into account, finding the records, a middle grade health records person going through the record to ensure that the request is fully complied with and the time lost to the NHS whilst the individual is undertaking this activity, any redaction and the administrative costs such as photocopying and sending the record by either courser or recorded delivery. We would like to see the text allowing a charge (which can be regulated by the supervisory authority or by the national competent authorities) by public bodies in providing information to an individual where that record is kept as part of their public duty.

- **The right to be forgotten and to erasure of personal data (Article 17) and the right to object (Article 19).**

It goes against good medical practice and current guidance in the UK to delete any information from medical records. Even if the information in the record is corrected, a note is placed on the record and the audit trail is kept. The exemption given to controllers from the necessity to erase data without delay in a case where the data subject objects to the processing is given under Article 19.3 of the EC proposal (COM(2012)0011) . However, the exemption for health purposes (19.3b) provides legal uncertainty because it only defines public health purposes under the exemption, which would not include the individual health care purposes required for keeping a complete medical record for each data subject. A simple addition to the text would solve any issues with legal uncertainty. We would strongly recommend the addition of three words to amend Article 19.3 (b) (COM(2012)0011): '**for health purposes** or for reasons of public interest in the area of public health in accordance with Article 81'.

- **Chapter IV: We are concerned that the 'one size fits all' approach in Chapter IV of the Commission's proposal is too prescriptive.**

The level of detail regarding impact assessments, data protection officers, etc. is trying to establish a 'one size fits all' approach which is not practical or workable across sectoral and geographic boundaries. We are particularly concerned about Article 28 on Documentation: The Commission has proposed that the data controller and processor should maintain documentation of **all** processing operations under its responsibility. The word 'all' is infinite and is therefore concerning from a health care perspective, where many data processing activities take place in each episode of care. A strict and legalistic interpretation of this text could have great administrative and cost implications for the NHS and health care providers in the UK, while achieving very little in terms of data protection for the patient. We strongly recommend the word 'all' is simply removed from the Article.

- **Processing of personal data for health purposes (Art 81)**

Article 81 of the EC's proposal (COM(2012)0011) gives exemption for explicit consent for the 'processing of personal data concerning health'. We strongly support the Council's draft text which refers to the 'processing of personal data concerning health-related purposes'. This broader definition supports UK practice, which has a shared health and social care data system for those involved in the direct care of the patient.

Aside from the title of the Article, we broadly support the EC's original proposed text on Article 81 (COM(2012)0011), as opposed to the changes made to this Article by the European Parliament, which are particularly problematic. We have however one comment on the original Commission text. Paragraph 81.1(a) states that data must be processed by a 'health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies'. While everyone processing personal data will have a contractual obligation of confidentiality, we are concerned that the broad scope of individuals involved in the direct care team may not fit entirely into the definitions of professionals who can process personal information given in 81.1(a). The text seems to suggest the person processing the data should come from a regulated profession. This may be problematic for the NHS as we are aiming towards a more integrated health and social care system. The HSCIC guide to confidentiality states that 'members of a care team should share confidential information when it is needed for the safe and effective care of an individual'. Safe and effective care is dependent upon relevant confidential information being shared amongst all those involved in caring for an individual. There is a wide team, including social workers, doctors, nurses, laboratory staff, social care staff, those that provide specialized care and the administrative staff who support care provision who may have access to personal data as a member of the direct care team, not all of whom have regulatory bodies.

- **Article 81 & 83 : Medical research**

From a medical research perspective, we have a number of concerns regarding the European Parliament's position on the Data Protection Regulation. We are a signatory to the position of non-commercial research organisations and academics on '**Protecting health and scientific research in the Data Protection Regulation'.**

If implemented, the European Parliament's amendments to Articles 81 and 83 would seriously impact on scientific research in the UK, including health research and the social sciences. The European Parliament position that emerged from amendments made by the LIBE committee is harmful and would make much research involving personal data at worst illegal, and at best unworkable.

The original draft Regulation proposed by the European Commission struck a crucial balance, setting out a proportionate mechanism for protecting privacy, whilst enabling health and scientific research to continue. It included a requirement for specific and explicit consent for the use of personal data concerning health, but provided an exemption from consent for research, subject to certain safeguards in Article 83.

The LIBE Committee's amendments to Articles 81 and 83 – now adopted by the European Parliament – very significantly reduce the scope of the exemption for research. For example, the use of personal data concerning health in research without specific consent would be prohibited or become very difficult in practice.

Consent is a crucial ethical principle and researchers will seek consent or use anonymous data where possible. However, it is not always feasible to seek consent, particularly where it is required to be specific and explicit. Where this type of research does take place, it is subject to ethical approval and strict confidentiality safeguards, and the identity of individuals is often masked.

If implemented, the European Parliament's amendments would put at risk significant European investments in genetics, cohort studies, biobanks, disease registries and the use of routinely collected data, and associated progress towards understanding society, health, and disease that delivers real patient benefit. We hope that the position of the European Council and subsequent trialogue talks can

recalibrate the balance between protecting privacy and enabling research that has been lost in the Parliament's amendments.