To: Article 29 Data Protection Working Party

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Dear Sirs

We have read with interest your consultation paper, *Working Document on the processing of personal data relating to health in electronic health records (EHR)*, though would like to make some comments on some of the conclusions drawn in the document.

The final conclusion - that explicit derogation will be needed under Articles 8 (4) identifying the public interest justification for EHRs and the safeguards required - might bring some clarity to a difficult area of legal interpretation, but would also have some unintended consequences for the present development of eHealth initiatives in the UK and in Europe as a whole.

Our intention in this response is to show where the terminology used in the document appears to miss key points of understanding (of the present state of eHealth and the role of pan-organisation databases for the future of healthcare) in drawing some of its intermediate conclusions, and indicate how its suggestion for independent legal interpretations of the role of and safeguards for EHRs will lead to difficulties in the near and more distant future for the development of better healthcare for the citizens of Europe, an aim supported strongly within the EU through DGs Sanco, InfSoc, and Enterprise.

The need for flexibility in the definition of EHRs and the safeguards surrounding them

Reading the document as a whole leads to the sense that an EHR is being interpreted as was originally coined in the mid-1990's, when the concept was developed as a reaction to the difficulty of paper-based records stored in multiple locations, inaccessible and inconsistent. A single pan-health-system electronic health record seemed an ideal solution at the time.

However, since then a more realistic and complex model of electronic medical records has developed, which may undermine some of the assumptions made in the WP131 document. This is reflected in some of the national developments across Europe. The possibility of a single all-encompassing health record has not proved viable.

There is a danger that the definition of an EHR used in the WP131 document would apply to no 'EHR' that is likely to be developed as none would actually be 'comprehensive' in design or reality. Alternatively, it would apply to any store of medical information which extends beyond a single episode of care, e.g. a General Practice records system, or a disease registry. This would mean that developing legislation to meet the requirements of the WP131 paper could be extremely difficult, given the diversity of systems to be covered. Equally, this is unlikely to result in a uniform elaboration of the Data Protection Directive across the EU.

The section on 'Organisational Structure of the EHR' attempts to address some of the different models, but without acknowledging that they may not be mutually exclusive as different aspects are needed for different aspects of care.

An 'emergency care record' seeks to provide a basic summary of the patient's current condition and treatment to inform any unscheduled care. This is being supported in both England and Scotland, and also is the basis of several 'personal health record' systems being offered in the USA. This would tend to be a 'national' system (though not necessarily in operation across all of a given member state - as the UK examples show), but which exists mainly for the sole benefit of the patient. However, it is unclear whether this type of record would be covered by the proposed definition of an EHR, as it is not intended to be 'comprehensive'.

'Integrated care records' represent a need to have a common care record across primary and secondary care institutions so that a patient gets the most appropriate care through the whole episode of care, no matter where the care is being provided. It is this area where the greatest benefit to individuals and the public should be achieved over time, but would be most severely hit by an excessively restrictive interpretation of consent. It is also more of an evolution of existing practice as understood by the public, who are now used to getting cash from an ATM across Europe and ordering goods online – they expect healthcare institutions to use IT systems to provide a better care service. These are unlikely to be 'comprehensive' as they would not be cradle to grave' necessarily, but would otherwise be susceptible to many of the arguments in the paper.

Equally, Personal Health Records[1] are coming to the fore, though mainly in the USA where there is no national infrastructure, but may also be available in Europe and would introduce fundamentally different ways of working. In the UK, Healthspace as planned is a typical example. The development of such citizen-oriented tools, possibly working across national jurisdictions, would be severely inhibited, especially if it is deemed impossible for a patient to be able to give 'explicit consent'.

Whilst your overall argument has much appeal, there is a significant danger that requiring nation states to define EHRs and regulate for them would actually prevent further developments in eHealth , much to the detriment of EU citizens. We would urge you to support the establishment of guidance on best practice in the use of electronic medical records generally under existing Data Protection laws, which should only benefit individuals and society, while retaining flexibility for future developments, rather than specific and restrictive legal solutions, which are likely to be out-of-date as soon as they have been adopted. This would also avoid the necessary period of uncertainty from the adoption of your document to the establishment of a supporting regulatory position in each member state – this could amount to several years – particularly if national elections should intervene.

[1] PHR (may be paper-based or electronic): "a collection of important information about your health or the health of someone you are caring for, such as a parent or child, that you actively maintain and update. The information comes from your healthcare provider, and from you " American Health Information Management Association. 'My PHR' Personal Health Record. URL: http://www.myphr.com/your_record/index.asp

The role and purpose of health records, including EHRs

Historically, medical records have been a combination of aide-memoire for the individual clinician plus a record of note for legal defence. As indicated above, they have more recently also taken on a co-ordination role, linking the workflow between individual clinicians in a team, and increasingly between institutions. In some countries, such as France, they have been held by the patient in order to provide continuity between professionals, where the patient has freedom to choose where they are treated; in other countries, extracts might be taken and sent to other clinicians as part of referral or discharge letters.

Many past improvements in medical knowledge have been gained by individual clinicians making use of their medical records to identify health factors and effective treatments in a way that personal reflection on experience could not achieve. With the increasing complexity of medicine and the greater understanding of the many influences on each individual's health, it becomes even more imperative that the quality of healthcare is monitored, and improved, through the effective use of medical records as a primary source of such information, rather than an accidental benefit as in the past.

The Institute of Medicine report, *To Err is Human Building a Safer Health System*, made clear that medicine as practised is far from perfect, leading to many avoidable deaths each year – and these figures have since been confirmed by similar figures from other healthcare systems. In this sense, we are dealing very much with the 'vital interests' of the individual, not only in the imminence of risk from their condition and need for treatment, but also from the risk of possible adverse affect of that treatment.

It is easy to consider that health records are simply tied to the individual encounter between an individual and their clinician, but in modern healthcare (and more so in the future), the relationship will be, and will need to be, more complex. As medicines become more complex and powerful, so the possibility of adverse events may increase, and thus our monitoring and feedback mechanisms need to be more sophisticated to support the changing nature of medicine. The electronic health record will not simply be a useful adjunct to healthcare, but a vital component in maintaining the safety and quality of care, and the effective exploitation of health data a key factor to the development of medicine, especially in terms of genetic tailoring of treatment to an individual's needs, which can only be achieved through a greater understanding of the treatment of groups and populations of individuals.

None of this undermines the need to protect individual's interests as clearly drawn out in your document through appropriate controls and establishment of the role of EHRs (and other medical record systems). However, some interpretations might render these advances infeasible by an over-emphasis on one part of the 'social contract', the need to protect the patient's confidentiality and privacy interests, against other, and possibly more fundamental, interests such as the need for health and safe effective healthcare. The quotation from Recital 2 at the beginning of section II highlights the need to balance these rights and objectives.

The role of the professional in healthcare and the implications for data-sharing

The reference to the Hippocratic Oath, while of historic interest, harkens back to days when medicine was in its infancy and generally provided by a sole practitioner. As indicated above, this is clearly no longer the case as care is normally provided by a 'care team' rather than an individual, and may, particularly for chronic care, be provided by a team working across different areas of care (primary healthcare, secondary care, and social or community care). Conditions, such as diabetes, require many different professionals to support the individual in coping with their condition, both on a routine basis and when a specific episode occurs.

To provide this care effectively, both in terms of cost-efficiency and overall patient well-being, then patient records need to be consistent and shared - a universal record, rather than individual records at each establishment. This not only ensures consistency, but also allows effective care management across institutional boundaries. No longer is care provided either in primary care or in secondary care, both in a flexible mixture of both, which may include other institutions as well.

This illustrates one of the terminology issues in the working document - in Section 6 of the document it is stated that:

> *Use of this information is allowed only within the limits of the treatment contract. This relationship of confidentiality excludes all third parties, even other health care professionals, unless the patient has agreed to passing on his data or it is foreseen especially by law.*

The first sentence suggests that there is a 'treatment contract', which will not be explicit in a healthcare system, such as the UK, where treatment is covered by a social welfare programme. We should also note that there is an increasing emphasis on preventative care, maintaining 'wellness' rather than just treating 'illness', requiring additional information on lifestyle and greater involvement of the individual in maintaining their own health. This will also change the role and scope of an EHR.

The second sentence refers to 'third parties even other healthcare professionals'. While it is clearly true that information should not be shared with another simply because they are a healthcare professional, there is a danger that this wording will be interpreted as a prohibition of sharing between healthcare professionals without express patient consent *even if* they are involved, directly or indirectly, in the care of the patient. The difficulty, particularly where there is no 'treatment contract' is whether the two parties are the patient and their immediate clinician in the consultation who is recording notes about the encounter, the patient and the immediate 'care team' (including clinical support staff), the patient and the 'wider care team' (possibly including technical staff analysing samples – certainly including people that the patient would not directly encounter), or the patient and the immediate institution, or institutions, providing care.

Conclusion

We are not in a position to argue over points of legal interpretation nor do we seek to do so. However, we do have concerns that there may be some misinterpretation of the WP131 document as it stands without a clearer expression of the changing nature of healthcare and health informatics.

We also feel that, while clarification in this area is definitely to be commended, an attempt to develop specific regulation on EHRs could be detrimental to the wellbeing of EU citizens whereas appropriate guidance on the more general issues of electronic medical records and privacy, which could be more easily shared and updated across the EU could be beneficial. The latter half of your document is an excellent start in this regard.

On behalf of the Clinical eScience Framework (CLEF) project

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