Update on the European Data Protection Regulation

MJ Taylor (University of Sheffield) and B Thompson (Wellcome Trust)[1]

SUMMARY

1. The European General Data Protection Regulation (DPR) is currently making its way through the legislative process.

2. The Civil Liberties and Home Affairs (LIBE) committee of the European Parliament has adopted amendments to the Data Protection Regulation that would have a serious negative impact on research if allowed to pass into law.

3. It is vital that the current drafting by LIBE of articles 81 and 83, and the commission proposed text of article 6, are resisted.

IMPACT ON RESEARCH

4. Under the current LIBE proposals all health research using personal data becomes more difficult. Some health research using personal data becomes impossible to conduct lawfully. The compliance costs imposed on researchers, funders, and most importantly patients are unjustified.

5. It becomes more difficult to establish either consent or the legitimate interests of the data controller as a lawful basis for the processing of any personal data than under the current legislative framework in the UK.

[1] Thanks to those members of ELSI 2.0 who have commented on this draft including, in particular Alison Hall and Tom Finnegan (PHG Foundation) and Linda Briceno Moraia, Jane Kaye and Colin Mitchell (HeLEX). http://www.p3g.org/elsi-20

6. All research using identifiable health data is jeopardised. Health research using patient data can only take place where “data enabling the attribution of information to an identified or identifiable data subject is [sic] kept separately” from other information. It would prohibit any research where that was not possible.

7. The definition of pseudonymised data is ambiguous.

    1. It is unclear whether the intention is to extend the scope of Regulation to include data that would not be considered identifiable currently.

    2. It is unclear whether the intention is to allow researchers to analyse only data that would be anonymous but for the possibility of linkage through data held separately. This would effectively prohibit the analysis of any data enabling identification.

8. Studies in England and Wales can be granted support under the Health Service (Control of Patient Information) Regulations 2002 if they are deemed to be in the public interest, it is necessary for researchers to have access to identifiable data, and it is not practicable to seek patient consent. Many of these studies would not be possible if these amendments were enacted.

9. Without further independent action by member states, all research using health data (including only potentially identifiable data held in securely managed environments) must have the specific, informed and explicit consent of individual patients regardless of the circumstances.

10. It is vital that the current LIBE text of articles 81 and 83 is resisted. The issues raised by the Articles are exacerbated by the original drafting of article 6. The drafting of articles 6, 81 and 83 requires significant improvement if research use of health data is not to be unjustifiably curtailed or prohibited.

11. The necessity for member states to provide domestic exceptions to the proposed blanket requirement for consent to research use of health data will undermine the stated aim of the Regulation to

better harmonise information governance standards. This will undermine international collaboration and cross-border research.

12. The health and wealth agenda of the UK is put at significant risk. The position of the EU as a world leader in medical research is threatened. Important opportunities to improve human health will not be fully realised.

13. In total MEPs adopted 91 amendments. Many of these will impact on the regulatory environment in which research is conducted.

ANALYSIS

In what follows there is an attempt to set out two different kinds of problem: a. the uncertainty that follows poor drafting b. the specific problems that would follow particular interpretations of articles 6, 81 and 83. Even if those particular interpretations are not intended by the drafters, the fact that the LIBE draft can be read consistently with them justifies resisting the current wording. Drafting improvements are suggested.

Article 6

14. Article 6 is relevant to the lawful conditions of processing. Article 6(1) provides the processing of personal data shall only be lawful if one of a series of particular conditions apply. Six alternatives routes (6(1)(a)-(f)) are described. Two are particularly relevant to research processing: 6(1)(a) which relates to processing with consent and 6(1)(f) which relates to processing necessary for the purposes of the legitimate interests pursued by the controller or, in case of disclosure, by the third party to whom data are disclosed.

15. It is more difficult for a researcher to rely upon either of these routes to lawful processing than it is for them to rely upon current equivalents.

16. Article 6(1)(a) requires *explicit* consent (rather than 'unambiguous' consent which is currently the minimum standard of consent for the processing of personal data that does not fall into a special category) and it also now requires satisfaction of a number of conditions for consent set out in Article 7. The collective effect is to make it more difficult for a researcher to rely upon consent as the basis of processing.

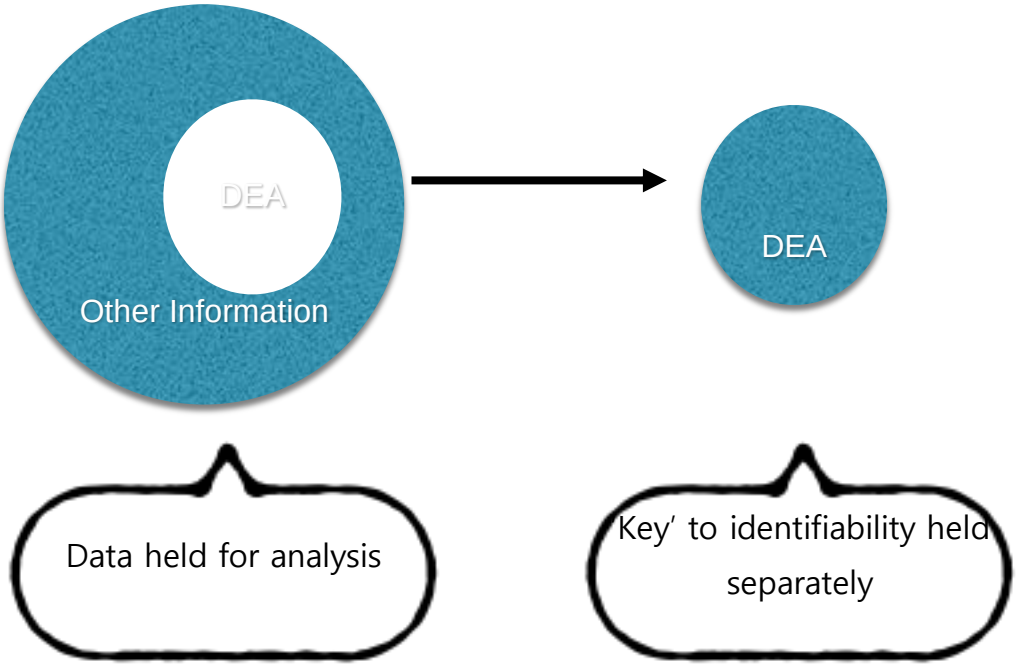
17. Under the LIBE amendments, Article 6(1)(f) limits for the first time permissible processing for the purposes of legitimate interests to those circumstances where such processing meets "the reasonable expectations of the data subject based on his or her relationship with the controller". This will make it more difficult for a researcher to rely upon a "legitimate interest" in processing the data where they do not have a relationship with the data subject (e.g. data was originally gathered for another purpose by a different data controller).

18. Article 6(2) provides that the processing of personal data necessary for research purposes shall be lawful subject to the conditions and safeguards referred to in Article 83.

19. Drafting issues with Article 6 leave it unclear whether Article 6(2) is intended as an alternative to 6(1) as a route to lawful processing. It can currently be read to require researchers satisfy an additional requirement. If Article 6(2) is an additional requirement, then *all* research processing of personal data must satisfy the requirements of Article 83: even research conducted on the basis of consent. This would be a disproportionate requirement. It would undermine an individual's informational autonomy to allow data enabling identification to be used for research purposes. It could potentially prohibit, for example, research registers which allow individuals to register an interest in being contacted by researchers about future research participation. This lack of clarity could have a deterrent effect, and result in researchers being more hesitant about initiating certain types of research.

Article 83

20. Article 83 governs the use of any personal data for research purposes. LIBE's Article 83(1b) requires researchers to ensure that "data enabling the attribution of information to an identified or identifiable data subject is [sic] kept separately" from other information "under the highest technical standards" and ensuring "all necessary measures are taken to prevent unwarranted re-identification".



21. Drafting issues leave it unclear whether it is intended to be permissible under article 83(1b) for "other information" (ie. that held for analysis) to remain identified or identifiable without the possibility of linkage with the separated data (ie. "the data enabling attribution" (DEA): the 'key'). It also leaves it unclear whether it is permissible for a researcher to have access to the DEA: 'the key'. These are critically important issues and require clarification.

22. There are a number of alternatives ways of interpreting article 83(1b) (at least A-E):

A. Data held for analysis would be anonymous but for the DEA which is unavailable to the researcher: "other information" is identifiable (ie within scope of Regulation) ONLY *because* of the possibility of linkage with the 'key' (DEA). The "other information" would otherwise be anonymous. The researcher **cannot** have access to the DEA.

B. Data held for analysis would be anonymous but for the DEA which is available to the researcher: "other information" is identifiable (ie within scope of Regulation) ONLY *because* of the possibility of linkage with the 'key' (DEA). The "other information" would otherwise be anonymous. The researcher **can** have access to the DEA.

C. Data is identifiable in other contexts but not to the researcher in the managed environment in which it is held: "other information" is identifiable (ie within scope of Regulation) *not only because* of the possibility of linkage with the DEA. The data would also be identifiable *if* placed with additional other information. But, such linkage is effectively prevented by contractual and technical measures (to a point where it is not likely to occur using means reasonably likely to be used)[2]. The researcher does **not** have access to the DEA (the 'key') *and* are not in a position to identify the data subject using means reasonably likely to be used.

D. Data is identifiable in other contexts and to the researcher using the key: "other information" is identifiable (ie within scope of Regulation) *not only because* of the possibility of linkage with the 'key' (DEA). The data would also be identifiable *if* placed with additional other information. But, such linkage is effectively prevented by contractual and technical measures (to a point where it is not likely to occur using means reasonably likely to be used). The researcher **does** have access to the DEA (the 'key').

E. Data is identifiable. "Other information" is **identifiable** (ie within scope of Regulation) *not only because* of the possibility of linkage with the 'key' (DEA). The data remains identifiable *per se.* For example, names and addresses are removed but the data are facial images, relate to rare disorders, or are

[2] This would be the 'default' way of understanding the threshold of identifiability capable of bringing data within the scope of the Regulation (see recital 23). It is possible that the requirement (under 83(1b)) to keep data separate "under the highest technical standards and all necessary measures are taken to prevent unwarranted re-identification" has lowered the threshold for identifiability in the case of research: data will be regarded as identifiable, even if it is not likely to be identified using means reasonably likely to be used, if the "highest technical standards" have not been adhered to in its pseudonymisation. This would appear to be unnecessary, disproportionate and inconsistent.

sufficiently rich in clinical history or other biographical detail that they could be associated with a particular individual without the addition of any further data.

23. Data in A (and potentially also C) would not currently be understood to be identifiable data. Such data would fall outside of the scope of current data protection law. It is not appropriate to extend the scope of data protection law to include data in this category when there is no prospect of an individual being associated with data 'using means reasonably likely to be used'.[3]

24. It is possible to read Article 83(1b) to permit ONLY A to B (inclusive). This is because all other scenarios permit the researcher to continue to hold data (as part of 'other information') that could enable the identification of an individual. This would prohibit any research reliant upon the *analysis* of identifiable or potentially identifiable data. This would have some perverse consequences. For example, it would permit B but prohibit C.

25. Unless article 83(1b) is read to include the full range of possibility (A-E) research will be prohibited that is currently lawful. It is particularly difficult to read the LIBE draft of article 83(2) to permit E. No material advantage to patient privacy is achieved by distinguishing between D and E.

26. While there are good reasons to challenge researchers to reduce the identifiers held where that can be done without undermining the integrity of research, and any identifiers not required for the purposes of research should be separately held where practicable, it is not appropriate to impose a blanket prohibition on the processing of data in any of the categories A-E.

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[3] This phrase relates to the test for identifiability referred to within Recital 23 of the LIBE proposal: "To determine whether a person is identifiable, account should be taken of all the means reasonably likely to be used either by the controller or by any other person to identify or single out the individual directly or indirectly. To ascertain whether means are reasonable likely to be used to identify the individual, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration both available technology at the time of the processing and technological development. The principles of data protection should therefore not apply to anonymous data, which is information that does not relate to an identified or identifiable natural person."

27. If Article 6(2) is an additional requirement, and Article 83 is read to prohibit the analysis of identifiable data (C-E), then the Regulation would have the absurd result that it was unlawful to analyse identifiable data for research purposes even with explicit patient consent. The absurdity is only apparent when the articles are independently interpreted in a particular way and then read together. The drafting of both articles needs to be improved.

1. The drafting of Article 6 needs to make clear that 6(2) is a route to lawful processing that is alternative and not additional to 6(1). This could be done by simply renumbering 6(2) as 6(1)(g).

2. The drafting of Article 83(1b) needs to make clear that *wherever practicable* data enabling the identification of a data subject that is *not required for the purposes of analysis* must be kept separately from other information. This would challenge researchers to use minimum identifiers and to separate identifiers from data held for analysis wherever practicable. It would not, however, prohibit any of the categories of processing A-E where that was the only practicable way to carry out the research. Reverting to the Commission's text of Article 83(1) would achieve this goal, since it requires data enabling identification to be kept separately only "as long as these purposes can be fulfilled in this manner". This is important even if Article 6(2) is read as an alternative to Article 6(1).

Article 81

28. This article is relevant for research involving data concerning health, for example epidemiological studies, registries, biobanks and the secondary use of clinical trials data.

29. Article 81 jeopardises the use of any identifiable health data in research. Article 81(2) provides that the processing of personal data concerning health shall be permitted only with the consent of the data subject *and* subject to the conditions and safeguards referred to in article 83. For reasons provided above, unless the drafting of article 83 is improved this could be understood to prohibit the analysis of identifiable data for research purposes even with patient consent.

30. As originally drafted, article 81 enabled Member States to legislate for an exemption from the need for consent to use data concerning health in research. However, the amendment means that the exemption could only apply to the use of pseudonymised data: even if research serves a high public interest member states may not provide for research that cannot use either anonymised or pseudonymised data.

31. Article 4(2a) defines pseudonymous data as data "that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution".

32. *Thus if* members states have provided for an exception to consent, then article 81(2a) prohibits the analysis of data sufficiently rich or rare that it could be attributed to a specific individual without the use of additional information (ie. Category E as described above). Member states could not provide for an exception to this prohibition.

33. Prohibiting the research use of any data that has not been pseudonymised will prevent research from taking place that is currently lawful on the basis of patient consent.

34. Without further independent action by member states, all research using health data (including pseudonymised data held in securely managed environments) must have the specific, informed and explicit consent of individual patients.

35. Article 81(1b) modifies the consent rules for the use of data concerning health in public health scientific research to allow consent to be "given for one or more specific and similar researches". The wording is ambiguous but does not appear to accommodate all forms of broad consent, which can be as unspecific as "health-related research".[4] It also seems unfortunately to confirm a background reading of "specific" to mean "narrow".

[4] e.g. to permit me to consent to "dogs and similar animals entering my garden" is not necessarily to permit me to consent to "any animal entering my garden".

36. The necessity for member states to provide individual exceptions to this blanket requirement for consent will undermine the harmonisation of information governance standards, international collaboration and cross-border research.

37. Restricting the circumstances in which member states might provide an exception to the requirement of consent to those where research serves “a high public interest” and that research “could not possibly be carried out otherwise” restricts the circumstances under which research could lawfully make use of identifiable patient data without patient consent further than the Health Service (Control of Patient Information) Regulations 2002.[5] It is not clear what “high public interest” means and to require that it was “not possible” to carry out research otherwise is to set a threshold that is unworkably high. This would upset the balance between patient confidentiality and health research established after parliamentary debate in the UK.

38. Prohibiting the research use of any data that has not been pseudonymised will prevent research from taking place that is currently lawful on the basis of the Health Service (Control of Patient Information) Regulations 2002. UK law currently recognises that sometimes it is not practicable to obtain consent (rather than not possible) for the use of identifiable data. These amendments will remove this possibility and will prevent research undertaken in this way.

39. Studies in England and Wales can be granted support under the Health Service (Control of Patient Information) Regulations 2002 if they are deemed to be in the public interest, it is necessary for researchers to have access to identifiable data, and it is not practicable to seek patient consent. These studies were approved by the Secretary of State for Health following independent advice by a Research Ethics Committee and the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care and included the following:

[5] Section 251 of the NHS Act 2006 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes.

- A case control study investigating the influence of demographic factors and treatment regimes on the risk of patients with schizophrenia committing homicide. Approval was sought to access hospital episode statistic data for age and sex matched controls and identify consultants to seek further information on the patients' care.
- A study of cancer care waiting times and effects on survival with a focus on the impact of socio-economic and ethnic inequalities in cancer care.
- A study to understand the impact of socioeconomic and demographic factors on the health outcomes of premature babies.
- A request to obtain contact information for patients undergoing colonoscopy to invite them to take part in a follow up study.

BACKGROUND

40. MEPs had a single vote on a block of 85 amendments, including those on research. MEPs almost unanimously voted to adopt these amendments, but the nature of the block vote makes it impossible to assess views on research in particular. It appears that the recent leaks around the use of personal data by the US National Security Agency have led Parliament to seek to tighten all rules around data protection and gave divergent political groups impetus to compromise.

Next steps

41. Following the vote in the European Parliament's LIBE committee the rapporteur has been given a mandate to enter negotiations with the Council and the Commission ('trilogue'). However, trilogue can only start once Member States authorise the Council Presidency to do so.

42. A plenary vote on the LIBE amendments in the Parliament is expected in spring 2014. If parliament do vote on the LIBE amendments (rather than a compromise text agreed with Council negotiators which now looks unlikely) this makes a second reading in Parliament (after the next elections) almost certain. Council have indicated an expectation to have the new EU data protection rules adopted by 2015.

43. The Wellcome Trust is coordinating activities with a core group of partners including Science Europe, the Federation of European Academies of Medicine, the European Federation of

Pharmaceutical Industries and Associations, Cancer Research UK and the Medical Research Council. We are welcome to contribute toward that activity.

Legislative process

44. The European Commission published a draft proposal in January 2012 of the General Data Protection Regulation (DPR), which would replace the existing Data Protection Directive and become law in the 28 Member States. The Regulation proposed by the Commission was largely supported by the health research community as it contained helpful exemptions for research from a number of requirements.

45. In January 2013, Jan Philipp Albrecht, the Rapporteur for the LIBE Committee on the regulation, presented his report on the proposed regulation. The amendments proposed significantly threatened the ability to process personal data for research purposes. Subsequently, over 3000 amendments were tabled by the LIBE Committee in March 2013.

46. Compromise amendments were developed from the full set of amendments in negotiations between the political groups. These compromise amendments were voted on in the LIBE Committee on 21 October 2013.