SHARE

BOTTLENECKS & CHALLENGES AND RTD RESPONSES FOR LEGAL, ETHICAL, SOCIAL, AND ECONOMIC ASPECTS OF HEALTHGRIDS – ROADMAP II

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Abstract: This document provides ethical, legal, social and economic components of the comprehensive roadmap for Health Grids and provides recommendations for facilitating the uptake of health grids in Europe. Relevant ELSE issues identified are discussed in detail in detail with respect to the two uses cases and applied to the three 'stages' of a grid – the computational, data and knowledge grid.

Document Log

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1. INTRODUCTION

In this detailed analysis of the key ethical, legal and socio-economic (ELSE) challenges to the adoption of HealthGrids we return to the core concepts and propose a series of key issues which need to be addressed by further investigation, organisational change or legislation in order to promote the adoption and use of HealthGrids.

We begin by revisiting the key legal issues (data protection, liability and protection of intellectual property); the socio-economic issues around user acceptance, work practice and cost/benefit analyses leading to sound business cases; as well as the role of the ethical values of autonomy, beneficence and justice.

Having established the key elements of these ELSE concepts we go on to look in detail at the specific challenges they pose to the adoption of an epidermal grid and a drug discovery grid using the use cases developed in Deliverables 5.1a and 5.1b respectively.

Once the key ELSE challenges have been examined a roadmap of ELSE milestones towards the adoption of the both epidemiology girds and drug discovery grids is developed which maps three stage of grid development : computational, data and knowledge grids.

On the basis of the milestones outlined the work of this deliverable will be further developed in deliverable 6.2 in which a fully integrated roadmap for health girds is proposed.

1.1.Purpose

The purpose of deliverable D4.3 is to use the lessons learnt in the different tasks of Work Package 4 (WP4) (i.e., the framework, the baseline and the first roadmap documents) and the investigations reported in the WP5, to revise and augment the analyses of the legal, ethical, social and economic challenges of grid computing in health.

In this document we will thus consider the Ethical, Legal and Socio-Economic (ELSE) issues as described in the baseline document, and define how, for each of the three major grid milestones defined in WP3 (data grid, computing grid, knowledge grid), different ELSE issues could present roadblocks to the technological developments. We will then make recommendations towards solving those potential problems.

In addition to the first roadmap documents (D3.3 and D4.2), we will use the deliverables produced in WP5, first looking at D5.1a the "use case scenario for epidemiology" and D5.1b its corresponding version dedicated to a "use case scenario for innovative medicine", which defined the requirements, needs and aims of both cases. We consider also D5.2a (epidemiology roadmap) and D5.2b (innovative medicine roadmap) which revised the ELSE issues presented in the roadmap I (D4.2) and analysed how they matched up (or not) to the requirements expressed in the use case scenarios.

Through the iterative process of the project, this deliverable will thus present a more advanced version of the ELSE roadmap. Before getting to the heart of the subject, it seems essential to remind ourselves briefly of the important elements raised in D4.2 and the recommendations there.

1.2. Application area

The document is intended for internal and external use. It will be also used as a dissemination tool for the SHARE project.

1.3. References

[R1]	D4.1 A Legal, Regulatory and Economic Baseline for Developing a Roadmap for the Adoption of grid Technology in Healthcare http://eu-share.org/deliverables.html
[R2]	D4.2 A Legal, Regulatory and Economic Framework for Developing a Roadmap for the Adoption of grid Technology in Healthcare http://eu-share.org/deliverables.html
[R2]	D3.2 Baseline on Technology and Security Aspects of healthgrids http://eu-share.org/deliverables.html
[R3]	D3.3 Bottlenecks & Challenges and RTD Responses for Technological and Security Aspects of Healthgrids Roadmap http://eu-share.org/deliverables.html
[R4]	D.5.1.a Use case scenario for epidemiology http://eu-share.org/deliverables.html
[R5]	D.5.1.b Use case scenario for innovative Medicine http://eu-share.org/deliverables.html
[R6]	D5.2.a Roadmapping for epidemiology http://eu-share.org/deliverables.html
[R7]	D 5.2.b Roadmapping for innovative medicine

	http://eu-share.org/deliverables.html

1.4.Document evolution procedure

This document will be updated incrementally via WP4 activity as new information becomes available. It will also be further developed in base don the resulty of the SHARE Roadmap workshop due to be held in December 2007.

Any comments or feedback should be sent to the authors.

1.5.Sources

Please collate all the foot note reference into this section, including addiotnal references to be sent by Isabelle Andoulsi and Alex Dobrev

1	For a detailed legal analysis of the data protection issues, please see Annex I of D4.2, dedicated to Data Protection, Confidentiality and Security Issues.
2	Following Article 8, paragraph 4 of the Directive *"Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority*". On the other hand, following to Article 13, second paragraph, " *Subject to adequate legal safeguards, in particular that the data are not used for taking measures or decisions regarding any particular individual, Member States may, where there is clearly no risk of breaching the privacy of the data subject, restrict by a legislative measure the rights provided for in Article 12* (i.e. right of access of the person concerned to his data) *when data are processed solely for purposes of scientific research or are kept in personal form for a period which does not exceed the period necessary for the sole purpose of creating statistics*".
3	Directive 2001/95/EC on General Product Safety requires that any product put on the market for consumers, or likely to be used by them, are safe. Furthermore, it requires producers to provide consumers with the relevant information enabling them to assess the risks inherent in the product and to take appropriate measures in order to prevent these risks (withdrawal from the market, warning to the market consumers, recall products already supplied…).
4	Directive 1999/44 /EC on the Sale of Consumer Goods is one example of this kind of legislation. For further details on this point, please see the deliverable D4.2, Annex II.
5	We could think that from the moment one of the components of the system is intended by its manufacturer to be used with a medical device, then this component constitutes a medical device and thus falls under the application scope of the directive. However, this one is not of the clearest in the determination of its field of application. For example, monitoring devices could be considered as medical devices under the directive, while tools used for the administration of general patient data will generally not be considered as medical devices.
6	These contracts should emphasize the responsibility of each of the participants in a grid, ant it more still when the components of the system are brought by producers or manufacturers who do not participate in the grid itself.
7	For a detailed legal analysis of the intellectual property rights implied by the implementation of grids, please see deliverable D4.2, Annex III.
8	See deliverable D5.1a "Use case scenario for epidemiology", p. 8.
9	See deliverable D5.1a "Use case scenario for epidemiology", p. 7. The same references can be

	found in the deliverable D5.1b dedicated to innovative medicine, pp. 6 and 7.
10	See deliverable D5.1b “Use case scenario for innovative medicine”, p. 6.
11	Deliverable D5.2a “Epidemiology roadmap”, p. 12.
12	Deliverable D5.2a “Epidemiology roadmap”, p. 18.
13	Which is important as the patient’s consent constitute one legal way to legitimate the processing of his data.
14	The Directive grants permission to process medical data in six other hypotheses. Article 8, 2 of the Directive prescribes that: *“Paragraph 1* (i.e. the ban on the processing of medical data) *shall not apply where:* *[…]* *(b) processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law in so far as it is authorized by national law providing for adequate safeguards; or* *(c) processing is necessary to protect the vital interests of the data subject or of another person when the data subject is physically or legally incapable of giving his consent; or* *(d) processing is carried out in the course of its legitimate activities with appropriate guarantees by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects; or* *(e) the processing relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims”.* The processing of medical data is equally permitted when it *“[…] is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and when those data are processed by a health professional subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy”*. Directive 95/46/CE, art 8, 3.
15	Directive 95/46/CE, art 8, 2(a).
16	Article 29 Data Protection Working Party, “Working document on the processing of personal data relating to health in electronic health records, adopted on 15 February 2007 by the Article 29 Working Party*”*, WP131, 00323/07/EN, available on http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/wpdocs/2007_en.htm
17	Article 29 Data Protection Working Party, *op. cit.*, p. 4.
18	For more details on this, see Article 29 Data Protection Working Party, *op. cit.*, pp. 13-21.
19	I.e., in line with Article 8, 4 of the Directive 95/46/CE and its Recital 34.
20	Communication to the European Parliament and the Council on Promoting Data Protection by Privacy Enhancing Technologies, COM(2007)228, Brussels, 2 May 2007, see http://eurlex.europa.eu/LexUriServ/site/en/com/2007/com2007_0228en01.pdf
21	PETs can be of different kinds. For example, they can be automatic anonymisation of data, encryption tools or cookie-cutters. As the Commission stated in its report the use of these tools can help to design information and communication systems and services in a way that minimises the collection and the use of personal data and facilitate compliance with data protection rules.
22	For a detailed analysis on this particular point, please see D4.2, Annex I.
23	For more information on this topic see the Communication from the Commission to the European Parliament and the Council on the follow up of the Work Programme for better implementation of the Data Protection Directive adopted on 7 March 2007, COM(2007) 87 final.

24	Communication from the Commission to the European Parliament and the Council o the follow up of the Work Programme for better implementation of the Data Protection Directive adopted on 7 March 2007, COM(2007) 87 final, p. 6.
25	The constitution of a new epidemiological data base will also raise other intellectual property rights problems, notably when this data base is composed of substantial extractions of other existing data bases or of data extracted from EHRs. There will be notably problems concerning the rights of the patients as for the exploitation of their data contained in EHRs. These problems were looked at in a detailed way in the deliverable D4.2, Annex III.
26	See D5.2a, pp. 15 and 16.
27	Directive 96/9/EC of the European Parliament and the Council of 11 March 1996 on the legal protection of databases, OJ. L77, of 27 March 1996, pp. 20-28.
28	See D5.2a, p. 21
29	Deliverable D5.2a “Epidemiological roadmap”, p. 23.
30	See D5.2a, p. 21.
31	See for example STROETMANN, K.A. JONES, T. DOBREV, A. and STROETMANN, V.N., *eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites*, Office for Official Publications of the European Communities, Luxembourg, 2006 (56 pp. - ISBN 92-79-02762-X), available on www.ehealth-impact.org
32	See the deliverable D5.2a “Epidemiological roadmap”, p. 27.
33	For details on optimism bias and risk in economic assessments, see HM Treasury (2003), THE GREEN BOOK: Appraisal and Evaluation in Central Government; available at: http://www.hm-treasury.gov.uk/media/05553/Green_Book_03.pdf
34	SHEM, S.. *Mount Misery*, New York, Dell Publishing, 1997, p. 213.
35	HAGEMEISTER, Dirk Thomas, “Software must not manipulate the physicians:”, *in The IT Challenge to Patient Care International Review of Information Ethics*, Vol.. 5, 09/2006.
36	Deliverable D5.1b “Use case scenario for innovative medicine”, p. 9.
37	For more details on this point see D5.2b, pp. 16 and 17.
38	See D5.2a, pp. 18-20.
39	See D4.2, Annex II.
40	See D5.1b, p. 26.
41	See our legal analysis on data protection for more information, starting in D4.1 and D4.2.
42	See D5.1b, p. 25.
43	RADOVKOV, Boyan (ed), Ethical Implications of Emerging Technologies: A Survey edited by the Information Society Division, Communication and Information Sector UNESCO, Information for All Programme (IFAP)., Paris: UNESCO, 2007.
44	Some computing grid applications are being deployed successfully (DEISA, EGEE).
45	In real life, a few successful data grids exist such as BIRN, BRIDGES or Medical Data Manager.
46	See for example STROETMANN, K.A. JONES, T. DOBREV, A. and STROETMANN, V.N. “eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites”, Office for Official Publications of the European Communities, Luxembourg, 2006 (56 pp. - ISBN 92-79-02762-X), available on www.ehealth-impact.org
47	See for example STROETMANN, K.A. JONES, T. DOBREV, A. and STROETMANN, V.N. “eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites”, Office for Official Publications of the European Communities, Luxembourg, 2006 (56 pp. - ISBN 92-79-02762-X), available on www.ehealth-impact.org

48	For details on corrections of market failures, see Mankiw, Gregory; Ronald Kneebone, Kenneth McKenzie, Nicholas Row (2002). Principles of Microeconomics: Second Canadian Edition. United States: Thomson-Nelson, pp. 157-158.
49	Ethical Implications of Emerging Technologies: A Survey Prepared by Mary Rundle and Chris Conley Geneva Net Dialogue Edited by the Information Society Division, Communication and Information Sector – March 2007. available at http://unesdoc.unesco.org/images/0014/001499/149992E.pdf (accessed 10th October 2007)
50	Alistair S. Duff: Neo-Rawlsian Co-ordinates: Notes on A Theory of Justice for the Information Age International Review of Information Ethics Vol. 6 pp18-23
51	Rawls, John (1973) [1971]: A Theory of Justice, Oxford: Oxford University Press

2. BACKROUND

2.1. THE LESSONS LEARNT ON THE LEGAL ISSUES

In this section we present a brief overview of the key legal issues as outlined in the roadmap I (D4.2).

Looking back on the discussion on data protection[1], we outlined that in broad terms the current EU level legislation is adequate but not ideal for promoting healthgrids. It is, however, adequate to support most of the longer running research initiatives around which healthgrids are currently based. Indeed, as the current EU level legislation stands, Member States can enact specific legislation covering specific tools such as healthgrids in order to exempt scientists and medical practitioners using healthgrids from some of the more onerous duties of the Directive 95/46/EC.[2]

On the other hand, the use of grids alters the issue of liability, as the patient-health practitioner relationship changes and thus traditional medical liability is no longer sufficient. This is mainly due to the fact that grid systems are composed of several products (software, medical devices, etc.) and services (more notably data and knowledge management services) and support other kinds of services in addition to the provision of healthcare, notably research. These different kinds of uses also imply different types of users, and not solely destined for patient care. All in all, if an error takes place due to a grid, liability will likely not be restricted to the traditional medical liability.

While the EU does have a range of legislation designed to protect citizens from harm resulting from goods offered on the market, and takes steps to ensure that goods that are on the market are safe according to EU standards, these are not at all well adapted for healthgrids.[3] Accordingly, it is important that the existing European framework of general product safety be re-examined to consider its applicability to transparently distributed networks such as healthgrids. For healthgrids, steps could be taken using guidelines or even specific legislation to address distributed computing services, which are at present only marginally covered.

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1 For a detailed legal analysis of the data protection issues, please see Annex I of D4.2, dedicated to Data Protection, Confidentiality and Security Issues.

2 Following Article 8, paragraph 4 of the Directive *"Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority*". On the other hand, following to Article 13, second paragraph, " *Subject to adequate legal safeguards, in particular that the data are not used for taking measures or decisions regarding any particular individual, Member States may, where there is clearly no risk of breaching the privacy of the data subject, restrict by a legislative measure the rights provided for in Article 12* (i.e. right of access of the person concerned to his data) *when data are processed solely for purposes of scientific research or are kept in personal form for a period which does not exceed the period necessary for the sole purpose of creating statistics*".

3 Directive 2001/95/EC on General Product Safety requires that any product put on the market for consumers, or likely to be used by them, are safe. Furthermore, it requires producers to provide consumers with the relevant information enabling them to assess the risks inherent in the product and to take appropriate measures in order to prevent these risks (withdrawal from the market, warning to the market consumers, recall products already supplied…).

The EU also has a range of legislation designed to provide consumers with a legal guarantee of high quality products and services,[4] but those texts do not apply specifically to the products composing grids or delivered by grids. The current EU level law is applied only within the general context of service provision and product delivery.

As we also outlined in our previous analysis, it is not always easy to determine the law applicable in terms of liability. The law on medical devices is very unclear with respect to healthgrids: while it may be argued that a healthgrid could fall within the ambit of the current Medical Devices Directive in that it is in part a software tool that impacts on a medical act, the whole construction of the Directive is based upon physical goods (which might have a software component) that are placed on the market for purchase or lease.[5] The directive is thus ill adapted to deal with the shared domain of grid-based services where software is sold and owned by a wide range of participants in a grid initiative. It thus seems that at present the only real way to have clarity over liability for the possible negative effects of healthgrids is through tightly constructed contracts in private law.[6]

If the use of healthgrids across the EU and international borders in shared public/private initiatives is to become a reality, then steps should be taken to develop guidelines and possibly legislation to harmonise the legal expectations of all actors in a healthgrid. As an interim step to EU legislation in this area, a suitable body such as the High Level Group on Health Services and Medical Care could be established to that intent.

Moving healthgrids beyond the domain of university-led and -funded research tools to the domain of health service provision will not be possible, however, if robust tools for sharing of the intellectual property inherent in the design and population of a healthgrid application are not developed. In our previous work, we underlined that as the law currently stands the rules of copyright are very protective and could constitute an impediment in the implementation of healthgrids because they treat computer software as a copyrightable literary work, the same as a play or a novel.[7] Currently, the owner of the copyrighted software running a healthgrid has the exclusive rights to reproduce his work, prepare derivative works, distribute copies to the public, perform the work publicly and display the work publicly. Under these circumstances any natural or legal person would have to pay to use computer programs while they

4 Directive 1999/44 /EC on the Sale of Consumer Goods is one example of this kind of legislation. For further details on this point, please see the deliverable D4.2, Annex II.

5 We could think that from the moment one of the components of the system is intended by its manufacturer to be used with a medical device, then this component constitutes a medical device and thus falls under the application scope of the directive. However, this one is not of the clearest in the determination of its field of application. For example, monitoring devices could be considered as medical devices under the directive, while tools used for the administration of general patient data will generally not be considered as medical devices.

6 These contracts should emphasize the responsibility of each of the participants in a grid, ant it more still when the components of the system are brought by producers or manufacturers who do not participate in the grid itself.

7 For a detailed legal analysis of the intellectual property rights implied by the implementation of grids, please see deliverable D4.2, Annex III.

constitute one of the most important components of healthgrids. Given that most grid applications will depend on shared access to multiple-copyrighted programmes it is unlikely that such a model of copyright is useful in protecting the entirety of a healthgrid application.

An open standards approach to software co-development could help the development and implementation of healthgrids. The open source licensing model actually uses copyright and contract principles to retain control of the work while enabling its use effectively for free and could thus encourage use and development.

With these first conclusions in mind and a further analysis of the use of grid technology in various medical sectors (research, healthcare, epidemiology, etc.), we outlined the following recommendations:

- A careful analysis of the full impact of data protection legislation on the potential for healthgrid development within the context of an ethical respect for privacy is needed;
- A stepwise approach to developing the liability framework distributing legal responsibility appropriately across the healthgrid users while providing legal certainty for all stakeholders, including patients, is required; and
- The balance between control over intellectual property rights and the protection of investments and the interest of a widespread and un-predefined community in interacting in the use of grid applications needs to be reconsidered.

2.2. THE LESSONS LEARNT ON THE SOCIO-ECONOMIC ISSUES

From a socio-economic perspective, deliverable D4.2 identified and discussed the following issues:

- An analysis of the extent of desirability of healthgrids is needed: what are alternative options for achieving the set goals?
- Also needed is an analysis of stakeholder perspectives and incentives, especially as regards financial implications of healthgrid uptake.
- It is likely that interventions aimed at adjusting private incentives will be necessary.
- Similarly, an adjustment of reimbursement schemes will likely need to follow to allow for sustainable uptake of new services that change clinical and working practices.

Finally, in order for the uptake and deployment of healthgrids to make a significant impact on the delivery of health services, social and behavioural issues must be addressed:

- Support and control the level of accuracy of results from using healthgrid processing;

- Ensure user confidence, based in particular on the above: no loss of quality leading to no loss of confidence.
- Facilitate change by supporting training and further education related to using healthgrids; and
- Facilitate change in working practices by minimising uncertainty and reducing risk for users.

In the sections to follow, these aspects will be further developed on the basis of the use cases defined by the SHARE project.

2.3. THE LESSONS LEARNT ON THE ETHICAL ISSUES

In D4.2, we introduced the fictional Oxbridge Cardiac Care Grid case, and used it to discuss the legal, ethical and socio-economic implications of such a grid application. Here we summarise the key points raised.

Autonomy, we noted, is intimately tied up with the legal duties of consent and confidentiality. Both however could prove difficult in the context of healthgrids.

The first question to ask therefore is whether the use of a healthgrid in the provision of care to a specific patient would require special consent. Looking at the example of the Oxbridge Cardiac Care Grid we can see that the doctor submitted the patient's data to a grid application in order to get assistance with the diagnosis. We will discuss later the need for consent to share the data in this way, but first must establish if the use of the grid application as such requires special ethical and legal consideration.

Here the question is on the impact of the use of a grid-based tool on the patient. Ethically we are looking at autonomy: is the patient's autonomy compromised by not fully understanding the technologies being used in providing care? Generally it is accepted that if a doctor uses state-of-the-art medical technology in the conventional way then a patient, in consenting to the care provided by that doctor, is consenting to the use of such technology. Thus, we do not expect a cardiologist to obtain special consent for using an ECG (electrocardiogram), nor a radiologist for using an MRI (magnetic resonance image). On the other hand, it may be moot whether a doctor in Accident & Emergency accessing a product such as the Map of Medicine expert referral plug-in requires special consent.

Two caveats should be observed, however. If the technology could do harm to the patient, special consent should be obtained, since respecting autonomy means providing sufficient information so that the autonomy of the 'informationally' weaker party can be exercised. Thus, the risks of an epidural anaesthetic must be explained before the needle is inserted. The same argument exists if the risk is social rather than medical. Thus testing for a genetic condition that is not amenable to treatment requires prior consent since knowledge of possessing such a gene will be a burden to the patient and might also affect rights to social goods such as health insurance and mortgages.

For us then the question is if the use of a grid application *per se* falls into these special categories. We would propose two guidelines here, based on an assumption of no loss of quality. For example, an assumption that there is no extra risk from networks failing, or from inferior equipment or software being used, or of the quality of knowledge accessed being inferior to that locally available (thus implying provenance information for any 'practice-based' evidence.

- If the use of a grid based tool is simply a way of getting a more complete diagnosis and moreover if it constitutes a reasonable use of medical expertise then no special consent would be ethically required;
- If the use of the grid based tool could expose the patient to any risk, such risks must be disclosed and special consent would be required.

We can see thus that the extent to which grid use poses a special ethical problem is not around consent to the use of the technology itself, but rather in consent to the sharing of medical information in the context of the duty of confidentiality.

The legal requirements of confidentiality have been extensively discussed both in this document and previous deliverables. Here we look at the ethical aspects of that duty. If submitting a patient's information to a grid based application in any way might allow other people to identify the patient, his or her autonomy is compromised.

Thus in healthgrids, one of the key ethical issues will be in the possible compromise of the patient's autonomy that will arise from sharing his or her data with people who in some circumstances are yet to be identified or, indeed, may not be fully identifiable. It is worth noting that it has been argued, notably by the European Article 29 Data Protection Working Party (Working Document on the processing of personal data relating to health in electronic health records (EHR), WP131), that consent has only a very limited place as a justification of the sharing of health related data in the electronic age. The Member States' data protection commissioners note, with particular reference to the development of Electronic Health Records systems that seeking a patient's consent to the sharing of information is not easily justified when to do so would be asking the patient to opt for a lower quality of care. They argue therefore that robust system of security of information and ethical practice should be adopted in which patients will be able to trust, notwithstanding that their information is shared, and providing for special opt-out possibilities when the nature of the information is especially sensitive.

In deliverable 4.2 we also explore the ethical principle of justice and of beneficence. The duty of justice is concerned with the duty to achieve a fair distribution of resources as well as the need to develop an overall just medical system in which the best level of health of the greatest number is achieved. It is in the respect for this principle that the greatest potential ethical benefit of healthgrids lies. The developments of applications such as MammoGrid have established that the sharing of a very large number of mammogram images across a wide network that allows radiologists to test suspect images against a known and tested database of cases significantly contributes to improved understanding of risk factors through epidemiology as well as leading to early detection of breast cancer.

The example of the MammoGrid application can also be used to describe the ethical duty of beneficence and non-malfeasance, also explored in more detail in D4.2, which demands that the use of a technology should do good, or at least do no harm. In the use of a MammoGrid, in which any harm of an individuals loss of autonomy is heavily outweighed by the ‘good’ of the creation of a huge database from which many may benefit in a way they could not were the technology not used. The HealthGrid in this case not only acts to the benefit of the known patient whose suspect image is submitted to the tool, but to the overall health of the population.

It can be seen therefore that healthgrids pose many challenges and opportunities on an ethical level, as well as on a practical legal level. It is of great importance therefore that research roadmaps for healthgrids provide not only for scientific development but also for social science research, which will allow us to explore further the extent to which the use of healthgrids can empower healthcare professionals to meet their four cardinal ethical duties of respecting autonomy, doing good, avoiding harm and contributing to justice in healthcare.

3. ANALYSIS OF THE USE CASE SCENARIOS

The use case scenarios developed in WP5 focus on epidemiology (5.*x*a) and innovative medicines (5.*x*b). The topics were chosen as they complement each other in exposing the problems that risk arising in the use of grids in different parts of the health sector and also in illustrating the potential benefits of grid technology.

D5.1a introduces the purpose of the use case scenarios in this project:

> "A use case scenario represents a significant example in the relevant application area. Such an example must be generic enough to be representative but specific enough to enable a clear and accurate analysis. […] It need not necessarily involve computers currently but must be sensible for the use of grids".[8]

In relation to epidemiology, D5.1a goes on to state:

> "[…] from the analysis of the problems in epidemiology, grid constitutes an enabling technology that can solve many technological issues and foster scientific development in the area, provided that the requirements for security, broadly conceived, data integration and reliability of epidemiological studies are adequately addressed".9

For innovative medicine, D5.1b explains:

> "The Pharmaceutical R&D enterprise presents unique challenges for Information Technologists and Computer Scientists […] The analysis of the problems of Innovative Medicine, (shows that) grid constitutes an enabling technology that can solve many technological issues and foster scientific development especially on Drug Discovery".10

The purpose of analysing these use case scenarios is to cross-validate the requirements and the needs identified in the legal part of the ELSE roadmap I (D4.2), and thus help us refine our recommendations.

In order to achieve this purpose, we analyse the two use cases with respect to their legal, socio-economic and ethical issues.

[8] See deliverable D5.1a "Use case scenario for epidemiology", p. 8.

[9] See deliverable D5.1a "Use case scenario for epidemiology", p. 7. The same references can be found in the deliverable D5.1b dedicated to innovative medicine, pp. 6 and 7.

[10] See deliverable D5.1b "Use case scenario for innovative medicine", p. 6.

3.1.Epidemiology Use Case

In deliverable D5.1a, epidemiology is defined as the scientific study of factors affecting the health and illness of populations.

Although there are many different activities in the context of epidemiology, this use case scenario concentrates on the development of extensive (population-level) retrospective studies of the morbidity and mortality of treatments, population features and additional clinical factors.

The use case scenario can thus be described as "A System Able to Link the Information from Distributed and Heterogeneous Databases, Identify Patients, Complete Episodes and Improve Automatically Quality Without Interrupting Clinical Practice".[11] In other words, it can be summarised as epidemiologists, public health authorities or pharmaceutical companies gathering data from different sources (primary care providers, hospitals, demographic information, prescriptions, morbidity records, social assistance, environment) integrating them and executing advanced statistical methods.

Deliverable D5.2a (epidemiology roadmap) sets the requirements of the use case as follows:

- automatic data gathering;
- enhancement of quality of data;
- sufficient security management;
- respect of ethical considerations;
- efficient performance of processing services;
- seamless integration of processing services; and
- reliability of long-term exploitation of the system.

Not all of these requirements raise ELSE issues, but those that do were analysed with respect to the first ELSE roadmap (see deliverable D4.2). Below, we analyse these problems again to see if legal solutions can be found within the existing European legal framework or if recommendations are needed to enable the implementation of grid technology in the epidemiology sector.

3.1.1. Data protection issues

As described in section 7.2 of D5.2a on "Sufficient security and ethical management", management of patient consent is a key issue for personal data: "the management of patient consent should be improved. Data owners should be advised with the requests that they have to make to the patients (i.e. the permissions they must seek) in order to

[11] Deliverable D5.2a "Epidemiology roadmap", p. 12.

ensure that their data is usable for research, storing and distribution over different countries".[12]

This comment shows that it has become common practice for information technologists and computer scientists to ask the patient for his consent when personal data related to his health are to be processed in the framework of epidemiological studies.[13] It is important, however, to underline here that obtaining patient consent is not the only way to legitimate the processing of personal data related to health. To qualify as legitimate, the processing of medical data has to be covered by one of seven hypotheses listed in Article 8 of the Directive 95/46/EC (the first hypothesis being patient consent).[14]

Article 8, 2(a) of the Directive thus provides that the data subject's explicit and valid consent[15] constitutes the very first source of the legitimacy for the processing of his medical data even if, at the same time, it is the weakest base to legitimate the processing of medical data due to the strict conditions for its validity and to the possibility for the data subject to revoke his consent to the processing of his medical data at any time and without justification.

It is in this context also that the Article 29 Data Protection Working Party issued on 15 February 2007 a working document on the processing of personal data relating to health in electronic health records (EHR),[16] providing guidance on the interpretation of the applicable data protection legal framework for EHR systems and explaining some of the general principles.

For the purposes of the working document, an electronic health record is defined as:
"A comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form and providing

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12 Deliverable D5.2a "Epidemiology roadmap", p. 18.

13 Which is important as the patient's consent constitute one legal way to legitimate the processing of his data.

14 The Directive grants permission to process medical data in six other hypotheses. Article 8, 2 of the Directive prescribes that:
"Paragraph 1 (i.e. the ban on the processing of medical data) *shall not apply where:*
[…]
(b) processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law in so far as it is authorized by national law providing for adequate safeguards; or
(c) processing is necessary to protect the vital interests of the data subject or of another person when the data subject is physically or legally incapable of giving his consent; or
(d) processing is carried out in the course of its legitimate activities with appropriate guarantees by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects; or
(e) the processing relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims".
The processing of medical data is equally permitted when it *"[…] is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and when those data are processed by a health professional subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy"*. Directive 95/46/CE, art 8, 3.

15 Directive 95/46/CE, art 8, 2(a).

16 Article 29 Data Protection Working Party, "Working document on the processing of personal data relating to health in electronic health records, adopted on 15 February 2007 by the Article 29 Working Party*"*, WP131, 00323/07/EN, available on *http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/wpdocs/2007_en.htm*

for ready availability of these data for medical treatment and other closely related purposes”.[17]

The working document of Article 29 Working Party could be of interest for epidemiology as EHR-data could thus be part of databases used in epidemiological research. The recommendations could be important also for the construction of epidemiological systems, i.e. in terms of organisational structures of epidemiological systems of research, detection and prevention of diseases, as well as in terms of categories of data stored in epidemiological databases and their modes of presentation and in terms of international transfer of medical data and of data security and transparency.[18]

In the context of the discussion on consent, it is however particularly important to note that the Working Party does not see consent as a valid basis for processing data in an EHR. It considers that, as the creation of medical records is a necessary and unavoidable consequence of the medical situation, a health professional may have to process personal data in an EHR, and thus withholding consent may be to the patient’s detriment. The Working Party argues that consent might not be valid if it is given for general processing of the EHR and for sharing with unnamed healthcare professionals (HCP). It argues that valid consent is limited to the sharing of data with a specific HCP and for a specific purpose. It would seem therefore that even sharing a record with several HCPs in the course of the treatment of a disease or condition may not be covered by a general consent where those HCPs and the nature of their intervention is not known by the patient at the time consent is given. By extrapolation, it can be concluded that consent would not legitimate the sharing of data from EHRs for epidemiological databases (nor for the distributed computing associated with healthgrids in general).

Given these remarks, it seems that patient consent would not be the best way to comply with data protection legislation for epidemiological studies either in the short term or in the long run. However, part 4 of the Working Party’s working document opens another door. That section elaborates on the “Use of EHR for other purposes,” than those mentioned in Article 8, 3, of Directive 45/96/EC particular when the processing takes place for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services and the personal data in question are processed by a health professional subject national law or rules established by national competent bodies the obligation of professional secrecy or by another person also subject to an equivalent obligation of the secrecy. Here, the Working Party is of the opinion that accessing medical data in an EHR for purposes other than those mentioned in Article 8, 3, of the Directive should in principle be prohibited. However, the Working Party is also of the opinion that processing EHR-data for the purposes of medical research and government statistics, which include epidemiology, could be allowed as an exception to the rule described

[17] Article 29 Data Protection Working Party, *op. cit.*, p. 4.

[18] For more details on this, see Article 29 Data Protection Working Party, *op. cit.*, pp. 13-21.

here above, provided that the medical research or the government statistics in question are in line with the Directive.[19]

In this context, a specific epidemiological study using EHR-data among other data could be allowed if it had been foreseen by a law or a legal provision (i.e. a special legal basis) for previously determined, specific purposes and under specific conditions in order to guarantee proportionality and thus protect the fundamental rights and the privacy of individuals.

On the other hand, epidemiological studies using different kinds of data but no EHR-data could be legitimate under Article 8, 2(a) of the European Directive. In these circumstances, the management of the patient consent should be improved, and as underlined in D5.2a, the management of the feedback to the patient should also be considered.

This could be feasible by using privacy enhancing technologies (PETs) as stated by the European Commission in its last communication to the European Parliament and the Council on Promoting Data Protection by Privacy Enhancing Technologies. The Commission defines PETs as "a coherent system of ICT measures that protects privacy by eliminating or reducing personal data or by preventing unnecessary and/or undesired processing of personal data, all without loosing the functionality of the information system".[20]

Following the Commission's opinion, PETs could contribute to meeting the criteria of the legal framework, which aim to minimise the processing of personal data and to use anonymous or pseudonymous data where possible. PETs could make breaches of data protection rules and violations of individuals' rights technically more difficult.[21]

D5.2a states that the current EU level legal framework presents various risks to the use of grids for epidemiology and enumerates in particular the following considerations:

- The data gathered at the beginning of an epidemiological study could be considered as excessive for a concrete study, since it is generally obtained for further studies.
- Data stored in the databases used in epidemiological studies is long-living and can have identifiable or implicit personal data within as it may be necessary for specific research in that arena, or indeed to satisfy duty of care.

[19] I.e., in line with Article 8, 4 of the Directive 95/46/CE and its Recital 34.

[20] Communication to the European Parliament and the Council on Promoting Data Protection by Privacy Enhancing Technologies, COM(2007)228, Brussels, 2 May 2007, see http://eurlex.europa.eu/LexUriServ/site/en/com/2007/com2007_0228en01.pdf

[21] PETs can be of different kinds. For example, they can be automatic anonymisation of data, encryption tools or cookie-cutters. As the Commission stated in its report the use of these tools can help to design information and communication systems and services in a way that minimises the collection and the use of personal data and facilitate compliance with data protection rules.

- The federation of data repositories produces virtual, distributed repositories, while according to the law it is not clear whether a virtual repository could have a unique individual data controller.

In answer to these considerations, we have found that the law does supply elements of answers to these questions, and need not necessarily be changed.

For example, the EU provides that Member States can enact specific legislation covering specific tools such as healthgrids in order to exempt scientists and medical practitioners using healthgrids from some of the more onerous duties of the Directive.[22] More specifically, Directive 95/46/EC can be considered as laying down a general framework that is substantially appropriate but not adequate to support most of the longer running research initiatives around which healthgrids are based. Under these circumstances, and as stated by the Commission, it seems necessary to translate the general rules included in the Directive into particular guidelines or provisions which would take into account the specificities of the new developing technologies.[23]

3.1.2. Liability issues

In D5.2a section 7.3 on "Reliability and quality of service in infrastructures and long-term exploitation", both elements (reliability of the services provided and quality of those services) are deemed essential to the deployment of grid technology in epidemiology.

Reliability lies, on one hand, on the development of robust services, and on the other hand, on the reliability of the infrastructure (both middleware and resources). While the issue of reliability of the software components of the system has been addressed in the technical parts of SHARE, the reliability of the infrastructure remains at present unresolved. This is particularly true in the production of studies as the infrastructures currently available tend to be intended for research rather than for the production of studies.

Since both research and the production of studies are key to epidemiology, grids must propose reliable, efficient and permanent services for both purposes if they are to become used in epidemiology. If these requirements are not fulfilled, liability problems will arise.

On the issue of liability for services, we have already outlined that EU level legislation is not at all adapted to the healthgrid domain, mainly because health services are organised at national or regional level and the European Union has no legal competence to draw up legislation that states specifically how a health service

[22] For a detailed analysis on this particular point, please see D4.2, Annex I.

[23] For more information on this topic see the Communication from the Commission to the European Parliament and the Council on the follow up of the Work Programme for better implementation of the Data Protection Directive adopted on 7 March 2007, COM(2007) 87 final.

should be organised. In this context, the only real way to have clarity over liability for the possible negative effects of healthgrids would be through tightly constructed contracts in private law. The solution proposed in the deliverable D5.2a, i.e. the certification of healthcare provision through grids, could be an interesting measure to favour trust in these systems from all users. However, such a solution cannot satisfy legal measures in the long term. Indeed, as the Commission explains, "the Internet and the new possibilities for data subjects to interact and to access services provided in third countries raise the questions on the rules for determining the applicable national law […]"[24] to those services. It is possible to imagine meta-rules to determine precedence: at present, the conservative rule 'choose the most restrictive among applicable statutes and regulations' would probably be acceptable, but would in due course come to be seen as unduly restrictive and working against the (evidentially) best treatment for the patient.

As we have already mentioned, if the use of healthgrids across EU and international borders in shared public/private initiative is to become a reality, then steps should be taken to develop guidelines and possibly legislation to harmonise the legal expectations of all actors in a healthgrid.

3.1.3. Intellectual property rights issues

While D5.2a (epidemiology roadmap) does not look in particular at intellectual property rights (IPR), the background section of the document does hint at possible effects of IPR legislation on the use of grids for epidemiology. The background lists the elements that researchers using ICT generally take for granted. Among others, researchers expect that the results of their research will be private and not available to third parties.

While such restrictions seem evident enough as regards the final results derived from a database, they are not quite so obvious when it comes to the actual database as it is constructed.[25]

Given that epidemiological systems must be properly secured,[26] direct access to databases will most probably be denied to persons who are not directly linked to the specific epidemiological system. This is because personal data will likely be processed in epidemiological systems, thus implying the application of the Data Protection Directive, which imposes that when personal data relating to health are collected and stored on networks or in a system, technical means be applied to the system in order to protect data from unauthorised access.

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[24] Communication from the Commission to the European Parliament and the Council o the follow up of the Work Programme for better implementation of the Data Protection Directive adopted on 7 March 2007, COM(2007) 87 final, p. 6.

[25] The constitution of a new epidemiological data base will also raise other intellectual property rights problems, notably when this data base is composed of substantial extractions of other existing data bases or of data extracted from EHRs. There will be notably problems concerning the rights of the patients as for the exploitation of their data contained in EHRs. These problems were looked at in a detailed way in the deliverable D4.2, Annex III.

[26] See D5.2a, pp. 15 and 16.

While the Data Protection Directive applies to the data in the database, another Directive also applies to epidemiological systems as far as databases are concerned: Directive 96/9/EC of the European Parliament and the Council of 11 March 1996 on the legal protection of databases.[27]

As explained in D4.2, Annex III, application of Article 7, 5, of the Directive provides that *a contrario* non-substantial extractions from a database and reuse may be undertaken by third parties, without the rights owner's authorisation, as long as these acts are not made in a repeated and systematic way that would imply a conflict with the normal exploitation of the database or produce an unreasonable prejudice to the legitimate interests of the database's maker. In this context, manual extractions of information from epidemiological databases could be legal and creators of an epidemiological system would have to implement authentication methods to prevent parties outside of the system extracting information from their epidemiological databases and reusing it in newly created systems.

3.1.4. Socio-economic issues

Deliverable 5.2a identifies "the reimbursement and financial implications and the service-oriented business model" [28] as the main concern with respect to the epidemiology use case. A particular challenge is identified as follows:

> "Currently, infrastructures are intended mainly for research and do not have a clear exploitation plan. The acceptance of applications is done through scientific committees, but the compromise of resources is not normally addressed."29

The reference to research covers technology, or more specifically grid technology research. In other words, the drivers of healthgrids at the moment are technology scientists rather than eventual users – in the use case these would be public health authority staff, epidemiologists, and pharmacologists. As a consequence, the financial flows and other resource availability are based in the "wrong" field, if looking from a long run perspective. Proof of concept and pilot developments testing robustness and functionality of the technology are necessary and can be paid for in the context of technology research. Yet the ultimate uptake depends on a business case for users after the technology has been fixed. The need to switch the financing model of healthgrids from technology research to being part of the resource portfolio in end-user organisations has to enter the strategic as well as the day-to-day planning of those developing healthgrids. This recommendation is scalable to other application areas beyond the epidemiology use case.

[27] Directive 96/9/EC of the European Parliament and the Council of 11 March 1996 on the legal protection of databases, OJ. L77, of 27 March 1996, pp. 20-28.

[28] See D5.2a, p. 21

[29] Deliverable D5.2a "Epidemiological roadmap", p. 23.

An important further aspect, highlighting the interconnection of all ELSE issues, is the need for legal and regulatory certainty. When assessing potential changes in resource portfolios, in this case concerning the fit of participation in healthgrids to the overall organisational objectives and strategy, decision makers have to account for risks. Uncertainties, especially of a legal and ethical nature, cause a high risk factor to enter the calculation, thus endangering deployment of an otherwise worthwhile investment.

The main social issues requiring attention, as recognised in D5.2a, are user-friendliness and training – basically addressing acceptance of healthgrids by users.[30] Even though details like interfaces may not present major technological or scientific challenges, they have a significant impact on acceptance. When presenting prototypes to eventual end-users (independent of whether they are public authorities, epidemiologists, or pharmaceutical companies) developers have to pay attention to the details seen by the target group. Even the most sophisticated and robust technology will be rejected if users feel they need a degree in engineering before being able to use it.

A final issue is the impact of healthgrids on current working practices and procedures. On the one hand, fewer changes lead to lower acceptance barriers. On the other hand, studies on the economic impact of eHealth show that precisely such changes are required for achieving substantial benefits.[31] This means that the promises of healthgrids and the current epidemiological practices have to be analysed in parallel, identifying the most advantageous form of liaison. As a general hypothesis, this will neither be to adapt fully the technology to existing procedures, nor to change completely current procedures in order to fit technology specifications.

One of the main conclusions of D5.2a, that effective healthgrid pilots are still necessary[32], holds also from the socio-economic perspective. It is, however, important to take into account the above recommendations in the design of such pilots. Also, in order to validate results of such pilots in a way that assists the construction of sound business cases, analysis of utilisation, cost, and benefits over time,[33] accounting for optimism bias and risk will be important.

3.1.5. Ethical issues

Many of the key ethical issues of the epidemiology case are signalled also within the legal issues. In looking at the data protection issues from a legal perspective, we raise also the ethical questions of autonomy, such as to whom does data belong, and, how is

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[30] See D5.2a, p. 21.

[31] See for example STROETMANN, K.A. JONES, T. DOBREV, A. and STROETMANN, V.N., *eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites*, Office for Official Publications of the European Communities, Luxembourg, 2006 (56 pp. - ISBN 92-79-02762-X), available on www.ehealth-impact.org

[32] See the deliverable D5.2a “Epidemiological roadmap”, p. 27.

[33] For details on optimism bias and risk in economic assessments, see HM Treasury (2003), THE GREEN BOOK: Appraisal and Evaluation in Central Government; available at: http://www.hm-treasury.gov.uk/media/05553/Green_Book_03.pdf

the patient's control over his or her information ensured? Similarly, in looking at legal questions of liability we consider questions of beneficence: who will benefit from large-scale data networks and how can the interests and needs of individuals be respected? And finally, in looking at the legal questions in intellectual property we address also some of the ethical questions of justice: how can a fair distribution of benefits be achieved in a communally built system?

However, the legal answers do not provide all the ethical answers. Although the broad ethical issues were discussed extensively in the deliverable D4.2, the issues raised in the use case on epidemiology raise a further interesting question of the impact in the ethical behaviour of the doctors and scientist.

In his novel *Mount Misery*, Samuel Shem sets out a frightening picture – a time when doctor's decisions are ruled not by their own decisions, but by the electronic decision support tools they use and the pre-coded forms supplied by the insurers:

> *They spent hours reading whichever D S M diagnosis was now bankable. If suddenly the insurance was paying top dollar for, say, 301.13, (Cyclothymic Disorder), the big Toshiba would be reprogrammed to reprogram all the little Toshibas, so that for data I typed in now it would spew out, time after time like a run of luck at craps in Vegas, 301.13, 301 .1 3, 3 01 .1 3 (…)*[34]

The ethical dilemma which Shem describes is one which many fear might arise if hidden decision support takes a significant role in medicine – the fear that the autonomy of the clinician will be overridden by a machine which is no longer programmed on the basis of medical information alone, but can be infiltrated by other data over which the clinician has no control. Whilst this is a particularly sinister dystopian vision, it would be possible to paint an equally disturbing picture in which human agency or greed played a very much smaller part, but the medical decision-making outcomes became equally horrific.

Placed in the context of the epidemiological use case described in this project, we can see that a number of specific ethical challenges arise. In particular, it will be important that the developers of such applications are fully aware of all the interests of the various parties wishing to implement a system in order to ensure that the interests of all are fairly balanced.

We have already observed that patient autonomy is a key aspect of medical ethics. We have noted that the use of grid applications may limit that autonomy in some way because patients will not have access to the data. Traditional medical ethics texts, such as those written by Beauchamp and Childress, Raanan Gillon, and others highlight prominently the need to consider the autonomy of the patients. Few, however, have looked at the need to protect the autonomy of the clinician. Dirk Thomas

[34] SHEM, S.. *Mount Misery*, New York, Dell Publishing, 1997, p. 213.

Hagemeister[35], writing on the ethical challenges of ICT to patient care, describes a brave new world not unlike that described by Shem in which the clinician's free will is compromised by hidden decisions within software on which he or she depends in daily decision-making. Hagemeister notes that in traditional medical care clinicians are often guilty of treating the diagnosis, not the patient – "how is the knee in room twelve" and "get ready, we've got a coronary coming in" are not unusual phrases to hear in a busy hospital. In such a setting, the advent of decision support that may 'pre-diagnose' will thus create special ethical problems in that the physician, already disconnected from the whole patient, may now even become disconnected from the diagnosis. As Hagemeister argues: "In an extreme situation, this could result in the diagnosis being adjusted to the framework defined by the information technology. This could simply be the case if the encoding system does not offer the real diagnosis as a selectable option and therefore, the diagnosis needs to be substituted by an available code, a problem that occurs especially in the initial phase of a new system."

In the case a grid application for epidemiology, it is therefore of very great importance that the tools that collect, aggregate and quality control the data that are used by the epidemiological tool are tested for possible bias which could effectively rule out certain configurations and certain results. It is of paramount ethical importance that the tool does not compromise the autonomy of the individual to make decisions – be they personal decisions as to who sees or handles one's data or professional decisions which in turn impact on the care given.

Similarly the code of a grid based epidemiology application must be rigorously tested to rule out bias that could lead to an unjustifiable exclusion of a particular group or to decisions that could do harm. One could, for example envisage an epidemiology tool which, based on current knowledge, would not collect a particular data parameter from a particular ethic group because no epidemiological evidence existed at the time for writing the code that the group in question showed the characteristics in question. While an automated system must be based on code rules written on current knowledge in the medical domain, sufficient safeguards must be built in to allow frequent querying and updating of the code to show such potential biases.

3.2.Innovative medicine USE CASE

D5.1b on innovative medicine defines these medicines as a treatment or a therapy of empirical benefit that is still outside the mainstream of conventional medicine.

The deliverable also defines drug discovery as the process by which drugs are discovered and/or designed.[36] The first goal of drug discovery is to find new molecules that bind with specific macromolecules known to play a role in a disease process in a manner that changes their function, either to increase resistance or to

[35] HAGEMEISTER, Dirk Thomas, "Software must not manipulate the physicians:", *in The IT Challenge to Patient Care International Review of Information Ethics*, Vol.. 5, 09/2006.

[36] Deliverable D5.1b "Use case scenario for innovative medicine", p. 9.

reduce the virulence of some pathogen. Drug development thus manages pre-clinical safety studies and later clinical phases, which include clinical trials. Registration and delivery of medicines discovered are the two last steps of the full discovery process. It is important to note here that *in silico*, i.e. computing-based simulation, drug discovery is one of the most promising strategies to speed up the drug discovery process.

The use case scenario in the SHARE project concentrates on *in silico* drug discovery, and therefore on the first steps of the drug development process rather than on the later clinical phases. *In silico* drug discovery contributes to increasing biological system knowledge, to managing data in a collaboration space, to speeding up analysis and consequently increasing the low success rate of the traditional “wet” approach[37] – all of which are key priorities for pharmaceutical companies.

As described in D5.1b, the pharmaceutical R&D enterprise presents unique challenges for information technologists and computer scientists: the diversity and complexity of the information required to arrive at well-founded decisions based on both scientific and business criteria is remarkable and well-recognised in the industry.

The scenario presented in D5.1b could take the form of academic or private molecular biology and biochemistry researchers and/or pharmaceutical companies of different sizes gathering data from different medical and biological sources (such as molecular, cellular, tissue and population as well as from molecular biology and chemistry), integrating them and executing advanced *in silico* simulation.

The requirements for the use case are described in D5.2b as follows:

- data integration;
- workflow enactment i.e. management of a large number and variety of software tools and dataflows between them;
- access to computing and data resources; and
- collaboration between public and private partners.

While not all of these requirements have legal implications, those that do were analysed in D4.2 and some legal constraints appeared to the deployment of the grid technology in the arena.[38]

3.2.1. Data protection issues

Drug development raises a number of legal issues, particularly in late stages where clinical trials are conducted and patients are involved in order to test the proposed medicines. It is in these late stages that data protection issues would arise, as personal data relating to health will necessarily be processed in these phases.

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37 For more details on this point see D5.2b, pp. 16 and 17.

38 See D5.2a, pp. 18-20.

Given that the use case scenario stops at the *in silico* phase of drug development, the data involved here are molecular, cellular or tissue data, as well as knowledge of molecular biology and chemistry. No person-specific data is handled and thus no data protection constraints appear.

Had the use case scenario included the clinical phases of the drug development process, the story might be different. However, since most of the bio-banks used to test the molecules only contain fully anonymised data, on which no keys can be used to reconstruct the patient identity, the data protection issues are less pertinent than in the use case scenario dedicated to epidemiology presented here above.

3.2.2. Liability issues

Section 7.2 of D5.2b looks at legal issues, and in particular at issue of liability in design work. The example here is of subsidiary claims of liability in the case of an experiment in docking where the experiment is badly designed and the experimenters are considered to have been negligent. Negligence can occur when the researchers' interaction with the system is based on automated data retrieval and aggregation. In effect, the researchers would be choosing a particular molecule and might be developing a new medicine on the basis of a machine decision.

Legally this poses only small problems so long as no mistakes are made. But if a mistake is made, or if the systems do not function correctly and, at the clinical trial stage, patients testing the new medicine are harmed or die, the liability issue could become more acute.

There are thus real liability constraints to the implementation of pharmaceutical grids within the European Union. Indeed, in case of failure of a pharmaceutical healthgrid, there will thus be two systems of liability at play, as the failure may be held to be due to a product or to a service. The problem is that at European level, there are currently no legal guidelines on how liability for services is shared, while rules regulating to the liability for products are multiple, as already explored in detail in D4.2.[39]

At present, such liability issues are thus subject to carefully drafted contracts that pre-define liability for possible mistakes. Moreover, where no contracts are drafted, in case of problems with the services composing the pharmaceutical grid, liability is governed by ordinary rules of law applicable in the different EU Member States. This situation provides neither the legal clarity nor the incentive necessary for researchers to want to use a healthgrid. As we previously recommended, we would argue that the European Union should adopt either secondary legislation such as a Directive or at least common contractual guidelines for clarifying the liability issues in terms of reliance on an automated decision tool support in the drug discovery phase of the drug development process.

[39] See D4.2, Annex II.

3.2.3. Intellectual property rights issues

D5.1b hypothesised that, for competitive reasons and intellectual property protection reasons, pharmaceutical grids will predominantly be private enterprise-wide internal grids with strict control and standards. In the list of requirements for *in silico* drug discovery, however, D5.2b explained the need for public-private collaboration, as joining new information technologies with life sciences to enable *in silico* drug discovery requires strong remote co-operation between different public and private experts in order to share the resources, to reduce the hardware costs and as a consequence reduce the time necessary to find new interesting molecules.

As pointed out in D4.2, there is a contradiction between the intellectual property rights and the needs of the grid technology, which would require that the access to databases and to software be free of rights. The challenge for EU and/or national legislators is therefore to find a way of balancing the two competing sets of rights. If they do not, a full exploitation of grid technology in pharmaceutical research, and most generally in healthcare, could be slowed down for a long time.

As such, it might be desirable for the Commission to develop guidelines to the use of open licensing and open standards, which could address the tension between the intellectual property rights of developers and the needs of the grid technology. Such an open standards software approach could then be a solution to help the development and implementation of healthgrids. As underlined in D5.2b, this solution is currently been examined within the WISDOM collaboration, where no intellectual property rights are claimed on the information circulating between the consortium different partners, including on analysis of potential hits.

3.2.4. Socio-economic issues

The economic issues raised in deliverable D4.2 are fully relevant to the drug discovery use case. In particular, the issues related to the switch from project-based, experimental activities to sustainable routine services, the role of public authorities and funds, and the scope of utilisation of grids that leads to optimal use of resources have to be addressed.

Existing activities in the domain of the innovative medicines use case are initiated by technology scientists. Although common wisdom tends to speak of this as a bad sign, it is not necessarily so. The point is more subtle – as in the epidemiology use case, the move towards sustainability (i.e. not the initial impetus) needs to be driven by demand from end users. The corresponding recommendation is similar to the one made in the epidemiology case – pilot applications used as demonstrators should pay attention to the details to which the end-users (public research organisations, private research SMEs and large pharmaceutical companies) are exposed.

The issue of diverging social and private incentives is also relevant. Impact assessment, (including ex-ante analysis) on the societal level includes all stakeholders, and all possible costs, benefits, and utility. Individual appraisal, usually at organisational level, is concerned with positive and negative effects to one particular stakeholder. “Given that grid applications, by definition, require the participation of a large number of partners, and that drug discovery impacts on an even larger number of stakeholders (from organizations to individuals), these two kinds of analysis do not necessarily yield consistent results”,[40] pointing to inefficiency of resource allocation. Although socially desirable, healthgrid services in the drug discovery and development domain may remain limited or fail to be established at all due to insufficient private incentives for the end-users. As also noted in D5.2b, the exploitation of existing public grid infrastructures (like EGEE) in some form of partnership between public and private actors has to be politically encouraged. Agreements on specific conditions, clarifying the rights and obligations of both public and private parties, have to be made at the earliest possible stage. These will diverge from case to case, but first contracts can serve as useful precedents and reference points.

The links between organisations across the EU and beyond that are established through specific technology-driven or otherwise motivated experimental and pilot projects should be used and further developed. A slowly emerging culture of cooperation and collaboration is laying the foundations for successful deployment of data, and later even knowledge grids. Further developing existing networks will also be beneficial in this respect.

In order to achieve the best outcomes in terms of effectiveness of research, the extension of *in silico* tests into further stages of the drug discovery and development process should be investigated. Based on the analysis presented in chapter 7 of D5.2b, performing more steps in drug discovery using healthgrids is likely to prove beneficial. For instance, by substituting some clinical trials, the risk for participating patients is significantly reduced. The effectiveness of the tests can also be increased by using various disparate databases through a data grid. This improvement in patient safety comes with issues about data protection and security[41]. During upcoming pilot projects, forward looking studies about the optimal level of adoption of grid-based in silico testing in the drug discovery and development process should take place. These studies can confirm or disconfirm the realisation of the above described benefits and, to the extent they exist, provide insights on their relative size. The outcomes can guide the efforts of research and development of the respective technology solutions.

A significant social aspect connected to the recommended cooperation between public and private actors, more specifically governments and the pharmaceutical industry, is the opportunity to use healthgrids for fighting currently neglected diseases. “By reducing the cost and increasing the effectiveness, i.e. probability of success, of drug

[40] See D5.1b, p. 26.
[41] See our legal analysis on data protection for more information, starting in D4.1 and D4.2.

discovery, healthgrids can make research financially worthwhile even for currently neglected diseases".[42] Using public resources and keeping results in the public domain to a certain extent can spread the drug development costs and facilitate wider access to drugs types currently unaffordable to those who need the medicines most – populations of poor countries and poor population segments in developed countries. Of course, this would require a significant commitment of political will and public resources.

3.2.5. Ethical issues

In silico drug discovery is, by definition, one step away from individuals. In looking at the ethical questions raised by the use of grids in this enterprise, it is important to focus on some of the big ethical concepts such as justice and beneficence, as well as the more individualistic concepts of autonomy.

In considering these ethical questions, it is worth using the check list of implications for the Universal Declaration on Human Rights of New Technologies developed by Mary Rundle and Chris Conley for UNESCO,[43] which notes that "ICTs contribute to health-improving and even life-saving benefits, ranging from clean-air technologies and coordinated medical research to early emergency alerts and quick access to medical information" and goes on to question if the technologies, in the context of Article 3's right to life, liberty and security, raise a "right universal access to these benefits of technology, regardless of ability to pay?"

Deliverable 5.2b noted that the potential benefits to society through the use of grid computing to assist *in silico* drug discovery were significant – not only in terms of the potential to alleviate suffering and illness, but also in the economic impact on reduction of illness and the drug development industry itself. It is therefore important that in the development of such technology, due consideration is given also to the ethical impact of failing to use grid technology. If drugs can be discovered more quickly and more efficiently using the technology is not within the ethical duty of beneficence for governments to support such developments?

The ethical duty of justice, which is concerned primarily with the fair allocation of resources, could also call for the use of a technology that can lead to quicker and more efficient drug development, again taking the ethical argument out of the private domain and into the political arena of public funding and support.

[42] See D5.1b, p. 25.
[43] RADOVKOV, Boyan (ed), Ethical Implications of Emerging Technologies: A Survey edited by the Information Society Division, Communication and Information Sector UNESCO, Information for All Programme (IFAP)., Paris: UNESCO, 2007.

4. MAPPING AND ROAD-MAPPING

Recommendations

Following our recommendations in D4.2 and now that we have looked at the use case scenarios and their respective requirements, we are able to fine-tune our recommendations further. We should note, however, that not all recommendations will be applicable to all kinds of grids for epidemiology or for pharmaceutical research or even in the healthcare sector.

Indeed, our vision for a fully functioning grid is that of a knowledge grid, based solidly on fully working computational and data grids.

A computational grid can be defined as a grid designed, constructed and configured to execute high performance computing tasks efficiently. The innovative medicine use case scenario built up in D5.1b can be seen as a good example of a computational grid as the computer power enclosed in the system created is essential to find the right molecules in order to develop medicines.[44]

A data grid meanwhile can be defined as distributed and optimised storage of large amounts of accessible data. The data stored and exchanged in that environment are heterogeneous and dispersed, including molecular data (e.g. genomics, proteomics), cellular data (e.g. pathways), tissue data (e.g. cancer types, wound healing), personal data (e.g. EHR) or population data (e.g. epidemiology). The epidemiology use case scenario built up in D5.1a is a good example of a data grid.[45]

Finally, a knowledge grid can be defined as intelligent and collaborative use of mainly data, but also computational grid, to create and manage relevant knowledge with provision of appropriate tools for all categories of users. This kind of grid builds on the two other grids, requiring the data from which to extrapolate the knowledge but also the computing power for possibly sophisticated calculations.

While the evolution computational => data => knowledge grid does not necessarily require that one be complete before going on to the second, nor is the progress totally chronological and linear, we have nonetheless chosen to produce recommendations on each of these three categories, bearing in mind that roadblocks to one could prevent going on to a fully functioning next or other step. It should also be noted that some of the recommendations drawn up for computational grids are also applicable to data grids and to knowledge grids. Indeed, the three kinds of grids as defined above are virtual constructions. In real life, it is very difficult to distinguish all the components of a grid or to find a data grid working without some computational power or a computational grid not enclosing data.

[44] Some computing grid applications are being deployed successfully (DEISA, EGEE).

[45] In real life, a few successful data grids exist such as BIRN, BRIDGES or Medical Data Manager.

4.1.Legal Recommendations

4.1.1. Legal Recommendations for computing grids

Recommendation on the division of liability in a multi-user system

As we have outlined above, the use case scenarios developed in D5.1b and D5.2b are good examples of a computing grid. It also shows best the traditional problems that are more likely to happen in a computing grid, i.e. problems of malfunctioning of the system and thus liability issues arising.

As mentioned in the introduction, using grids blurs the liability issues in terms of medical practice. While the EU has a range of legislation designed to protect citizens from harm resulting from goods offered on the market, the construction of healthgrids makes it difficult to ascertain at which EU level legislation would apply to each part of the system. This is particularly the case with the law on medical devices, which is very unclear with respect to healthgrids.

As it is not possible for the victim of a healthgrid system malfunction to determine where to attribute responsibility (e.g. which person or organization is blameworthy), the first recommendation made in D4.2 is particularly applicable here. A stepwise approach should thus be taken to develop the liability framework, distributing legal responsibility appropriately across the healthgrid users. Such an approach would help to favour the reliance on the system while providing legal certainty for all stakeholders, including patients.

Recommendation on liability for healthgrid services or services provided through the grid

Services composing the healthgrid or provided from it might include general medical information through a website or might be the provision of medical advice or specific decision support to clinicians or might even involve the collection of biomedical data for remote monitoring by a clinician. Such services might conceivably cause damage to someone relying on the system. As we saw in the case story developed in D4.2, a citizen might follow bad advice and fall ill, or even die; a clinician might follow the recommended procedure after using a decision support tool and might harm a patient; or a remote monitoring service might fail to transmit relevant data thereby putting a patient’s life a risk. For example, in a MammoGrid-style economy, if an image-standardizing tool interacts badly with an image annotation program, it may lead to false positives, false negatives or both.

There is currently no general European harmonisation of liability rules for services. Therefore, liability for services is governed by ordinary rules of contract law applicable in the Member States.

However, when a service is a purely technical one and the provider is an Internet intermediary who transmits or stores third party information, such as a web-based store-and-forward service for biosignal data for example, the technical service provider will benefit from the rules of exoneration of liability established by the eCommerce Directive. These rules may minimise the risks for technical partners of healthgrid service providers, who act as 'intermediaries'. For example, a web site hosting service will not be liable for the illegal sale of medical products made through an ePharmacy website.

In this framework, the European Commission should consider supporting the adoption of EU level guidelines that would identify the various parties involved in delivering healthgrid services and annex services and establish the various liabilities that each party must accept. Such guidelines should be widely disseminated in order to develop users' confidence in the use of healthgrids in general. In particular it should be investigated whether specific guidelines on those specific services could be drafted under the provisions for a Code of Conduct established in Directive 2000/31 on eCommerce.

Recommendation on product safety

As mentioned in D4.2, in the framework of the European level legislation applicable to product safety, national authorities have been established to monitor product safety and to take appropriate measures to protect consumers. Under these circumstances, an information system has been put in place that imposes collaboration between distributors, producers and the national authorities but also between Member States and the European Commission (RAPEX).

At present, this system is not used at all for products used in the composition of grids systems. The European Commission should thus adopt policy tools encouraging the use of the RAPEX system for such products.

Recommendation regarding the Medical Devices Directive

As outlined in the introduction to this document, the law on medical devices is very unclear with respect to healthgrids. While it may be argued that a healthgrid could fall within the ambit of the current Medical Devices Directive, in that it is a software tool that impacts on a medical act, the whole construction of the Directive is based upon physical goods (which might have a software component) that are placed on the market for purchase or lease. In this situation, many of the currently available monitoring devices are covered only by general product liability, but not by specific liability provision.

In this framework, special guidelines should be issued in order to clarify the application of medical devices legislation to specific tools used in healthgrids.

4.1.2. Legal recommendations for data grids

Recommendation on patient consent

As stated above, the use case scenarios developed in deliverables D5.1a and D5.2a are good examples of a data grid application, albeit with computational grid elements also. They demonstrate the traditional problems that are more likely to happen in a data grid, i.e. problems of data processing, legitimacy of data processing, legality of data processing, quality of the data, patient consent, patient rights, transfer of data between EU Member States and abroad.

As regards data protection issues, we argued that in broad terms the current EU level legislation was adequate but not ideal for promoting healthgrids as it does not address any particular issue related to healthgrids systems and services.

However, the European Working Party on Data Protection, established under article 29 of the Directive and composed of the national data protection authority of each Member State, has recently acknowledged that some special rules may need to be adopted for key eHealth applications. This has an impact on the way healthgrids are designed and specially on the way the data are collected and processed in these systems.

In February 2007, the Working Party issued a working paper looking at the applicability of data protection legislation to Electronic Health Record (EHR) systems. In its report, the Working Party noted in particular the limitation of the use of consent to permit the processing of heath data. The Working Party notes that if processing health data in an EHR system is the primary way of processing health data in a given health system, then a patient's care may be compromised if he or she opts-out of such a system by not giving his or her consent to the creation of an EHR. Accordingly, consent should not be used as it cannot be said to be truly and freely given.

The remaining provisions setting aside the general prohibition on article 8 of the Directive 95/46/CE can also be said to pose some problems – notably the idea that a patient ought to know the full finality of the use of data before his or her data may reasonably be used. But, as noted by the Data Protection Working Party there are some problems in using consent as a valid basis for processing data in eHealth applications. Indeed, if the creation of, for example, electronic medical records is a necessary and unavoidable consequence of the medical situation, withholding consent may be to the patient's detriment.

Therefore it would seem appropriate for the European Commission to co-ordinate the adoption of specific rules for the processing of health information to allow for proper balancing of patients' and public health interests, without recourse to the concept of consent.

Recommendation on specified and explicit purposes

As broadly explained in D4.2, according to the Data Protection Directive, data may only be collected for specified and explicit purposes. This principle requires that, prior to processing personal data, the controller has to define clearly and precisely the purpose(s) for which the data are to be processed. Moreover, the processing should be transparent.

Furthermore, the data collected may be used only for the initial purpose and should not be re-used in a way incompatible with the initial purpose. Generally speaking, the purpose of the new processing has to be compared to the initial one(s) in order to assess whether there is a close relationship between them. A new purpose that is clearly different from the initial one(s) will be considered incompatible.

It should be noted that, if further processing is deemed incompatible with the original purpose, further processing for historical, statistical or scientific purposes may be allowed if the data subject consents or if national legislation provides for such processing, which is not the case in all Member States of the European Union.

This situation seems to be problematic especially when healthgrids are used in order to conduct epidemiological studies (as we saw it in the analysis here above). Under those circumstances, in order to make optimal use of healthgrids in all sectors, the European Commission should support the adoption of guidelines on the definition of the concept of finality of purpose that would provide an adequate balance between protection of the interests of the individual on the one hand and public health management and disease prevention on the other.

If healthgrids can be used for risk detection, disease monitoring and preventive care, legal guidelines should be established that clarify the circumstances in which professionals can make further use of personal data related to health in the interests of public health. Such guidelines should allow for secondary uses even where such uses could not have been foreseen at the time of data collection.

Furthermore, while most Member States have already adopted guidelines at national level for such re-use of data for research or statistical purposes, efforts should be made to harmonise these approaches across the EU so that meaningful cross-border work can support the health of all EU citizens.

Recommendation on technical and organisational security measures

Efforts should be made to harmonise national standards on the technical and organisational measures of data security. While the Data Protection Directive calls for such standards to be adopted, little has been done at a regulatory level to harmonise guidelines across the EU.

4.1.3. Legal recommendations for knowledge grids

A knowledge grid builds on the computing grid and on the data grid in order to exist. It requires a data grid to function, while at the same time it is very likely to rely also on a computing grid.

The recommendations made above regarding the computing grids and the data grids are thus also applicable to knowledge grids. However, the issue of intellectual property rights is particularly problematic for knowledge grids and we therefore address those below.

Moreover, the status of knowledge 'in the grid' is also problematic and must be considered.

Recommendations on intellectual property rights

As we saw in the two use case scenarios, the collaboration between private and public institutions will be particularly significant for scientific research in healthgrids, and may create numerous problems with respect to ownership of intellectual property.

As pointed out in D4.2, there is a contradiction between the intellectual property rights and the needs of the grid technology, which would require that the access to databases and to software is free of rights.

The challenge for EU and/or national legislators is therefore the find a way of balancing the two competing sets of rights. If they do not, a full exploitation of grid technology in pharmaceutical researches and most generally in healthcare, could be slowed down for a long time.

As such, it might be desirable for the Commission to develop guidelines to the use of open licensing and open standards, which could address the tension between the intellectual property rights of developers and the needs of the grid technology. Such an open standards software approach could then be a solution to help the development and implementation of healthgrids.

On the other hand, the use of healthgrids in the drug discovery sector raises the issue of the ownership of both methods used to discover the medicines and the results achieved. Indeed, all the grid nodes that contribute resources to compute the docking probabilities could claim some ownership of the results and the designers of the software used in the process would certainly be in position to claim ownership of the method. In this context, one may ask whether it is important to know, say, which grid node was the one to identify a particular candidate molecule.

In this context, it is of essential interest, notably in patents, to determine guidelines that would determine, in case of collaboration in the research, what every actor is entitled to according to his contribution to the system.

Recommendation on privacy and health information infrastructure

A suggested above, a Directive or Code of Conduct on Privacy and Health Information Infrastructure should be developed within the context Directive 95/46/EC and could take the form of either a dedicated Directive or could be an EU-level Code of Conduct to be approved by the European Working Party on Data Protection set up under article 29 of the Directive. Any such Directive or Code would be complementary to Directive 95/46/EC on Data Protection and Directive 2002/58/EC on Privacy and Electronic Communications.

This could help to solve the problem of data processing legitimacy. In particular, it could provide possible bases of legitimacy other than the data subject's consent.

It could also provide the following solutions:

- appropriate safeguards to allow for the further processing of personal data (and especially of medical data) for substantial public interests (without requiring the data subject's consent) like scientific research (example of appropriate safeguard: a first coding by the initial data controller and a second coding by a trusted third party gathering all the data from the data controllers before sending them to the researchers);
- appropriate safeguards to allow keeping the data for longer periods for scientific use;
- terms under which identification numbers or other identifiers may be used;
- terms under which (coded) personal data may be transferred to third countries for scientific research.

4.2. Socio-economic recommendations

In deliverable D4.2 we identified a number of socio-economic issues that require further attention. The analysis of the use cases allows us now to refine our recommendations for the healthgrid ELSE roadmap. D4.2 stressed the need to ensure that healthgrids, as well as the services delivered over the grid infrastructure, respect the private interests of all stakeholders. This is a key factor towards socio-economic sustainability. More detailed steps towards that goal include appropriate economic and business analyses, accuracy and vigour of processes, user friendliness, and building of confidence. Before going into specific recommendations related to computing, data, and knowledge grids, we summarise some general issues stemming from our analysis.

One of the main socio-economic themes requiring attention is the need for business cases for all stakeholders involved in developing and using healthgrids. This is critical because any stakeholder can de facto veto the whole process, and end-users can prove to be reluctant to fully endorse a new service that asks them to change their working processes. And the latter is essential for reaping benefits form healthgrids[46]. No matter how advanced the technology solution is, if end-users do not see the benefits *to them* exceeding the costs and efforts, healthgrids will not have a future. Pilot applications used as demonstrators should pay attention to the details to which the end-users (public research organisations, private research SMEs and large pharmaceutical companies) are exposed.

The move towards sustainability of haelthgrids needs to be demand driven. Currently, the development of healthgrids is driven mainly by technology scientists rather than eventual users. As a consequence, the financial flows and other resource availability are based in the "wrong" field, when looking from a long run perspective. Proof of concept and pilot developments that test robustness and functionality of the technology are necessary and can be paid for in the context of technology research. Yet the ultimate uptake depends on a business case for users after the technology has been fixed. The need to switch the financing model of healthgrids from technology research to being part of the resource portfolio in end-user organisations has to enter the strategic as well as the day-to-day planning of those developing healthgrids.

An expected challenge is that in some cases the private incentives of stakeholders may not be sufficient to support grid deployment, even if the utilisation of grids improves social welfare. Impact assessment, (including ex-ante analysis) on the societal level includes all stakeholders, and all possible costs, benefits, and utility. Individual appraisal, usually at organisational level, is concerned with positive and negative effects to one particular stakeholder. Given that grid applications, by definition, require the participation of a large number of partners, and that health services impact on an even larger number of stakeholders (from organizations to individuals), these two kinds of analysis do not necessarily yield consistent results, pointing to potential inefficiency of resource allocation. Although socially desirable, healthgrid services may remain limited or fail to be established at all due to insufficient private incentives for end-users. One way to approach this challenge is to encourage the exploitation of existing public grid infrastructures (like EGEE) in some form of partnership between public and private actors. Agreements on specific conditions, clarifying the rights and obligations of both public and private parties, have to be made at the earliest possible stage. These will diverge from case to case, but first contracts can serve as useful precedents and reference points.

The links between organisations across the EU and beyond that are established through specific technology-driven or otherwise motivated experimental and pilot projects should be used and further developed. A slowly emerging culture of cooperation and collaboration is laying the foundations for successful deployment of data, and later even knowledge grids. Further developing existing networks will also be beneficial in this respect.

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46 See for example STROETMANN, K.A. JONES, T. DOBREV, A. and STROETMANN, V.N. "eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites", Office for Official Publications of the European Communities, Luxembourg, 2006 (56 pp. - ISBN 92-79-02762-X), available on www.ehealth-impact.org

An important further aspect, highlighting the interconnection of all ELSE issues, is the need for legal and regulatory certainty. When assessing potential changes in resource portfolios, in this case concerning the fit of participation in healthgrids to the overall organisational objectives and strategy, decision makers have to account for risks. Uncertainties, especially of a legal and ethical nature, cause a high risk factor to enter the calculation, thus endangering deployment of an otherwise worthwhile investment.

A final issue is the impact of healthgrids on current working practices and procedures. On the one hand, fewer changes lead to lower acceptance barriers. On the other hand, studies on the economic impact of eHealth show that precisely such changes are required for achieving substantial benefits[47]. This means that the promises of healthgrids and the current practices have to be analysed in parallel, identifying the most advantageous form of liaison. As a general hypothesis, this will neither be to adapt fully the technology to existing procedures, nor to change completely current procedures in order to fit technology specifications.

Concrete recommendations for “socio-economic actions” are not always adequate. Such recommendations usually concern the specific allocations of resources, which is beyond the scope of the roadmap exercise at hand. Nevertheless, we can give some guidance on the issues that should be addressed for reaching the three milestones of computing, data and knowledge grids, as defined at the beginning of this chapter, as well as the ways to address these issues.

4.2.1. Recommendations for computing grids

Pilot projects and prototype applications, which are an inherent part of the technology roadmap, need to be future oriented in the sense that the ultimate routine operation users have to be persuaded both of their value and their applicability, i.e. their ability to fit into real clinical or research workflows. This has to be taken seriously from the very beginning, even in proof-of-technology demonstrators: the goal should always be to give users, especially clinicians, tools that they would consider using with patients in real healthcare situation.

Ex-ante analyses over time, based on initial pilot experience, have to focus on ensuring acceptance, technical and regulatory certainty, and sufficient private incentives in the steps to follow. An inherent part of such assessments should be to estimate potential net benefits (i.e. expected benefits less expected costs over time), accounting for different risks and for optimism bias in estimations. Such studies will facilitate access to initial funding, but can also be beneficial in the necessary dissemination work among the health sector.

[47] See for example STROETMANN, K.A. JONES, T. DOBREV, A. and STROETMANN, V.N. “eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites”, Office for Official Publications of the European Communities, Luxembourg, 2006 (56 pp. - ISBN 92-79-02762-X), available on www.ehealth-impact.org

4.2.2. Recommendations for data grids

Work towards achieving the next milestone in complexity – data grids – will benefit from more focused prospective assessments of socio-economic impact in order to a) identify already existing, as well as potential barriers, and b) build convincing business cases ensuring sustainability. The analysis of alternative resource allocation options from a societal perspective, but also on organisational level, becomes necessary.

An organisational milestone can be defined here in the move from technology science towards service provision. By that stage, a notable amount of legal and regulatory certainty has to be achieved, so that private incentives can be assessed and adjusted (including via government intervention) if necessary.

4.2.3. Recommendations for knowledge grids

Although by this stage most economic aspects should be settled, i.e. the market failure (missing legal and regulatory conditions allowing efficient resource allocation) corrected,[48] new challenges arise. The effective deployment of knowledge grids will crucially depend on collaboration between institutions, meaning more than "simple" access to each others' data and computing resources. This collaboration requires the utilisation of human resources and in some cases a significant strategic re-orientation and re-organisation of working processes, and even management structures. As the health sector, including clinical research and public health, is (and should be) highly regulated, policy makers on regional, national, and EU level should review the existing regulatory framework against the requirements arising from the exploitation of knowledge grids. Particular attention should be given to flexibility of government regulated budgets and reimbursement schemes. The latter should encourage cross-organisational collaboration, including such beyond national borders, by means of using knowledge grids.

No less important is the cultural component – the increased transparency and control become barriers when users (physicians, clinical researchers, but also managers) fear their autonomy threatened and their expertise put in question. Dissemination programmes acknowledging the problems, but highlighting the benefits for each individual user, need to precede the deployment of knowledge grids.

[48] For details on corrections of market failures, see Mankiw, Gregory; Ronald Kneebone, Kenneth McKenzie, Nicholas Row (2002). Principles of Microeconomics: Second Canadian Edition. United States: Thomson-Nelson, pp. 157-158.

4.3.Ethical Recommendations

As noted in the UNESCO survey on Infoethics[49], "a large-scale grid is not without its infoethics hazards." Whether at a computational, data or knowledge level a certain level of security risks is implicit, because a grid is by definition sharing computing power and data with others.

A key ethical issue will therefore be to ensure that the necessary digital identity management and other security-related technologies show full respect for the rights of individuals to respect for their privacy. This in turn will make the make the demand for digital identity management and other security-related technologies more pronounced, and will on an ethical level require that appropriate bodies are established which can ensure that such issues are fully taken into accounts. Similarly, education tolls will have to be developed which ensure that those developing HealthGrid technology have ready and targeted educational tools to ensure that they are up-to-date with the latest research on meeting ethical demands in complex computing environments such as HealthGrids.

As well as respecting the concepts of autonomy through appropriate digital dignity, the potential harm of loss of autonomy must be ethically weighed against the efficiencies and access that will necessarily arise from the use healthgrids. At its various stages a healthgrid will provide vast computing power, huge data storage and accessibility, and ultimately highly complex decision-making. The technology itself of course is neutral; it is up to the policy makers and operational scientists to ensure that the correct balances and trade-offs steer the development of healthgrids. Mary Rundle and Chris Conley dicsuss wide ranging aspects of this in noting that a grid architecture by its nature demands distinctions based on content. They argue that since the technology facilitating these distinctions are currently designed to allow "deep packet inspection" by governments or companies providing Internet services, this could mean that meaning that these entities could monitor and possibly block the flow of specific information. Whilst this threat to freedom of expression is obviously more profound in girds used to share political news, rather grids for scientific applications such as epidemiology or drug discovery, it is important to note that such capacity to scrutinise content could in healthgrids weigh against the benefits of efficiencies and access that will accompany the vast computing power, data accessibility, and data storage of grid computing in healthcare.

In the development of healthgrids, we must therefore develop good ethical guidelines on how to share information, including the use of anonymisation and pseudonymisation wherever possible as well as general information campaigns which will make patients more aware of the way their information may be shared so that if they feel the need to do so they will know when and how to refuse to allow such sharing to take place.

[49] Ethical Implications of Emerging Technologies: A Survey Prepared by Mary Rundle and Chris Conley Geneva Net Dialogue Edited by the Information Society Division, Communication and Information Sector – March 2007. available at http://unesdoc.unesco.org/images/0014/001499/149992E.pdf (accessed 10th October 2007)

As the Oxbridge Cardiac Care Grid case explores, the importance of the application lies in supporting the healthcare professional's decision so that he or she may be better equipped to do good and avoid doing harm. As such, one could thus argue that a healthcare professional, in acting ethically, would indeed be obliged to use suitable grid applications if they were available. A healthcare professional refusing to use standard medical technology such as a sphygmomanometer or refusing to prescribe antibiotics would be considered in breach of his or her duty of beneficence. Thus, as the sophistication of grid aided diagnosis develops we will one day arrive at a time when a healthcare practitioner not linked to the appropriate grid networks will be in breach of his or her duty of care.

However, until we have reached a time when grid applications are stable, well 'fed' with data and fully integrated into the evidence base of good clinical practice, such arguments will not apply. At present, in the more experimental stages of healthgrids, it will be important to ensure that the use of the applications does no harm, but perhaps most importantly to ensure that the patient is aware of any possible medical and social risk (such as breach of confidentiality) so that the applications can continue to develop without allegations of breach of ethical duties.

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We noted above that as well as posing challenges HealthGrids could deliver ethically positive elements, in particular in meeting the ethical demands of beneficence, the duty to do good or at leas not harm, and the ethical concept of distributive justice. In particular it may be argued further that HealthGrids make a very positive contribution in terms of meeting the ethical demands of justice – in particular in terms of a Rawlsian concept of distributive justice. Alistair Duff [50] has argued in particular that Rawls's seminal work, *A Theory of Justice*[51], and subsequent elaborations, must be taken seriously by anyone who wants to think ethically about the information society. It is argued that Rawls' ideas are a useful tool for promoting ideals of social justice in the whole area of access to information.

In healthcare the Rawlsian 'difference principle' - which states that inequalities in the distribution of social goods should be permitted so long as they work for the benefit of the worst off - has been used a s basis for social health systems which are based on universal access funded through tax collection. Using this principle we can argue that HealthGrids facilitate access to high quality information and can be used to address a provision of high quality healthcare in geographies where either for population of financial reasons the wealth in 'health information' is not equally distributed. Thus , where a disease is rare the HealthGrid can be used as a tool of distributive justice to share an information bases across a range of geographies, similarly where expertise is

50 Alistair S. Duff: Neo-Rawlsian Co-ordinates: Notes on A Theory of Justice for the Information Age International Review of Information Ethics Vol. 6 pp18-23

51 Rawls, John (1973) [1971]: A Theory of Justice, Oxford: Oxford University Press

not equally distributed HealthGrids can be used as a tool for the distribution of that expertise from areas of plenty to areas of scarcity.

Ethical Recommendations – for Computational, Data and Knowledge Grids

Ethical concepts are by their very nature widely applicable and with as near as possible universal application potential. Thus the three core medical ethical concepts which have been held as a key to ethical development and deployment of HealthGrids (autonomy, beneficence and justice) are used to discuss a huge range of concepts in healthcare from the breach of confidentiality for the safety of a population in the treatment of contagious diseases; the balance of interests between mother and child in the termination of pregnancy; or the fair allocation of scarce resources, such as organs for transplantation. In all cases a proper assessment of the ethical questions will require that the core concepts are revisited. The construction of the key questions will in fact change very little as a result of where in the decision making process one is. Thus, if one takes the example of a contagious diseases tracing system, whether one is at the early stage of system design – in which the data collection tools will be developed, or in the implementation of the system in which automated decision pathways for notification are being used; at each stage the designers and users of the system will need to revisit the key ethical questions ensure that key issues have been duly considered.

The key ethical recommendations for the HealthGrids Roadmap do not therefore differ significantly whether they concern the development of a computational grid, a data grid or a knowledge grid. The matter of importance for a roadmap of any type of grid will be the inclusion of systems and tools for ensuring that ethical concerns are raised and discussed at all the key developmental stages. Thus the key ethical recommendations are three simple steps: education, advice, implementation code.

Recommendation: Educational Tools

An EU wide education programme on ethics in HealthGrids should be established, based on a network of ethics committees and academic researchers across the EU who could provide baseline materials to be adapted and adopted at national and local level. The programme would ideally be modular and accompanied by teaching notes and exercises so that a common standard of baseline education on ethical concepts can be achieved throughout Europe. Such a programme would need to be regularly updated and might benefit from an EU wide annual or bi-annual conference in which experts could share new thinking on emerging technological issues. Of course the programme would be flexible on scope so that it could be adapted to local needs. Thus the same basic building blocks could be used in undergraduate programme for doctors, lawyers and computer scientist and supplemented with real-life scenarios for post-graduate and 'hands-on' training. The basis of such a training programme could be built from an EU research grant, although to remain sustainable local and regional funds would have to be made available to ensure the continuous development of the materials.

Recommendation: EU Advisory Committee Network for HealthGrids

In order to ensure that the ethical questions in HealthGrids were addressed in a consistent manner across EU borders, an EU wide HealthGrids Ethics Committee system should be established which could harmonise local ethics committees responses to HealthGrid usage. To this end the Ethics in Science Programme of the European Research Programmes should focus attention on the development of such a system

Recommendation: EU Ethical Code for Health Grids

In order to support the implementation of the education programmes and the proper execution of the guidance delivered by the EU Health Grids Ethics Committee, a common EU code of conduct on health grids should be adopted. Guidelines should be established at EU level on methods for the appropriate balancing of key ethical duty of respect for autonomy, beneficence and justice in the development and use of health grids. To this end the European Group on Ethics in New Technologies (EGE) should adopt a position on health grids which can in turn be used to provide a common basis for the development of ethical guidelines for specific HealthGrid applications whether such grids operate at national, EU or international level. Thus a common EGE position on HealthGrids could be used, for example, to adopt a code of conduct of the development and operation of a brain injury grid operated across 7 EU countries.

4.4.Final Note

The list of recommendation above covering very specific legal questions as well as more general socio-economic issues and overarching ethical issues would could serve as the key milestones in a roadmap for the adoption of HealthGrids. It is important to note however that while present sequentially many of the steps would need to be undertaken concurrently.