SHARE roadmap 1

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SHARE Roadmap 1: Towards a debate

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Abstract. We present the 'HealthGrid' initiative and review work carried out in various European projects. Since the European Commission's Information Society Technologies programme funded the first grid-based health and medical projects, the HealthGrid movement has flourished in Europe. Many projects have now been completed and 'Healthgrid' consulted a number of experts to compile and publish a 'White Paper' which establishes the foundations, potential scope and prospects of an approach to health informatics based on a grid infrastructure. The White Paper demonstrates the ways in which the healthgrid approach supports many modern trends in medicine and healthcare, such as evidence-based practice, integration across levels, from molecules and cells, through tissues and organs to the whole person and community, and the promise of individualized health care. A second generation of projects have now been funded, and the EC has commissioned a study to define a research roadmap for a 'healthgrid for Europe', seen as the preferred infrastructure for medical and health care projects in the European Research Area.

Keywords. healthgrid, e-health, grid applications

Introduction

Grid technology has been identified as a key technology to enable and support the 'European Research Area'. The impact of this concept is expected to reach far beyond eScience, to eBusiness, eGovernment, and eHealth. However, a major challenge is to take the technology out of the laboratory to the citizen. A *healthgrid* is an environment in which data of medical interest can be stored and made easily available to different actors in the healthcare system, such as physicians, healthcare centres, patients and citizens in general. Such an environment has to offer all appropriate guarantees in terms of data protection, respect for ethics and observance of regulations; it has to support the notion of 'duty of care' and may have to deal with 'freedom of information issues'. Working across member states, it may have to support negotiation and policy bridging.

Early grid projects, while encompassing potential applications to the life sciences, did not address the specificities of an e-infrastructure for health, such as the

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deployment of grid nodes in clinical centres and in healthcare administrations, the connection of individual physicians to the grid and the strict regulations ruling the access to personal data. However, a community of researchers did emerge with an awareness of these issues and an interest in tackling them.

1. The Healthgrid Initiative

Pioneering projects in the application of grid technologies to the health area have recently been completed, and the development of technology to address high level requirements in a grid environment has been making good progress. Because these projects had a finite lifetime and the healthgrid vision required a sustained effort over a much longer period, and because there was a need for these projects to cross-fertilise, the HealthGrid association (http://www.healthgrid.org), was established to bring about the necessary long-term continuity. Its goal is to encourage and support collaboration between autonomous projects in such a way as to ensure that requirements really are met and that the wheel is not re-invented at the expense of other necessary work.

Writing about the healthgrid initiative very soon after its inception, this community identified a number of objectives: identification of potential business models for medical grid applications; feedback to the grid development community on the requirements of the pilot applications deployed by European projects; development of a systematic picture of the broad and specific requirements of physicians and other health workers when interacting with grid applications; dialogue with clinicians and those involved in medical research and grid development to determine potential pilots; interaction with clinicians and researchers to gain feedback from the pilots; interaction with all relevant parties concerning legal and ethical issues identified by the pilots; dissemination to the wider biomedical community on the outcome of the pilots; interaction and exchange of results with similar groups worldwide; and the formulation and specification of potential new applications in conjunction with the end user communities. (Cf [1] for a brief history and [2] for a panoramic vision statement.)

A healthgrid may in theory be deployed to support the full range of healthcare activities, from screening through diagnosis, treatment planning to epidemiology and public health. Thus HealthGrid has been actively involved in the definition of requirements relevant to the development and deployment of grids for health and was among the first to identify the need for a specialist middleware layer, between the generic grid infrastructure and middleware and the medical or health applications.

2. The White Paper: From Grid to Healthgrid

The White Paper [3] defines the concept of a healthgrid more precisely than before: The ultimate goal for eHealth in Europe would be the creation of a single healthgrid, i.e. a grid comprising all eHealth resources, incorporating a 'principle of subsidiarity' of independent nodes of the healthgrid as a means of implementing all the legal, ethical, regulatory and negotiation requirements. We may anticipate, however, the development path to proceed through specific healthgrids with perhaps rudimentary inter-grid interaction/interoperational capabilities. Thus, we may identify a need to map future research and advice on research policy, so as to bring diverse initiatives to the point of convergence.

Healthgrid applications address both individualised healthcare and epidemiology with a view to public health. Individualised healthcare is improved by the efficient and secure combination of immediate availability of personal clinical information and widespread availability of advanced services for diagnosis and therapy. Epidemiology healthgrids combine information from a wide population to extract knowledge that can lead to the discovery of new correlations between symptoms, diseases, genetic features and other clinical data. With this broad range of application in mind, the issues below are identified as key features of our analysis.

- Business case, trust and continuity issues: Healthgrids are data- and collaboration grids, but large-scale deployment requires 'security' to be scaled up to a very high level of confidence. Federation of databases introduces additional complexity.
- Biomedical issues: Distributed databases and data mining capabilities, expert system services able to interrogate these, biocomputing, biomodelling and simulation have a strong need for resources that can be provided through the grid. Compliance with medical information standards is necessary.
- Security issues: Security in grid infrastructures is currently adequate for research platforms, but not for real healthcare applications.
- Management issues: The central concept of a 'virtual organisation' (VO) at the heart of eScience, which gave rise to grids, is very apt for healthgrid, but additional flexibility is needed to structure and to control VOs in the large, including, for example, the meta-level of a VO of VOs.

3. The SHARE Project: From White Paper to Road Map

In the White Paper, the HealthGrid community expressed its commitment to modern trends in medical practice, especially 'evidence-based medicine' as an integrative principle, to be applied across the dimensions of individual through to public health, diagnosis through treatment to prevention, from molecules through cells, tissues and organs to individuals and populations. In order to do this, it had to address the question how to collect, organise, and distribute the 'evidence'; this might be 'gold standard' evidence, i.e. peer reviewed knowledge from published research, or it might be more tentative, yet to be confirmed knowledge from practice, and, in addition, would entail knowledge of the individual patient as a whole person. The community also had to address the issues of law, regulation and ethics, and issues about crossing legal and cultural boundaries, expressing these in technological terms – security, trust, encryption, and pseudonymisation. Then it had to consider how healthgrid middleware services would satisfy these requirements; and, if it was to succeed in the real world, how to make the business case for healthgrid to hard-pressed health services across Europe while they are struggling with their own modernisation programmes.

The vision of health that informs the White Paper and the work of Healthgrid since has been defined in the 'Action Plan for a European e-Health Area' [4] as follows:

"... the application of information and communications technologies across the whole range of functions that affect the health sector. e-Health tools or 'solutions' include products, systems and services that go beyond simply Internet-based applications. They include tools for both health authorities and professionals as well as personalised health systems for patients and citizens. Examples include health information networks, electronic health records (EHR), telemedicine services, personal wearable and portable communicable systems, health portals, and many other information and communication technology-based tools assisting prevention, diagnosis, treatment, health monitoring, and lifestyle management."

The 'vertical integration' implicit in this visionary statement can be translated into more concrete terms by mapping it to its human subjects, their pathologies and the implicit disciplines. The relationships between the different ontological and epistemological levels and the various modalities of data have been captured by Fernando Martin-Sánchez [2] in the schematic diagram below (see fig 1).

In the light of the White Paper and its impact, the EC has funded SHARE, a 'specific support action' project to explore how to realise the vision of the White Paper: the two objectives of the project are:

- a roadmap for research and technology to allow a wide deployment and adoption of healthgrids both in the shorter term (3-5 years) and in the longer term (up to 10 years); and
- a complementary and integrated roadmap for e-Health research and technology development (RTD) policy relating to grid deployment, as a basis for improving coordination amongst funding bodies, health policy makers and leaders of grid initiatives, avoiding legislative barriers and other foreseeable obstacles.

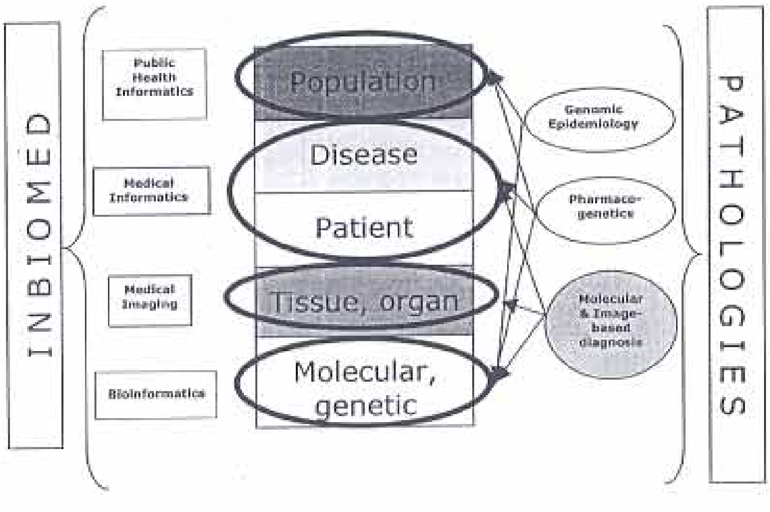

Fig 1 Disciplines, levels of being and pathology diagnostics (F. Martin-Sánchez)

The project must address the questions, *what* research and development needs to be done now? —and *what* are the right initiatives in eHealth RTD policy relating to grid deployment? —with all that implies in terms of coordination of strategy, programme funding and support for innovation. In summary, therefore, the project will define a comprehensive European research and development roadmap, covering both technology and policy aspects, to guide EU-wide uptake of healthgrid technologies, and their applications into health research and into health care service provision.

4. Technical Road Map: Step One

At a first step SHARE has identified five key deployment and standardization challenges for healthgrids and proposes a series of interlaced milestones to address each of these. The milestones are as follow:

- MD1– deployment of computing grid nodes in medical research centres;
- MD2 – deployment of data grid nodes in medical research centres;
- MD3 – deployment of knowledge grid nodes in medical research centres;
- MS1 – production of a standard for exchange of medical images on the grid;
- MS2 – production of a standard for the exchange of EHR on the grid.

MD1, MD2, MD3 correspond to the deployment of infrastructures while MS1 and MS2 are related to the availability of standards.

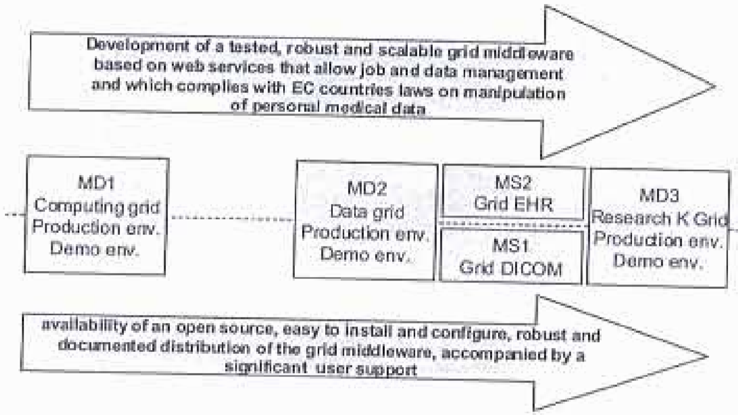

Figure 2.

5. Technical Road Map: Step Two

At a second step we have introduced some overlap to represent concurrency and a cyclical relationship between the standardisation milestones and the second deployment milestone of a data grid production environment. Further discussions have also led to considering "the development of a tested, robust and scalable grid middleware based on Web Services", and "the availability of a robust, user friendly open source distribution of grid middleware with appropriate user support" as separate milestones.

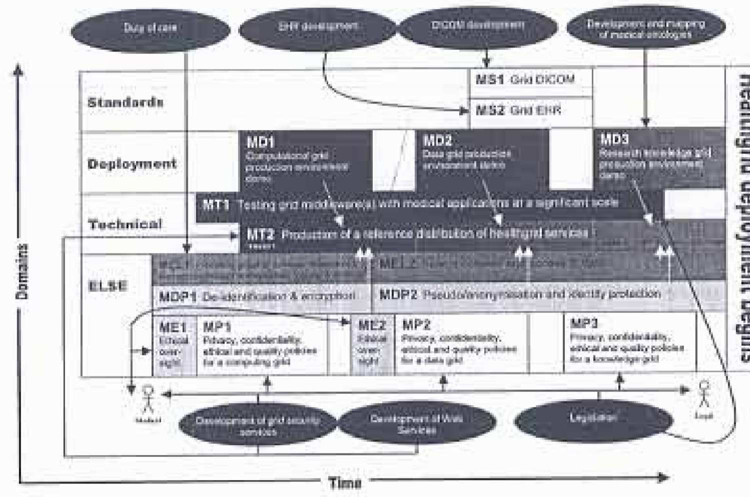

Figure 3.

6. Technology Milestones

MT1 – Testing healthgrids with mid-to-large medical applications

Testing of grid middleware(s) for scalability and robustness should begin at an early stage. It is anticipated that this will be an ongoing activity, with different generations of grid operating systems offering newer, faster and more stable capabilities.

MT2 – Production of a reference distribution of healthgrid services

Shortly after testing has begun, work should commence on the production of a reference distribution. Standards for web services and particularly grid security services are still evolving, and therefore new versions of the distribution should be made available as standards are adopted and implemented.

7. Standardization Milestones

Two standardisation milestones have been created for sharing medical images and records. As examples: MS1 – Grid DICOM and MS2 – Grid EHR respectively, but standards in other areas of bio- and medical informatics will be required. HealthGrid community must liaise with standards developers to define any necessary extensions.

8. Deployment Milestones

MD1 – A computational grid production environment
This initial deployment step would at first seem to require little effort as other projects have attempted it before. However, there are a number of issues associated with the installation of grid nodes in hospitals and medical research centres, including economic factors, hiding the complexity of grid mechanisms from users, and security concerns.

MD2 – A data grid production environment
Although several prototype data grids for medical research have been demonstrated by healthgrid projects, developing and maintaining a production quality data grid will require a number of issues relating to the distributed storage of medical data to be resolved.

MD3– A knowledge grid production environment
The next task will be to deploy services that can build relationships between data items, and will provide appropriate representation to medical researchers. The development of medical ontologies and the mapping between ontologies will be particularly important for the successful deployment of knowledge grids.

9. Legal and Liability Considerations

The effort to develop healthgrids should not only be directed at the technical and deployment issues. Other challenges also arise which are linked to the legitimacy and ethics of using such a technology and its social impact on the health work-space.

Medical Data Processing between ban and permission
In the healthcare sector, the use of the grid technology implies automated processing of health personal data, especially for therapeutic purposes. The key European principles relevant to the processing of personal data were first established by the Council of Europe and further developed in Directive 95/46/CE of the European Union[2]. The purpose of the Directive is to allow the free flow of personal data between member states of the European Union, to facilitate the internal market and to protect the fundamental rights and freedoms of natural persons, in particular their right to privacy with respect to the processing of their personal data.

The Directive bans the processing of sensitive or medical data, but the principle of this ban is not absolute; some texts in the Directives tend to grant permissions to the processing of personal data under exceptional conditions. For example, the explicit and valid consent of the data subject constitutes the most important source of legitimacy in the processing of medical data although it is subject to very strict conditions for its validity and the data subject may revoke this consent to the processing of his or her medical data at any time and without justification. Processing is allowed if

- it 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;

2 For references to statutes, directives and other legal references, see SHARE Deliverable 4.2 at [5].

- it 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 or her consent;
- it 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;
- it relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims;
- 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.

Finally, the European Directive offers the opportunity to the Member States to add exemptions to those listed above, for reasons of substantial public interest. These exemptions should be subject to suitable safeguards. For instance, under Article 8, 4 of the Directive, national exemptions might be adopted for scientific research. For example exemptions could be added to the processing of medical data as long as the following conditions are verified by the data controller.

- The data processing must be legitimate. In other word, the data processing corresponds to one of the social justifications laid down by the European Directive in its Article 7. For example, the data was processed after an unambiguous consent was expressed by the data subject.
- The data controller must ensure the good quality of the data to be processed. For example, the data must be and remain accurate and if necessary up to date.
- The data controller must also respect the rights of the data subject and ensure that these are observed at all stages of the processing.
- The data controller must ensure that security and confidentiality requirements are met.
- The controller is required, prior to carrying out the processing, to provide the relevant national supervisory authority with certain items of information regarding the planned processing. The information recorded will then normally be accessible to data subjects or to third parties.

Personal Data transfer
For EU Member States, the transfer of personal data between two or several controllers established on the territory of one member states or on the territories of several member states involves the problem of communication of personal data to third parties. Indeed, the transfer or disclosure of personal data to third parties is considered to be a processing operation and, as such, is subject to the processing legal requirements discussed in the previous section. However, the transfer of medical data is subject to more specific requirements. Medical data may not be communicated unless the conditions listed below are fulfilled:

- the medical data to be communicated are relevant for the communication purpose;

- the recipient of the communication is subject to confidentiality rules equivalent to those incumbent on healthcare professionals, and the communication is legally authorised and is realised for public health reasons or for another important public interest.

The national legislations of the different member states of the European Union are by and large harmonized by now, and the transfers of personal data between these member states should not create any problem. However, the controller must refrain from transferring personal data to a recipient located in non-EEA countries, if the country involved does not ensure an adequate level of protection, unless the controller adduces adequate safeguards as regards the protection of the privacy, fundamental rights and freedoms of individuals and the exercise of the corresponding rights.

Liability Issues

This section addresses questions of liability that may impact healthgrid participants. In particular, developers need to be aware of these so as to prevent any damage to patient health, rights and freedoms. Healthgrids are complex systems. They involve different actors such as doctors, specialists, hospitals, pharmaceutical companies, data controllers and processors, technicians, etc., located in different countries. Due to this complexity, the establishment of the person to be held responsible for a specific damage can be problematic.

The products and services offered by a healthgrid could turn out to be a cause of death of the patient or of delay in diagnosis and treatment. This may, for example, be due to the lack of regular testing and monitoring of products and services. The question here is who would be liable for such damage? The basic principle has long been established that if a product does not conform to the offer made or causes damage, the consumer (or another person representing him or her) may claim for compensation. Any liability issue will thus normally depend on the general rules of law applicable in the different EU member states.

The situation is also not simple from the services perspective. Services supplied through healthgrids may cause damage to patients. These services could either be services that constitute the grid system or services provided by the internet within the grid domain, including health related websites. For example, currently there is a lack of data and knowledge management services. A citizen might thus be seriously harmed or even die if the information transmitted to the general practitioner treating him or her is not accurate or false, or if it is not supplied on time. As long as the related service is part of the grid infrastructure, Directive 2000/31 (the so-called the 'Directive on Electronic Commerce') might apply.

10. The ELSI Roadmap

Addressing the issues listed above is a challenge as the advice of medical and legal bodies is crucial. A well planned and structured set of actions is required. The ELSI roadmap could be the answer but it won't be enough unless it is harmonised with the technical roadmap milestones.

Ethical and Legal Milestones (MEL1, MEL2)

MEL1 The primary concerns for MEL1 will be liability and determining what the responsibilities of the healthgrid actors are. Possible damage that could happen to the patient could be outlined along with some preventative measures. Logging and auditing must be addressed early to monitor whether enough testing was done to healthgrid services and products.

MEL2 Patient consent is crucial to the legitimacy of medical data processing and transfer, therefore verifying that the patient has expressed his or her consent should take place prior to any data manipulation. Moreover, appropriate and user friendly ways of allowing patient access to data is also recommended.

Data Protection Milestones

The milestone MDP1is concerned with patient privacy and how it could be best protected within the HealthGrid environment. Patients' identification issues should be discussed, starting with de-identification of medical images. For MDP2 researchers need to make sure robust anonymisation, pseudo-anonymisation and other identity protection techniques are developed and deployed in the grid infrastructure.

Ethical Control Milestones (ME1, ME2)

ME1 will focus on the requirements and tools to facilitate oversight, with automation being explored. ME2 will satisfy the arrangements for automated ethical control for a data grid which will be more complex with long-term data storage.

Policy Milestones (MP1, MP2, MP3)

These policies will cover data processing and transfer issues such as legitimacy, accessing the minimum data required, the ethical transfer of data, compliance with confidentiality rules and limiting the period of data storage.

11. Conclusion

Issues of patient ownership of her/his data and the tension between hospitals' IT policies and the requirements of grids will prove problematic unless addressed with political will; likewise the drag on technology transfer between EC projects. In total, SHARE predicts that the journey from a sustainable computing grid to a generalized knowledge grid should take from seven to fifteen years. The transition to data grid may prove harder than suggested and the transition to knowledge grid will be breaking new ground. It is therefore possible that this timescale will be multiplied by a factor of up to 3 and that a more realistic timeframe might be twenty to fifty years.

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