Draft proposals for a standardisation policy regarding medical device interoperability

References

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CONTENTS

1. General objectives

The Hospitals, Patients, Health & Territories Act, whose decrees are being published, recommends, *inter alia*, stepping up telemedicine and in particular telemonitoring for tracking patients. It has given a legislative base to "this form of remote medical practice that uses information and communication technologies".

Technological developments are furthering the use of these practices extremely quickly. From the standardisation viewpoint, French experts have anticipated these concerns by getting under way and developing projects to define medical device communication in the home and by taking part in standardisation projects on the interoperability of data and systems for health.

The widespread concerns regarding the challenges of telemedicine call for an in-depth look at these subjects. Among these can be mentioned

- Adapting health care supply to demographic trends as far as both patients (population ageing) and healthcare professionals (lack of care in areas of rural France) are concerned;
- The need for people to remain independent and in good health for as long as possible;
- The increasing specialisation and complexity of medicine;
- The development of techniques in medicine.

1.1 Scope and definitions

The **DGCIS** and **Snitem** have begun a joint think tank, in partnership with the **CNISAS**, aimed at drafting proposals for a French standardisation policy in the area of Information and Communication Technologies applied to Health (Health ICTs) and to medical devices that communicate.

CNISAS: Commission de Normalisation de l'Informatique de Santé et de l'Action Sociale (AFNOR) – Standardisation Committee for Health Informatics and Social Policy (AFNOR)
DGCIS: General Directorate for Competitiveness, Industry and Services (under the Ministry for Industry)
SNITEM: French National Association for Medical Technology Industries

Snitem has been running this group project along three main lines:

- To analyse the current situation in terms of norms and standards in the medical device communication domain, including the work carried out by the IHE initiative on the one hand and the Continua Alliance association on the other;

- To add to this fairly general analysis by an expert analysis in the more specific area of telecardiology (whose medical benefit has recently been recognised by the French National Authority for Health (HAS) because of the considerable challenges in this area as much in terms of interoperability – mainly from the cardiologist's workstation – as in the compromise to be found with regard to vital risks).

- To draft proposals for a French standardisation policy for interconnected medical devices taking into account recommendations put forward in the FIEEC report [French Federation of Electrical, Electronics and Communication Industries] in June 2008 and the Lasbordes report in November 2009.

Lastly, by involving experts from various medical specialities and by focusing on the elements shared by the disciplines thus represented, and given the challenges set out, the scope of this study, within the framework of telemedicine, will be confined to cardiology, respiratory care and dialysis. The aim will therefore be to define a generic framework that could thus be applicable to the various specialities.

Definitions

The framework for medical devices that communicate can be defined, on the one hand, as the acquisition, processing and transmission of the signal and related data and, on the other, as communication with the software to manage the health record in particular. Relations with the financial sponsors are not taken into account within the scope even though they are mentioned.

Interoperability is defined as the property of a **product** or system, whose **interfaces** are completely **understood**, to **work with other** products or systems, present or future, without any restricted access or implementation (Wikipedia).

A distinction should be made between "interoperability" and "compatibility". In simple terms, there is compatibility when two products or systems can work together and interoperability when we know why and how they can work together. In other words, we can only talk about interoperability of a product or system if we completely understand all its interfaces.

There are various levels of interoperability:[1]

- Interoperability of **networks and telecoms:** this is the ability of network **components** to correctly **forward** data from a source machine to a terminal machine;
- Interoperability of **software and information systems:** this is the ability to communicate, to run programs and to **exchange data** between several functional units in such a way that the **user** does not need or barely needs to understand the features of these units.

In more concrete terms, for the first level there is the ability to make medical devices for different specialities communicate on the same communication infrastructure and for the second level the ability to replace medical devices by different makers in a transparent way for an end user (plug and play).

Lastly, conformity is achieved in relation to a set of standards. Some systems can be compliant with a standard but that does not mean they inter-operate. Others can be non compliant and inter-operate. It is therefore essential to carry out conformity and interoperability tests.

1.2 Overview of standards

The standardisation scene is sufficiently well-endowed today to enable the construction of profiles adapted to the needs of medical devices that communicate. The overview showed here takes into account the national, European and international dimension in the health sector.

At national level:

We will single out the institutions producing technical frameworks, in other words the standardisation organisations.

[1] Interoperability Didactics – Emmanuel Cordonnier

Among the institutions:

- The DGME (General Directorate for State Modernisation) has defined the RGI (Reference Framework Repository for Interoperability), the RGS (Reference Framework Repository for Security) and the RGAA (Reference Framework Repository for Accessibility for Administrations) which is aimed at administrative authorities and users using the government's on-line services;
- ASIP Santé with the interoperability framework for health which defines integration and content profiles as part of medical information exchanges with the electronic health record.

Among the organisations:

- AFNOR (the French Standards Association) produces the applicable French standards and provides the institutional link with European (CEN) and international (ISO) levels. The health and welfare sector is taken care of by the CNISAS committee.
- The aim of InteropSanté, an association that hosts HPRIM, HL7 France and IHE France, is to standardise and promote health information exchanges within the French health information system.
- EdiSanté is a group of stakeholders in the health, health insurance and social welfare sectors that works on the standardisation of their exchanges with a view to continuity of services and more effective management of the health and social welfare system.

At European level:

Three main organisations preside in the field of standards:

- CEN, the European Committee for Standardisation
- CENELEC, the European Committee for Electrotechnical Standardisation
- ETSI, the European Telecommunications Standards Institute, which has more specifically produced standards such as GSM, DECT, UMTS and wireless telephone.

CEN/TC251 is the committee that carries out the work in the field of healthcare. Four work groups cover the domains:

- WG 1: Information Model and Medical Records.
- WG 2: Terminology.
- WG 3: Security, Safety and Quality.
- WG 4: Technologies for Interoperability.

Moreover, there is talk of the last group specialising in the telemedicine sector.
The standards produced by this organisation are barely rolled out today.
Lastly, the three organisations are currently working on a joint programme called Mandate 403.

The aim of IHE Europe, an international association under Belgian law, is to deploy the profiles defined at international level. Continua Alliance is also represented in Europe and promotes the implementation guidelines.

At international level:

ISO, the International Organisation for Standardisation, has validated a whole host of standards that are currently recognised in healthcare such as HL7 V2.5, DICOM and CDA (Clinical Document Architecture), now used in many countries. Other standards are recognised for security and the IHE organisational process has also been validated (see section 2.1). The ISO is made up of the following work groups:

- WG 1: Data structure
- WG 2: Data interchange
- WG 3: Semantic Content

- WG 4: Security
- WG 5: Health cards
- WG 6: Pharmacy and Medicines Business
- WG 7: Devices
- WG 8: Business requirements for electronic health records

The IEEE has defined a series of IEEE 11070 standards that plays an important part in the field of medical devices. These ISO-validated standards are widely used in IHE profiles and in Continua Alliance's guidelines.

This series has two other series (see section 7.4):

- A common series defining the communication protocols for any type of device including wellness at home devices;
- A specialised series adapted to various devices such as thermometers, electronic scales, blood pressure monitors, cardio fitness, etc.

IHE (Integrating the Healthcare Enterprise) has defined a number of profiles within the cardiology, medical device and infrastructure domains that are perfectly adapted to the needs of the various types of medical devices. We will refer to the list given in section 7.3. Lastly, Continua Alliance, which is more geared towards medical devices, is an organisation that offers certification of devices that have successfully passed the implementation tests in the implementation guidelines it produces. These guidelines are wholly based on the IEEE's 11070 series.

This overview therefore shows that the range of medical devices can take advantage of this whole corpus of standards and that the development of interoperability in this sector is mainly linked to the willingness of the stakeholders, both institutional and industrial.

1.3 Reminder of regulations

At French level:

As a reminder, article L6316-1 (Act no. 2009-879 of 21 July 2009 – art. 78), for which the decree specifying application has not yet been published, relating to telemedicine gives some definitions:

- Telemedicine is a form of remote medical practice using information and communication technologies. It puts in contact, with one another or with a patient, one or more healthcare professionals, one of whom is necessarily a medical professional and, where appropriate, other professionals providing care to a patient.

- It helps to establish a diagnosis, to monitor a patient at risk for preventive purposes or for post-treatment follow-up, to request specialist advice, to prepare a decision regarding treatment, to prescribe products, to prescribe or to carry out services or procedures, or to monitor the condition of patients.

- The definition of telemedicine procedures and their terms of implementation and financial coverage are set by decree, taking into account any shortcomings in the health care supply due to insularity and geographical isolation.

The Social Security Code (Article L262-3, amended by Act no. 2009-1646 of 24 December 2009 – art. 37) says:

Medical consultations are held at the doctor's surgery, except when the patient cannot travel because of his/her condition or when a telemedicine activity as defined in article L. 6316-1 of the Public Health Code is concerned. Medical consultations are also given in medical centres.

The Public Health Code, through its article L5211-1, quotes:

- A medical device is any instrument, apparatus, piece of equipment, material or product, with the exception of products of human origin, or other article used alone or in combination, together with any accessories and software used to make it operate, designed by the manufacturer to be used in people for medical purposes and whose main desired effect is not obtained by pharmacological or immunological means nor by metabolism, but whose function may be assisted by such means.

- Medical devices that are designed to be partly or totally inserted into the human body or a natural orifice, and which use electrical energy or another source of power to make them function (devices that are powered by the human body or gravity are not included in this definition), are called active implantable medical devices.

And through its article L5211-3:

- Medical devices cannot be imported, placed on the market, brought into service or used unless they have first received a certificate proving their effectiveness and their compliance with the essential requirements concerning the health and safety of patients, users and third parties.

- The certificate of conformity is drawn up by the manufacturer itself or by the bodies appointed by the French Health Products Safety Agency.

- Medical devices used for biomedical research are exempt from a certificate of conformity for the aspects that are covered by research studies and provided that they afford the guarantees for the health and safety of patients, users and third parties that are laid down in section I of book II in part I of this code.

The health data hosting decree also has to be added to the scope of the work (decree no. 2006-6 of 4 January 2006 relating to the hosting of personal health data and amending the current Public Health Code (statutory provisions) and the legislation concerning personal data protection once medical devices become connected.

At European level:

A medical device is defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

An accessory is defined as any article which, whilst not being a device, is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

The following directives applying to the sector concerned have been inventoried:

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
- European Parliament and Council Directive 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices.
- European Parliament and Council Directive 2000/70/EC of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma.
- European Parliament and Council Directive 2001/104/EC of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices (text with EEA relevance)
- Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.

For the European Directives, the only one taken into account is that of 5 September 2007, Directive 2007-47/EC. (amending Council Directive 90/385/EEC regarding the harmonisation of Member State legislation relating to active implantable medical devices, Council Directive 93/42/EEC relating to medical devices and Directive 98/8/EC regarding the placing of biocidal products on the market.)

It is moreover stated in this directive that "software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device."

It is therefore advisable to differentiate the so called "administrative" applications such as patient administration management and movements within a healthcare establishment from the medical applications such as the health record or the electronic health record.

See for instance European Parliament and Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Regarding CE marking, there is no requirement concerning the interoperability of medical devices that communicate. On the other hand, medical or medical decision-making software, regarded as medical devices, should bear CE marking.

1.4 National, European and international objectives

At national level, the diagnosis into the relevance of developing telemedicine has now been clearly set out through the many reports that have been produced since 2008 (such as the report by Pierre Simon and Dominique Acker – see References). Telemedicine can only develop with the help of "concerted public/private action concerning the interoperability of solutions within an international framework, the development of good practices for implementing telehealth and the setting up of a public/private committee with the ability to decide on investments." (FIEEC Report, 2009).

At European level, the final declaration of the interministerial conference on eHealth, which took place in Barcelona in March 2010, highlights the importance of guaranteeing successful deployment of

health information systems coupled with organisational reforms and backed by suitable leadership and skills (European Cooperation on eHealth, 15 March 2010). Solving the problems of interoperability is one of the five objectives mentioned in the declaration that should be taken into account and more importantly the development of recognised international standards and certification in order to facilitate the deployment and use of applications for telehealth.

At international level, the WHO is now also taking into account the development of telehealth by publishing a report on the foundations of cyberhealth (2006) and says that "the WHO will help member states to promote the development of standardised national health information systems so as to facilitate exchange between countries".

Lastly at international level, these same objectives are also recognised what with the development of specialist groups in standards organisations and consortia such as the ISO, IHE, Continua Alliance, etc.

It has therefore become crucial that the work conducted in France be placed in this international context, making sure on the one hand that it is perfectly suited and on the other that national input is taken into account at European and international level.

1.5 Stakeholders

A whole range of stakeholders of various types (institutions, manufacturers' groups, etc.) play a part in this area. The following table lists all the stakeholders involved in the interoperability processes of the areas in question.
We have listed the institutional actors and user associations, manufacturers' associations or groups, standardisation organisations and organisations either issuing certification (e.g. health data hosting) or entitling a label to be displayed.

	Institutions/Users	Manufacturers' associations	Standardisation organisations	Label/certification body
National	ANAP ASIP Santé Learned societies Ministries responsible for health, social issues and industries CNR-SDA	FIEEC GIXEL Lesiss SNITEM	AFNOR HL7 France, IHE-France (Interop'Santé) Phast Edisanté	IHE-France ASIP Santé
European	DG INFSO Other DGs European learned societies	EUCOMED EUROM COCIR	CEN CENELEC ETSI	IHE-Europe Continua Alliance ETSI
International	WHO International learned societies		ISO IEC HL7 DICOM W3C ITU	IHE International Continua Alliance

GLOSSARY:

Acronym	**Meaning**
AFNOR	French Standardisation Association
ANAP	Agence Nationale d'Appui à la Performance *(public agency working to improve the performance of French hospitals)*
ARH	Regional Hospitalisation Agency
ARS	Regional Health Agency
CEN	European Committee for Standarisation
CENELEC	European Committee for Electrotechnical Standardization
CNR-SDA	National Reference Center for Home Care and Autonomy
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare I
Continua Alliance	Continua Alliance international consortium
DG INFSO	Directorate General: Information Society and Media
DGME	General Directorate for State Modernisation
DICOM	Digital Imaging and COmmunications in Medicine
Edisanté	Association, group of stakeholders in the health, health insurance and social welfare sectors
ETSI	European Telecommunications Standards Institute
EUCOMED	Organisation representing either directly or indirectly 4,500 designers, manufacturers and suppliers of medical technology in Europe
EUROM	
FIEEC	The French Federation of Electrical, Electronics and Communications Industries
GIXEL	French association for electronic components systems, smart card industries
HL7	Health Level Seven International
IEC	International Electrotechnical Commission
IHE	Integrating the Healthcare Enterprise
Interop'santé	Interop'Santé Association
ISO	International Standardization Organisation
Learned societies	Societies bringing together people in a specific skills area and reporting on their work and research projects.
Lesiss	Les Entreprises du Système d'Information Sanitaires et Sociaux *(Enterprises for Health and Welfare Information Systems)*
Min Industrie	Ministry for Industry
MISS	Mission
Other DGs	Other Directorate Generals at the European Commission
PHAST	Association
SNITEM	French National Association for Medical Technology Industries
ITU	International Telecommunication Union
W3C	World Wide Web Consortium
WHO	World Health Organisation

1.6 Areas studied

This study is based on three specialities that commonly use medical devices and telemedicine. The specialities chosen are of relevance because they enable varied use cases to be covered: barely invasive (respiratory care), moderately invasive (cardiology) and invasive (dialysis) using different organisational processes. Without being generic, the modelling, which is the purpose of this work, could be applied to discovering other specialities following a further study.

1.6.1 Telecardiology

Telecardiology is a means to monitor remotely a heart rhythm implant, whether a pacemaker or defibrillator, implanted in a patient and to communicate with this implant. This communication is made possible by a transmitter that is left with the patient and is either scheduled at a set date or automatically monitored on a permanent basis. The medical device is then able to send a whole range of data that are added to the patient's secure health record on a daily basis and to send a warning if an abnormal event occurs.

1.6.2 Telerespiratory care

Patients suffering from respiratory disorders can be monitored automatically in their home on a daily basis. It is possible to monitor a number of parameters such as pressure, leaks around the mask, respiratory events and compliance.

1.6.3 Teledialysis

Teledialysis enables the doctor to monitor a dialysis session remotely. During the session, the operating settings of the dialysis generator can be consulted in real time and combined with an interview by videoconference.

2. Methodology

2.1 Main stages of integration profiles definition

An integration profile is a major communication function that allows two or more computer systems to carry out a succession of coherent exchanges (workflow), previously identified and specified using globally recognised, operational standards.
For example, the IHE-PDQ (Patient Demographics Query) integration profile provides the means to look for a "patient" identity from a list of pre-defined features. It brings two systems into play: one system that will make the query (the consumer) and one system that delivers the patient identities (the source system).
The stages for integration profile definition are well documented today and as a rule use the IHE approach, which has been validated at ISO[2]. This approach has been taken up at the CEN (European Committee for Standardisation) as part of Mandate M/403, the aim of which was to define a fresh standardisation approach by combining the efforts of various European committees (CEN, CENELEC and ETSI) and with the support of international organisations (ISO, HL7 Inc, IHE, Continua Alliance, etc.).

All the stages of the IHE process are as follows:

- Definition of the core requirement
- Specification of integration profiles that meet the requirements

2 TS DTR283810-1. Health Informatics – IHE Global Standard Adoption – Part 1 : Process

  - Description of core use cases
  - Description of information flows and their sequences (workflow)
  - Choice of standards
  - Detailed specification of exchange flows
- Validation of integration profiles
- Development of test tools
- Testing on platform
- Deployment among end users

In relation to the definition of integration profiles, we are more especially interested in the first two stages.

2.1.1 Definition of core requirement

Definition of the core requirement first consists, in a given domain (here telerespiratory care, teledialysis or telecardiology), in listing the main exchange functions that we want to computerise. To do that, users are invited to define the core processes to be supported.

Telerespiratory care:

The main activities listed are as follows:

- Between the patient and the prescriber through the medical treatment consultation and the prescription;
- Between the prescriber and the provider through the prescription of the medical device for the patient;
- Between the service provider / equipment manufacturer and the patient for the service of implementing the medical device, equipment and follow-up;
- Between the insurance companies, the doctor and patient for financial coverage by the insurance companies.

Telecardiology

- Between the patient and the cardiologist who installs the device, the healthcare establishment or the non-hospital-based cardiologist further to the prescription procedure;
- Between the medical device supplier and the healthcare professionals;
- Between the healthcare professionals and the manufacturers for monitoring the devices and interpreting data.

Teledialysis

A distinction is made between haemodialysis and peritoneal dialysis. The people involved in the treatment cycle this time are the patient, the kidney specialist, the medical analysis laboratory and the dialysis centre.

The main activities listed bring the following people into play:

- The patient and the kidney specialists for the medical treatment and prescriptions (for pharmacy and medical analyses);
- The medical analysis laboratory and the doctor for the test results;
- The dialysis centre and the patient for the dialysis session;

- The manufacturers who provide devices and equipment, medicinal products and consumables, the prescribers and the providers.

For each of the activities, the most frequent use cases are identified and selected by restricting the number of options so as to allow for implementation that can be controlled and accessed by the majority. As the number of use cases increases, the interoperability functions useful to the domain are covered. Furthermore, the aim is to ensure that similar exchange conditions can be used by the different domains (here telerespiratory care, teledialysis or telecardiology) in order to factorise the development effort and the use of a greater number of standards. For the medical devices that concern us, a detailed analysis of each of the core processes has helped to identify common, generic elements of activity that are described in the following section.

2.1.2 Specification of integration profiles

The core use cases are then expressed as technical use cases bringing into play the information systems or applications that support the information flows exchanged. They help to define and to set the limits of each integration profile that can then be specified in detail, including the role of each system and its behaviour in the exchange workflow.

An integration profile covers numerous aspects of interoperability between systems: from the transport layer, security, data structures and semantics and lastly the service contracts. An integration profile is therefore a stack of standards adapted to a requirement.

To make these specifications, a list of internationally-recognised standards are identified and become candidates for selection. This choice is based on a number of criteria such as

- operational standards deployed on a large scale at international level;
- applicable standards, in particular the standards must be compatible with patient safety requirements, respect for the patient and the regulations;
- sustainable, upgradeable standards, that is to say that the structure that carries the standard must be able to upgrade the standard;
- standards meeting both the needs expressed and environmental requirements.

These criteria given by way of example will have to be analysed more closely to determine a set of established criteria satisfying the requirements of the domain.

It is worth mentioning, for example, the low-level communication between medical devices and bases (or transmitters) as well as between medical devices among themselves. This remains a sticking point at the very source of creating the information chain. For a medical device to be able to exchange information on a local network, it first has to be able to connect up physically to that local network. This is where “mechanical” problems (of connection type) and physical layer problems (electrical signal formats and modulation types) are to be found, problems which have arisen for years in the context of industrial local area networks. It is possible to be rid of the “mechanical” connection issue by firmly opting for wireless communications (Radiofrequency or IdDA). However, given the abundance of offers in the area (Bluetooth, Wibree, Zigbee, Wifi to mention but a few) the choice still remains fairly extensive regarding

i) the carrier used (the 1.2 GHz band is the most frequently used but 868 MHz ISM bands are also widely used in the medical field and frequency bands are even set aside for it.

ii) the type of modulation using carrier band (FSK, PSK, QPSK, etc.),

iii) the network layer protocols that are very different from one solution to the next.

The choice of technical solutions is clearly an essential challenge in drafting the specifications. It is worth noting that the crucial point is not the absence of standards but rather the fact of defining a harmonious profile with standards that are consistent among themselves and that integrate well with each other.

Once the choice has been made, the profile is specified by analysing the standards and adapting them to the requirements. By adaptation of the standard (too generic as a rule) we mean a reduction in the options and making the semantics explicit. Integration of the standards in relation to each other (matching up the fields, values, etc.) is a significant part of the detailed specifications.

2.1.3 Validation of integration profiles

The integration profiles are produced in committees that bring together users to define the needs and engineers from industry to produce the technical specifications. Validation of the profiles is submitted to a public comment phase and comments are processed by the committees.

Profiles are then implemented and tested during real-time test phases between systems called Connectathons. These phases help to record maladjustments or anomalies that may still remain. They then change in line with any modifications requested by the whole community that uses this profile.

2.1.4 Application of the method to the medical device communication domain

This method that has now been tested in the area of hospital information systems and regional or national platforms using shared health records (such as electronic health records) is quite applicable to medical devices. The process applicable to the need is given below:

1 – Definition of the requirement for telecardiology, telerespiratory care and teledialysis
2 – Define the list of profiles - Look for the stakeholders concerned - Define the organisation
3 – Compile a list of existing standards and profiles
4 – Define the roadmap

The first stage of requirement definition has been started for the fields of telerespiratory care, telecardiology and teledialysis thus helping to understand the following phrases better. Stage 2 of definition should help to put forward an overall organisation involving healthcare organisations, industry, service providers and the patient along with institutional players.
In stage 3, an inventory of existing standards and profiles involves experts on standards from standardisation committees such as AFNOR in France and from health interoperability consortia (IHE and Continua Alliance).

Lastly, the final stage should, for all the stakeholders involved, provide the resources to succeed in carrying out the deployment of interoperability in the field of interconnected medical devices by defining a short- and medium-term roadmap.

For the initiative to be truly successful, all these stages call for a clearly-positioned role for each of the stakeholders on the one hand and, given the complexity of the issue, for these same stakeholders to agree on the other hand. Such an organisation still needs to be set up.

2.2 Taking part in European and international authorities

The requirement expressed for medical devices that communicate is a generic need backed by many international manufacturers. It is therefore essential to rely on international expert committees. Taking part in international and European standards bodies provides the means to have French specificities taken into account and to gear technical choices to the advantage of national stakeholders, whether healthcare professionals or manufacturers.
An active national organisation as outlined below will give all the support necessary to provide a link with international authorities.

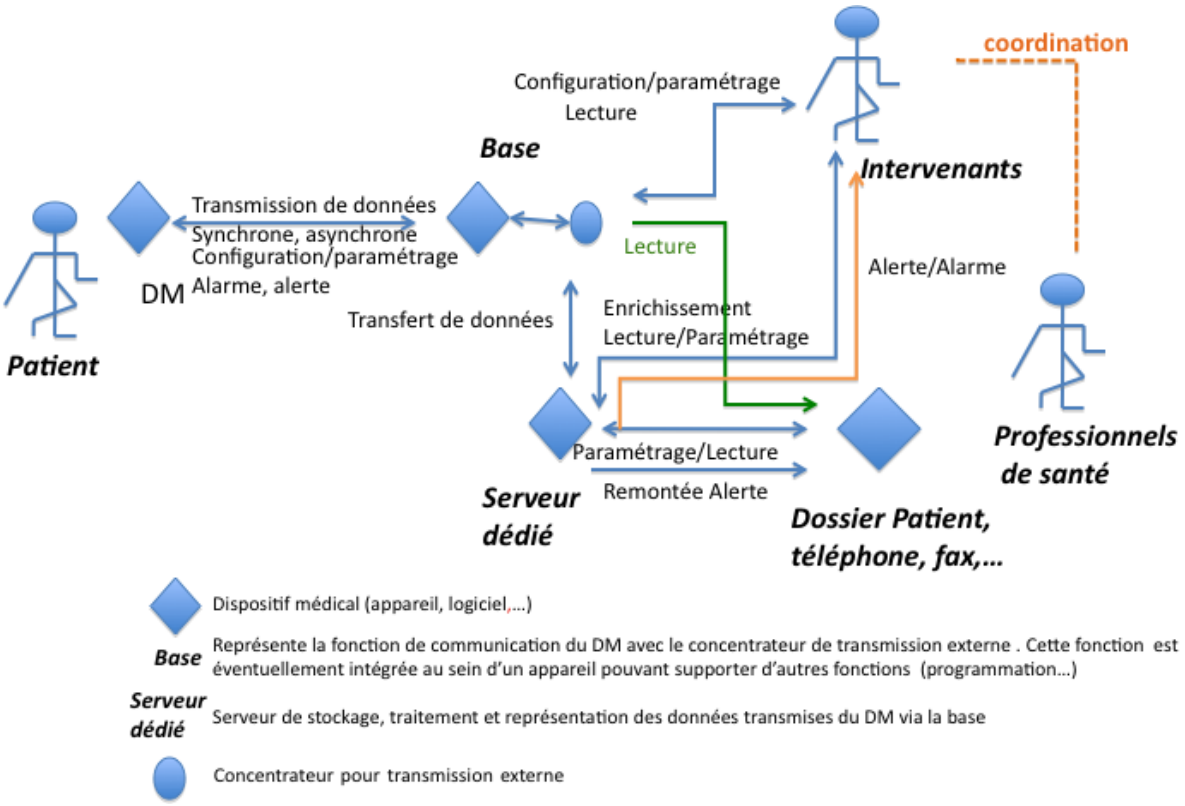
3. Profile definition: concrete examples

3.1 Core processes

The core processes of the three domains in question have been analysed and a summary of the activities encountered has been made:

- Medical device prescription: the doctor prescribes a medical device for a patient. The patient is directed to
  - a specialist for implantable devices;
  - a healthcare professional or a service provider for installed medical devices (especially in the patient's home)
- Putting the medical device in place
  - Implantable device: the medical device is implanted by a specialist;
  - Installed device:
    - the device is adjusted (with the patient);
    - the device is configured and started up in the patient's surroundings;
    - the device is monitored as it works (maintenance of the apparatus) and values are recorded (periodic or detailed report over a given period).
- Training and support
  - As regards the prescriber: learning about the devices available and their features;
  - as regards the patient: learning how to use the device or the constraints it causes in everyday life.
- Patient monitoring
  - The doctor analyses the values: using the data stored on the device or by accessing a server where the data are stored

A generic workflow has thus been drawn up and is shown below:



The medical device sends technical or medical data in synchronous or asynchronous mode to a device called base in this instance which, itself, sends the information to an external concentrator or server storing data from the devices. There are as many servers as there are types of medical devices. This server then distributes the information to the actors concerned – the health information systems (HIS, the doctor's health records, etc.) – and to the contributors (providers or healthcare professionals) for the data concerning them.

The alerts and alarms that consist in sending information about the patient's condition and/or a technical state influencing the way the device measures or works (see definitions in standard NF EN ISO 11073_10201) use the same communication channels.

This workflow has been compared to the work done by IHE and Continua Alliance consortia. The result of this work shows that the needs expressed are genuinely close to existing international projects and confirms the approach used.

3.2 Integration profiles

An inventory of the integration profiles, norms and standards that can support this generic workflow is given in appendix 1 and is based on the work done by IHE International and Continua Alliance.

It highlights that there are already enough projects available and that it is better to rely on these groups to perhaps add to the already considerable collection of existing profiles. These profiles rely on recognised standards such as those in the ISO 11073 collection.

Two profiles have thus been identified which solutions providers could start work on:

- One profile concerning the intra-hospital workflow: integration of data from medical devices into the healthcare organisations' information system through the storage server;

- one profile concerning the home care – healthcare organisation workflow that takes into account all the external exchanges to the storage server.

These two complementary profiles thereby cover the whole communication chain from the patient's home through to the end user, whether healthcare professionals or service providers.

To begin with, priority is given to the **first profile**, which today corresponds to an organisational, economic and technical environment regarded as better controlled and more consensual by all of the stakeholders. As for medical imaging where the implementation of interoperability began with the transmission of information with a view to its end use, standards today are well under control and operational (HL7 and DICOM in particular) for the dedicated server – health record workflow. Interoperability of the upstream part (data sources) is of a structural nature for the solutions themselves. Standardisation will develop more easily with the support of prescribers to begin with and subsequently through patients' associations who are users of medical devices that communicate in the home. Development of this second part could then take place more easily.

For the moment it is impossible to identify the profiles that have already been implemented because of the confidential nature of this type of information for manufacturers. However, their participation at world-wide level in the main standardisation authorities shows their concern to integrate these specifications.

3.3 Roadmap

The roadmap has two main thrusts:

- An organisational thrust whose aim is to define roles and activities of the stakeholders concerned. The Lasbordes report[3] provides some answers in keeping with the organisation proposed ;

- Another thrust concerning the definition of integration profiles considering the priorities chosen.

As soon as the work has been started, initial results and first implementations on the test bench could be available within the following year, provided, however, that positive support is given by the institutions and authorities.

Feasibility of the programme is not a technical problem but depends on the stakeholders' willingness to unite their efforts in carrying out the project.

4. Conditions of deployment of medical devices that communicate

The use of medical devices by patients in their home is developing considerably because of a policy to cut down on the length of stay in hospital. This use has already been experiencing a significant growth over the past few years (source: French National Health Insurance Agency). Whilst medical devices

3 Telehealth: a new asset to serve our well-being. 15 October 2009

today are used in stand-alone fashion, developments in technology will enable them to move towards greater communication, thereby providing them with fresh possibilities helping to ensure

- greater patient safety (feedback of alerts to the doctor for swifter intervention);
- continued and regular monitoring of changes in the patient's condition, with the possibility of organising pooled treatment and better use of resources. This permanent connection helps to support the development of patient education and prevention. This additional level of interactivity, in line with its adaptation to the patient's everyday life, also helps to develop his or her involvement and compliance and could contribute to a greater degree of independence.

The number of medical devices that communicate will therefore grow significantly and will do so in more and more disciplines.

The regulations concerning this field are wide-ranging today and may, in some situations (health data hosting decree for example), require significant investments beforehand.

The organisation charts for deployment of interconnected medical devices set up by manufacturers often rely (and especially in the case of telerespiratory care) on external home care providers ensuring contact with and daily monitoring of the patient. These providers still most probably have a whole range of additional services to be defined and proposed.

Despite a whole host of technical, organisational, medical and economic demonstrations for deploying these devices (particularly in the three domains studied), no payment model has yet been defined at national level.

The main key factors to the development of interconnected medical devices identified in the current context can be summed up as follows:

- The quality with which the matter of patient safety will be dealt will be one of the factors behind the development of medical devices that communicate. The following paragraphs show that there are a great many software strings interfaced together which process the information sent by medical devices.

- Ease of installation and use for the patient. A patient equipped with various medical devices that communicate should be able to use them without increasing the number of boxes, telephone lines, training courses, etc. For a patient suffering from various diseases and equipped with different medical devices that communicate, interoperability of the equipment becomes a major challenge.

- Motivation relating to the development of new applications and the use of ICT despite a lack of visibility for the new services that this will give rise to;

- The still incompletely-defined role of service providers is becoming increasingly pivotal in the patient monitoring process. The quality of end services provided to the patient will, for them, be one of the main selection criteria.

- The economic model put in place will have to be clear for all the stakeholders (manufacturers, health insurance, supplementary and private health insurance companies, etc.) and also for the patient.

The coherence of the pieces of equipment, their communication tools, the processing of the data sent, the care given by the provider(s) as well as an acceptable financial model are the main challenges to ensure the development of interconnected medical devices to the best advantage and to coordinate the patient's treatment in the best possible way.

To summarise:

Domaine	Contraintes	Leviers
Règlementaire	•Décret hébergeur(ticket d'entrée) •Marquage CE •Réglementation ne suit l'évolution des professions (infirmier) ou nouveau métier	•Se préparer à la mise en conformité au décret (propose un cadre permettant le développement
Technique	•Sécurité des données Patients •Volonté des constructeurs à rester propriétaire (télécardiologie)	•Elaboration de normes et standards •Formation/information des acteurs
Fonctionnel	Nouveaux services : fonctions liées au plateforme multiservice, à la télémaintenance et au configuration des dispositifs, autres fonctions répondant aux nouveaux usages	Développement du disease management (intégration de capteurs) Qualité des services, amélioration et continuité des soins Aspect ludique pour le patient
Organisationnel	Redéploiement des responsabilités entre les acteurs Elargissement de leur responsabilité Rôle des acteurs à définir	•Normalisation des services Amélioration de l'efficicence (BPR)
Tarifaire	Modèle économique non encore trouvé. Les solutions explorées posent des questions non résolues Pas de vision claire	Mutuelles et assurances (recherche d'une efficacité économique, gestion de l'urgence)

5. Conclusion

Medical device interoperability brings considerable advantages for patients and represents an element of efficiency in the way they are cared for. The work in progress at IHE and Continua Alliance already covers a whole host of aspects. The work carried out has helped to firmly identify two integration profiles that are of interest to French stakeholders and would help to significantly improve the scope for deploying medical devices that communicate.

The selection criteria for standards to be used in the profiles identified during this work need to be analysed more deeply than was done to begin with (see 0).

The work also has to open up to the social welfare sector which will be a big consumer of home care devices and a connection has to be found with the people involved in this sector (CNR-SDA, CNSA, etc.)

For the time being, the developments carried out by manufacturers that correspond to these two profiles are based on proprietary standards that need to be deployed and used on a large scale. Nevertheless, the involvement of research laboratories belonging to international groups in the development of these profiles is absolutely essential in order to give them the necessary visibility.

Furthermore, the deployment on a huge scale of interconnected medical devices is also linked to the setting up of a satisfactory economic model, which does not yet exist, and which is applicable for all the stakeholders.

Within this context, a wide scale circulation of this work should help to identify the stakeholders (manufacturers, healthcare organisations, service providers, patients, etc.) who are prepared to get involved in the development of standards within French organisations that can then be passed on at international level.

After identifying these stakeholders, Snitem would be able to play a project manager role by uniting the development of these integration profiles, organising their work in coherence with the IHE and Continua Alliance initiatives and the standardisation organisations (CEN, ISO, CENELEC, IEC, ETSI and ITU) and by ensuring the support of the authorities and especially the General Directorate for Competitiveness, Industry and Services). Snitem shall make sure that users are included in this federation because their place is also a core component for consideration in the organisation to be set up.

6. Proposals

The development of medical device communication cannot take place without a truly determined initiative, in other words, the roadmap suggested has to be implemented. Based on market stimulation (the means are there) and more particularly the advantage of use for professionals, we therefore propose to:

1. implement the roadmap by launching the two profiles identified in the data analysis workflow and by setting up a work group run by one of the organisations set out in point 5, including the manufacturers concerned, user representatives and French representatives of the IHE and Continua Alliance initiatives so as to make sure the work that will be carried out is consistent at international level.
2. encourage implementation by relying on the projects or local initiatives and with the support of end users while making sure that coordination at manufacturer level is set up in order to make the profiles specific to specialities across the board;
3. fine-tune the standards selection framework drawn up by the work group;
4. provide support for the convergence of the projects and local initiatives by encouraging them to be consistent with the flow model as defined in this report. This is a first stage before the actual use of the profiles to be developed by all the projects;
5. support the experts by helping them financially so they can take part in standards organisations at national, European and international level. To do that, Research Tax Credits should be allowed to apply;
6. convince manufacturers' R&D units that they should be consistent with standards;
7. communicate inside and outside of companies with the help of experts in charge of monitoring or standards;
8. thoroughly study the terms of patient coverage and reimbursed procedures, especially for telemonitoring.
9. determine what gain in efficiency can be obtained by the interoperability and use of profiles by the systems, which thus helps to compile remote services, such as those involved in respiratory, cardiology and diabetes specialities.

7. Appendices

7.1 Work group participants

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7.2 References

1. Telemedicine Report by Pierre Simon and Dominique Acker: «La place de la télémédecine dans l'organisation des soins» *(The place of telemedicine in the organisation of medical care)*, November 2008.

2. Lasbordes Report: Telesanté: un nouvel atout au service de notre bien-être» *(Telehealth: a new asset to serve our well-being)*, 15 October 2009.

3. FIEEC Report: «Une stratégie industrielle pour les marchés du futur» *(An industrial strategy for future markets)*, June 2008

4. IHE Technical Frameworks: www.ihe.net

5. Continua Alliance: www.continuaalliance.org

6. Barcelona Declaration: Final Conference Declaration - European Co-operation on eHealth 15/03/2010.

7. Initiative launched by the European Commission (2010/C 217/08) on objects that communicate

7.3 List of IHE Integration Profiles

Domain	Profile	Description
PCD	[ACM]	Alarm Communication Management
	[DEC]	Device Enterprise Communication
	[DEC-PIB]	Patient Identity Binding
	[PIV]	Point-of-care Infusion Verification
	[RTM]	Rosetta Terminology Mapping
	[DPI]	Device Point-of-care Integration
	[MEM]	Medical Equipment Management
	[SA]	Semantic Architecture
CARD	[IDCO]	Implantable Device Cardiac Observation
	[REWF]	Resting ECG workflow
ITI	[XDR]	Cross Entreprise Document Reliable

7.4 Other standards

Continua Alliance: Continua Design guideline. Version 1.0. June 2009

IEEE common: Health Informatics Personal Health Device Communication

prNF EN ISO 11073-20601: Application Profile Optimized Exchange Profile
prNF EN ISO 11073-00000 Framework and overview
prNF EN ISO 11073-10101 Nomenclature
prNF EN ISO 11073-20201 Application Profile Polling Mode
prNF EN ISO 11073-20202 Application Profile Baseline

IEEE specialized series: Health Informatics Personal Health Device Communication-Device specialized
prNF EN ISO 11073-10471 Independent Activity Hub
prNF ISO/IEEE 11073-10404 Pulse Oximeter
prNF EN ISO 11073-408 Thermometer
prNF EN ISO 11073-10407 Blood Pressure Monitor
prNF EN ISO 11073-10417 Glucose Meter
prNF EN ISO 11073-10415 Weighing Scale

ISO/IEEE 11073-10441	Cardiovascular Fitness and Activity Monitor
ISO/IEEE 11073-10442	Strength Fitness Equipment

Protocols:

Health Device Profile, version 1.0, Bluetooth SIG
Multi Channel Adaptation Protocol, version1.0, Bluetooth SIG
ZigBee Health CareTM
Wibree
Wi Fi
IEEE 802.15 WPAN™ Wireless Personal Area Network

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