

The PICNIC Story*

Dimitrios G. KATEHAKIS

*Foundation for Research and Technology – Hellas, Institute of Computer Science
(katehaki@ics.forth.gr), PO Box 1385, GR-711 10 Heraklion, Crete, Greece*

Abstract. This chapter describes how the *Professionals and Citizens Network for Integrated Care* (PICNIC) project was conducted in order to meet its objectives in preparing the regional healthcare providers to implement the next generation, comprehensive, user-friendly, secure healthcare network for patient centred care, and through it contribute to the de-fragmentation of the European market for health telematics. It describes the methodology followed in order to reach certain project results, starting from the selection of common documentation tools and methods, to the delivery of a new model for providing services, assessment plans, and a number of open source software components running on a number of diverse pilots throughout Europe in line with the overall PICNIC architecture.

1. Introduction

PICNIC stands for *Professionals and Citizens Network for Integrated Care* and was a European Commission co-funded research and development project, established under the 5th Framework of European Research “Information Societies Technology Programme”. PICNIC begun in January 1, 2000, was split into two phases, and involved partners and subcontractors coming from Denmark (DK), Finland (FI), France (FR), Greece (GR), Germany (DE), Iceland (IS), Ireland (IE), Netherlands (NL), Spain (ES), Sweden (SE) and the United Kingdom (UK). The design phase involved 15 partners (Danish Centre for Health Telematics of County of Funen – DK, Tele Danmark Consult A/S – DK, Satakunta Macro Pilot – FI, VTT Information Technology – FI, General Medical Services (Payments) Board – IE, North Western Health Board (NWHB) – IE, Servicio Analuz de Salud – ES, ECOMIT – ES, South & East Belfast Health & Social Services Trust (SEBT) – UK, Systems Team plc/ In4tek – UK, Erasmus University – NL, Foundation for Research and Technology – Hellas (FORTH)– GR, University of Ioannina – GR, MN-Medizinische Netzwerke – DE, and the University Hospital of Iceland – IS), while the deployment phase involved 8 partners (General Medical Services (Payments) Board – IE, VTT Information Technology – FI, NWHB – IE, SEBT – UK, Erasmus University – NL, FORTH – GR, Minoru/ OpenHealth – FR, and the Danish Centre for Health Telematics of County of Funen – DK) and 2 subcontractors (Compaq/ HP – IE, and SPECTRA – SE).

Most of the application areas in PICNIC aimed at realising citizen-centred, shared care and was initiated by regional healthcare providers who were planning their next generation Regional Health Care Networks (RHCN) to support their new ways of providing health and social care. Under a shared care scheme the PICNIC partners envisaged

- *healthcare professionals* to collaborate and to access relevant information timely and securely for decision support and research;

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- *managers* and *health authorities* to access relevant information including information coming from both clinical and administrative data in order to make rational decisions;
- *citizens* to access information enabling them to take a more active role in the process of disease prevention, health education, care and rehabilitation.

The aim of the project was to prepare the regional healthcare providers to implement the next generation of secure, user-friendly healthcare networks in order to contribute to the de-fragmentation of the European health telematics market. This was being done by:

- developing scenarios of new ways of patient centred delivery of care;
- describing the services, so that a total picture of RHCNs could be presented towards industry and other healthcare authorities;
- specifying an overall architecture;
- delivering a number of certified Open Source (OS) components for the services in close co-operation with industry;
- integrating these components into applications that deliver similar services across participating regions;
- developing of a set of demonstrators, including extensive prototyping of the highest priority services to validate the concept;
- delivering plans and instruments for regional assessment;
- facilitating the exploitation of the PICNIC results by other regions and industry to provide products for a European, and potentially worldwide, market.

A schematic diagram of all the above is seen in Figure 1.

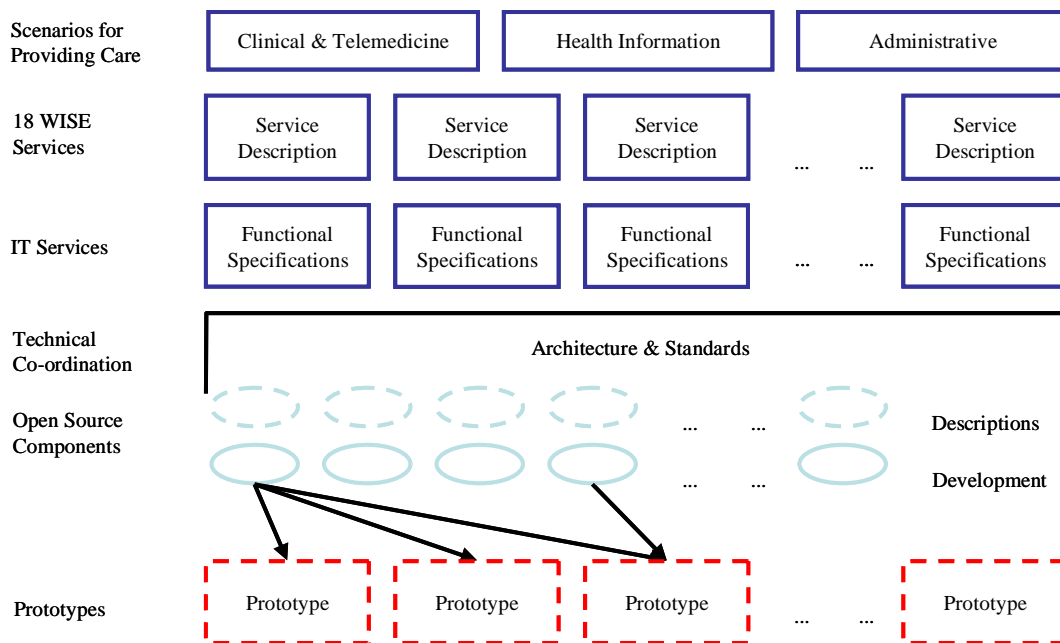


Figure 1 – The work of PICNIC comprised scenario building, service modelling, definition of IT-response to these, functional specification, creation of an architecture, identification of common components and finally building prototypes and implementing and evaluating these inside the regions.

Section 2 (Common Documentation Tools and Methods) describes the selection process for the development of common tools to be used for the description of the requirements for PICNIC services and components. The scenario for the delivery of new ways of patient centred care that involves all the 18 pre-selected services, based on the

development of a set of scenarios describing the objectives in health and social care for each of the PICNIC regions, is presented in Section 3 (New Model for Providing Services). Section 4 (New Services) describes the selected services from a European vision, with the level of detail needed so that they can be used for providing the functional specifications required for the development of OS software components and for services' prototyping. Section 5 (Open Source Development) deals with the development of the common components and open interfaces required by PICNIC, while plans and instruments used to assess the regional prototypes that use the common components, are described in Section 6 (Assessment Plans and Instruments). The PICNIC pilots are presented in Section 7 (The Pilots), while technical validation and component certification are further elaborated in Sections 8 (Technical Validation) and 9 (Certification) respectively. Finally Section 10 (Conclusions) concludes on the PICNIC story and delivers some of the lessons learnt.

2. Common Documentation Tools and Methods

From the beginning of the PICNIC project the technical co-ordination team considered necessary to develop common tools to describe the requirements of the PICNIC services. As in the modern approach adopted generally in software development, the PICNIC team planned to use Object Oriented (O-O) modelling techniques, since healthcare standardisation efforts, e.g. by Health Level Seven (HL7) and the Technical Committee 251 of the European Committee for Standardization (CEN-TC251), have recently gone towards the O-O approach.

To maintain uniformity across regions and along the project lifeline it was necessary for PICNIC partners to agree on the tools and methods that are to be used in the project. The modelling tool was already identified in the technical annex of PICNIC and can be characterised as follows:

- A modelling tool that supports “round-trip engineering” (i.e. provides support through all the phases of the project from problem identification and analysis to specification, design, testing and implementation)
- Software tools and principles that were used to build the common components and the prototypes.

The Unified Modelling Language (UML), incorporating Rumbaugh's Object Modeling Technique (OMT) [1] and Jacobson's Use Cases [2], is the industry standard which has been widely adopted as the development approach for O-O projects. This is because it was thought that the visual properties of UML based tools are strong and intuitive enough to be usable and understandable to users with minimal training.

The task of UML modelling tool selection was divided into the following sub-tasks:

- Analysis/ identification of potential tool sets;
- Selection and purchase of a group licence;
- Installation and on-site training of users.

Three companies were invited to give presentations about their products and start negotiations for licences for PICNIC. The three tool-sets were carefully analysed and considered and in the end the Rational approach was seen as the solution that could best support PICNIC work, since the Rational Unified Process, (RUP) offers the possibility to go back and forth from modelling all the way to deployment in a co-ordinated fashion [3].

The training course that followed (Espoo, Finland in 1-3 March 2000) provided an in-depth technical study of object-oriented analysis and design for client-server development and concentrated on the modelling techniques based on UML to develop a model based on realistic case studies. The objectives of using UML were that upon completion of this course, participating regions were able to:

- apply effective requirements management skills to produce a clear statement of product requirements;
- capture and document requirements with use-case-modelling techniques;
- set up a documentation hierarchy and standards for different levels of requirements for a product;
- use attributes and traceability to help manage requirement scope and change throughout product lifecycle;
- have used the Rational tools (*RUP*, *Rational RequisitePro* and *Rational Rose*) extensively;
- have created several diagrams to gain basic modelling skills; and
- understand when and why specific diagrams are modelled.

Topics covered during the training were:

- the requirements management process;
- best practices and the RUP;
- analysing the problem;
- defining the system: the vision, product features and use case model;
- finding actors and use cases;
- managing system scope;
- modelling basics;
- using the Rose modelling tool in a team;
- creating use case model; and finally
- creating use case realisation.

After course the participants discussed their experiences in view of the proposal to use the *AnalystStudio* suite in the PICNIC project to generate use cases from the service scenarios. The conclusion of the discussion was that in the ideal situation (see Figure 2):

- Each region produces a folder of scenarios. Each scenario describes the process of how service is delivered between customer and provider. Scenarios cover both intra- and inter-organisational processes.
- Each region nominates a Regional Analyst/ UML Secretary.
- The scenario work is done in four parts which are produced in the following format:
 - S1 = Context and background in which the scenario exists (using a predefined Word document template);
 - S2 = A narrative describing the scenario (using a predefined Word document template);
 - S3 = A more detailed narrative describing what Information Technology (IT)-services (the matrix of 18 or other IT services) are needed in the scenario (using a predefined Word document template); and
 - S4 = Use Cases describing the scenario (produced with *Rose* modeller by the Regional Analysts).

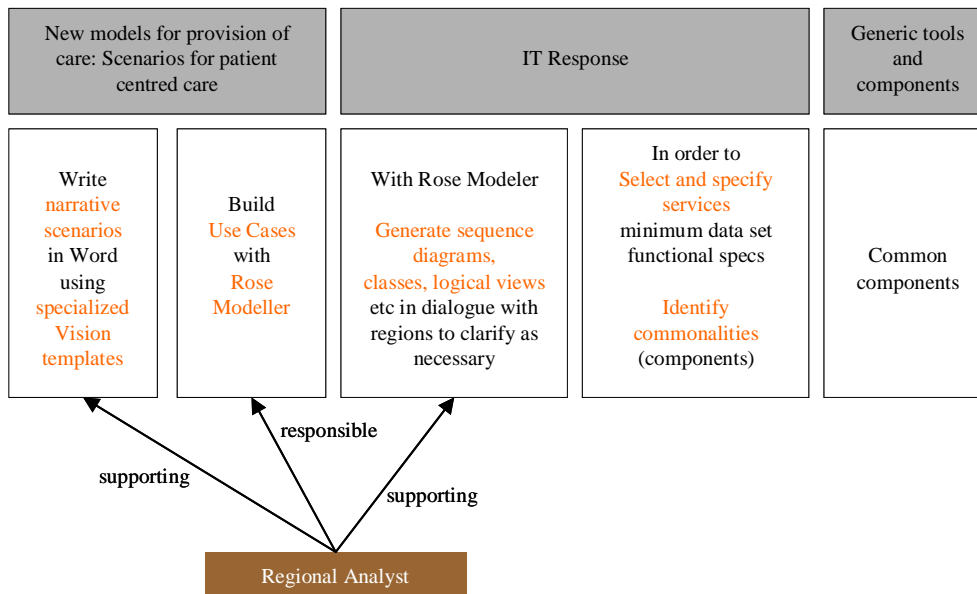


Figure 2 – The UML methodology used in PICNIC.

3. New Model for Providing Services

The vision of the next generation, user-friendly, secure RHCNs for patient centred care was the motivating factor that drove the regions and defined the scope of PICNIC. Therefore the task facing the PICNIC partners was to think ahead and visualise the health requirements for the next 5 to 10 years.

3.1 The 18 WISE Services

PICNIC started with the aim of taking the concept of the 18 services developed by the *Work In Synergy for Europe* (WISE) project [4]. These 18 services are required by a RHCN in order to deliver a full range of IT services to any “member” healthcare organization within the RHCN, and had been divided into three groups as seen on Table 1.

Table 1 – The 18 services as devised by the WISE project.

Clinical Services and Telemedicine	Health Information Services	Administrative Services and Electronic Commerce
1. Clinical Messages	9. Surveillance Information	15. Reimbursement
2. Clinical e-Mail	10. Yellow Pages	16. Electronic Commerce
3. Clinical Booking	11. Professional Guidelines	17. Patient Identification (ID)
4. Shared Records	12. Disease Quality Management	18. Resource Management
5. Care Protocols	13. Public Health Information	
6. Mobile and Emergency	14. Continuing Professional Development	
7. Home-care Monitoring		
8. Telemedicine		

Group 1: Clinical Services and Telemedicine

The Clinical Services are the most important functionality in a RHCN, and consist of patient-related information communicated to healthcare professionals concerning the treatment of the individual patient.

Clinical Messages is a service making it possible to exchange form-based information such as prescriptions, laboratory results, referrals, and discharge summaries almost automatically between different providers of health. When communicating Clinical Messages, a “store and forward” e-mail technique is often used because of the well-known technique and the opportunity to communicate 24 hours/ day.

Clinical e-mail is a secure, firewall-protected and/ or encrypted e-mail service dedicated to transfer patient-related information. Today telephones are used very frequently to give short, but important, patient-related information; normal e-mail would be very adequate to use in these cases. Nevertheless, e-mail is not used much for cross-sector communication, among other reasons because of the need for special security in health.

Clinical Booking is an IT service making it possible to book an appointment for treatment or investigation at other hospitals or specialist clinics. In Clinical Booking, an immediate answer is needed, and therefore on-line IT systems are normally used.

Shared Records is an IT service making it possible to share patient record data for the same patient between different professionals in different institutions in the region. Record Sharing demands a high degree of functionality and common structure, and such services therefore often use the same IT application, distributed to different professionals.

Care Protocols is an IT service making it possible to transfer exact defined information between health professionals in cases where different professionals participate in the treatment of the same patient group. Before communication is possible, protocols and guidelines have to be defined and agreed by the participating professionals, stating who should provide what treatment.

Mobile and Emergency are IT services dedicated to support mobile units like ambulances, doctors on duty and home nurses visiting patients at home. It makes it possible to transfer patient related information from systems at home-care units and in General Practitioner (GP) surgeries, in order to get access to the patient’s journal and retrieve updated information or save new information.

Home-Care Monitoring is an IT service making it possible to look after patients located at home, often as alert systems making it possible for weak patients to call assistance.

Telemedicine is an IT service used during the actual care of patients, making it possible to provide expert supervision to other professionals or directly to the patient. Telemedicine is the “classic” health telematics service, and is especially relevant if large geographic distances are a problem.

Group 2: Health Information Services

Health Information Services are information services providing health-related information to the public in general, to specific patient groups, or to specific groups of healthcare professionals. The information is typically general guidelines and procedures, and not information about the individual patient.

Surveillance Information is IT systems dedicated to communicate epidemiological information to professionals for medical surveillance. Such information are today typically gathered by national research-institutes and distributed regularly by means of newsletters etc.

Yellow Pages is an IT service making it possible to get practical information about healthcare providers, often with advanced facilities to search data in large databases. The Internet-based Web sites technology has in recent years resulted in the appearance of many such yellow pages from hospitals, health authorities etc.

Professional Guidelines are services for healthcare professionals with general information and guidelines about cost, quality, protocols and procedures, making it possible for health professionals to improve their practice. The gatekeeper role of GPs in many European countries especially has crystallised the need for such information systems.

Disease Quality Management is services with information making it possible for health professionals to optimise care quality when making cross sector treatment of specific diagnoses.

Public Health Information is a service to the public in general or to specific patient groups to inform and guide about diseases, prevention and services provided by the regional healthcare system.

Continuing Professional Development is a service to the healthcare professionals, to make it possible to improve their education continuously.

Group 3 - Administrative Services and Electronic Commerce

Administrative Services and Electronic Commerce are regional health services to professionals related to administrative, financial and management issues.

Reimbursement is a service making it possible to transfer bills from healthcare professionals to public or private insurance. Despite the fact that healthcare organisation differs between the countries in Europe, the reimbursement situation is important in all countries and is often the first regional telematics implementation in health.

Electronic Commerce is an IT-service making it possible to order, deliver and pay for goods and services to healthcare. In trade, the United Nations' Electronic Data Interchange (EDIFACT) standards are used world-wide for this purpose; the developments are supported by the international EDIFACT and European Article Number(ing) (EAN) organisations.

Patient ID is an IT service making it possible for health professionals to access central databases for quick and secure identification of patients. Because of lack of well-known national ID-numbers, a secure identification of patients is a problem in several countries.

Resource management is an IT service providing information to health professionals giving access to cost and quality information from other health providers in the region. Especially in countries which have introduced provider-purchaser systems in health, where knowledge of costs and quality has become important for healthcare professionals and administrators.

3.2 Development Methodology

Having the 18 WISE services as a starting point, PICNIC needed a storyboard in order to articulate the future healthcare response, with the empowered citizen at the centre and professionals through a RHCN service providing services and support which aim to maintain the citizen's quality of life despite clinical illness which impacts not only on family life, but also on the citizen's ability to sustain his occupation. The storyboard was constructed around a single typical healthcare story, based on a generic patient character ('Miguel') which is prevalent in each partner country, as a superimposition and cross mapping of the several storyboards produced by each of the 8 partner countries, and captures generic requirements common across all countries in one story.

The methodology to developing the "Miguel" story was the following;

- A series of workshops were held involving all the partners to discuss and describe current practice, including difficulties, pressures and their vision of future care delivery and, in discussion with each other and the IT partners, to develop an outline scenario of future care provision.

- One of the partners, a healthcare provider, was tasked with developing a real life storyboard based on their actual experiences in treating patients. They were asked to combine a number of real cases to encompass all the 18 services in the PICNIC project and to set these into a real family setting.
- This single “storyboard” was then sent to each healthcare partner with a request that it was used as a template to develop a storyboard for their own region with their own regional requirements built into the story. This regional storyboard would focus on the implementation of the prototype which that country was committed to within the project showing the particular services they required to enable the prototype to be implemented.
- The descriptions received from each country were then analysed and consolidated into one single “storyboard”. This involved analysing each partner’s story and extracting the interventions, actions or functions described and relating these to one or more of the 18 services.

This approach enabled the 18 services to be described and linked within one scenario, the “Miguel Story”, which follows in Section 3.3 and is fundamental to the PICNIC project, since it combines in a single scenario all the services on which builds its solutions for a new approach to the provision of healthcare in a region [5]. The story clearly demonstrates the requirement for a new way of combining and delivering these services and the usage of modern technology to facilitate such a new delivery scenario.

3.3 *The Generic Storyboard*

Miguel is a 51 year old man who has been working for many years as a salesman for a major company. The company is in the process of technological change after its acquisition by a big multi-national from the sector. Miguel lives with his wife Anna, 48 and two children, Julia, 19 studying Tele-communications in the capital city of the region and Antonio, 17 who is finishing high school and plans to study medicine.

Before referring Miguel to the local health centre his GP gives him information on web sites where he can find evidence based information on how to stay healthy and well. It also contains the details of an Internet chat room where he can talk with other people who suffer from diabetes. (13. Public Health Information)

When Miguel visits the diabetes web site he finds that the information has been compiled by experts and translated into non-expert language by the editors of the Internet portal system. Within the web site there are virtual tours which have to be paid for. Miguel uses his personal identification smart tag to pay for the tour. (16. Electronic Commerce)

The GP recognises that there are two realistic courses of action to manage Miguel’s illness. As part of the information needed to make his decision on the most cost-effective course of action the GP downloads cost information from different health providers in the region. (18. Resource Management)

The GP also downloads epidemiological information from the National Research Institute on Diabetes. (9. Surveillance Information)

The GP explains to Miguel that he can send his primary health record electronically to the health centre via a secure regional electronic network. He asks Miguel’s permission to release all of the shared patient record, which can be updated from all available sources. However, Miguel does not authorise the release of all the information because he wants an independent second medical opinion. (1. Clinical e-Mail, 4. Shared Records)

Miguel has no apparent medical problem although his GP (since they moved to the new house in the countryside the GP's surgery is far away so they attend the new health centre, which has a team of young staff) recommended that he lose weight, change diet and stop smoking. He smokes between half a packet and one packet a day and for "work reasons" drinks between 4 and 5 units of alcohol a day, "the norm". In his last work journey, while visiting a client he suffers a loss of consciousness. He is taken to the local health centre (isolated rural centre within his usual car routes) where they detect an abnormal level of glucose in his blood and abnormalities in the ElectroCardioGram (ECG). The local GP decides to send him to a hospital where Miguel is admitted to intensive care to treat an acute myocardial infarction and coma.

The doctor at the health centre views Miguel's electronic healthcare record which includes data from Miguel's GP, his last discharge report from hospital and the District Nurse's notes. (4. Shared Records)

Anna, Miguel's wife uses her Wireless Application Protocol phone to browse extensive information on glucose and insulin values over time. Sometimes she looks up Miguel's complete electronic diabetic record on the Internet. Miguel can also access his record on his television screen. (1. Clinical Messages, 4. Shared Records)

Miguel's GP and community nurse join a distance learning course through the network to keep them up-to-date with the evidence-based management and treatment of diabetes with ischaemic heart disease. (14. Continuing Professional Development)

Miguel has difficulty keeping to his diet and his GP arranges a tele-consultation with a specialist dietician at the Regional Hospital (telemedicine). Miguel continues to take his blood pressure readings and he is now able to regulate these himself and send the results to the GP by electronic message. There is therefore joint control between Miguel and his GP. (1. Clinical Messages)

The doctor at the health centre refers Miguel to the hospital via a clinical e-mail using his unique patient identification number. To prepare for his arrival at the hospital the doctor electronically orders previous medical records from other hospitals and when he receives these he adds them to Miguel's shared records. (2. Clinical e-Mail, 17. Patient ID, 4. Shared Records)

Miguel is not very communicative; he is dreamy and frequently has aggressive and unjustified violent reactions. He doesn't sleep at night and on various occasions at midnight they have called the emergency services for chest pressure with no evidence of ischaemic effects. Recently they have attended the Accident and Emergency (A&E) department at the general hospital where they have recommended a neurological assessment to evaluate a possible cognitive disorder.

Once he overcomes this acute problem he is discharged from the hospital and advised to follow treatment with insulin, anti-coagulants, anti-hypertensives, anti-ischaemics and anxiolytic therapy and to stop smoking and stop drinking alcohol, to go on a diet and live life in a different way, including changing his job in the case that he can return to work.

During the ambulance journey to the hospital the paramedics electronically send Miguel's vital signs to the hospital. Medical experts at the hospital use this information to advise the paramedics how best to manage Miguel throughout the journey. (6. Mobile and Emergency)

The specialist in charge of Miguel's care at the hospital is a certified user of the International Diabetic Electronic Advisory Line (IDEAL). This means that she receives regular updates of guidelines for diabetic examinations, treatments and surveillance, and

she runs these guidelines against Miguel's electronic records. (5. Care Protocols, 12. Disease Quality Management)

Following successful treatment at the hospital Miguel decides he wants to return home by bus. He uses his smart tag on the bus which allows him to travel at a reduced rate. (16. Electronic Commerce)

Miguel's discharge information is sent to his GP in the form of a clinical message. The agreed care protocol for shared care, between secondary hospital and primary care and professional guidelines are sent with the discharge message. (1. Clinical Message, 5. Care Protocols, 11. Professional Guidelines)

Once at home Miguel wants to maintain his quality of life and arranges that his twice daily readings of blood glucose and blood pressure are sent electronically to the local health centre and by return he is advised how to adjust his insulin and anti-hypertensives. He also monitors his progress against the Care Protocol which can be viewed on the television. (1. Clinical Messages, 7. Home-care Monitoring, 5. Care Protocols)

He has to go for an arterial examination of the cardiac vessels in the regional university Hospital, 100 Kms from his home and be monitored by his GP (under indications from the cardiologist, the endocrinologist and the haematology unit in his local hospital) who will have to handle the necessary elements of his temporary disability and eventually put him in touch with social security since his problems seem incompatible with the type of work he does.

Miguel and his GP prepare for the arterial examination through tele-consultation (telemedicine) with the cardiologist at the University Hospital. The GP also sends the cardiologist a video clip of Miguel's past condition. The appointment is booked electronically. (3. Clinical Booking)

Back home, Miguel starts his treatment plan including insulin administration, anti-coagulant controls and anti-hypertensives and his new diet (Miguel has always enjoyed good food). His wife accepts a part time job as a nursery assistant. She is very worried about the restructuring going on in the company and the continuous calls from Miguel's work colleagues and his boss about not reaching the sales standards. She has serious doubts that if they don't have the income that they had (a very important part of which came from hitting sales targets), it could be difficult for them to send their children to university and pay for the new house mortgage, the house that they moved to just a year ago on the outskirts of the locality. However, for fear of the effect it could have on her husband she has not spoken to him about her worries following the specialist's advice.

Two months later Miguel and Anna decide to go for a holiday to Germany to see their cousins who live there. Once he arrives there Miguel uses the Yellow pages facility to find a doctor in Berlin who speaks Spanish. At the end of the visit to Germany the doctor electronically bills Miguel's insurance company who in turn refund the doctor for the consultations. (10. Yellow Pages, 15. Reimbursement)

4. New Services

Following the development of the set of scenarios for each of the participating regions, together with the generic storyboard, the next task was to describe the corresponding IT services and the technology to be used for each of the selected services. This was another key part of the PICNIC project, since the participating regions (together with the industry)

were expected through their description to analyse and define the high-level needs and features of the IT services at a European level.

4.1 Development Methodology

The PICNIC regions selected the 12 highest priority WISE services, and named a group chairman for each one. For each service and for each participating region, an overall position statement was provided, summarizing at the highest level, the unique position the IT service intends to fill in the marketplace. This position statement identified the target population, provided a statement of the need or opportunity, the name and category the service belongs in, the key benefit(s), primary existing service alternatives and the IT service principal differentiation.

Finally, the service chairmen were asked to deliver a harmonized description of the IT service, having the approval of all participating partners. As a product, a high level view of the IT service capabilities, interfaces to other applications and systems configurations, as well as the perspective behind the IT service, together with a summary of capabilities, assumptions and dependencies was provided [6].

4.2 Results

From the IT service descriptions, as well as the overall statement summarizing at a high level of abstraction, the unique position each IT service intended to fill, it became apparent that there are a lot of “service inter-relations”, and that some of them need co-exist in order to deliver their respective services. This is clearly depicted in Table 2.

Table 2 – Result of the PICNIC IT services harmonization process.

IT Service	Comments
1. Clinical Messages	Exchange of structured, patient-related information. Common approach for all (DK, ES, IE, IS, GR). In many cases it requires the <i>Patient ID</i> service.
2. Clinical E-mail	Transfer of unstructured patient-related information. Common approach for all (DE, DK, IS).
4. Shared Records	Seamless access to patient record data. Two approaches (ES, UK) vs. (GR, FI, IS) that can be merged into one. Requires the <i>Patient ID</i> service.
6. Mobile and Emergency	Interaction with healthcare related information through a number of alternative information access devices. Three different approaches exist. The DK approach is <i>Clinical Messages</i> . The UK approach is <i>Shared Records</i> . The IE approach is a combination of <i>Shared Records</i> and <i>Clinical e-Mail</i> . May depend on IT services like the <i>Shared Records</i> , <i>Telemedicine</i> , <i>Mobile and Emergency</i> and <i>Clinical Messages</i> . Can be offered at home.
7. Home Care Monitoring	Looking after patients at home. Common approach for all (FI, GR, IS, UK). May depend on IT services like the <i>Shared Records</i> , <i>Telemedicine</i> , <i>Mobile and Emergency</i> and <i>Clinical Messages</i> .
8. Telemedicine	Medicine at a distance. Different flavours across the regions (DK, GR, IS, UK). Very close to <i>Mobile and Emergency</i> . Can be part of the <i>Home Care</i> IT service. In some pilots, it requires the <i>Clinical Messages</i> and <i>Yellow Pages</i> service.
9. Surveillance Information	Communication of epidemiological information to healthcare professionals. Common approach for all (ES, IE). Requires the <i>Shared Records</i> service.
10. Yellow Pages	Up-to-date information about healthcare, social providers and facilities.

	Common approach for all (DE, DK, GR, UK). Minor differences, mainly deal with end-user categories and access rights.
13. Public Health Information	An environment to create, discuss, bring to a consensus, publish and distribute health and social care related content. Single definition (DE, FI).
15. Reimbursement	Preparation, submission and transmission of claims for payment. Single service with two approaches. IE focuses on the payment of prescription drugs dispensed by community pharmacists. ES involves transferring claims at the point of discharge to the relevant funding agencies. Requires the <i>Patient ID</i> and the <i>Clinical Messages</i> IT service.
16. Electronic Commerce	Order entry and submission of certain services between business units/ healthcare organizations and citizens. Single definition (DE, FI).
17. Patient ID	Unique identification of patients. Single definition (ES, IE). Basic component in many services.

Through this analysis, it became evident that *Patient ID* seems to be rather more a common component than an independent IT service, and is required by most of the other end-user applications. For example the *Clinical Messages*, the *Shared Records* and the *Reimbursement* services, explicitly require patient identification in order to function. This is also the case for all other services that depend on the three previously mentioned services, or that need to relate to a single identifiable patient.

In deploying *Telemedicine*, it was necessary to develop services that permitted remote consultation between professionals in specialised centres, peripheral hospitals and other points of care and that provide citizens with effective healthcare in their homes, in isolated places, and in cases of emergency. The telemedicine service should be available for emergency and the application could be running on mobile equipment. As such, *Telemedicine* is one of the features offered by the *Mobile and Emergency* service.

In the case of the *Home Care* IT service, *Telemedicine* can be applied in the patient's home either by the patient to the professional or by a healthcare worker to hospital service. In addition to this, *Home Care* also depends on other services such as *Shared Records* (to attach clinical findings), *Clinical Messages* (to send requests) and *Mobile and Emergency* (e.g. for alarm management).

Mobile and Emergency can be defined to be an end-user service, similar to the *Shared Records* service, but with the additional capability of supporting *Clinical Messages* and *Clinical E-Mail*. The only additional capability is the need to support mobility (i.e., access to shared patient and other data from mobile Information and Communication Technology (ICT) devices). In addition to the above-mentioned services, *Telemedicine* ought to be available for emergencies and run on mobile equipment, as well.

Surveillance Information IT service can be thought of as a specific in terms of its objective, although technologically it could be thought of as being close to the *Shared Records* IT service.

Taking the above information into account, it was concluded at this stage of the analysis that *Home Care Monitoring* and *Mobile and Emergency* were composite services existing as a combination of other, more atomic services. *Clinical Messages* and *Shared Records* seemed to form a set of core services, while the *Patient ID* component seemed to be fundamental, and therefore needed to be extensively prototyped, as a core IT service. Therefore at this stage, the emphasis seemed to be focused on these three services (i.e. *Clinical Messages*, *Shared Records* and *Patient ID*).

The diagram in Figure 3 depicts the existing interrelationships. In brief, it is shown diagrammatically that:

- *Patient ID* is not an end-user service, since it does not respond to any great degree to any real-world end-user need directly, but rather indirectly. It is nevertheless a

very important service within the IT architecture of a RHCN, providing its functionality (i.e. service) to a number of applications and other IT services. It must be thought of as a fundamental component without which it is almost impossible to develop a number of the remaining end-user services.

- *Home Care Monitoring* and *Mobile and Emergency* are “composite” services that depend on the existence of several “atomic” services (*Shared Records*, *Clinical Messages*, *Telemedicine*, *Clinical E-mail*, etc.), which are available to mobile users, to the home of a citizen or health professional or are employed in health emergency incidences.
- *E-commerce*, *Yellow Pages*, *Public Health Information* form a separate set of services that are not directly linked to the patient’s personal clinical management, but rather to adjacent services, linked to ordering and paying for goods and services using tools for electronic commerce, healthcare–related resources, and content.
- *Clinical Messages* and *Shared Records* are the IT services mostly needed as supporting elements of an RHCN supporting *Mobile and Emergency*, *Home-care Monitoring*, *Reimbursement*, *Telemedicine*, as well as *Surveillance Information*.

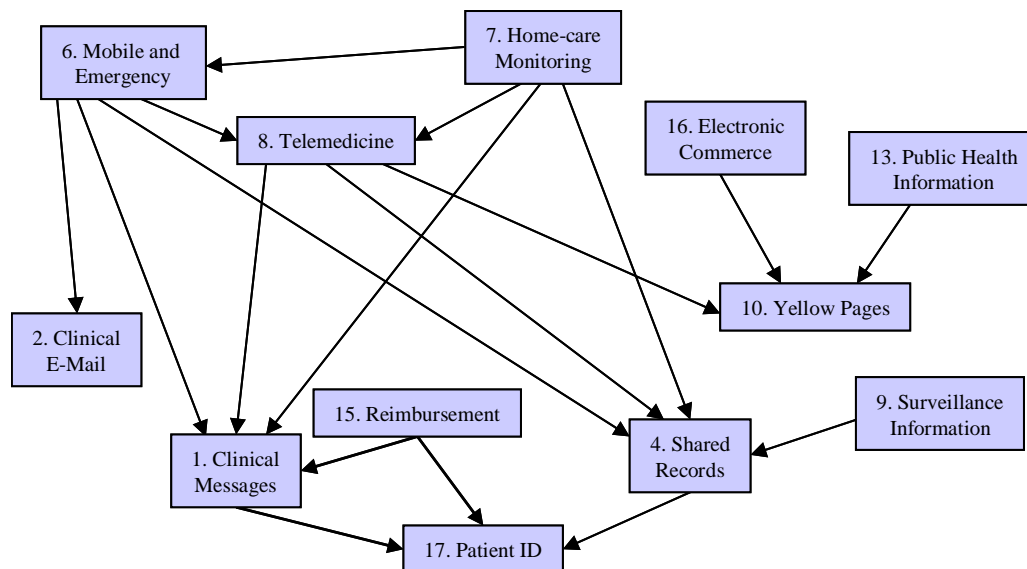


Figure 3 – IT services’ interrelation. An arrow represents the existence of a relationship/ dependency between two services pointing at the core service (e.g. *6. Mobile and Emergency* → *4. Shared Records* can be interpreted as “The *Mobile and Emergency* IT service may (or does) depend on the availability of the *Shared Records* IT service”).

4.3 Core Services and Components

Following the services redefinition phase, the level of detail produced provided PICNIC partners with the information it needed to create use-case models. Subsequently, a second template was circulated in order to collect, analyse and define high-level needs and features for each of the IT services initially selected for prototyping (i.e. *Clinical Messages*, *Shared Records*, *Mobile and Emergency*, *Telemedicine*, and *Reimbursement*). This template focused on the capabilities needed by the target users, and why these needs exist. As a result, a set of descriptions of functional specification and minimum data sets, for each of the included IT services was provided [7], together with the involved actors, as well as those non-trivial modules (i.e. components), forming subsystems of each IT service, that

fulfill a clear function and can potentially form the crux of a common development team effort. Generic use cases for the services depicted the features of each IT service, as identified by the participating regions. The subsequent sequence diagrams produced carried enough detail to provide the needed information for the extraction and classification of a set of 18 common components, distinguished in one of the three following categories: *Healthcare Application*, *Healthcare Common Middleware*, and *Generic Common Middleware* (Table 3).

Table 3 – Components described through the PICNIC IT services functional specifications. Classification was done, based on [8].

Abbreviation	Component/ Service	Clinical Messages	Shared Records	Mobile and Emergency	Telemedicine	Reimbursement
<i>Healthcare Applications Layer</i>						
MSUS	Message Set Up Service	√		√		√
REAP	Reimbursement Application					√
SRAP	Shared Records Application		√	√		√
<i>Healthcare Middleware Layer</i>						
<i>Healthcare Common Services</i>						
CLPS	Claims and Payments Server					√
COAS	Clinical Observation Access Server		√	√	√	√
CEMS	Clinical E-mail Server			√		
COLS	Collaboration Server				√	
PIDS	Patient ID Server	√	√	√	√	√
SRDS	Shared Records Data Server		√	√		√
SRIS	Shared Records Indexing Server	√	√	√	√	√
SRUB	Shared Records Update Broker		√	√		√
<i>Generic Common Services</i>						
AUDS	Auditing Server	√	√	√	√	√
AUTS	Authentication Server	√	√	√	√	√
CMCS	Communication Service	√		√		√
ENCS	Encryption Server	√	√	√	√	√
RESS	Resource Server	√	√	√	√	√
TERS	Terminology Server	√	√	√		√
UPRS	User Profile Server	√	√	√	√	√
<i>Bitways Layer</i>						

At the end of this stage, quite a large number of software components were identifiable [9], and in the majority of cases could serve the needs of more than one of the initial PICNIC IT services. The PICNIC National Health Advisory Board and the industry board at a PICNIC workshop in December 2000 recommended that the project should focus on high priority, healthcare-specific, common components. The decision regarding the focusing of the service areas to be covered by the project were made by the participating regions in order to select the highest priority areas to concentrate software development resources upon. This was done in order to implement pilots with substantial implementation scale. Component development was therefore concentrated in three groups, around the following high priority areas:

Component Group 1: Messaging

Clinical Messaging offers one of the most important functionality in a RHCN, and consists of highly structured patient-related information concerning the treatment of the individual patient.

Group 1 concentrated on the exchange of clinical and administrative data between different applications and included the use of already developed standards. Messaging between healthcare records and isolated applications was developed and implemented using HL7 v3 Clinical Document Architecture (CDA) Level 1 standard messages. As a result, a number of HL7 v3 CDA message specifications (XMLS), plus operational eXtensible Markup Language (XML)/ Document Type Definitions for messaging were developed [10].

Component Group 2: Access to Patient Data (APD)

Accessing patient data focused on the development of an integrated environment for professionals or citizens who need a uniform way to access parts of patient record data that are physically located in different clinical information systems. Delivering fast, secure and authorized access to distributed patient record information from multiple, disparate sources, was the main objective of this group. This environment should not be confused with autonomous clinical information systems (CIS), message based communication of Electronic Health Record data, centralized Clinical Data Repositories (CDR), or monolithic information systems that have embedded in their structure mechanisms for accessing directly host systems.

Group 2 concentrated on the four components identified as required [11] for the provision of on-line access to patient data stored in different locations and applications.

Component Group 3: Collaboration

Access of healthcare workers (general practitioners, other doctors, nurses, etc.) to specialists is an important tool to improve quality in healthcare by means of quicker diagnosis, quicker response to emergency and guidance for correct treatment and further examinations.

Group 3 was involved in the development of an environment for the provision of examination, monitoring, treatment and administration of patients through immediate access to expertise and patient information regardless of where the patient or relevant information is geographically located [12].

5. Open Source Development

During the original negotiation process for the PICNIC contract, PICNIC was attracted by the potential offered by OS, despite the fact that the original work plan of the project did

not include OS. In the course of events, it became quite evident that there is a plethora of tools and utilities of various kinds that cover many aspects of software development, office automation, system programming, artistic work, etc, and sites like SourceForge.net [13], FreshMeat.net [14], and FreshPorts.org [15] offer a topic oriented repository for OS software projects with a continuously updated index, descriptions and links, as well as search capabilities. Despite the fact that, in the healthcare domain, the case for OS still has to be proven, Open-eMed (previously Telemed) [16] seemed to be highly successful.

Subsequently, since sharing of knowledge, as well as source code, was required by PICNIC, in order to deliver similar services throughout Europe by means of the same software components, the PICNIC OS policy was formulated as follows:

- All models and specifications generated regarding *architecture and standards, scenarios and model for patient centred care, IT response, and common components development* must be in the public domain.
- Common components, developed by PICNIC industrial partners, must be placed in the OS domain (through the appropriate OS license).
- The software of the pilots and prototypes utilising these OS common components will not be made available in OS. Its intellectual property rights will be owned by the developers and shared within the PICNIC consortium according to the European Union model contract.
- A “PICNIC Open Community” must be established and encouraged, in order to build a community of OS developers who are committed to the further development, enhancement and re-use of the PICNIC components.

The common components that were selected to be delivered as OS implementations for the APD component group were:

- *COAS* for obtaining clinically significant information directly from a CIS and also for sending new content update information. The already existing Object Management Group (OMG) *COAS* [17] specification served as the basis for the description of the needed interfaces to this service and its further implementation.
- *PIDS* for enabling unique patient identification across the RHCN and for the provision of a master patient index. The already existing OMG *PIDS* specification [18] served as the basis for the description of the needed interfaces to this service and its further implementation.
- *SRIS* for holding indexing information on the content of the patient data in different patient record segments within the RHCN.
- *SRUB* for the prompt propagation to *SRIS* of any modification pertaining to the patient data, and therefore being used as a mediation tool for maintaining consistency with live data.

The collaboration component group decided to deliver the following OS components:

- *COLS* for the provision of the platform that allows general practitioners and medical experts to share patient-related information in the context of a teleconsultation session both inside and across RHCNs; and
- *RESS* for the identification of available healthcare related agents (e.g. organizations, devices, software, etc) and the means for accessing them.

FORTH of Greece delivered *COAS*, *SRIS*, and *SRUB* components, HP Ireland delivered the *PIDS* component, while the Swedish company SECTRA delivered the *COLS* and *RESS* components. All PICNIC components are available through the PICNIC OS community web site [19], which is an implementation of the OS components of SourceForge.net. Each component’s package includes documentation about the installation of the component and also additional material, guidelines, and test data about its implementation.

The OS licence governing PICNIC software components is the Berkeley Software Distribution (BSD) License [20] that allows others to use the OS code and its modifications

for any purpose (even commercial) as long as the copyright notices remain intact for the initial developers to get the due credit. Other licenses considered were the GNU General Public License (GPL) [21] along with its less restrictive form the GNU Lesser General Public License (LGPL).

For the development of these components a number of OS tools, libraries, compilers, etc. were used. They are listed below:

- The *GNU Compiler Collection* (GCC) [22], especially the C++ front end, was used for the compilation of the source code and its libraries in order to provide the run time environment for most of the components.
- The *GNU Make* [23] and the *Apache Ant* [24] utilities were used as building tools for the components executables.
- Various OS databases are used as data storage means, such as *OpenLDAP* [25] (i.e. an OS implementation of the Lightweight Directory Access Protocol (LDAP) protocol and the LDAP directory server) and *PostgreSQL* [26] (an advanced relational database management system).
- In order to communicate with the data stores some interface mechanisms are needed with their corresponding Application Programming Interfaces (APIs). In addition to the LDAP Application Program(ming) Interface for the C/ C++ programming languages provided by *OpenLDAP*, the Object Data Base Connectivity (ODBC) API was used. For UNIX and UNIX-like platforms the *unixODBC* [27] and *iODBC* [28] ODBC driver managers were deployed.
- The *Jabber* XML messaging protocol [29] and the OS implementation of the Jabber server were employed and extended to provide the open messaging platform for the collaborative work of medical personnel.
- The *Concurrent Versions System* (CVS) [30] was used as a source code repository during the development of most of the components, in order to guarantee access to the previous versions of source files and controlled source code.
- The *Adaptive Communication Environment* (ACE) and The *ACE Object Request Broker* (ORB) (TAO) [31] were employed as middleware solutions to provide the communication platform for various components and to solve accidental complexities in a cross platform manner.
- The *Boost* C++ Libraries [32] that provide a rich collection of utilities to ease the development of C++ programs.
- The *wxWindows* Graphical User Interface (GUI) framework [33] that is a truly cross-platform GUI toolkit for C++.
- The *Apache Xerces* XML parser for C++ [34].
- Finally, the development and testing of the most of the components were performed in OS Operating Systems such as *GNU/ Linux* [35]; and *FreeBSD* [36].

During development support was provided through mailing lists and newsgroups. This kind of support is certainly “unpredictable”, since there is no guarantee that the problem you have encountered will be answered soon if at all. Nevertheless, PICNIC found the OS community to be highly responsive and very helpful in various occasions during the development of the components. The majority of issues faced in PICNIC proved to be minor problems that other OS developers had already encountered in the past. Additionally, commercial support was offered in practice: for example in order to have complete and compact documentation for the TAO CORBA ORB it was found necessary to purchase “TAO Developer’s Guide” from Object Computing, Inc. [37].

The objective of the “PICNIC Open Community” was to build consensus for the “PICNIC Open Architecture” as the emerging architecture for RHCNs world wide. This is more than disseminating or promoting the architecture, it involves fostering an active and open dialogue between the PICNIC team and outside parties to create a community of

interest around the PICNIC project, the architecture, and the OS components. Success was indicated if, from the OS community perspective, the results created by the PICNIC team were felt to be “owned” by the community as whole.

6. Assessment Plans and Instruments

The ‘traditional’ user validation approach to software assessment was not considered to be suitable in the case of the PICNIC components, since the components sit within a regional ICT infrastructure which is not visible to the users. The proof of concept from the users’ perspective is the delivery of innovative services that are facilitated by means of the common functionality offered by the RHCN. Assessment requires not only a technical validation of visible systems and underlying infrastructures, but the economical perspective as well as the social/ organisational and juridical/ ethical perspectives must be integrated into an assessment methodology. Since a regional infrastructure must operate in the context of a national infrastructure and be interoperable with local infrastructures or systems, the dimension of scale is important for the assessment. Therefore the boundaries of the systems under assessment must be clearly described.

Besides the integration perspectives and the hierarchy of system scales, assessment had to address a pre-implementation approach. Since the PICNIC project was established as a European subsidised project to be delivered within a limited period of time, a traditional assessment of all those systems within all these perspectives was not possible. The main reason was that the traditional assessment approach is based upon post-implementation analysis of a systems costs & benefits, while some of the PICNIC pilot systems were planned to be implemented just at the end of the project.

The main questions PICNIC had to deal with were whether:

- it is possible to develop an assessment method that can be used before systems are operational and ready to be tested; and
- it is possible to integrate this assessment method with traditional assessment methods used to assess systems that are implemented within project time.

PICNIC initially had to develop a proactive assessment methodology. In contrast with traditional assessment methods, proactive assessment methodology is a set of coherent methods that can be used to assess systems during design and development stages. According to Remmen [38][39], traditional assessment may be characterised by consequence assessment that is reactive on operational implementations, whereas constructive assessment stresses the importance of interactive involvement of all stakeholders. Proactive assessment is in that classification comprehensive [40][41]; it tries to understand stakeholders opinion on factor-effect relations before implementation. The aim is to enrich design decisions and to optimise the expected benefits by assessment methods. For example, not the real costs but the expected costs are established to predict the real costs and to recalculate break-even points. Also the expected benefits for several stakeholders can be evaluated before even the systems are running in order to minimise the critical success factors.

In addition to traditional assessment methods that establish a range of ‘factors’ and ‘effects’, proactive assessment requires the definition of the relation between factors and effects. Since this may depend on regional characteristics and specific medical services, we had to differentiate. However, to be able to compare assessment results, we tried to harmonise and standardise the templates and questionnaires used across the regions as much as possible.

Since proactive assessment must be performed in parallel to design and development, it must fit into the development stages of the project. In fact, it followed a three-dimensional approach, as depicted on Figure 4:

- the stages of the project in which the product becomes less abstract and more physical;
- the scale of the product that determines the scope, the context and the sub-systems; and
- the perspectives that are relevant for factors and effects, their mutual relation and for the different stakeholders who argue mostly from the perspective of their stake.

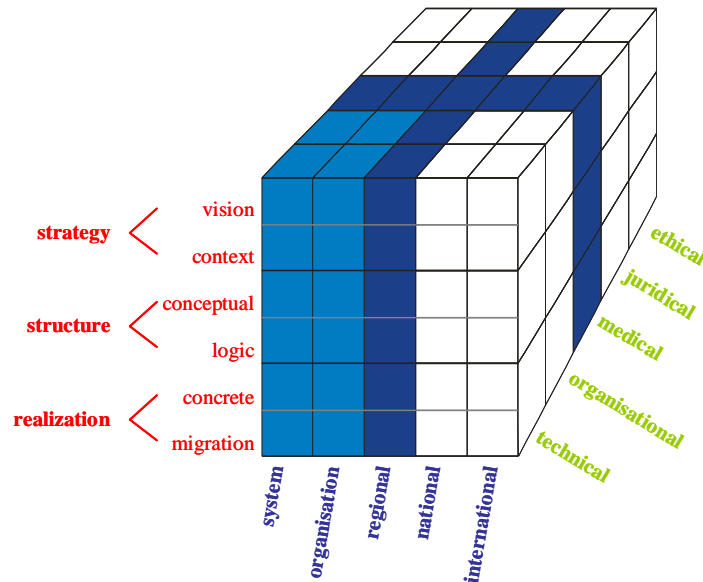


Figure 4 – The three-dimensional CUBE model helps to understand each other in a complex project, dealing with several system-levels, stakeholders and development stages and different people at the same time.

The second step was to integrate traditional and proactive methods into a coherent methodology.

PICNIC established the following regional *characteristics*: *Partner; Name of prototype; Region; Main problems; New scenario; IT solution; Main purpose; Main users; Number of users; Covered patient population; Stakeholders; PICNIC components used; Developers of these components; Developer of prototype; and Integration of components and prototype.*

Starting with extensive lists of factors and effects based on the FinOHTA report [42], experiences of the *Coordination and Continuity in Primary Health Care (COCO) Project*, and a large literature review [43][44][45][46][47], the participating regions were asked to select the most appropriate ones for each service. The stakeholders in the regions selected the following relevant *factors*: *IT-awareness; Current use of IT; Current provision of service (as starting point facts); Organisation of health care (as health care structure issue); Development degree of chosen technology; Security included; Reliability of technology (as technical design decisions); Number of patients; National policy (as service organisation issues); Attitudes and expectations of actors shared; Incentives and disincentives shared (as development decision issues); and Investment costs (as financial issues).*

The regions determined as possible *effects* the following: *Less costs on treatment; Less costs on diagnosing; Less costs on labour (as economical effects); Change in reliability; Change in process time (as technical effects); More efficient/ faster treatment; Work satisfaction; Less people needed; Easier for patients to get access (as organisational effects); Decision support in treatment; Change in health care process (as medical effects); and satisfaction with Physicians, Nurses, Authorities, Patients, Patient family.*

PICNIC selected those *methods* that covered the factors and effects that were pointed out to be relevant by the involved stakeholders receiving services. The following set was constructed: *Technical verification; Functional Validation; Costs and Benefit analysis of the 'before and after situation'* (as traditional methods); *Expected benefit optimisation; Alternative analysis; Prediction of effects* (as proactive methods).

The main *instruments* were checklists, matrices of factor-effect relations, and stakeholder specific questionnaires adjusted for each region. Besides plenary debates to discuss and reconsider design decisions, stakeholder specific meetings were organised to fill the templates. Stages in the process of assessment in PICNIC are depicted in Figure 5.

The PICNIC participants were also asked to evaluate the newly developed, proactive approach. Answering the questions whether or not it is possible to develop an assessment method that can be used before the systems to be assessed are operational and whether it is possible to integrate this assessment method with traditional assessment methods, it became clear that, like other assessment approaches, proactive assessment has its strength within its own limitations. Proactive assessment promises the maximum you can get with assessment methods in design and development projects. Furthermore, proactive assessment can easily be integrated with traditional assessment. In fact, a following traditional approach establishes experiences that are needed for proactive assessment of following projects. In this way the Integral Technology Assessment approach may provide the best conditions for a formalized ongoing learning circle.

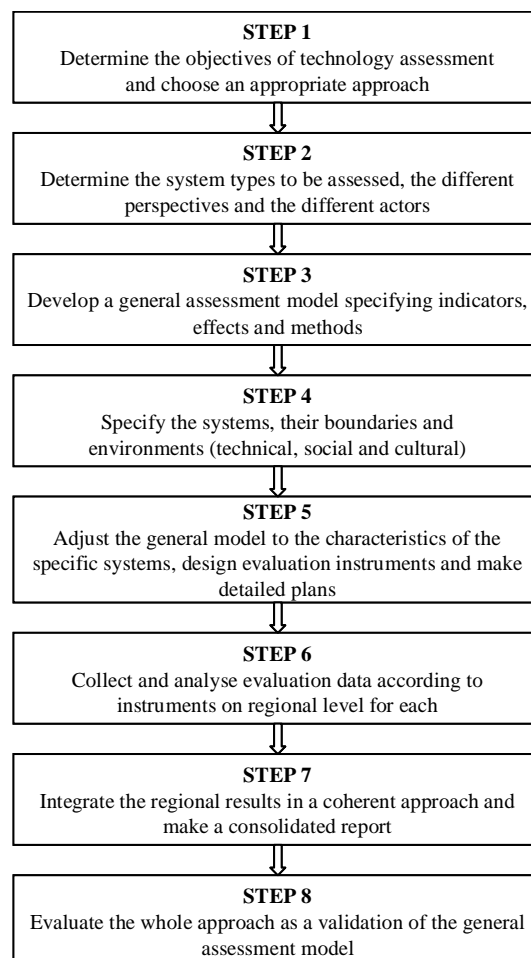


Figure 5 – Stages in the process of assessment in PICNIC.

As main recommendations established [48] [49] [50] were the following:

- The challenge seems to be to use the PICNIC approach as additional to local architectures and as blueprint at regional and/ or national levels.
- Security issues should be dealt with at a national level.
- Arrangement of a National or European (web-based) platform to exchange experiences as well as assessment results may benefit to a common learning circle. Standardised formats to record experiences should be provided to make the information easy accessible.
- Projects that are funded significantly with public money, and have a limited time-scale should always perform proactive assessment, preferably combined with traditional assessment, and should always require open standards, open source, as well as available and accessible documentation.
- Since proactive assessment requires some experience with traditional assessment methods as well as an experienced conversation leader, participants could be selected by the conversation leader. This leader should provide time and space for annoying and strange questions and ideas.

7. The Pilots

PICNIC pilots were implemented in co-operation with selected industrial partners within each of the participating regions. This offered the opportunity to test the concepts of the PICNIC architecture and the functionality offered by the PICNIC components in a number of sites delivering similar services, under a different application domain, across Europe. Since security requirements had to conform to the national legislation of each participating region, and in accordance to the regional/ national plans, standards, and requirements, different technical solutions were adopted in each case. A concise description for each of the PICNIC pilots follows in the rest of the Section.

7.1 County of Funen, Denmark

The County of Funen signed in May 2001 a contract with the Swedish company SECTRA, to deliver and implement a Radiology Information System (RIS) for all the radiology departments and the nuclear department (338 employees making 260,000 examinations annually). The RIS system was complemented with a picture archiving and communication system. The two systems will form the base for treatment and diagnosing and improve both the quality and functionality in the departments.

Odense University Hospital, Radiology Department, have a section for oncology patients, where the patients are examined by radiology images. This section performs 11,000 examinations per year and the patient often comes in to the department for further check-ups during the treatment. Some of the patients came from the County of South Jutland and it was necessary to formalize the exchange of images, videos, referrals, diagnosis reports and other relevant clinical information for the patients. The County of South Jutland, during year 2001, implemented a system to connect the emergency departments in the County Hospitals. Essential functionality is transfer of radiology images, still pictures, sound, videoconferences and referrals.

The Collaboration Monitor that was developed through PICNIC was a simple application, which included the core functionalities of creating *the collaboration context*, *collecting relevant material*, *inviting participants*, *providing real-time collaboration*, and *supporting event notifications*. An example of a medical collaborative activity supported by the Collaboration IT service is described below:

- a GP receives a patient with a skin problem;

- the GP captures a skin picture in (JPG-format);
 - the GP creates a “collaboration context” for the episode of care;
 - the GP accesses the “collaboration context”;
 - the GP selects a service (set of clinical document templates);
 - the GP updates the collaboration context with a referral using a template provided by the selected service;
 - the GP updates the collaboration context with the skin picture;
 - the GP invites a specialist (hospital or private doctor) to report on the case;
 - the GP requests to be notified when the specialist accesses the collaboration context
 - the specialist logs on to the collaboration IT service (authenticates) and receives the invitation to participate in the collaborative activity;
 - the specialist accepts the invitation to participate in the collaboration and is added to the address book of the “collaboration context”. The event is recorded in the activity log of the “collaboration context”;
 - the specialist accesses the “collaboration context”;
 - the specialist accesses the collaboration items, i.e. the referral and the skin picture;
 - the GP receives notification that the specialist has entered the context;
 - the GP accesses the “collaboration context” to interact with the specialist in real time;
 - the specialist is aware that the GP is in the context;
 - the specialist posts a message requesting details regarding a vague aspect of the referral;
 - the GP and the specialist engage in chat conference regarding the particular episode of care;
 - the specialist writes an examination report, based on an appropriate template;
 - the specialist updates the “collaboration context” with the report;
 - the specialist updates the status of the “collaboration context”; and finally
 - the GP can access the examination report and inform the patient at the next visit.
- The PICNIC components that were validated in the pilot comprised: XMLS, and COLS.

7.2 *Pharmacy Patient Validation and Reimbursement, Republic of Ireland*

Within the health service of Ireland, the General Medical Services (Payments) Board (GMS) was responsible for making all payments in respect of primary care contractors for publicly funded health services, including consultations, appointments, procedures and prescriptions. The GMS reports to and was funded by the Department of Health and Children (DoHC). The GMS makes payments to a total of around 5,500 primary care contractors, including 1,200 community pharmacists.

The DoHC have a number of strategies in place which directly support the PICNIC project and were perceived as enabling strategies for PICNIC, including:

- the deployment of a Unique Patient Client Identifier (UPCI): the Personal Public Service Number (PPSN). This was utilised by the GMS central client eligibility index and was funded by the Information Society via the DoHC; and
- all public bodies, including GP practices and community pharmacies in Ireland were being linked to a new “Government Virtual Private Network” funded by the Department of Finance.

This infrastructure was the background against which the GMS were developing their prototype and was a vehicle for facilitating the mobilisation of PICNIC within Ireland. The

GMS wanted to provide the 1,200 pharmacists, and later another 3,300+ contractors, access to its back-end systems (PIDS database and Claims and Payments system).

The prototype included the provision of a “PIDS Access/ Messaging Component”, which was integrated into the pharmacy management applications running in the community pharmacies. Once a pharmacy application vendor integrated this component into their application, the application was able to access the back-end GMS systems to:

- verify the identity and eligibility of a client, under the appropriate GMS scheme and the amount spent on prescriptions to date in the current month;
- update the central GMS system with the value of a prescription dispensed to a client; and
- upload prescription reimbursement files to GMS and download the corresponding exception file (error report) from GMS.

The integration of the separate systems which presently support pharmacy reimbursement was seen in terms of access to information resources, and in terms of content, structure, and visualisation of healthcare record segments, with the goal of creating a virtual electronic prescribing record.

The GMS contracted with HP Ireland to develop the common components and integrate the common components into the pharmacy prototype. The “PIDS Access/ Messaging Component” enabled the communication of XML messages between the pharmacies and GMS, using the PICNIC CDA Level 1 message format. This included the conversion of the prescription reimbursement files and exception files to XML.

Once the “PIDS Access/ Messaging Component” was tested with the GMS infrastructure, it was given to the pharmacy application vendors who integrated them into their applications.

The PICNIC components that were validated in the pilot comprised: XMLS, and PIDS.

7.3 North Western Health Board (NWHB), Republic of Ireland

The NWHB is one of 10 Health Boards within the Republic of Ireland and is responsible for providing Health and Social services for a population of approximately 220,000. Health services are coordinated nationally by the Dept. of Health. The Irish government has a number of strategies in place, which directly support the PICNIC project and are perceived as enabling strategies for PICNIC. These are as follows:

- The Health Strategy which sets out six frameworks for change, one of which is information and another which is strengthening Primary Care.
- The Reach initiative which will enable the citizens of Ireland access to an e-broker service for all public services and which will allow a seamless delivery of service across a number of services at particular “life events”
- The use of a unique number is a fundamental part of the e-broker strategy and the PPSN is the identifier to be adopted.

The aims of the NWHB prototype were to

- support the Public Health Nurses (PHNs) to enable them to record more accurate and accessible information about their clients;
- improve the service to clients by enabling PHNs to review groups of clients and individual clients to determine the service they are receiving and should receive e.g. may set up specific clinics to deal with specific problems in their area;
- enable demographic details to be recorded once but used many times through the link to the GMS database; and
- support PHNs in compiling patient and area profiles for use by other health professionals and management to better plan and deliver services.

In summary, the Public Health Nursing service works as follows:

- The PHN may receive a referral from a number of sources and plans to visit a number of patients within a day. Some of these visits are repeat visits (e.g. to do a dressing) and some of these are new visits. At her first visit the PHN records basic patient information and demographics. At the end of the visit a PHN records details about the visit including what tasks/ procedures were carried out and she schedules another visit, if necessary. She may also make referrals to other professionals.
- At the end of each month the PHN prepares returns showing her activity for the month by care group and she prepares her travel claim which is submitted to her supervisor.
- At the end of the year the PHN prepares a detailed annual report of her area. In the present system this can take up to a week of her time.

The prototype allowed NWHB to see the use of mobile devices by the largest group of mobile professionals within its service – PHNs. The deployment allowed PHNs access and record the care group and activity for each patient and produce information which can be shared and used by other professional groups. The prototype was also linked with patient identification services in the GMS to allow the PHN to simply enter the PPSN and pull down all of the demographic details associated with that patient.

There are approximately 80 full-time PHNs in the NWHB. The pilot system was deployed in 6 PHN areas for a two month period and will be rolled out to all PHNs.

The PICNIC components that were validated in the pilot comprised: XMLS, and PIDS.

7.4 Access to Patient Data, Crete, Greece

A number of “Research and Technology Development” projects have contributed to the development and funding of HYGEIANet [51], which involved FORTH, the regional authorities as well the majority of the healthcare organizations of the island of Crete. This participation contributed significantly in understanding the issues related to healthcare delivery and IT, and assisted in shaping the regional strategy for establishing a regional health information network. The strategic objective is to ensure that patients can be confident that the healthcare professionals caring for them have reliable and rapid access, 24 hours a day, to the relevant personal information necessary to support their care. An important consideration has to do with the commitment to evolve from the currently available infrastructure, while adding the new capabilities when they become available.

Within that context, the Access to Patient Data service in Crete aims towards the provision of a uniform way of accessing and presenting, seamlessly, integrated health information about a person, within two hospitals, one in Sitia and one in Rethymno. In both cases the medical record exists in a number of both inpatient and outpatient clinics, which do not communicate with each other directly in all cases. Effort was based on extending the currently available integration infrastructure, by means of more robust security and authentication services, as well as the incorporation of a multitude of clinical information systems. A set of standardized interfaces was tested upon operational systems that originate from multiple vendors.

The deployed user scenarios involved:

- Patient Identification.
- Browsing the longitudinal health record of the patient.
- Direct access to clinical information at the place produced.

The platform was built on the PICNIC components and implemented within the boundaries of the hospitals of Rethymno and Sitia, to support a seamless access, to

authorized users, over patient clinical information segments, distributed throughout the hospital, and across the areas of responsibility of the aforementioned hospitals.

Clinical information systems that were involved in the Rethymno pilot included PATH-IS (Pathology Information System), XRFDC (X-Ray Film Digitisation Console), and Cardio-IS (Cardiology Information System), all developed by *FORTH*, together with the Laboratory information Systems of *Greek Informatics* (Πληροφορική Ελλάδα), as well as the Administrative, Financial and Pharmacy Information Systems of *UniSoft*.

The clinical information systems that were involved in the Sitia pilot include PHCC-IS (Primary HealthCare Center Information System), PATH-IS (Pathology Information System), RAD (Radiology), and Cardio-IS (Cardiology Information System), all developed by *FORTH*, together with the Laboratory information Systems by *Greek Informatics* (Πληροφορική Ελλάδα) and both the Administrative as well as the Financial Systems by *Computer Team*.

The PICNIC components that were validated in the pilot comprised: PIDS, COAS, SRIS, SRUB, RESS.

7.5 Collaboration, Crete, Greece

The telecardiology collaboration service as well as a teleradiology service already existed and were operational years [52] in several Primary Healthcare Centers of the island of Crete. The tele-consultation environment in use, as well as the underlying collaboration platform of WebOnCOLL [53] have been developed in full by *FORTH*, and are expected to gain a European dimension through the participation and the utilization of the common specifications of PICNIC. The involved PHCCIS (Primary HealthCare Center Information System), XRFDC (X-Ray Film Digitisation Console), and CARDIS (Cardiology Information System) are all products of *FORTH*.

The OS components developed within PICNIC were used to upgrade the functionality of the collaboration infrastructure and prove the feasibility of an intra-regional collaboration service. Furthermore, the number of the existing pilot sites, both in terms of primary healthcare centers as well as in terms of consultation centers was increased.

- The pilot for *Telecardiology* involved
 - the primary health centers of Anogia, Mires, Archanes and the Venizelion Hospital in Heraklion;
 - the primary health centers of Spili, Perama and the district hospital of Rethymnon; and
 - the primary health centers of Kandanos and the district hospital of Chania.
- The pilot for *Teleradiology* involved
 - the district hospital of Rethymnon with the Venizelion Hospital in Heraklion (CTs and X-rays);
 - the primary health center of Anogia and the district hospital of Rethymnon (X-rays);
 - the primary health center of Perama and the district hospital of Rethymnon (X-rays); and
 - the primary health center of Kandanos and the district hospital of Chania (X-rays).

Operation Example: A patient arrives at a remote primary care center suffering from severe chest pain. The general practitioner conducts clinical exam, and takes an ECG. The medical history of the patient and his symptoms raise suspicion of myocardial infarction. Should the GP administer thrombolysis? Research has shown that 30 minutes delay in the initiation of thrombolysis reduces the life expectancy by approximately a year. The GP requests help, using the tele-cardiology service, from a regional Tele-cardiology center. The

GP requests the creation of a shared episode folder (i.e. a collaboration context). Once the collaboration context is created the GP adds relevant clinical data to the shared episode folder including a teleconsultation request and the recent ECG of the patient. The data that included in the clinical document requesting a second opinion are: demographic data of the patient, the time of initiation of the pain, symptoms, blood pressure, history of patient as regards myocardial infarction, some data related to counter indications of thrombolysis and an ECG. The cardiologist at the tele-cardiology center takes into account these data and perhaps he may request from the GP to send one or more ECGs. Taking into account the data that have been sent to him, the cardiologist consults the GP as regards the procedure of thrombolysis. Finally, the patient may be transferred to the cardiology clinic for follow up.

In addition to the above, the Collaboration IT-service has been tested and demonstrated by Odense University Hospital, Denmark and Venizelio hospital in Heraklion, Crete. The Collaboration components have been used to perform an on-line collaboration between Denmark and Greece. This demonstration has been made as a validation of the technical concept by using the RESS and COLS components in applications from different suppliers.

The PICNIC components that were validated in the pilot comprised: XMLS, COAS, SRIS, SRUB, COLS and RESS.

7.6 South & East Belfast Health & Social Services Trust (SEBT)

Within the Northern Ireland (NI) Region, Health and Social services are coordinated by the Department of Health and Social Services (DHSS). The DHSS have already a number of strategies in place directly supporting the PICNIC project and are perceived as enabling strategies for PICNIC;

- the deployment of a UPCI across the whole of Northern Ireland. The UPCI is funded by the NI regional Strategy and will utilise the PIDS component within the PICNIC project
- All GP practices in the region are being linked to the regional datacomms network by “fixed” lines. This will reduce the complexity of security procedures for the end-user and greatly increase the speed of transmission. This project is also being funded by the regional strategy.

SEBT are responsible for the provision of Community Health and Social Care for the south and east sector of the city of Belfast serving a population of 200,000. SEBT also has a Mental Health Hospital within its organisation. Liaison with the Acute Hospitals within the Greater Belfast area and the GPs within South and East Belfast is recognised as critical in the provision of total patient care. The SEBT area covers 21 GP Practices involving 65 GPs, the potential for the NI region is approximately 990 GPs.

It is against this background that the PICNIC project is seen as a vital improvement in the provision of information to improve patient information for the Health Professionals and in so doing improve patient care.

The SEBT prototype was used by “out-of-hours” GPs attending a patient outside normal surgery hours. It can be assumed that the patient is not on that particular GP’s list. Therefore, in these circumstances, the GP has no knowledge about the patient and has no information on the patient’s current health, any recent or current treatment, hospital episodes or drug regime. The GP is therefore relying on the information given to her/him by the patient and their own clinical judgement.

The PICNIC deployment within SEBT was designed to enable access to GP Practice information, A&E information from the Belfast City Hospital, the local Acute Hospital, and PARIS the Trust’s Patient centred information recording system covering Health, Social Care and Mental Health. The initial GP group was based on one out-of-hours service centre and is seen as stage 1 in a rollout program across such centres in NI and throughout the UK.

The Shared Record Server enabled 24 hour a day access for the out-of-hours GPs to access information through the shared records application accessible via a PC or potentially a mobile device. The “out-of-hours” system (i.e., the PICNIC pilot system) enabled a generic search screen. The absence of a unique patient identifier in NI was overcome, as the generic search screen enabled users to retrieve information by requesting names or addresses with certain parameters. From the results screen the user was able to indicate which client/ s were considered to be the subject client and retrieve a minimum data set of information. The information could be further filtered by time parameters or number of encounters.

The PICNIC components that were validated in the pilot comprised: PIDS, COAS, SRIS, SRUB, and RESS.

8. Technical Validation

The objective of the PICNIC technical validation phase was to produce a plan to enable the regions to test the integration of the PICNIC components together with the functioning of the components when installed in the prototype on the pilot sites. A general implementation guideline was produced and was supplemented by each developer producing guidelines for the individual components, in order to provide feedback on the ease of integrating the components and the extent of change required to either the target configuration or the prototype software. Therefore, two testing stages were used, involving *component testing*, as well as *integration testing*.

- *Component testing* implies testing individually each unit and module. The test attempted to test the components as individual components where this was possible and carried out a link test to ensure that the prototype system worked as a whole. Each unit and module was tested individually. This phase initially was carried out by the developers, either by the same programmers who were developing the applications or other independent testers. Component testing took place at the same time as components were being developed. Some kind of supervision of this activity was planned, in order to ensure that components were tested correctly.
- *Integration testing* aims to demonstrate that the interfaces among all the components work correctly and that the system can work as a whole without faults when installed in the target system, and is not intended to prove the functionality of the system. Integration testing was carried out by the developers and the IT staff of the prototype site and in some cases required user intervention. Integration testing, comprising sub-system and system testing involved a larger number of people and had to be carefully planned. The advisable approach was that integration testing had to be carried out by an independent group of testers, different from the development team. This would consist of the IT staff on the prototype site assisted where applicable by their local IT support organisation.

The conclusions from the testing of the integration of the components showed that no major operational problems were found and all sites were able to implement and run the prototypes. The success of the prototypes on all the sites and the lack of any major problems demonstrated the capabilities of the components to be exploited and deployed in a marketing scenario. It can be claimed based on the test results that the components met the requirements specification and functioned in a highly stable manner. All sites are planning full operational implementation and are confident of systems becoming operational user systems.

Guidelines provided for the implementation proved of significant importance and these would potentially require to be further enhanced as deployment takes place in locations not involved with the initial development and deployment of the components. All developers

will continue to monitor that generic installation and user guidelines that are of sufficient detail to enable the components to be installed and run on a non-PICNIC site by other than the developer staff.

This major piece of work enabled the components to be marketed and fully exploited. Already the PIDS, used on the GMS and NWHB sites, will be further developed as a result of component deployment in the full operational pharmacy system and extension to GPs. FORTH has plans to incorporate the PICNIC components within the development of their national, integrated regional health system. Finally SEBT intends to roll out the PICNIC components to access data on line from GP, A&E and Community systems, incrementally over the next 18 months following the critical path of direct line installations to GPs and extend beyond “out-of-hours” GPs by linking A&E departments.

To prepare their components for exploitation on the commercial market the component developers recognised the need to develop the following aspects of the components.

- Pricing structures:
 - pricing of the components for marketing;
 - distribution costs and % revenue to local distributors;
 - capital costs, licence fees and revenue costs;
 - training and support costs.
- Support:
 - on going support for implemented components;
 - local distributors appointed on a sub-contracting basis;
 - remote support from developers;
 - full system documentation;
 - training packages and implementation guidelines;
 - commitment to continual enhancement of the components.
- Service Level Agreements:
 - Service Level agreements as part of the supply package when the components are purchased.
- Open Source:
 - Clarification of the part the OS concept regarding exploitation and further development of the components and quality control in an OS environment.

9. Certification

The purpose of the certification work in PICNIC was to document the guidelines and process for certification for OS software developers who are enhancing/ developing components based upon the PICNIC architecture, specifications. In this work, the PICNIC consortium was supported by the Netherlands Organisation for Applied Scientific Research (TNO).

9.1 Component Certification

For PICNIC there were two principal reasons for applying a method that assesses the final software product and pays less attention to the process and the internal products:

- since the software is developed by centres across Europe, each with their own “informatics culture”, it would be difficult to assess all these different processes of software development; and
- the future users of the OS software will be more interested in a clear description of the quality of the source code than the way it was developed.

Certification is a way in which the quality of software can be demonstrated. The major reason is to secure a minimal level of quality in the products that are subject to the certification process. There are 3 generally accepted approaches to certification, these being:

- evaluation performed by the relying party itself (*self certification*);
- evaluation performed by someone other than the relying party (*full external certification*); and
- evaluation performed by the relying party itself but monitored by someone other than the relying party (*self certification with external reference*).

Certification is most often performed by a specially registered organisation that follows specific standards that specify how audits must be executed. What is certified is a statement of conformance by the certified that they conform to a standard in whole or partially.

The improvement of the software development method was not an issue in the PICNIC project, hence a method for the assurance of an external software product was chosen. In other words, what was tested was the quality of the software for the end-users (programmers that will modify the common components for local use) rather than the quality of the process of design and implementation. The international standard applicable to this type of evaluation is International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 9126 [54]. PICNIC selected to use the Quality in INformation Technology (QUINT) method, which is an extension to ISO/ IEC 9126), and where three steps have to be considered when writing the test plan:

- specification of quality requirements;
 - selection of relevant and important characteristics;
 - specification of characteristics with indicators, methods and levels;
- specification of effort;
 - planning of effort needed for testing;
 - testing;
- executing the tests;
 - performing measurements;
 - analysing the results.

The first step was to determine if a quality characteristic is relevant in the project (see Figure 6). Next, the relevant quality characteristics were prioritised. Prioritising quality characteristics is always an important step, because they usually conflict with each other. For instance: execution speed is in conflict with security, readability and changeability of source code, traceability etc. Depending on the goals, the targets for quality characteristics were then set and for each quality characteristic several levels were determined:

- *Minimum level*: none of the relevant quality characteristics should measure below the minimal level. In case one single characteristic scores below its minimum level, the project fails and the product is unusable.
- *Current level*: when the software product replaces a current situation, a current level is also available. In general, the acceptable level will be equal to or higher than the current level.
- *Acceptable level*: if all characteristics score above the acceptable level, the product has passed the test.
- *Target level*: each quality characteristic should have a challenging target level.
- *Maximum level*: this is a theoretic level and describes the upper limit of what is possible.

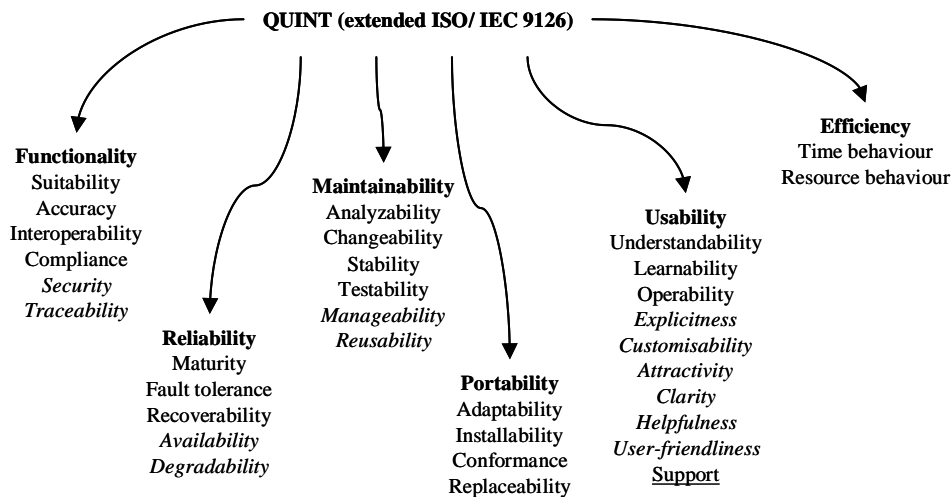


Figure 6 – Six groups of quality characteristics. Extensions to the ISO/ IEC 9126 are in italic. Addition for use by PICNIC is underlined.

The relative importance of each quality characteristic determined the minimum, acceptable and target levels for the quality characteristic. The required levels of quality characteristics then determined how the developers' time had to be divided. The fact that in PICNIC the levels for the quality characteristics varied per service was discussed in a workshop held in Copenhagen during the development of the certification approach (February 2003), the output of which was documented and used in the software validation process that followed. The availability of measurable results is expected to help in stating the user requirements and estimating the costs for future healthcare system implementations.

9.2 Certification Model

OS software has several intrinsic characteristics that enhance the quality of software:

- sources of OS software are public;
- others than the authors inspect the software;
- only well documented software is easily be used by others; and
- all OS software will not have hidden features that pose a security thread.

Negative aspects of OS software is that it depends on a functioning community that is maintaining the software. In general there is no reason why Open Source software cannot be of a high quality. In order to ensure the minimal quality of submissions of PICNIC common components to their pool of OS software a Quality Management System (QMS) had to be in place. This system described all the relevant responsibilities and procedures in a set of documents:

- the rules that govern the working of the PICNIC committee;
- the PICNIC common components acceptance criteria;
- the template for the PICNIC common component validation test report;
- the PICNIC test harness.

The process described above pertains to the implementation only of the PICNIC common component under consideration and does not pertain to the complete system as put on the market by the manufacturer. The PICNIC trust mark is issued after the successful certification procedure and indicates a proper implementation.

The following scenario must be executed in the process that leads to a certificate for a product that has implemented a PICNIC Common Component:

- The manufacturer installs a QMS, including the Notified Body Function (NBF) that conforms to the TNO QMIC[®] Quality Management system and the management accepts responsibility for the functioning of the NBF;
- the Notification Body (e.g. TNO) notifies a NBF within the organisation of the manufacturer, and subsequently this manufacturer becomes a PICNIC recognised supplier for this PICNIC common component;
- the manufacturer uses the PICNIC common components acceptance criteria; and
- tests the product;
- when the results of the tests indicate that there is a conformance to the PICNIC acceptance criteria the NBF issues a certificate.

This is the process of self certification on the basis of the certificate the responsible organisation will issue the PICNIC trust mark. During the process of testing and certification the Notified Body could perform checks on the functioning of the NBF.

PICNIC certification describes the rules for acceptance into the PICNIC pool of components, together with related ongoing tracking and use in measurement. Since the community members will have their own acceptance criteria, it is expected that certification will evolve over time based on the participants' needs.

10. Conclusions

OS software development works! PICNIC used many existing OS components in its developments, enhanced some of these and wrote its own PICNIC components, and the resulting prototype systems were integrated successfully without any major problems. However, undertaking socio-economic assessments of individual components, when they are embedded in an application or service comprising many components, turned out to be a complex task.

The PICNIC architecture was validated through the deployment of the components in 6 regional pilots, which were used operationally to deliver benefits to patients and other stakeholders in the RHCN. Whilst most researchers/ developers seem to concentrate on the technical aspects of architecture development, i.e., platforms etc, in fact the most important/ difficult aspect of deploying an architecture relate to the organisational and political aspects of establishing the Regional Health Economy (RHE) who are the users of the architecture and the associated RHCN services.

It has been proven that the main issues surrounding the deployment of trans-national ICT services, such as the Collaboration service, relate not so much on the technical/ security aspects, but rather on establishing the correct legal, regulatory and reimbursement procedures, together with the use of a language of common understanding and the appropriate terminology considerations. In trans-national RHE, where these aspects have already been addressed in existing "paperwork" systems, the ICT service can easily be deployed.

Despite the fact that this paper did not touch issues related to the architecture, technology, and exploitation aspects of the PICNIC project, it has delivered a concise presentation of the overall story. PICNIC developed a new paradigm for healthcare ICT architecture based on

- a healthcare information infrastructure comprising of a set of OS components that support the architecture;
- a proactive assessment;
- a number of case studies with independent evaluation reports; and

- a certification model.

These products are all available through OS to all, without charge, even though “free” products still have to be marketed to defined customers. European healthcare ICT services suppliers will not speculatively adopt an architecture/ framework of standards, no matter how robust the case for its use, without a clear demand for such a framework coming from the buyers of ICT services. The lead in adopting a RHCN architecture must therefore come from the ICT policymakers in the regional health authorities. Many authorities, however, do not appreciate the need for inter-enterprise integration architecture, as they are still in the business of trying to integrate islands of information within their organisations via “traditional enterprise” approaches. The need for inter-enterprise integration tools/ methods only becomes apparent, therefore, at a later stage of development of the RHCN, when integration across organisational/ regional boundaries is attempted.

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