

**Towards a distributed e-laboratory:
Analysis and design for more efficient laboratory referrals.**

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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Summary

The National Health Information Strategy 2004 emphasises the need for changes in the way that health information is made available and utilised. The application of health information can effect major improvements in population health. However to do this we first need to improve the quality of patient records and the accessibility of the contents. The National Virus Reference Laboratory (NVRL), in UCD, provides a virology testing service for a range of stakeholders over the whole of Ireland. The variety of investigation request formats arriving at the NVRL means that the provision of data is variable and data entry demanding and time consuming. The aim of this project was to take the first steps towards electronic laboratory requesting at the NVRL by establishing a common investigation request format which would be adopted by all partner organisations. Electronic laboratory testing lessens workload, decreases turnaround time and facilitates the standardisation of laboratory data, thereby increasing quality and accessibility. Electronic laboratory testing will also contribute to the introduction of the electronic health record.

By observation of the current investigation formats received by the NVRL from the partner organisations, and the use of UML class diagrams, an NVRL investigation request format was designed and introduced for a select number of partner organisations. After further analysis, a set of three new NVRL investigation request formats are now in the process of being approved by NVRL management. Since the goal for the future is to have electronic laboratory testing, a vision for an electronic laboratory testing system for the NVRL was also considered using use case diagrams.

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Chapter 1: Introduction

The National Health Information Strategy 2004 emphasised the need for changes in the way that health information is made available and utilised. The application of health information can effect major improvements in population health. However to do this we first need to improve the quality of patient records and the accessibility of the contents.

Increasing complexity of clinical laboratory medicine has called for a trend towards increasing areas of specialisation. Laboratory testing for viruses (clinical virology) is one of these specialities, and The National Virus Reference Laboratory, located in UCD, provides a service for virological testing for the whole of Ireland. Any provision of services away from the site of primary care creates problems with the transmission of investigation requests and reports. Duplicate data can reside on numerous databases that are separate and uncoordinated. At the National Virus Reference Laboratory this problem is increased by the diversity of stakeholders. A variety of investigation request formats can make the provision of data variable and data entry demanding and time consuming.

Recent public health legislation means that all laboratories must notify to a medical officer of health any disease that is listed on a list of notifiable diseases. This notification requires a minimum data set for each patient notified. Consequently laboratories now have an obligation to collect certain data from the patients using their services.

It is important that there is effective communication between partner organisations to provide an efficient clinical laboratory service. The aim of this project was to take the first steps towards electronic laboratory requesting by establishing a common investigation request format which would be adopted by all partner organisations. To do this it was decided to observe the current investigation formats received from the partner organisations. A common format would be developed from this which could then be designed into a specific NVRL investigation request formats for distribution to the partner organisations. If these were used by everyone then it would unify the data that is received, and ensure that required data is provided.

Electronic requesting of laboratory investigations requires standards and coding to ensure that laboratory results are interpreted consistently. A culture of change must be fostered so that the adoption of standards is a real prospect. Standards are deemed necessary for improving the quality, comparability and usefulness of health information.

In this work a design for a electronic laboratory requesting system is proposed to allow laboratory investigation requests and reports to be transmitted between the NVRL and partner organisation laboratories. This would lessen workload, decrease turnaround time and facilitate the standardisation of laboratory data, thereby increasing quality and accessibility.

The rest of this dissertation is laid out as follows:

Chapter 2: A review of the clinical domain detailing the background to the service that is provided by the National Virus Reference Laboratory and outlining the current environment for laboratory investigation requests.

Chapter 3: A review of technology relevant to the domain of electronic laboratory requesting and the current achievements in electronic messaging.

Chapter 4: Outlines the analysis of the current investigation requests and the development of improvements in the design of investigation request formats to create a standardised approach.

Chapter 5: Gives a description of an electronic laboratory requesting system which would facilitate the electronic requesting and reporting of laboratory results, reducing turn around time and thereby improving patient care.

Chapter 6: Discussion of findings.

Chapter 7: Conclusions.

Chapter 2: Review Clinical Domain

2.1 History of virology

In the second half of the 19th century Louis Pasteur (1822-1895), Joseph Lister (1827-1912) and Robert Koch (1843-1910) put together a new experimental approach for medical science which became the dominant paradigm of medical microbiology and outlined an experimental method to prove that a disease was caused by a certain infectious agent. This approach was known as 'Koch's postulates'. However it was soon apparent that there was a group of infectious agents that did not fulfil this theory since they could not be isolated or seen even by the light microscope. Unlike bacteria this agent could not be filtered out of an infectious solution. Consequently for the first part of the 20th century viruses were referred to as 'filterable agents' and were thought to be liquid and not particles until they were first shown in an electron micrograph in 1939 (Levine, 1996).

As a subject matter virology has had an interesting history. The medical consequences of viral infections in humans have resulted in extraordinary efforts on the part of virologists to study, understand, and eradicate these agents. Illnesses now known to be caused by viruses have been recognised for thousands of years. A Chinese description of a pestilence dating from the tenth century B.C. is now believed to have been smallpox. Legends of cursed ships such as the Flying Dutchman were probably as a result of Yellow Fever brought from Africa (Levine, 1996). Most forms of life are susceptible to infection with viruses. Most viral infections are mild and the patient makes a full recovery. However in unusually susceptible patients, such as those who have had organ transplants, these viruses can cause severe disease. There are also some viruses that are always severe and have a high mortality rate. (Timbury, 1997).

2.2 History of laboratory virus testing

Viruses are the smallest known infective agents. They can only multiply inside living cells and because of this special methods have to be employed for culture in the laboratory. Material suspected of containing a virus such as a tissue extract or a sample of body fluid is liquefied

and centrifuged to remove contaminating material then inoculated onto a suitable medium for growing viruses. This is a single layer of cells growing on glass or plastic (monolayer). If there is virus in the sample material it will infect the cells in the monolayer and multiply causing the cell layer to be damaged or even destroyed. The appearance of the monolayer after infection is frequently characteristic for a given virus. Infected cells in the monolayer may also be detected by fluorescence. Some viruses can only be isolated by inoculation into laboratory animals, however this method is rarely employed for routine diagnostic purposes. Viruses will induce production of specific antibody in the blood. Evidence of viral infection can be shown by development of antibody to the virus at the time of symptoms of disease or the presence of virus or virus product in the patient's blood or other tissue. Virus diseases are diagnosed frequently by immunological techniques, that is, by detection of antibody to the virus at the time of the symptoms of disease. Automated technology using commercially available kits allows large numbers of patients to be tested rapidly and economically. However in many instances the antibody is only produced after the acute phase of the infection (that is when the patient is in the recovery phase) therefore other more 'direct detection tests' can be employed for diagnosis of viral infection such as detection of viral antigen in patient blood, detection of viral nucleic acid, electron microscopy and of course virus isolation. (Timbury, 1997)

Although virology is a basic biological science in its own right it has also become integral in the newly emerged discipline of molecular biology which deals with subcellular entities and structure, function and organization of macromolecules. The advent of specific molecular analysis tools such as antibody detection and polymerase chain reaction (PCR) to detect viruses in body fluids or tissue samples gave a huge boost to the field of virology in the last half of the 20th century. The ability to detect nucleic acid sequences of clinically relevant viruses in real-time has had a major impact on virological diagnosis (Levine, 1996).

Technological advances have given the ability to diagnose most viruses of clinical interest both qualitatively and quantitatively. Results can now be generated with a short turn-around-time, which is essential for patient disease management. Technological improvement in

sequence detection enables the full characterisation of a virus including subtypes, variants, mutants and genotypic resistance patterns. New antiviral strategies are being developed in conjunction with new diagnostic strategies facilitated by the short turn-around-times to results. Patient monitoring using serial quantitative testing allow for pre-emptive antiviral therapy for patients at risk of disease reactivation. Excluding the presence of a viral infections can avoid unnecessary therapy, thereby reducing the cost of patient care.. These days results generated within one working day are expected. (Niesters, 2002)

There has been a rapid evolution of laboratory procedures, methodologies and equipment and over the years medical professionals have increasingly become dependent on the expanding range of sophisticated diagnostic services provided by clinical laboratories. This development has been of significant benefit to healthcare helping clinicians to diagnose and treat illnesses and monitor recovery. However this increased reliance on laboratory results for diagnosis has come at a cost and so the focus is now frequently aimed at cost containment. (Campos, 1999)

The laboratory needs to provide a rapid and effective service to clinical staff. On the other hand there is an increased demand on clinicians to understand and maintain competency in laboratory test ordering. In order to help the clinicians it is important to convey the necessary information about appropriate test ordering, specimen collection and transport. Although most laboratories have them, users often do not have ready access to a laboratory user manual. Due to the nature of the profession there is usually a high rate of turnover of medical personnel (Marcon, 2003). Laboratory tests are ordered for a variety of reasons, confirm or rule out suspected diagnosis, confirm a previous result, for therapeutic management of disease (increase, decrease or change therapy), to test for cure. Providing the clinician with relevant information can ensure appropriate test ordering and directly improve the quality of patient care. The design of the paper requisitions can directly affect the accuracy of test orders from the clinician by providing relevant information (Marcon, 2003).

2.3 Emergence of Reference Laboratories

The ever increasing complexity of clinical laboratory medicine has led to increasing areas of specialisation (Marcon, 2003). Within medical microbiology, the speciality of medical virology has led to the requirement for a specialised medical virology laboratory. The National Virus Reference Laboratory (NVRL) was established over thirty years ago by the Department of Health and Children and University College Dublin (UCD) to provide a national diagnostic and reference service for clinicians investigating virus infections. Since that time NVRL has remained an integral part of the Department Medical Microbiology at UCD. Recently the NVRL has been incorporated into the Centre for Research into Infectious Diseases (CRID) at the College. This has led to a significant expansion of the facilities available to NVRL activities which include a state of the art laboratory for molecular diagnostics, a dedicated laboratory for reference testing for the Irish Blood Transfusion Service (IBTS), a Bio safety level 3 plus containment laboratory and a range of new research laboratories. The laboratory is fully accredited by both the Clinical Pathology Accreditation and the World Health Organisation as a National Laboratory for Poliovirus, Influenza, Rubella and Measles. The current workload of the laboratory extends to around 500,000 tests per annum. An out of hours service is available with clinical support to deal with emergencies such as organ donation, needle-stick injuries and dialysis. This ensures continuity of service with testing available 365 days a year on a 24-hour basis when necessary. A wide range of tests are performed routinely. The aim of the laboratory is to provide a fast, efficient and effective laboratory service to clinical personnel and to provide professional advice on virus infections (Hall, 2005).

The NVRL has been computerised since 1987. The first laboratory information system (LIS) captured core patient information and provided result reporting. Unfortunately the data from this first system could not be transferred when the present LIS, WinPath, was installed in 1992. Nevertheless all data from that time onwards is available for searches and statistics.

Therefore there is a rich source of data for laboratory management purposes and also for research.

An important feature of computerisation in the laboratory is the availability of interfaces between laboratory analysers and the LIS allowing for automatic downloading of results.

Laboratory practices must change constantly to keep up with increasing demands to improve the sending, tracking and auditing of results. In the future further demands will be made on laboratories to provide data for clinical decision making (Campos, 1999). Information technology and health informatics will play a major role in meeting these needs.

2.4 Description of workflow at the National Virus Reference Laboratory.

Figure 2.1 shows a schematic diagram showing the flow of work at the NVRL. Specimens arrive at the NVRL from hospitals, general practitioners and clinics via couriers, post and hand delivery. In specimen reception the laboratory attendants, supervised by a senior laboratory technician, open the packages. The specimens and accompanying forms are matched then both are barcoded with a unique NVRL laboratory number. Whole blood specimens for serology investigations (detection of antibody) must be centrifuged to remove the blood cells and the supernatant (serum) is then separated into test tubes. The specimens for serology investigations are sent to the laboratory and kept at 4°C until testing. Samples for molecular biology investigation must be frozen immediately at -20°C to prevent degradation of the nucleic acid. The investigation request forms are taken to the laboratory for coding (to indicate which test codes should be requested). The forms are then given to the administrative staff for data entry into the LIS. Once the data has been entered, worklists can be created by the laboratory personnel and the specimens can be collected for testing. Results are generated manually or by transfer by interface from various analysers to the LIS. Some results have to be interpreted from quantitative raw data into qualitative results, usually positive or negative. Some results require further testing to be undertaken on the sample

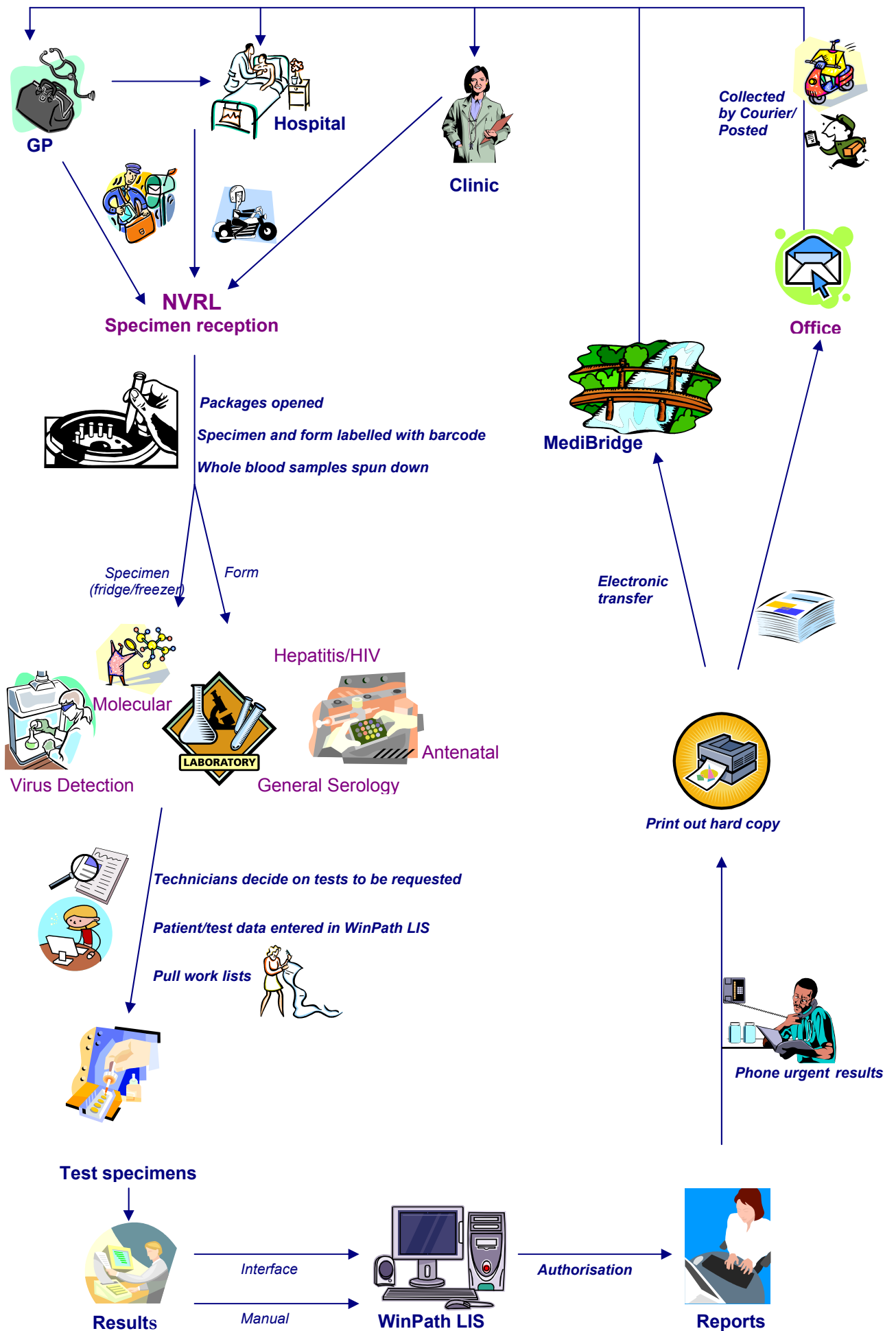


Figure 2.1- Flow of work at the National Virus Reference Laboratory

before the report is finished. When all the results have been entered the report is authorised by the clinical or senior technical staff. Authorised reports are printed and the hard copy given to the laboratory office for distribution. Paper reports are sent via post or collected by courier. For partner organisations linked to MediBridge for the purpose of receiving NVRL reports (see chapter 3), the finished results are also sent once a day electronically. Only reports that have been printed are sent electronically.

2.5 Description of stakeholders

The NVRL receives specimens from clinicians all over the country, delivered mainly by post or by courier, but occasionally by hand from the patient or a general practitioner. The specimens sent to the NVRL are taken from patients for many reasons and not just for the diagnosis of current viral infections. The main patient categories of partner organisation are:

- In patients from primary hospitals
- Patients from general practitioners
- Out-patients from primary hospitals and clinics dealing with specific populations e.g.
 - addiction centres
 - well-woman clinics
 - refugee centres
 - genito-urinary medicine
 - antenatal
 - occupational health in medicine, agriculture and the food industry

2.5.1 In patients from primary hospitals

Samples from these patients are primarily sent for virological investigations to confirm or out-rule current viral infections as the cause of illness. In addition immunosuppressed patients such as those who have undergone, or are about to undergo, transplant procedures require viral screening to establish those infections which may recur due to the immunosuppression.

2.5.2 Patients from general practitioners

As with the in patients, patients from general practitioners are usually exhibiting symptoms and the samples are primarily sent for virological investigations to confirm or outrule current viral infections as the cause of illness. Approximately six percent of the samples received by the NVRL are sent directly from the GP practice. Unfortunately many general practitioners do not know where to send virology investigation requests, or perhaps even that the disease they are investigating has a viral aetiology. They send their patient's samples to the laboratory of their local hospital for distribution which not only wastes valuable time but compromises the usefulness of the specimen which can deteriorate over time.

2.5.3 Out-patients from primary hospitals and clinics

Samples from these patients are primarily sent for investigations to screen patients for the presence of viral antibody, usually in the absence of any clinical symptoms. There is a requirement to assess the effectiveness of vaccinations such as Hepatitis B or Measles Mumps and Rubella (MMR) or to evaluate the need for vaccination as in health care workers or other populations at risk of infection (for example from the addiction centres). The antenatal population is screened to look for risk of viral infection which could affect the unborn child and these results can initiate antenatal and/or postnatal therapy. Refugees arriving in this country from a country where a particular virus is endemic are screened for antibodies to that viruses.

2.6 Public health and Public health legislation

Public health surveillance is the monitoring of the occurrence of disease in an ongoing, timely and complete fashion. It is used to trigger outbreak investigations and follow trends to indicate public health priorities. Effective surveillance relies on a combination of clinical data (from the clinician) and laboratory data. Since existing electronic formats in laboratories were are not standardised or connected, laboratory reporting in the public health domain had not

kept pace with technology. Until recently public health had managed to maintain a paper based tradition which is inefficient and of limited use (Jernigan,2001). In the United States of America, since 1997 the Centers for Disease Control and Prevention (CDC) have been working towards electronic laboratory reporting for public health surveillance. In Atlanta, Georgia on March 24th and 25th 1997 the Centers for Disease Control and Prevention, the Council of State and Territorial Epidemiologists and the Association of State and Territorial Public Health Laboratory Directors held a meeting to provide a forum for discussing barriers to effective laboratory reporting standards. The recommendations in 1997 cited that there should be a unified approach to electronic reporting of clinical laboratory data. The recommendations specified the Health Level Seven (HL7) standard message format (Health Level Seven, Inc., 2005), with Logical Observation Identifier Names and Codes (LOINC) (Regenstrief Institute, 2005) for specific laboratory procedure names (found in the OBX3 segment of HL7 message (See section 2.1 in chapter 3)), and Systematised Nomenclature of Medicine (SNOMED) (Snomed International, 2005) for description of findings, notably organism names (found in the OBX5 segment of HL7 format (See section 2.1 in chapter 3)) (Centers for Disease Control and Prevention, 1997). These standards will be discussed later in Chapter 3. A second meeting on January 7th and 8th 1999 supported these recommendations (Jernigan, 2001).

Since 2003 the CDC has initiated the National Electronic Disease Surveillance System (NEDSS) (Centers for Disease Control and Prevention, 2005) to improve public health surveillance through enhanced IT infrastructure. Electronic messaging for laboratory reports is one element to be implemented by using the NEDSS information architecture (Jernigan, 2001). The vision of NEDSS is to have integrated surveillance systems that can transfer public health data efficiently and securely over the Internet. This will help to identify and track emerging infectious diseases, investigate outbreaks and monitor disease trends. (Public Health Information Network, 2005). Recent events have increased the availability of funds for public

health surveillance to ensure the identification of potential bioterrorism attacks by having the infrastructure in place before any emergency (M'ikanatha, 2003).

In Ireland, the Infectious Diseases Regulations, 1981, lay down a list of infectious diseases and set out the rules for reporting cases of infectious disease. The 1981 Infectious Diseases Regulations were subsequently amended in 1985, 1988, 1996, 2000 and 2003. Under the 1981 Regulations medical practitioners are obliged to notify the local medical officer in writing as soon as they become aware or suspect that a patient is suffering from, or is a carrier of an infectious disease. Immediate notification is obligatory in the case of certain infectious diseases such as cholera, or where a serious outbreak of infectious disease is suspected. Until 2000, returns of all diseases notified were sent to the Department of Health and Children (DOHC) at the end of each week so that aggregated data could be collated nationally. As of the 1st of July 2000, the 2000 amendment (S.I. No. 151 of 2000) transferred this function from the DOHC to the National Disease Surveillance Centre (NDSC). Since 1st January, 2005, the NDSC has changed its name to the Health Protection Surveillance Centre (HPSC) as part of their move into the new Health Service Executive. The list of notifiable diseases laid down in the 1981 Regulations has been amended through the years. On 1st January 2004, a revised list of notifiable diseases was established (Infectious Diseases (Amendment) (No.3) Regulations 2003) and the requirement for laboratory directors to report infectious disease was also introduced (S.I. No. 707 of 2003). This amendment was a major step forward in the surveillance of infectious diseases in Ireland (Food Safety Authority of Ireland, 2005). This legislation has meant that now all primary laboratories, that is laboratories taking responsibility for the provision laboratory results and their interpretation, must notify to a medical officer of health any disease that is listed on a list of notifiable diseases (Case Definitions for Notifiable diseases, 2004). Laboratory reports are critical to public health surveillance as they initiate investigations of cases of notifiable diseases and disease outbreaks. As we have said before, until recently public health has relied on paper based laboratory reports with separate databases then being created for the analysis and reporting of specific

notifiable diseases, such as influenza, Salmonella or Meningococcal meningitis. The HPSC is the body given responsibility for the collation of all notifiable disease data. The HPSC in partnership with the Food Safety Authority of Ireland, the Food Safety Promotion Board and the Department of Health and Children, has developed the Computerised Infectious Disease Reporting (CIDR) information system to help manage the surveillance and control of infectious diseases in Ireland by facilitating the secure collection of notifiable data and the provision of analyses and reports. It is hoped that the majority of infectious diseases be reported through CIDR by the end of 2005 (Health Protection Surveillance Centre, 2005). This will require the enforced standardisation of laboratory reports for public health purposes by having a common repository for data originating from many different sources. The laboratory data can be uploaded into CIDR using files extracted from the source LIS, highlighting the fact that most laboratories have common data fields that using technology can be transformed into a common format.

Although current legislation only applies to infectious disease, other major public health issues would also benefit from ongoing surveillance. A legislative solution for the registration and monitoring of conditions such as cancer and heart disease, which represent a major threat to the health of the population, would enable observations in trends and occurrences and thus determine the impact of treatment and prevention programmes (National Health Information Strategy, 2004).

Therefore we can see that the NVRL has a wide and varied brief and must deal with partner organisations of every technological standard including primary hospitals working towards a paper free environment to general practices that do not even yet have a computer. A variety of investigation request formats arrive from these organisations ranging computer printouts to pages from GP prescription pads. There are increasing demands on the NVRL to provide more than patient reports but health information required for health monitoring and planning.

Chapter 3: Review of Relevant Technologies

As we have seen, at the NVRL the partner organisations are many and varied and at present there is little if any uniformity of data being received with requests for investigations. As long as there is a name or initials and date of birth or hospital number of the patient and an address to send the report back to the clinician the NVRL will process the request. Considerable effort will be required for the NVRL and partner organisations to arrive at a common request format. To begin this process, it is necessary for NVRL to establish what data is required to support efficient data communication and this work is in the scope of this project and will be covered in later chapters. In addition to agreed data formats, there is also a need to agree on a communications infrastructure. A lot of work is being done in the field of health informatics which is necessitating the standardisation of laboratory investigation requests.

3.1 Laboratory investigation requesting.

The usual method for requesting laboratory investigations is that a clinician fills in a paper request form that will accompany the patient's specimen to the laboratory for testing.

However technology is improving the ways in which the clinician is able to order investigations and receive results, so that he can treat the patient in the most efficient way possible.

3.1.1 Electronic ordering of requests

Order comms is a system for electronic ordering of requests, especially for medical staff on hospital wards. The system accepts an order for laboratory investigations (and other diagnostic and treatment services) electronically. With this, the system can include real-time education and checks for completeness of information appropriate test ordering. Using interactive order screens the user can have immediate access to electronic copy of a laboratory user manual, which will give specimen, test order and transport requirements. Laboratory

results can also be accessed electronically. However for patients from clinics, general practice or outreach programs investigation request orders cannot usually be entered electronically into the LIS but transmitted via paper requisitions. However an organisation with order comms has the valuable opportunity to impose standardisation of investigation requests.

3.1.2 Point of care testing

Point-of-care testing (POCT) is defined as patient sample testing at or near the site of patient care. The purpose is to provide immediate information to clinicians about a patient's condition. Although POCT negates the necessity for traditional laboratory investigation requesting there is an overriding need for the information provided by the point-of-care tests to be transferred to the laboratory information management system to be collated and analysed. The same technology is applicable for distributed point of care testing systems and other integrated but distributed electronic health care systems.

3.2 Coding and standards

The adoption of standards is deemed necessary for improving the quality, comparability and usefulness of health information and for implementing an electronic healthcare record (National Health Information Strategy, 2004).

3.2.1 Health level seven standards.

Health Level Seven (HL7) is a non-profit organisation which has produced a family of standards for exchange, management and integration of data in the healthcare domain (Muller, 2005). HL7 was founded in 1987 by a group of American hospitals and their suppliers with the original emphasis on linking systems within the hospital such as patient administration, order communications, billing systems and the laboratories. The standards produced by HL7 facilitate the transfer of health data resident on different and disparate computer systems in a health care setting. HL7 facilitates the transfer of laboratory results, pharmacy data and other

information between different computer systems. The Mission Statement of HL7 is “ To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems” (Health Level Seven, Inc., 2005). For electronic laboratory requesting messages HL7 describes what part of the message contains the information about the sending laboratory, the patient, the tests performed and the results. The strength of the HL7 protocol is flexibility, however implementation requires a consistent, standardised approach to prevent misinterpretation of messages. HL7 messages consist of variable-length data fields combined into groupings (segments) with the OBX segment containing information relating to observations (such as laboratory test results). OBX-3 contains the test identifier and OBX-5 contains test findings (results) (White,1999).

HL7 version 2.4 has become the de facto international standard in Ireland because it singularly focuses on the interface requirements of the entire healthcare organization. HL7 produces the most widely used standards for healthcare interoperability (HL7 Ireland, 2005). Most of the leading suppliers use and support the development of HL7 standards across six continents. HL7's activities include the development and publication of standards and encouraging the use of HL7 worldwide. HL7 is an accredited standards development organisation, regulated by ANSI (American National Standards Institute) and collaborates with other healthcare standards groups including the European CEN/TC 251 (Health Level Seven, Inc., 2005).

Since 1996, HL7 has been working on a new generation of standards known as Version 3 (V3). The aim of HL7 V3 is to produce consistency in definition of information objects and their representation in messages, allowing for the definition of standards for information representation other than just messages, including forms and patient record structures (Health Level Seven, Inc., 2005).

The recent release of HL7 version 3.0 has increased the functionality of and expanded the capabilities of medical information exchange. HL7 version 3.0 uses extensible markup language (XML) (see below) for healthcare information encoding. XML technology and functionality will extend the HL7 version 3.0 standard to serve as a foundation for a universal electronic medical record (Marotta, 2000). Although HL7 version 3.0 has been adopted by the National Health Service in the United Kingdom, Ireland will not follow suit in the near future (Tim Benson (Abies Ltd) personal communication).

3.2.2 Extensible markup language

Extensible markup language (XML) is a set of rules for designing text formats that allow data to be structured. Like Hypertext Markup Language (HTML), XML uses tags (words bracketed by <>) to delimit pieces of data. Unlike HTML however, the shape of XML documents is decided by the developer who creates a document type descriptor (DTD) which dictates the shape of the document. For instance XML can be molded into HTML but the reverse operation is not possible. This flexibility has made XML a powerful tool for system integration. Development of XML started in 1996 and the XML designers used the basis of the ISO standard Standard Generalized Markup Language (SGML), and the experience of HTML development, to make a powerful and simple to use technology. In 'the XML family' there is a growing set of supporting markup languages which offer useful services such as XSL for expressing style sheets and XSLT (both of which can be created using XML) to transform and rearrange data items. One of the major advantages of XML is that it is license free and platform independent (World Wide Web Consortium Communications Team, 2001). One of the weaknesses of XML on the other hand is that an agreed format with an agreed set of tags and agreed structural rules still needs to be agreed in order for meaningful exchange of information to take place.

3.2.3 Logical Observation Identifier Names and Codes

The Logical Observation Identifier Names and Codes (LOINC) (Regenstrief Institute, 2005) database is a universal code system which can be used for reporting laboratory test names and laboratory results. A HL7 message carries one record for each test observation. In these HL7 messages two fields are used to carry test identifiers and test values. Until recently most laboratories used their own unique codes in these fields. These codes then have to be mapped to the codes used in the receiving system. In 1994 a group of researchers met to develop a code system for laboratory test names to avoid this labour intensive mapping process. The group used many sources to construct the code system and examined the contents of millions of HL7 messages. The resulting database released in 1995 contained over six thousand laboratory test results. After seventeen releases this number has now increased fivefold. Today LOINC codes have been adopted in the United States of America, and also in Switzerland, Hong Kong, Australia and Canada. Many instrument vendors map their instrument measurements to LOINC codes and can deliver the LOINC codes with the results as they are produced. Also laboratory information system vendors frequently include an indexed field for LOINC codes in their test database. When LOINC codes are included by laboratories in their outbound HL7 messages the results can then be easily integrated into the receiving databases (McDonald, 2003).

3.2.4 Systematised Nomenclature of Medicine

Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT) is a scientifically validated clinical reference terminology system developed to make health care data more usable and accessible. The SNOMED CT core terminology provides a common language that enables a consistent way of capturing, sharing and aggregating health data across specialties and sites of care. SNOMED CT can be applied to electronic medical records, for decision support, for clinical trials and research, disease surveillance and patient monitoring. It contains over 366,170 health care concepts with unique meanings (Snomed International, 2005).

Laboratory results coded with SNOMED terminology can be represented in a reliable, reproducible manner facilitating efficient accurate data exchange between different laboratory information systems. SNOMED CT has received endorsement by many professional associations and is already imbedded into many laboratory information systems to describe anatomic pathology data (White, 1999). It has been recognised by many standards setting organisations and government bodies.

3.2.5 CEN- European Committee for Standardisation

The principle task of CEN is to prepare European Standards. CEN TC251 (Technical Committee 251) is the body put together to facilitate ‘Standardization in the field of Health Information and Communications Technology (ICT)’ (European Committee for Standardisation (CEN), 2005). One of the workgroups of CEN TC251 is involved with the development of European standards to facilitate communication between independent information systems within and between organisations, for health related purposes. This especially includes standards for the Electronic Healthcare Record. This work will ultimately facilitate the electronic transfer of orders for laboratory investigation and the electronic transfer of reports. By mandating minimum context information surrounding a request and investigation report, it will also facilitate the seamless incorporation of lab results such as those produced within NVRL into the EHR. This should reduce the need for human intervention in information interchange and also minimise time and effort required to introduce information interchange (European Standardisation of Health Informatics (CEN/TC 251), 2005).

3.3 Laboratory messaging systems

3.3.1 The OpenLabs project

The OpenLabs consortium was formed in 1991 as part of the European Community’s Advanced Informatics in Medicine Programme. The OpenLabs project began work with one

of the objectives to provide and implement standard solutions for electronic data exchange between laboratories. The main focus was to improve the efficacy and effectiveness of clinical laboratory services. The OpenLabs project aimed to provide generic solutions that were capable of connecting to a wide range of existing laboratory applications. The principle was to allow different laboratory applications to interoperate over an open computing platform using the standards for medical informatics (as mentioned CEN TC251) (Boran, 1996). Adopting standards is crucial in reducing difficulties when building a distributed system. There is often a requirement for laboratories in one region to specialise in a co-ordinated fashion and exchange samples to save expenses (Pansini, 2002). However the main hold-up of results is the exchange of information when there are separate systems. This is also true when there is integration of data from satellite laboratories of individual departments and for point-of-care testing (Hakman, 2001). This trend of decentralisation in a domain highly dependent on information technology solutions means that communication becomes of vital importance.

3.3.2 MediBridge

MediBridge is a commercial solution for the communication of laboratory data and is focused on quick and secure data interchange between institutions. This data exchange is primarily laboratory data covering laboratory results and laboratory requests. In particular secondary care institutions avail of this technology. The receiver can automatically integrate the data into their own software package. Health Information is fully encrypted by the software before being transmitted from one Health Institution to another or between Health Care Professionals. Once the information has arrived on the recipient's workstation the information is decrypted and is available for that Health Care Professional to view or integrate with their own Information System. The system also provides a Results Reporting application that the recipient may use to print or view the transmitted results.

The application provides the user with the ability to review, store, print and search for the Laboratory Results for their Patients. The MediBridge software application is owned by a Belgian company who currently service some 12,000 Institutions (DMF Systems, 2005).

3.3.3 The National Healthlink Project

The National Healthlink project is a Department of Health and Children funded project, which allows for transfer of electronic messages between primary and secondary care in Ireland. The recently developed a HealthlinkOnline web application is used to transfer hospital correspondence securely between secondary and primary care agencies. A migration from proprietary standards to the internationally recognised HL7 standard messaging had many advantages for the project. However the adoption of this standard caused many practical issues. General practitioners nationwide are interested in the Healthlink project however on those who are in the catchment area of a participating hospital can avail of the scheme which currently requires no payment for the service. The less labour intensive web enabled Healthlink application should facilitate greater numbers of participants (The Healthlink Development Unit, 2005)

3.3.4 Electronic Communications Projects

In Ireland most Health Boards are developing their own electronic communications projects, including the Mid Western, North Western, South Eastern, Southern and in the Eastern Region at the Adelaide and Meath Hospital incorporating the National Children's Hospital (AMNCH) in Tallaght. The primary functional objectives of these projects is to provide a secure link between primary and secondary healthcare for the transfer of laboratory results, but also ultimately for referrals, discharge letters and the development of electronic patient records. Efforts are being made to work together to avoid duplication and ensure consistency of outcomes. These projects aim to support primary care in the areas of results, secure e-mail, document library and secure Internet access to general practitioners (National General Practice Information Technology Group (GPIT), 2005).

3.4 Security Legislation

Although it is not technically difficult to send information between organisations, the Data Protection Acts 1988 and 2003 indicate that all Data Controllers must be aware that they have key responsibility in relation to the information they process. Security is a vital aspect of the use of healthcare information systems and with healthcare data appropriate security measures must be taken against "unauthorised access to, or alteration, disclosure or destruction of, the data and against their accidental loss or destruction." (Data Protection Commissioner, 2005). When determining measures, a number of factors need be taken into account including the nature of the data concerned and the harm that might result from unauthorised or unlawful processing. There is a greater duty of care relating to the processing of sensitive personal data. (Data Protection Commissioner, 2005). Many organisations use a third party organisation whose business is to take the responsibility of secure data transfer.

3.5 How the technology is used in a reference laboratory

Until the advent of electronic messaging the only requirement of the laboratory information system was to provide a hard copy of the laboratory investigation results containing as much data as was necessary for the report to be returned to the clinician and for that clinician to be able to identify the patient. The need for standardisation became apparent when the first partner organisations, primarily large primary hospitals, started to receive a copy of their reports electronically. If the results were to be incorporated into the partner organisations' laboratory information system, then each field needed to be mapped to allow transfer. The recent development of specifications for electronic investigation requesting has exposed even more standardisation issues, not least because in the field of medical virology clinical information can be vital in the selection of optimal testing strategies and the essential interpretation of test results.

It is important that there is effective communication between partner organisations to provide an efficient clinical laboratory service. The aim of this project is to establish the way this can be achieved.

Chapter 4: Towards a harmonised paper / electronic requesting system.

4.1 The current situation

The NVRL can receive specimens from all over the country from large teaching hospitals to small hospitals to clinics to general practice. There is no current request form specific to the NVRL. In the past the NVRL has issued a variety of investigation request forms, most recently for specimens for molecular analysis which have strong requirements for clinical information to be provided. However in general hospitals have their own wide range of forms and are reluctant to add to the collection with one specific to the NVRL. As a result there is an inherent problem with the paperwork that is received at the NVRL, in that there are almost as many types of request forms as there are requests. Hospital laboratories frequently use printouts from their laboratory information systems to send as the request form, especially those that have ward order comms.

As long as there is a name or initials and date of birth or hospital number of the patient and an address to send the report back to the clinician the NVRL will process the request.

Frequently general practitioners do not know where virological tests are done; therefore they send the specimen to the nearest primary hospital that then refer the specimen to the NVRL where appropriate. The primary source takes ownership of the results and the reports must be sent back to them.

To deal with the problem of delay of reports using traditional delivery methods (postal system) some sources have gone down the road of organising courier services to collect their reports. Others have bought into software to receive electronic reporting of results provided by the NVRL through MediBridge.

4.2 Problems with this situation

One of the main problems with this situation is that there is no uniformity with the investigation request forms. Many formats makes it difficult to read the information, the tests,

clinical details, patient data all in different positions and it is hard for the technical staff in specimen reception to establish what tests are required and even harder for administrative staff doing data entry.

Another problem is that we do not always get the information we require filled in on the forms. Recent legislation means that we should have full home addresses for all patients in case of notifications to public health. Also we have a responsibility to differentiate public and private patients, and in-patients with outpatients, so that the taxpayer will not be carrying the cost of private medicine. Clinical information is important to aid the selection of an optimal testing strategy and the interpretation of test results

The forms and specimens can take some time to arrive at the NVRL increasing the time it takes to for the specimen to be processed and consequently spoiling the quality of the specimen and therefore the quality of the results. The results can be delayed getting back to the clinician, delaying diagnosis and treatment for the patient

It is essential to recognise the importance of communication with all our primary care users. McNulty et al (2003) outlined findings from focus group held with general practitioners held to discuss methods of communication with their local microbiology laboratory. The challenges are greater with communicating microbiology and virology results due to the lengthy free text nature of the reports. It was found that in general practitioners were enthusiastic about the potential of electronic reporting as they felt this would reduce clerical time spent filing reports and following up on lost results. However electronic transfer of reports does highlight problems with misinterpretation of patient demographics from paper requests, which can lead to critical mismatch of data on transfer of the results. Fortunately this problem is lessened by electronic requesting as the patient demographics mirrors that of the source computer system.

4.3 The common elements of the forms

Many of the request forms that had been sent to the NVRL accompanying specimens were collected to identify the common data elements. Appendix (i) shows examples of the forms collected. These common data elements are discussed in section 4.4 with the design of new NVRL investigation request forms. Figure 4.1 shows a list of the common data items identified on the forms collected and the proportion of forms, as received during March 2005, which had those data items entered by the administrative staff into the LIS.

	% of forms with data item present n=17543 (March 2005)
Required data items	
Surname	99.99
Forename	99.93
Sex	97.96
Hospital	99.98
Clinician	96.31
Requested investigations	99.91
Date received	<i>N/A (Assigned by NVRL)*</i>
NVRL laboratory number	<i>N/A (Assigned by NVRL)*</i>
Specimen type	<i>N/A (Assigned by NVRL if not present on form. Can be determined visibly)*</i>
Specimen date	<i>N/A (Assigned by NVRL as date received if not present on form)*</i>
Useful data (requested)	
Date of birth	99.01
Clinical details	48.01
Data items received and entered if present	
Home address	50.32
Hospital number	72.37
Ward/Clinic/GP name	56.75

Figure 4.1- Table showing frequency of receipt of data items on request forms.

It can be seen that although most of the required data items (mandatory fields in the LIS) are present on 99% of forms, clinical details are only present on approximately 48% of forms. Clinical information can be important to aid the selection of an optimal testing strategy and the interpretation of test results. Lack of clinical information can lead to inefficient use of laboratory resources.

4.4 Revised set of forms

In order to begin the process of a unified investigation request format a set of forms corresponding to the most recent NVRL investigation request forms were then designed using these common data elements, placing the fields in the order found on the request entry screen of the laboratory information system at the NVRL. See Appendix (ii) for this set of forms.

The following a description for each of the type of forms designed.

NVRL request (General)

The general NVRL request contains the core data required to perform virological tests. The data includes: Forename, Surname, Date of birth, Sex, Address, Hospital number, Investigation, Clinical information, Specimen type, Specimen date, NVRL laboratory number. This general form could be used for any specimen sent to the NVRL, but is more specifically used for specimens sent for virus detection. The importance of clinical information is emphasised on the form.

Serology

Specimens for antibody detection (serology) contain specific clinical information fields for vaccination history and exposure category. This form is used for most blood specimens sent for antibody screening.

Addiction resource clinics.

This group of partner organisations have been consistent users of the NVRL services for some time and have used NVRL investigation request formats provided in the past. The form designed for use by the addiction resource clinics contains the same information as the one for serology but in A4 format as favoured by the clinics.

Occupational health

The form designed specifically for occupational health departments contains information on the date and type of occupational exposure. It is used most frequently by occupational health departments for staff to test for immune status and vaccine response, but also in the case of

occupational exposure such as needlestick injury. In these instances blood samples are often requested to be stored for future analysis.

Molecular Biology

Forms for molecular analysis contains the specific clinical information of type of therapy and the date of commencement of therapy as the patients have frequently been screened already and are being tested as part of ongoing treatment and monitoring.

Hepatitis and HIV

Both these forms contain information on exposure category and are used for investigation requests for those individual viruses. Patients who have tested positive for these viruses attend specific clinics for therapy and are monitored over time.

Chlamydia

This form is used by genito-urinary medicine clinics and contain information on exposure category and specific fields for appropriate specimen type.

Cytomegalovirus (CMV)

This form contains the information on date and type of transplant for patients who are post transplant and who are being screened for reactivation of CMV. It is used by the transplant units in the major hospitals.

Figure 4.2 gives the details of the above investigation request forms in the form of an inheritance hierarchy UML class diagram.

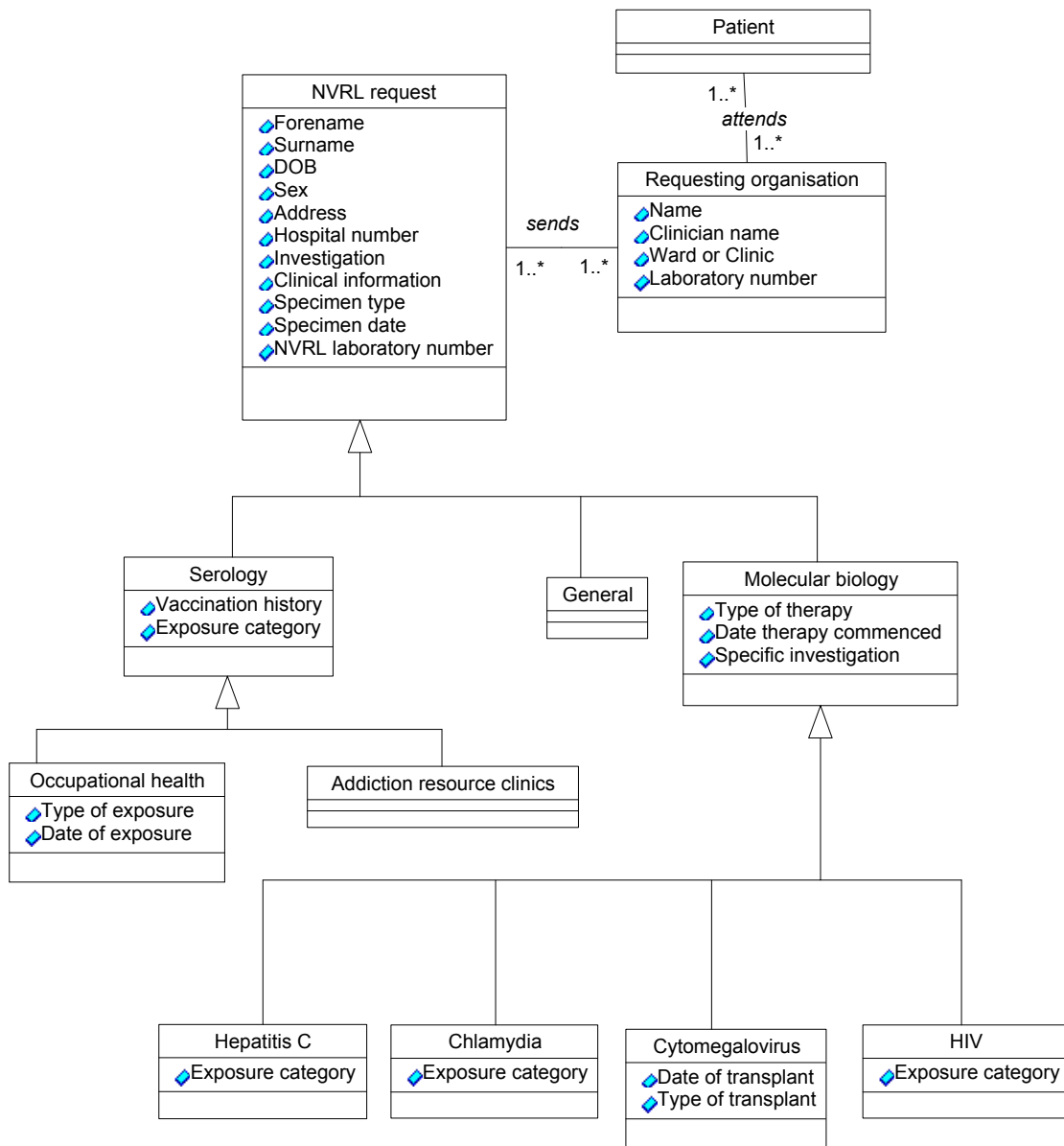


Figure 4.2 The NVRL investigation request form inheritance hierarchy.

After agreement with the NVRL laboratory director the General and Serology investigation request forms were placed on the NVRL website (www.nvrl.ie) in pdf format for use by any partner organisation.

4.5 Personalised forms with partner organisations details

The addiction response clinics were identified as a group of partner organisations that would be frequent users of our service. These clinics traditionally do not have their own request forms and were keen to use request forms provided by the NVRL. It was decided to send to the 20 most frequent users of the NVRL service from that group, a request form that was

personalised for their organisation. This was provided in printed format and also on disk as a pdf file along with a pdf file of the NVRL user manual. This personalised request form can be seen in Appendix (iii). The personalised version of the request forms contained the source address field completed for that organisation and also the source code for use by the administrative staff when entering the data in the NVRL LIS. The personalised version of the request forms were used by most of the organisations that received them.

4.6 Discussion on minimum data sets

A draft recommendation for the minimum data set for transmission of clinical laboratory test reports was outlined in August 1999 by the Messaging sub-group of the National GP-IT Group. The minimum data set included the following items as mandatory:

For identifying the patient:

- Unique identifier
- Surname
- Forename
- Address
- Date of birth
- Gender

For the specimen:

- Unique specimen identifier (laboratory number)
- Specimen type and source
- Date/time of receipt

For the test result:

- Result type (text/numeric)
- Test identifier (code)
- Result

For the report:

- Unique request identifier
- Priority
- Report status

The recommendations also contained a number of optional data items (such as date and time of collection of specimen, very important information in virology) which would be provided for in the message structure, but which would not necessarily need to be included in all messages. Also discipline specific requirements such as long textual based results common in virology were also recognised for special consideration.

The minimum data set is given to partner organisations as recommendations, not requirements. Patient care should always be the primary goal. The aim is to ensure that the correct information will belong to the correct specimen and the final results will therefore be returned to the correct patient.

4.7 Gap analysis

We can see that the investigation request information received at the NVRL could be defined as adequate for a reporting system. However in general the data received is far from comprehensive. All fields included in recommendations for minimum data sets are not present in the current investigation request information. We have an obligation to provide certain data for public health purposes which we cannot do with our present investigation request information. In the future this requirement is likely to expand and we must be prepared to meet these needs.

The sustained effort required by administrative personnel to enter the data into the LIS is, in most cases, unnecessary. Most partner organisations sending investigation requests already have entered all the data into their own system.

The lack of a unique patient identifier means that links between specimens can be missed, especially important for monitoring of disease and therapy.

Electronic laboratory requesting will facilitate a consistent approach to investigation request information resulting in complete data and improved data reporting. In Chapter 5 we will discuss a strategy to ensure electronic laboratory requesting will be a realistic goal for all partner organisations in the future.

Chapter 5: Analysis and Design of an Electronic Laboratory Request

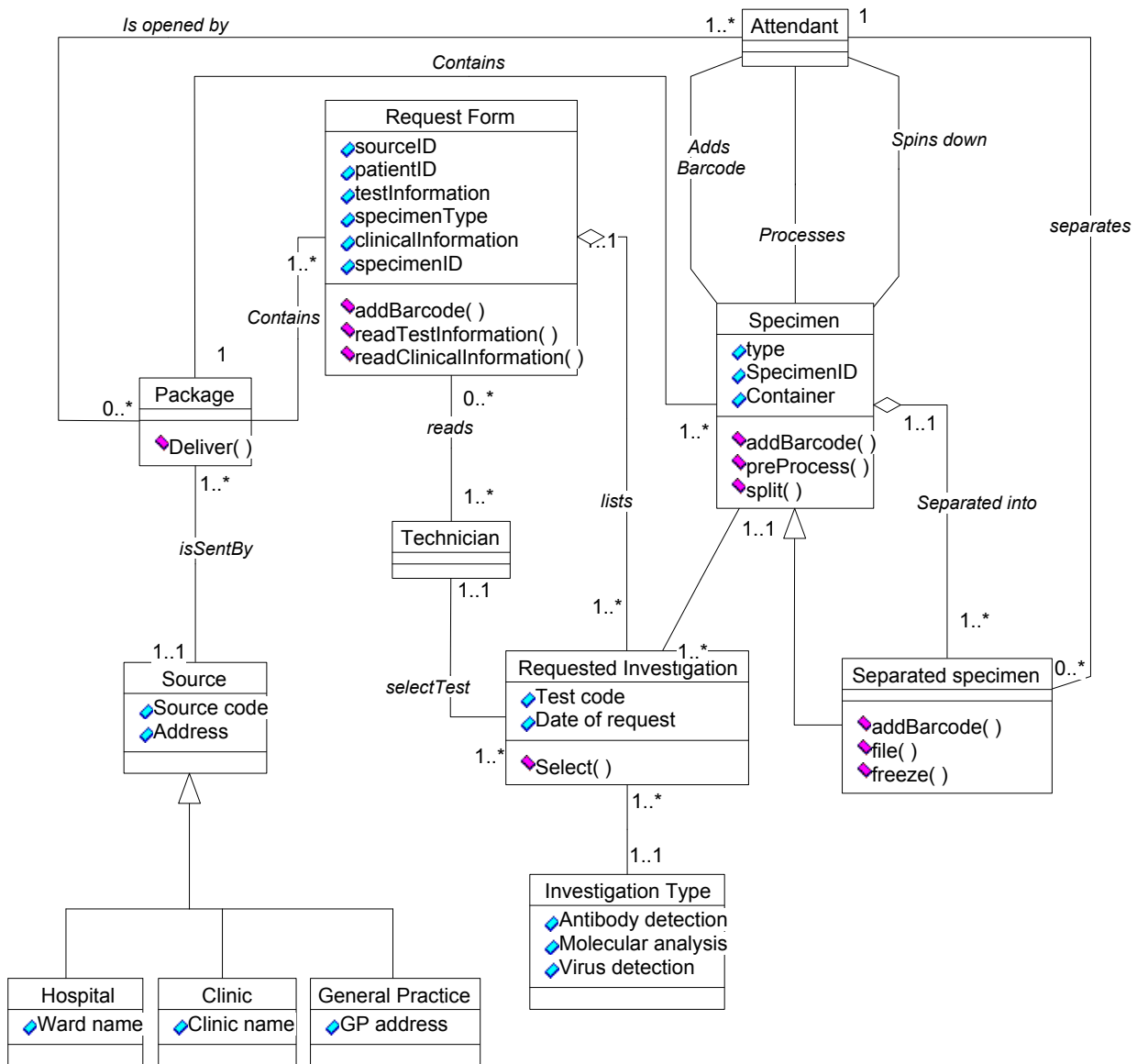
Previously we have seen that at the NVRL there is a need for a unified laboratory request and that electronic laboratory requesting will be the way forward for an improved service to the patient. In this chapter we will discuss how an electronic laboratory requesting system could be developed at the NVRL.

5.1 Domain Model

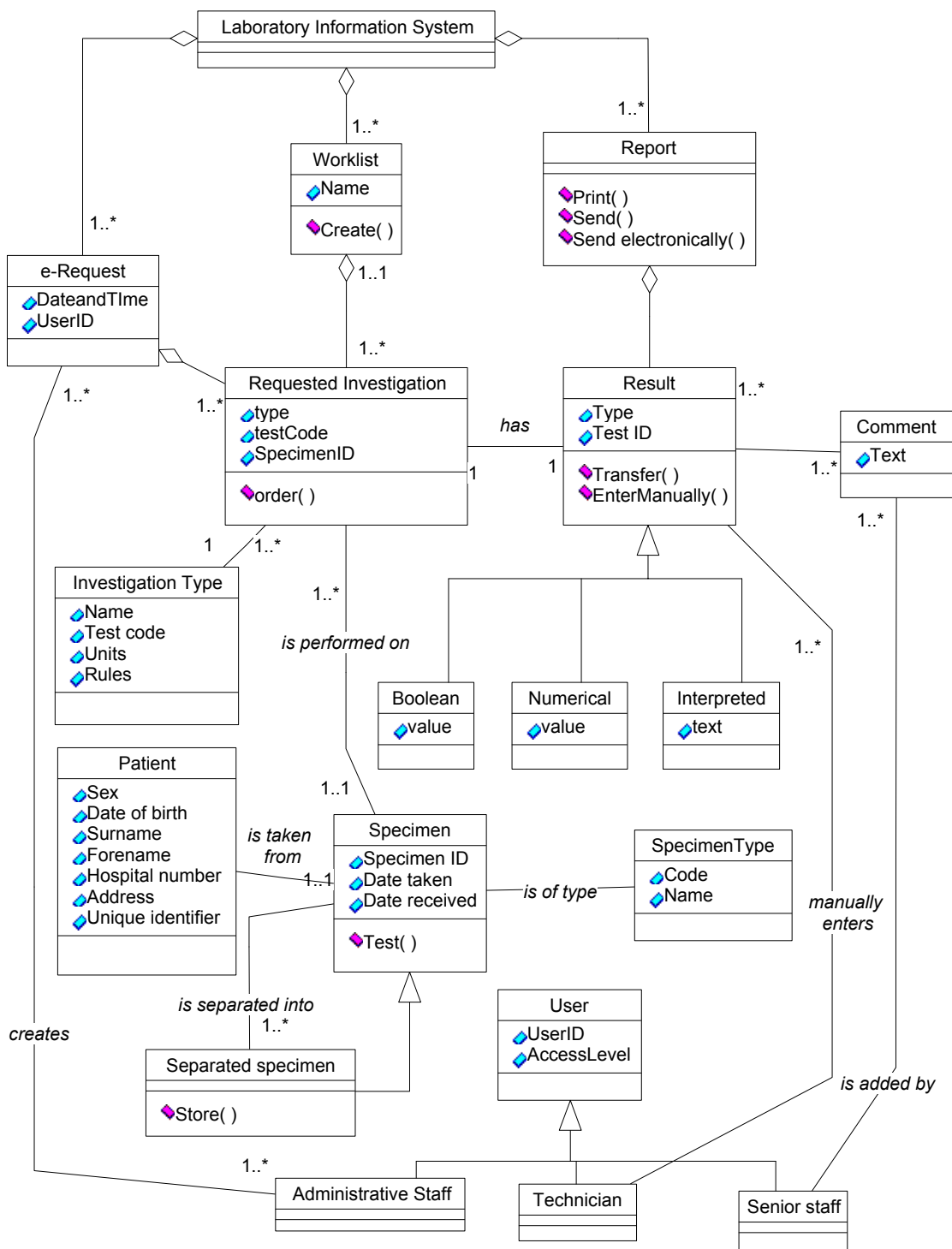
Figures 5.1 and 5.2 are UML class diagrams describing the interactions between the main artefacts and entities at the NVRL during a typical working day.

Figure 5.1 shows the interactions in the laboratory on receipt of specimen into specimen reception and as the investigation request forms and the specimens are pre-processed .

Figure 5.2 shows the interactions in the laboratory as the investigation request form is used to create an investigation request, the specimen is processed and a report is issued.



Figures 5.1 UML class diagrams describing the interactions in the NVRL on receipt of a specimen into specimen reception



Figures 5.2 UML class diagrams describing the interactions in the NVRL as an investigation request is processed

5.2 Domain Description

There follows a description of the NVRL domain following the interactions as outlined in the UML class diagrams 5.1 and 5.2.

User

There are three categories of user outlined in the domain, attendant, technician and senior staff. These categories have differing access levels with only senior staff being able to authorise results. Senior staff include clinical staff and senior technicians.

Source

Work at the NVRL arrives from one of three source categories, a hospital, a clinic or a general practice. The clinician looking after a patient initiates a request for a laboratory investigation by completing a request investigation form. The relevant specimen is taken from the patient, packaged together with the form and the package is delivered to the laboratory.

Package

Many specimens can be delivered together in one package. At the NVRL the package is delivered into specimen reception where laboratory attendants, under the supervision of a laboratory technician, open the package and take out the specimens and forms.

Specimen

The specimens and forms are matched and a unique NVRL barcode number is added to the specimen and the request form. One specimen will usually be tested for more than one test. The average is three tests per specimen. Many types of specimen containers are sent from the different partner organisations. This is especially relevant for blood tubes. The tube sizes vary with length and diameter and also type of lid (screw-on, snap-on). Many of the analysers used in the NVRL are designed to use the primary blood tube however the analysers have to be calibrated for one tube type and are not validated for other sizes of tubes. At this stage it may

be necessary to pre-process some specimens, for example by centrifugation of whole bloods to separate the serum and put it into a standard tube size.

Separated specimen

Separated specimens are barcoded with the same NVRL barcode as the primary specimen. Specimens for molecular analysis must be processed rapidly and then frozen at -20°C to prevent degradation of the nucleic acid. Guidelines state that blood specimens for molecular analysis should usually be separated and frozen within six hours of venapuncture. Specimens for serology or virus detection are brought to the laboratory and refrigerated at 4°C until testing.

Request form

There must be an investigation request for every specimen. However one investigation request form may contain requests for a group of specimens (say for example for a post transplant CMV screen with blood, urine and throat swab). Also one form may contain tests for more than one section of the laboratory. The request form contains all information required to process the specimen.

Requested investigation

The request form is taken to the relevant laboratory depending on the type of investigation requested. There are three types of investigation: antibody detection, virus detection and molecular analysis. The technical staff in the laboratory examine the test information and the clinical information on the request form and select the tests to be investigated. The test codes are written onto the forms. The forms are then given to the administrative staff.

Investigation type

Each investigation has a unique test code that corresponds to a test name. Some test codes have specific factors associated with them such as units, flags or rules.

e-request

The administrative staff enter the data into the LIS from the investigation request forms, including the patient information, the specimen information and the test codes.

Worklist

When there are sufficient tests requested the technicians use the LIS to pull a separate worklist for each test code. Each worklist has a name and contains the NVRL number and the test code. Using the worklist the specimens are taken out and tested.

Result

Results generated from the specimens are transferred to the LIS, either manually by the technicians or automatically by interface to automatic analysers. Results may be qualitative (for example negative or positive), or quantitative (numerical readings taken from an analyser).

Some numerical results are interpreted to negative or positive from the values, either automatically by the analyser, or using the LIS rule base.

Comment

Additional comments are also added to some results, either automatically using the LIS rule base, or manually by senior staff. Completed results are authorised by senior staff.

Report

Authorised results are then printed out and given to the office to be distributed back to the clinicians. Partner organisations that are set up to receive NVRL reports via MediBridge receive electronic reports once a day.

5.3 Specific Requirements for an Electronic Laboratory Requesting system

Figure 5.3 shows a high level use case diagram for an electronic laboratory requesting system.

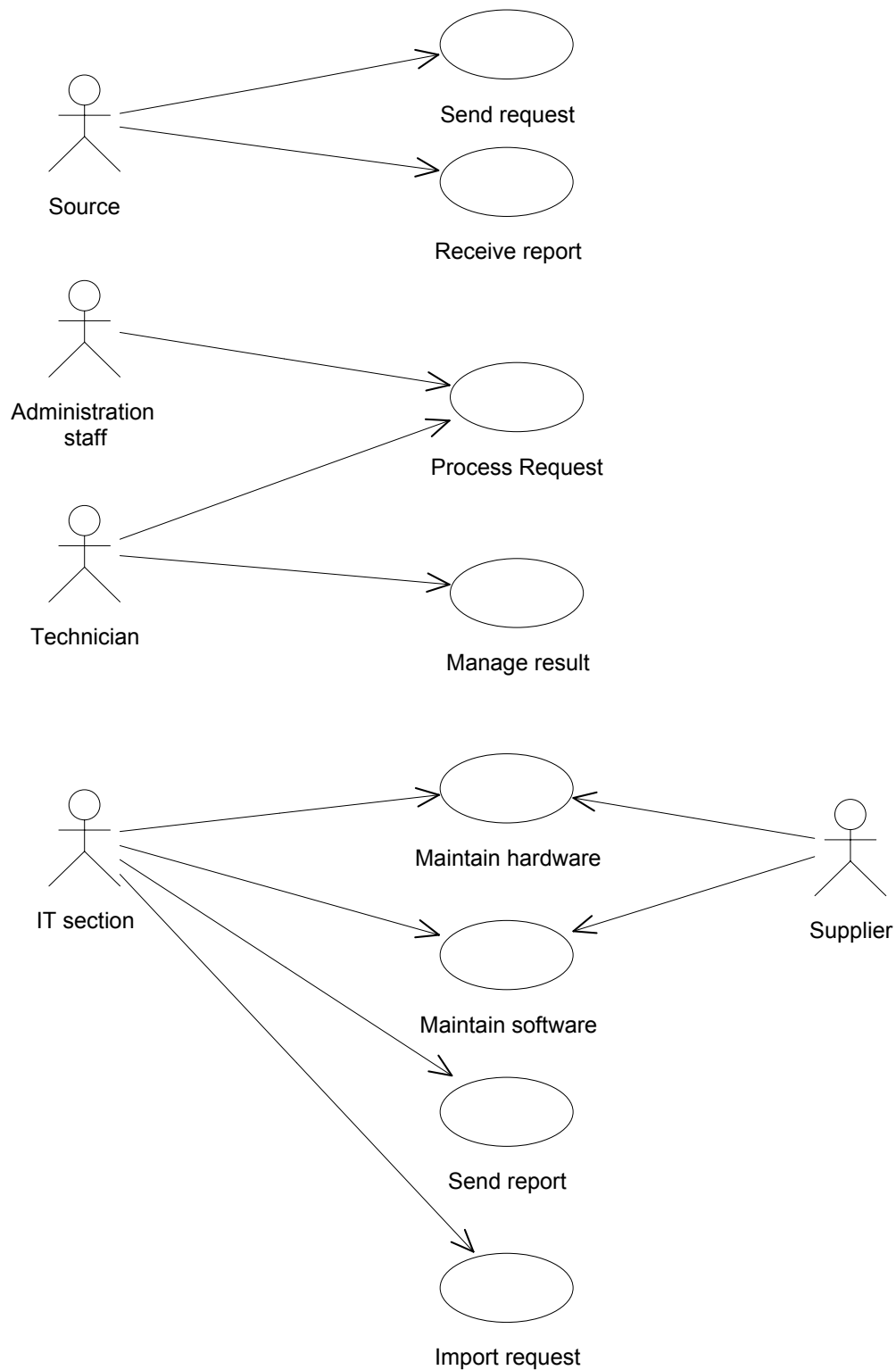


Figure 5.3 High level use case diagram for an electronic laboratory requesting system

There follows a listing of the functional requirements for an electronic laboratory requesting system at the NVRL. This must not be considered a system requirement specification but a

record of how the NVRL would like the system to perform. The requirements only refer to the **electronic** laboratory requesting and reporting system and does not take into account the WinPath LIS which already performs the function of laboratory information management at the NVRL.

A Send Request

R A1: There shall be a file sent from the requesting organisation with a unique filename to identify the sender and the date and time of the file.

R A2: The file shall be sent safely and securely according to guidelines of the Data Protection Acts 1988 and 2003

R A3: The file should contain all the required data (see section 5.4) in a standard format for importing into the NVRL LIS

R A4: There shall be included a unique identification number for each investigation request that will match up that request with the correct sample when it arrives at the NVRL

R A5: A copy of the file shall be kept for auditing purposes plus a printout of the investigation requests containing sufficient information for matching to samples on arrival

R A6: Investigations shall be requested using NVRL test codes (mapped from requesting organisation codes)

R A7: Urgent investigations should be clearly identified.

B Process Requests

R B1: There must be a facility to remove and add investigation requests as appropriate keeping in mind that this will also affect the requesting organisation LIS

R B2: All patient names shall be stripped of spaces, hyphens and apostrophes before import to standardise format

C Import of requests

- R C1: On import of the file into the NVRL LIS all required data fields shall automatically be populated in the patient record
- R C2: Records without required data fields should still be uploaded using default data (such as 'not given'). No records should be rejected because of lack of data.
- R C3: Import of investigation requests into the NVRL LIS shall not require any manual manipulation of records before importing
- R C4: Import of investigation requests into the NVRL LIS must not require excessive maintenance, for example to maintain mapping of codes.
- R C5: Import of investigation requests into the NVRL LIS shall be designed for ease of use, shall be automated as much as possible and shall not require extensive training for users
- R C6: The system shall have the facility to remove orphan requests on the system (in the absence of a sample arriving). This will also happen automatically after a specified period of time has elapsed (user definable).

D Manage reports

- R D1: On completion of all results, the report shall be extracted to a file for export from the LIS
- R D2: There shall be a separate file for each requesting organisation
- R D3: The file shall contain all data fields received with the imported file.
- R D4: There shall be included a unique identification number for each report that will match up that report with the correct patient information in the requesting organisation LIS
- R D5: The file shall have a unique filename to identify the requesting organisation, the sender (NVRL) and the date and time created
- R D6: The report shall contain all text associated with the results as would be printed on a hard copy of the report

R D7: Results from investigation requests not requested electronically shall be extracted for electronic reporting providing there is a unique identification number provided by the requesting organisation

E Send reports

R E1: Transmission of reports to the requesting organisation shall be designed for ease of use, shall be automated as much as possible and shall not require extensive training for users

R E2: The file shall be sent safely and securely according to guidelines of the Data Protection Acts 1988 and 2003

R E3: A copy of the file contents shall be kept for auditing purposes.

R E4: There shall be the facility to send a file again if required.

R E5: There shall be the facility to send one single report if required

R E6: All transmission activity shall have the facility to be audited

F Receive reports

R F1: The requesting organisation shall send acknowledgement of receipt of the file from the NVRL

R F2: The requesting organisation shall be responsible for import of the reports to the LIS

R F3: A copy of the file received shall be kept for auditing purposes

R F4: The reports shall not require any manual manipulation of the record before importing to the requesting organisation LIS

R F5: Investigations shall be mapped back to requesting organisation codes

R F6: All patient names shall be repopulated with spaces, hyphens and apostrophes as pre-defined by the requesting organisation

R F7: Test codes not included in the original electronic request shall be automatically requested on import

G Hardware maintenance

R G1: There shall not be expensive hardware requirement for the system to be put in place and maintained

R G2: The system must be robust and reliable as downtime can compromise patient treatment

H Software maintenance

R H1: There shall be the facility to include a number of optional data items which will be provided for in the message structure, but which will not necessarily need to be included in all messages.

R H2: There shall be the facility to change the data items as required by national and international standardisation.

I Additional notes

1: The quality of patient information provided with the investigation requests is not in the control of the NVRL.

2: Patient information may be amended in the requesting system after upload into the NVRL LIS creating field mismatching on return

3: Without a unique patient identifier there will never be a foolproof way of transmitting electronic laboratory reports.

4: The system must work on or be compatible with

a. Windows 2000 operating system or higher.

b. WinPath LIS

c. SQL database

5.4 Standards and minimum data

It should be noted that required data for an NVRL electronic laboratory requesting system may not necessarily correspond to the recommended mandatory minimum data as discussed previously in 4.6. In fact certain data items not designated as mandatory would be required data for NVRL investigation requests, such as date and time of collection of specimen.

However in order to ensure the future proofing of an electronic laboratory requesting system there must be the facility to transmit all items in the minimum data set including all optional data items. Also discussed previously in 4.6, the required data set is given to partner organisations as recommendations, not requirements, with patient care always the primary goal. Although an electronic laboratory requesting system can be achieved without adopting standards but by translation of data items to be recognised by the receiving system, a truly successful implementation of an electronic laboratory requesting system is dependent upon the general adoption of information standards so that two systems will see all data consistently and laboratory results are interpreted reliably. This will require a significant cultural and technical challenge, necessitating training and ongoing support.

Chapter 6: Discussion

There has been a rapid evolution of laboratory procedures, methodologies and equipment and over the years medical professionals have increasingly become dependent on the expanding range of sophisticated diagnostic services provided by clinical laboratories. This development has been of significant benefit to healthcare helping clinicians to diagnose and treat illnesses and monitor recovery. For a laboratory service provider it has become of great importance to convey to all users of the laboratory service, the necessary information about appropriate test ordering, specimen collection and transport. The design of the investigation request format can directly affect the accuracy of test orders from the clinician by providing appropriate information and indicating the required data.

There are a number of factors required in virological investigations that will ensure the quality of test results. One of the most important is as the quality of the sample, which ultimately is not in the control of the laboratory. Another is the length of time it takes for the specimen to arrive in the laboratory. However just as important is the information received with the investigation request form sent with the specimen. Insufficient clinical details means appropriate tests cannot be identified. Also the date of onset of symptoms is vital as in some diseases it can take some time for the organism to be detected. It is important to match patients previous results to choose appropriate testing algorithm and for result interpretation. It may be the case that a repeat sample was requested on a previous report to confirm that result. This will commence a different testing algorithm than if the patient had not been tested before. It may be too soon to test the patient again arising in a waste of resources. Serological (antibody) testing may require comparison of two samples (acute and convalescent) therefore sample date is be critical. In many diseases it is important to monitor the virological profile of the patient over months and years to watch progression of the disease. Matching patients previous results, especially over a long period of time can be very problematic. For some examples when trying to match patients by name, 'Baby' Smith can turn into 'John' Smith, females can change their name on marriage, children can change name when their mother

marries, there can be a difference between 'official' and commonly used name (Peggy and Margaret), different cultures have different naming traditions, spaces, hyphens and apostrophes can be used variably and need to be made uniform (Mc Donald/McDonald, O'Reilly/O Reilly/OReilly, Smith-Jones/ Smith Jones). However when trying to match patients by hospital number we find the same patient will have a different hospital number in a different hospital or that different patients may have the same hospital numbers in different hospitals. In my experience I have seen investigation requests for specimens which have been taken from babies at birth, with the hospital number of their mother provided for identification, and that indeed we have been provided with all information belonging to the mother but with 'Baby of' inserted in front of the name on the investigation request.

When entering investigation request form information into the LIS there are many problems with deciphering the data and turning it into meaningful information (and this does not mean simply the bad writing on the forms, which is of course taken for granted). We acknowledge that it is desirable for systems see all data consistently, but in the absence of specific information we discover that there are apparently more than one doctor with the same name in the same hospital. There are also many doctors with the same name in different hospitals and in fact a particular doctor may attend at more than one hospital/clinic within the same week (shared sessions and private practice). Since we do not get a full name and medical registration number with the investigation request form information, at the NVRL we have resorted to generic clinician codes for ease of data entry, therefore the real information which can then be derived from these codes is minimal. Likewise there are the same ward names in many different hospitals (Our Lady's, St Agnes' and St Patrick's being favourites). There is also the issue of investigation request data that is not received or incomplete. Some clinicians only provide initials and date of birth for some patients for example sexual health clinics. This is usually so the patient will remain anonymous. Some clinicians only provide a identification number for some patients for example occupational health so as not to identify staff results to other staff. Some patients deliberately give false information as they do not wish to be

identified. Unfortunately these patients also frequently attend many hospitals, clinic and GPs in their lifetime. Clinicians frequently do not provide relevant clinical information to laboratories. Incomplete or inaccurate data slows down the reporting process.

Having established that the information currently provided to the NVRL with investigation requests was less than adequate, it was the aspiration of this work to establish an NVRL investigation request format which would be adopted by all partner organisations. This, it was hoped, would enforce some standardisation on the information received and would enlighten the partner organisations as to the data that is required by the NVRL to provide a better service. In addition this desired standardisation could be the first step in an electronic laboratory requesting solution that could revolutionise the transfer of laboratory requests and results.

The process of designing an NVRL investigation request format, as discussed in Chapter 4, yielded a number of interesting pieces of information. It was determined that most investigation requests do include the minimum data requirements, albeit in a variety of formats, but relevant clinical information is not provided about half the time. When provided with a personalised NVRL investigation request form, non-hospital based organisations were found to be more than happy to make use of them, and administrative staff involved in data entry found the forms straightforward to process. On analysis of the most recent set of NVRL investigation request forms, it was found that there was in fact no need for more than three types of forms to be distributed. These three investigation request forms correspond to the three investigation types available at the NVRL, namely antibody detection, molecular analysis and virus detection. As a consequence the NVRL management are now in the process of approving the design of three NVRL investigation request forms for distribution to all partner organisations. These investigation requests are based on the format as outlined in this work and include the mandatory items of the minimum data set for transmission of clinical laboratory test reports as discussed in Chapter 4.

This is a first step in the journey towards the introduction of an electronic laboratory requesting system which would be an element of the introduction of the electronic healthcare record. A vision of an electronic laboratory requesting system at the NVRL is discussed in Chapter 5. Implementation of electronic laboratory requesting however is a project which will require cooperation between partner organisations and available resources for investment. In the first instance it may be better to work with larger laboratories who have greater control over their data and have stronger technological support. With good-will an electronic laboratory requesting system will be possible, but the usefulness of the data may be limited without the adoption of standards. The adoption of standards is deemed necessary for improving the quality, comparability and usefulness of health information and for the implementation of an electronic healthcare record. The adoption of standards in electronic laboratory requesting will vastly improve data communication. The National Laboratory Information System Procurement plan for a new national LIS system to be supplied to all laboratories when replacing their existing systems, was recently awarded to CliniSys (formally Sysmed) who are the vendor for the NVRL LIS. The concept of a national LIS will facilitate laboratory data communication and will encourage electronic laboratory requesting. We are fortunate at the NVRL to already have this system in place and will be in an excellent position to take advantage of the situation.

It is quite clear that the electronic healthcare record is the way forward. In the National Health Information Strategy 2004 on page 57 it states:

'The electronic record is an evolving technology an architectural models for it are still being developed. Internationally, its implementation is still at a very early stage. In the Irish context the acute hospitals that have web-enabled modern ICT systems using relational database technologies with order entry and result communications functionality, would appear to have a good basis for its application. A unique identification is a key requirement for its full implementation'.

As we have discussed previously, at the NVRL we are a specialised testing and referral laboratory receiving specimens from all over the country. The matching of patient information would be made immeasurably easier if all patients had a unique identification number. A recent exercise at the NVRL in trying to ascertain the number of individuals in Ireland infected with a particular virus over the last 20 years (on behalf of the HPSC in order to plan for resources) it was proven to be a mammoth task due the inconsistency of the data and the moving around of patients.

A central theme throughout the National Health Information Strategy 2004 is the importance of transforming raw data into useful information to be applied to patient care, service planning and policy preparation. In his foreword in the National Health Information Strategy 2004, the then Minister for Health and Children, Micheal Martin T.D. states that

'Health information is a valuable resource'

and that

'health informatics and other fields are likely to transform our information base and provide more effective means to protect health, combat chronic disease and plan and deliver healthcare.'

He also states that

'At its core, the (Health Information) Strategy is about fostering a change of culture with respect to the development and application of health information at all levels.'

In the laboratory services we now need to 'foster a change of culture'. We must adopt standardisation, remove variable data elements and standards and ensure that laboratory results can be interpreted consistently. Most importantly we must contribute to the introduction of the electronic healthcare record by introducing electronic laboratory requesting.

Health information is a valuable resource; in the laboratory we provide health information; we must ensure that this information is of the highest quality.

Chapter 7: Conclusion

The aim of this project was to take the first steps towards electronic laboratory requesting by establishing a common investigation request format which would be adopted by all partner organisations. To do this it was decided to observe the current investigation formats received from the partner organisations and determine a common format which would be designed into a set of specific NVRL investigation request formats for distribution to the partner organisations. Once these NVRL investigation request formats had been designed, a select group of partner organisations were sent personalised versions of the form. The form was used and were found straightforward to process. A first step in the journey towards the introduction of an electronic laboratory requesting system was investigated. Implementation of electronic laboratory requesting however is a project which requires cooperation between partner organisations and available resources for investment. As indicated in the National Health Information Strategy 2004, we now need to 'foster a change of culture'. We must adopt standardisation, remove variable data elements and standards and ensure that laboratory results can be interpreted consistently. In this way we can contribute to the introduction of the electronic healthcare record.

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Appendix (i)

Appendix (ii)

Appendix (iii)