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# Towards an Electronic Register, Tracking and Management System for The National Childhood Primary Immunisation Programme

THESIS

7003

# Towards an Electronic Register, Tracking and Management System for The National Childhood Primary Immunisation Programme

Bernie Ó Cuilleanáin

A dissertation submitted to the University of Dublin,
In partial fulfilment of the requirements for the degree of
Master of Science in Health Informatics

2002

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## Abbreviations

| | |
|---|---|
| CCA | Community Care Area |
| CDC | Centers for Disease Control and Prevention |
| DH&C | Department of Health and Children |
| EHIBCC | European Health Industries Business Communications Council |
| EHSS | Eastern Health Shared Services |
| ERHA | Eastern Regional Health Authority |
| EU | European Union |
| FDA | Food and Drug Administration |
| GMSPB | General Medical Services Payments Board |
| GP | General Practitioner |
| GPIT | General Practice Information Technology |
| GRO | General Register's Office |
| ICGP | Irish College of General Practitioners |
| IMB | Irish Medicines Board |
| IMO | Irish Medical Organisation |
| ISSS | Integrated Social Services System |
| NDC | National Drug Code |
| NDSC | National Disease Surveillance Centre |
| NVAC | National Vaccine Advisory Committee |
| OMG | Object Management Group |
| OO | Object Orientated |
| PIMS | Practice Information Management System |
| PN | Practice Nurse |
| POS | Point of Service |
| PPSN | Personal Public Service Number |
| RCPI | Royal College of Physicians of Ireland |
| RFP | Request for Proposal |
| RSS | Reduced Space Symbology |
| SEHB | South Eastern Health Board |
| SRS | Software Requirements Specification |
| UCC | Uniform Code Council |
| UI | Unique Identifier |
| UML | Unified Modelling Language |
| UPR | Universal Patient Registration |
| VFM | Value for Money |
| VISI | Vaccine Identification Standards Initiative |
| WHO | World Health Organisation |

## Glossary

| | |
|---|---|
| Adjuvant | A substance that is used in a vaccine to improve the immune response |
| Adverse Event | Any undesirable response that may result from an immunisation |
| Anaphylaxis | An immediate and severe allergic response, following administration or ingestion of a substance |
| Antigen | Any substance eliciting an immunologic response such as the production of an antibody specific for that substance |
| Attenuated Vaccine | A vaccine that contains a live organism that has been weakened by chemicals or other processes so that it will produce an adequate immune response without causing the serious effects of an infection |
| Bacteria | Singular Bacterium. A large group of microscopic unicellular plant cells, which generally divide by transverse binary fission, possess rigid cell walls and are widely prevalent in nature |
| BCG | Bacille Calmette Guerin Vaccine. The vaccine used for the prevention of TB |
| Childhood Immunisation Programme | A series of immunisations that are given to prevent children contracting infectious diseases |
| Cold Chain | Vaccines are required to be stored between $2^0C - 8^0C$ in order to maintain their efficacy. This requirement is known as maintaining the 'cold chain' |
| Combination Vaccine | A combination of two or more antigens i.e. the Diphtheria/Tetanus/Pertussis in one vaccine product |
| Combivalent | Multiple antigens in one product |
| Concomitant | Vaccine doses given at the same time i.e. the simultaneous administration of the 5 in 1 and MeningitisC |
| Congenital Rubella Syndrome | Infection of the unborn child by the mother with rubella virus during the first three months resulting in a wide variety of severe congenital malformations |

| | |
|---|---|
| Contraindication | Any condition (especially disease) which renders some particular line of treatment improper or undesirable |
| Disease | An interruption or disturbance of the bodily functions or organs, which causes or threatens pain or weakness and or loss of function |
| DTAP | Adsorbed Diphtheria toxoid and Tetanus toxoid |
| Epidemic | An outbreak of disease that spreads within a specific region and or country |
| Herd Immunity | Level of vaccine uptake in order to protect the community against certain infectious diseases |
| Hib | Haemophilus Influenzae type b (Bacterium) |
| Immune | A state of being protected against infectious diseases |
| Immune system | The body's complex system which defends the body against infection, disease and foreign substances |
| Immunisation | A process or procedure that induces an organism's reaction to antigens rendering it able to resist an infection |
| Immunity | The condition of being immune or protected against infection, disease and foreign substances |
| Inoculation | Introduction of material i.e. vaccine and or bacteria into the body's tissues |
| IPV | Inactivated Polio Vaccine. Contains polioviruses of all three types which have been inactivated or weakened by formaldehyde |
| Live Vaccine | A vaccine that contains a living organism |
| MenC | The Meningococcal C conjugate vaccine |
| MMR | Measles, Mumps and Rubella (Combivalent type) |
| Monovalent | A vaccine that contains the antigen of one infectious organism i.e. Tetanus |
| OPV | Oral Polio Vaccine. A 'live' vaccine where disease inducing ability has been attenuated |
| Outbreak | Spread of disease, which occurs in a short period of time and in a limited geographic location |

| | |
|---|---|
| Pandemic | An outbreak of disease that spreads throughout the world |
| Pathogen | Bacteria, viruses, parasites or fungi that have the capability to cause disease in humans |
| Td | Tetanus and diphtheria |
| Toxoid | A modified bacterial toxin that has been rendered non-toxic but has the ability to stimulate the formation of antitoxin |
| Immunisation | The term used to refer to the administration of any vaccine antigen or toxoid |
| Immunisation Schedule | Guidelines of immunisations that are recommended for specific ages and or circumstances |
| Vaccine | A product of weakened and or killed micro organism given for the prevention or treatment of infectious diseases |
| Virus | A tiny intracellular parasite that grows and reproduces in living cells |

**Abstract**

This dissertation was undertaken to assess the need for and requirements of an Electronic Register, Tracking and Management System for the National Childhood Primary Immunisation Programme and to propose a design for such a system.

An effective system will register the child's details and record the vaccine product details and the General Practitioner's details in the child's Electronic healthcare record at the time of each immunisation consultation. The supply chain management of vaccine products will be integrated with the tracking and management system.

The National Children's Primary Immunisation Programme is administered by General Practitioners to an annual cohort of children in excess of 54,000. The Irish State provides the Childhood Immunisation Programme free of charge to all children. There is no obligation on parents to have their children immunised. There is no financial inducement, legal or social requirement to have children immunised prior to starting school.

In this dissertation the procurement, storage and administration of vaccine products and the management of immunisation data were studied in two Health Boards areas.

Presently a pen and paper system is primarily used to capture immunisation consultation data, which is then forwarded by post to the local Health Board office. Normally vaccines are collected by practice staff from the Community Care Area office using an inadequate transport system for vaccine products. This process has developed as a local response to the management needs of the Childhood Immunisation Programme rather than as part of a logically designed system.

An ICT-based system is proposed which will combine birth registration data with a National Unique Identifier to form a 100% accurate population register for the National Children's Immunisation Programme. Bar-coding and scanning technology will be utilised to accurately capture essential vaccine product data at point of service (POS) and when necessary the children's and GP's details.

A small number of General Practices were selected for the study. A questionnaire was prepared and interviews and observational studies were carried out. This process allowed the author to study the present immunisation management system in General Practice and to delineate the problems and the difficulties of the existing system. The specific requirements for the proposed electronic system were gathered. Using the material collected from the General Practices, the User Requirements were defined and the Domain Analysis and the proposed Design were portrayed using the Unified Modelling Language (UML).

The major benefits of the system proposed in this dissertation include the early detection of rare adverse reactions, the elimination of transcription errors, the creation of a concise Electronic healthcare record for scientific studies, for medico legal purposes, for the early detection of communities with low uptake and for the tracking of individual defaulters. Electronic healthcare records have the potential to significantly reduce the tracking and management cost of immunisation and other preventative health interventions.

# Chapter 1 Introduction

## 1.1 Background

In excess of 54,000 children are born in Ireland annually (CSO, 2001). The State offers immunisation to these children to protect against ten infectious diseases, nine of which are administered between the ages of 2 months and 15 months under the National Childhood Primary Immunisation Programme. In addition to the children born in Ireland up to 10,000 more children require immunisation due to the return to Ireland of their emigrant parents or due to the immigration of non-nationals.

Presently the tracking and management of data pertaining to childhood immunisation in General Practices is a pen and paper based system. The recording of product details which are entered manually has been shown to be subject to significant error (Grabenstein, 2002). Following the immunisation of a child the completed data is sent by post to the relevant Health Boards.

The vaccine products are collected by a practice staff member or spouse from the local Community Care Area using an inadequate transport system which is not compliant with EU regulations (Office for Health Gain, 2002). The ordering and collection of vaccine products is haphazard, frustrating for the practice staff and unnecessarily time consuming.

## 1.2 Objectives

This dissertation will examine the present data management product storage and distribution in the National Childhood Primary Immunisation Programme and will outline its deficiencies and inadequacies. The need for and benefits of a proposed design for an Electronic Register, Tracking and Management System for the National Childhood Primary Immunisation Programme will be discussed.

The initial objectives are to establish:

- The workload both clinically and administratively of the present Immunisation Data Management System

- The current thinking internationally on the management programme of the data pertaining to Childhood Immunisation Programmes

- The international concepts of a computer based Data Management and Tracking System and their usefulness in increasing the uptake of vaccines

- How Information Technology should improve the accuracy of data capture and management

- How an Electronic Tracking and Management System based on a National Register with automatic data capture technology would allow real time analysis of the programme and judicious and rapid management interventions

The final objective is to propose a model for a design of an Electronic Register, Tracking and Management System for the National Childhood Primary Immunisation Programme based on the User Requirements utilising the Unified Modelling Language (UML).

## 1.3 The Immunisation Schedule

The child should be brought for its first immunisation at two months of age and for its final childhood primary immunisation at 15 months of age. The schedule for each year's cohort of children spans three calendar years.

The present Immunisation Schedule, for the nine infectious diseases for which the General Practitioner (GP) vaccinate, uses a mixture of combivalent and monovalent vaccines. Combivalent vaccines combine into one unit dose vaccine product the

antigens of a number of infectious organisms. An antigen contains the biological code of an infectious organism which is incorporated into a vaccine. The antigen primes the recipient's immune system so that it can attack and destroy the infectious organism should it invade the recipient in the future. This is known as the immune response. The use of combivalent vaccines reduces the number of injections a child receives to complete this programme.

The Immunisation Schedule between 2 months and 15 months is shown in Table 1:

| **Month** | **[1)]5 in 1 Vaccine** | **MenC Vaccine** | **[2)]MMR Vaccine** |
|---|---|---|---|
| 2 | * | * | |
| 4 | * | * | |
| 6 | * | * | |
| 15 | | | * |

[1)]The 5 in 1 vaccines contain the antigens of Diphtheria, Tetanus, Pertussis, Inactivated Polio Vaccine and Haemophillus Influenzae type B bacteria

[2)]The MMR vaccine contains the antigens of Measles, Mumps and Rubella viruses

**Table 1: The Immunisation Schedule (Immunisation Advisory Committee, 2002)**

## 1.4 Scope

The task of vaccinating in excess of 54,000 children annually and managing the data of both the child, the vaccinator and the vaccine product is both time consuming and tedious and yet deserves and requires scientific precision. The Childhood Immunisation Programme starts a few days after birth and is completed at school leaving age. For this study the age group from 2 to 15 months was selected as this section of the Primary Childhood Immunisation Programme is carried out in Ireland by the GPs since 1996.

This portion of the Childhood Immunisation Programme will be used to demonstrate the requirements of an Electronic Register, Tracking and Management System based on a National Electronic Register.

There are in excess of 2330 General Practitioners, between part time and full time General Practitioners, working from approximately 1700 centres of practice (Office for Health Gain, 2002).

## 1.5 History

Edward Jenner, an English country General Practitioner (GP) was the founding father of immunisation. He observed that cow maids who had contracted Cowpox, a viral infection similar to Smallpox but which was much less virulent, were subsequently protected from Smallpox epidemics. In 1796, he demonstrated that scratching fluid from a Cowpox lesion into the skin of human volunteers, subsequently prevented them from contracting Smallpox. Immunisation became an accepted procedure during the 19$^{th}$ century. Vaccines were developed for other infectious diseases such as Rabies and Plague (Bland, 1998). A list of the introduction dates for first generation vaccines for humans is given in Appendix B.

The Irish National Primary Immunisation Programme in 2002 provides for immunisation against ten infectious diseases. Tuberculosis (BCG) is administered shortly after birth by doctors in the public health preventative service in specialised clinics. Vaccines which provide protection against nine other diseases, Diphtheria, Tetanus (Lockjaw), Pertussis (Whooping Cough), Poliomyelitis, Haemophillus Influenzae type B (Hib), Meningococcal Meningitis, Measles, Mumps and Rubella are administered to the children by their General Practitioners. A brief data dictionary on the vaccine preventable diseases is given in Appendix C.

A major advantage of the Irish Immunisation Programme is that it is provided free of charge by the State. However, a major disadvantage is that parents can decide not to have their child vaccinated. There is no financial inducement and no legal or social

requirement to have their children vaccinated prior to starting school in Ireland as there is in some other countries.

## 1.6 User Requirements

The use of computer based immunization tracking systems by various health care providers has to date been unsatisfactory due to the quality of data capture by clinical and administrative staff. Data entry has been time consuming, expensive and subject to significant errors (Adams et al, 2000).

In order to develop a software application that will suit the National Childhood Immunisation Programme, the understanding of the User Requirements is a prerequisite. The General Practice module will be studied in particular and its integration with the Health Board, the National Register and other agencies.

The success of the proposed software application system will depend on the precision of the assessment of the user requirements and analysis process. Several methods will be employed including background information materials, questionnaires, face-to-face interviews, and personal observation. As Schmuller points out "if you don't understand what the client wants you will never build the right system" (Schmuller, 1999).

During the interviewing stage of the project the present minimal data items used in the Childhood Immunisation Programme will be discussed and recorded. These data items will be enhanced in order to meet the requirements of the proposed Electronic Register, Tracking and Management System. The Domain Analysis will define the minimal dataset and the requirements of the Childhood Immunisation Programme which will facilitate the initiation of the design phase using the Unified Modelling Language (UML).

## 1.7 The Unified Modelling Language (UML)

The UML will help set out the user specifications for an Electronic Register Tracking and Management System for the National Childhood Primary Immunisation Programme.

The UML is a modelling language which allows the system analyst to section complex problems into smaller and more manageable parts using an accepted set of notations. A standard set of diagramming techniques is used which provides a graphical representation of the system (Dennis et al, 2002). Each diagram plays a different role in the development process (Schmuller, 1999). The success of the proposed system is dependant on understanding the needs of the users allowing the analyst, the client/user and the software developer communicate using a common language.

Once the interviewing and questionnaire process is complete the minimum dataset will be developed. The key users of the system will be the GPs and the Practice Nurses who are supported in some practices by secretaries and occasionally by Practice Managers. The GP will be identified as being the main practice stakeholder and end owner of the system.

The results of the questionnaires and the interviews will be used to define a Domain Analysis of the patient immunisation consultation and data management. The author's background knowledge of the domain as a Practice Nurse will help in this process. The Domain Analysis will be demonstrated diagrammatically and discussed.

The nouns of the domain will be listed and will be utilised to identify the Classes and their relationships to each other. From the information gathered in the Class Diagrams, a Use Case Diagram will be developed which will highlight how the user will interact with the system and the functionality of the system. Each of the Classes and the Use Case Diagrams will be discussed in detail.

To complete the process the explicit requirements will be defined. These requirements will demonstrate what the system will do for the user and how the user will interact with the system.

## 1.8 Brief Guide to Dissertation

Chapter 2 reviews the current literature, with particular reference to the international developments and the benefits to be obtained from developing an Electronic Register, Tracking and Management System

Chapter 3 looks at the System Requirements Specifications and the Requirements Analysis of the proposed system

Chapter 4 describes the Problem Statement, and looks at the questionnaire design, the study methods, the results and the analysis

Chapter 5 defines and describes the Class and Use Case Diagrams and studies the Dynamic Models

Chapter 6 outlines and defines the Functional Requirements

Chapter 7 concludes the study with a discussion which will include primarily the findings, the benefits of the proposed system, the limitations of the study and future work. It will also revise the present system and discuss the important issues for consideration in order to develop an Electronic Register, Tracking and Management System

Note: Three terms are used interchangeably internationally, Immunisation, Vaccination and Inoculation. In this study the term 'Immunisation' will be used.

# Chapter 2 Literature Review

## 2.1 Introduction

Mass immunisation against infectious diseases has literally transformed the planet (Liu, 1999). It is a most cost effective and successful health intervention whose very success in eliminating infectious diseases challenges it's own continuity. Many parents, grand parents and health professionals have no experience of the avoided infectious diseases (Downs, 2001). There has been extensive sensational media coverage of putative reactions, sub standard production, lack of efficacy and excessive efficacy of vaccines. Some parents are fearful of harming their child by consenting to immunisation. Doubt has been cast on the relevance and safety of childhood immunisations where the infectious disease is no longer prevalent in the community (Bedford et al, 2000). Downs (2001) states that motivated and trusted GPs, who can devote time to giving information overcome parental concerns.

Significant decreases in the uptake of vaccines in a community has resulted in the rapid re-emergence of infectious diseases, as was seen in the former USSR following it's dissolution and the removal of compulsory immunisation (Gangarosa et al, 1998). In Britain a drop in the uptake of Pertussis vaccine, due to parental fears of adverse reactions, was followed by the re-emergence of Whooping Cough (Pertussis) (Gangarosa et al, 1998). An outbreak of measles in 2000 occurred in Dublin following a fall in the uptake of the MMR vaccine. There were 1253 cases of Measles reported of which 6 required intensive care. There were three Measles related deaths (Eastern Regional Health Authority, 2000).

Smallpox, for which the first vaccine was developed, has been eliminated for many years (Bedford et al, 2000). Smallpox immunisation levels have not been maintained but Smallpox has not re-emerged as the natural pool of the virus was eliminated. Following September 11$^{th}$ 2001, the fear that Smallpox might be reintroduced by bio

terrorists resulted in large quantities of Smallpox vaccines being produced and stored worldwide.

Vaccine products in general clinical use are extensively monitored for infrequently occurring adverse reactions. In Ireland the Irish Medicines Board (IMB) are responsible for gathering this information (Oireachtas Joint Committee on Health and Children, 2001).

## 2.2 The Present System

A fresh cohort of babies require immunisation annually with an increasing number of vaccines against infectious diseases (Adams et al, 2000). In Ireland the vaccinator records his details, the child's details and the vaccine product details at each immunisation consultation and forwards this information to the Health Board. This information is entered manually into the Health Board computer database system.

Difficulties arise in aggregating data due to name and or address changes and the lack of a National Unique Identifier. Manual data recording and management is labour intensive and is subject to human inaccuracies in the recording of the alphanumeric details of the products administered, of the child vaccinated and of the vaccinator and in the subsequent transfer of the data to a computer system. It has been shown that the details entered either by vaccinators or during subsequent transcription is less than complete or accurate (Office for Health Gain, 2002).

The arrival of a large number of people seeking asylum in Ireland is estimated at 900 per month. This has increased the administrative burden due to language barriers and difficult names. There has been an estimated 42% increase in the numbers seeking asylum in the year 2000 over the numbers in 1999 (Eastern Regional Health Authority, 2000). In 2001, 1272 non-nationals were delivered in the Rotunda Hospital in Dublin. This figure represented 19.7% of the total number of babies born for that year (Geary M, 2002).

At present the individual Health Board electronic record systems are not linked resulting in a failure to collate data on children who are vaccinated serially by GPs in different Health Board areas.

In the Eastern Regional Health Authority (ERHA) area vaccine products are collected by General Practice staff from their local Community Care Area (CCA) office. The ordering and supply of vaccine products are at the best haphazard, as without practice registers few GPs can accurately project their vaccine usage. The Office for Health Gain in their recent report state that 'it is not apparent that current stock management and control procedures in all community service areas ensure that all vaccines are available to end users in the quantities required, when required, or in date for the likely period of use with 'cold chain' maintained and recorded as such '(Office of Health Gain, 2002).

## 2.3 The Challenge

The World Health Organisation (WHO) the European Union (EU) and the United States (US) recognise the challenge that post licensing surveillance of vaccines poses for early recognition of rare adverse vaccine reactions. With an Irish annual cohort of 54,000 new babies to be vaccinated an equivalent figure for the United States of 4 million and a worldwide figure of 130 million, the enormity of the task of vaccine data capture, recording and collation for national and international purposes becomes apparent. This challenge has been recognised internationally and it is accepted that it requires national commitment and international co-operation and standards (Heijbel, 2001).

## 2.4 Identifying the Problems of the Domain

In order to comply with the recommended standards of data accuracy and to record the volume of data pertaining to a National Childhood Primary Immunisation

Programme key problems need to be identified, assessed and eliminated with the introduction of new protocols and technologies.

Adams et al (1999) reported that prior to the introduction of point of service (POS) data entry 37.3% of administered doses were missing from the tracking system. With the introduction of more vaccines into the Immunisation Schedule, tracking of immunisation data will be critical to identifying missed doses in children (Adams et al, 2000).

The use of various schedules in different administrative areas and of vaccine products produced by competing manufacturers can result in difficulties where children attend multiple vaccine providers. Combivalent vaccines containing acellular Pertussis antigen should be sourced from the same manufacturer for repeated immunisations of a child (Committee on Infectious Diseases, United States, 1999).

The administrative time required and the delays incurred in tracing defective vaccine products and their recipients using a paper based record system are all too apparent. When there has been a prolonged passage of time following the use of a defective product the task is even greater.

In 1969 a healthy child suffered severe brain damage following the administration of the first dose of Diphtheria Tetanus Pertussis (DTP) vaccine. It was alleged that the damage had been caused by a reaction to the Pertussis component of the vaccine. An award was given to the appellant by the Irish High Court thirty three years later (Finlay, 1992). The Department of Health and Children is now obliged, after a lapse of more than thirty three years, to track the other recipients of that vaccine batch.

In 1998 and 1999 it was discovered that 4500 out of date doses of poliomyelitis vaccine were given by GPs, during an investigation into the administration of oral Polio vaccine products contaminated during their manufacture with serum donated by a British donor, who was subsequently found to have variant Creutzfeldt Jacob Disease (vCJD) (Payne, 2001).

A recent press release on behalf of The Minister for Health and Children stated that the Irish Medicines Board (IMB) had advised him that a single batch of BCG vaccine was being recalled from the Irish Market due to the possibility of reduced effectiveness. It continued to report that 'there is no health threat to persons who received the vaccine from the batch concerned other than they may not have received immunity from the vaccine '(Department of Health and Children, 2002).

The production of comprehensive immunisation records is difficult in the Irish setting where immunisations have been given by different doctors. Under Irish Law the immunisation of children is not mandatory. An increasing number of institutions now require a vaccine record, as do children travelling abroad. With the current system, when immunisations have been given by different GPs, it is difficult to generate a vaccine status report (Committee on Infectious Diseases, United States, 1999).

Without adequate investment in information and clinical computer technologies the advantages of Electronic healthcare records cannot be achieved. The Food and Drug Administration (FDA) in the United States have said that the investment required would be significantly less than the present cost of drug and biological errors (Food and Drug Administration, 2001). Unless investments are made by governments towards some of the fixed costs associated with computer technology, many doctors will continue to use hand written medical records, at a huge potential risk to patients (Cabral, 1997).

Poor handwriting leads to misunderstandings among health care professionals and is both risky and time consuming (Cabral, 1997). In 1994 Wilton and Pennisi evaluated the accuracy of transcribed computer-stored immunisation data and found an overall transcription error rate of at least 10.2%. Grabenstein (2002) remarked that when one has to read someone else's records, 'it is often a challenge to decipher hastily scribbled notations and omitted or ambiguous data and erroneous transcriptions inevitably occur'. Busy health care providers have the task of manually transcribing vaccine identities, manufacturer names and lot numbers into patient's records and this task competes with other clinical responsibilities and limited time (Grabenstein, 2002).

Failure to achieve 95% uptake targets is a continuing challenge to Health authorities across the developed world. In Ireland the National Disease Surveillance Centre (NDSC) reported an immunisation uptake level of 86% in 2000 falling to 84% in 2001 (NDSC, 2001). The most noticeable decrease was seen with MMR, which dropped from 79% to 73% (NDSC, 2002).

The use of dedicated immunisation clinics with limited appointment systems have been reported as being an obstacle to increasing vaccine uptake levels in a community. The National Vaccine Advisory Committee (NVAC), in the United States, as reported by the Oireachtas Joint Committee on Health and Children advised that appointment only systems acted as barriers to immunisation and that immunisations should be available on a walk in basis (Oireachtas Joint Committee on Health and Children, 2001). NVAC also advised that all patient contacts be used to check immunisation uptake (Oireachtas Joint Committee on Health and Children, 2001). Downs (2001) points out that low rates of opportunistic immunisation are attributed to GP's time constraints.

Several studies have recorded that parental recall of their children's immunisation history is unreliable as the only source of the immunisation record (Rodewald et al, 1999). One study showed that mothers accurately recalled the immunisation status of children younger than six months of age but as the child got older mothers had difficulty remembering the vaccine status and tended to underestimate the number of vaccine doses given to the child (Valadez et al, 1992). In another study, high percentages were recorded from mothers for both underestimating and overestimating the number of vaccines given to their children (Suarez et al, 1997). Extra vaccine doses are then administered when the vaccinator is unsure of the child's vaccine status, which leads to unnecessary waste.

Failure to vaccinate in childhood against the Rubella virus may subsequently expose young women to the horror of giving birth to their child with the Congenital Rubella Syndrome consisting of abnormalities of the heart, brain, eyes, ears and the body in general (Oireachtas Joint committee on Health and Children, 2001). The National Virus Reference Laboratory reported that antenatal screening, in Dublin's three

Maternity Hospitals for Rubella immune status showed that 96% of the cohort of women registered for the first six months of 2001 were immune. This percentage figure fell to 94% and 93% in the following two six month periods respectively (McDonnell, 2002). The 4%, 6% and 7% of the cohorts of women screened in these time periods who were non-immune were at risk of contracting Rubella during their pregnancies. These figures demonstrate the need for urgent intervention to ensure that all women are immune to Rubella prior to conceiving.

A comparative and prospective study in Dublin showed that the actual immunisation uptake was greater than that reported to the Health Board. The results showed a significant underestimation by a factor of 8%-21% (Harrington et al, 2000). This study would appear to illustrate the need for user-friendly point of service immunisation data entry into an electronic system that avoids the need for multiple documenting and transcription of information. Downs (2001) similarly reported that under reporting of immunisations by GPs might be as high as 10%. He states also that failure to capture data may rarely occur at the Australian Childhood Immunisation Register (ACIR). The under reporting and failure to capture data results in loss of value for money (VFM) as it results in an unnecessary administrative workload tracing children apparently overdue for immunisation (Downs, 2001).

Parents of young children move homes, change their doctor and can also change the child's name both officially and unofficially. These changes create administrative difficulties for Health authorities whose responsibility it is to track, collate and record vaccine data. A study in Dublin found a mobility of 47% in a cohort of 270 babies before their fourth birthday (Clarke, 1993). The 1994 United States National Health Interview Survey documented that approximately 25% of children had multiple vaccine providers in the first two years of life and that frequently their vaccine records were unavailable or incomplete (Committee on Infectious Diseases, United States, 1999).

Immunisation should be a safe medical intervention. Minor reactions may occur following immunisation including local swelling and pain at the injection site and sometimes a slight temperature. Serious complications may rarely occur following

immunisation. Vaccines are administered to healthy persons, frequently infants and children. The threshold for acceptable risk of adverse reactions to vaccines is lower than that for therapeutic agents, which are administered to ill persons (Chen et al, 1997). Melgaard (2001) tells us that 'adverse events are having an increasingly important effect on public confidence in immunizations'. In Ireland all adverse reactions should be reported to the Irish Medicines Board. In the US specified adverse reactions must be reported using the Vaccine Adverse Event Reporting System (VAERS). Twenty percent of the 10,000 –12,000 VAERS reports filed annually are classified as serious (they cause disability, hospitalisation, life threatening illness or death (Chen et al, 1998).

Heijbel (2001) reported that in a series of two hundred consecutive reports of adverse events following immunisation submitted to the Swedish Medical Products Agency (SMPA), only 33% documented the lot number. He commented that as more vaccines and vaccine combinations reached the market the workload involved in transcribing vaccine information data and the risk of transcription errors will increase.

## 2.5 The 'Cold Chain'

Vaccines, which are made up of proteins, nucleic acids, lipids and carbohydrates, are heat sensitive. Its storage temperature determines the degradation rate of a vaccine. Raised vaccine temperature causes extensive degradation (Galazka et al, 1998).

All vaccines are biological products and are subject to regulation. Their care, transport and storage are subject to regulation both by the Irish Medicines Board (IMB) and the European Union (Office for Health Gain, 2002). In order to maintain the efficacy of vaccines they must be stored between $2^0$C – $8^0$C from the time of manufacture until the time they are administered. This requirement for storage within this temperature range by the manufacturers, transporters, agents and GPs is known as maintaining the 'cold chain' (World Health Organisation, 2000). The 'cold chain' is not peculiar to the vaccine and biological industries, but also applies to other

industries such as the food industry. In the existing system, the attention to maintaining the 'cold chain' has gradually improved in recent years but the standard is not yet satisfactory (Office for Health Gain, 2002).

The South Eastern Health Board (SEHB) awarded a company called Temperature Control Pharmaceuticals (TCP) in October 2001 to distribute vaccines from the SEHB's main Hospital Pharmacies to the General Practices using temperature controlled vans. This is the only Health Board that uses Hospital Pharmacies to store and manage vaccine products and that uses distribution vehicles that guarantee the maintenance of the prescribed environmental temperature. This service complies with the EU requirements for the transport of biological products. TCP have been licensed by the IMB for storage of 'cold chain' products as well as their distribution (McCormack, 2002).

Other Health Boards do not use the services of Pharmacists or their assistants to manage the storage and allocation of vaccine products. This duty is normally an add on responsibility given to a staff member without adequate training (Office of Health Gain, 2002).

Although proper refrigeration is often taken for granted, errors in vaccine handling may occur more commonly than is generally assumed. Substantial drops in vaccine potency caused by unsatisfactory conditions of delivery and storage have been reported. Studies in Hungary, Poland, Britain and the North of Ireland showed considerable weakness in the 'cold chain' during vaccine transportation from manufacturers or from central distribution points to health clinics (Galazka et al, 1998).

In 1996 the World Health Organisation (WHO) recommended the use of a new technical device known as a vaccine vial monitor (VVM) as part of its Expanded Programme of Immunisation (EPI). In the United States all oral Polio vaccines carry a VVM, which is a small circle of colour, printed on the label of vaccine vials. The vaccine vial monitor changes colour as it is exposed to heat. The use of the VVMs help healthcare workers determine whether vaccines have been spoilt by too much exposure to heat while in transit. The main benefits of the VVMs are that they

reduce wastage of good vaccines and ensure that potent and efficacious vaccines are administered to the children (World Health Organisation, 2000).

Product Liability Law places responsibilities on all who handle a product prior to its sale to a customer or in the healthcare industry prior to its administration to a patient. Accordingly, failure to maintain the 'cold chain' could render a doctor or Health Authority or agent liable for a defective product under the Product Liability Law (Irish Government, 1999).

The recent Office for Health Gain Report states that ' the cold chain record, batch numbers and expiry date of stock is not always checked on receipt of vaccines. The current processes operating at Community Care Area level do not in all cases comply with best practice and do not ensure that ordering and invoice certification processes for vaccines are adequate and verifiable by batch number at every stage of the supply chain from manufacturer's agent through to end user. The issue of forecasting vaccine requirements at regional levels in an appropriately timely manner needs to be developed. As many vaccines are now solely manufactured to order, this timeframe is essential to ensure security of supply. The current arrangements for stock management at regional level are not comprehensive and are unsustainable in the longer term. The direct delivery of vaccines to end users would eliminate the need for multiple storage depots in Health Boards. It will be necessary to put in place arrangements that will systematically verify continuous maintenance of the 'cold-chain' for all vaccines at all stages, during transportation and ultimate storage'. In 2001 regulations regarding the 'Carriage of Dangerous Goods by Road' were introduced which have implications for the transportation of vaccines by road (The Office for Health Gain, 2002).

## 2.6 The Need for a National Unique Identifier

Population Registers are a pre-requisite for health interventions, the absence of which presents major problems in accessing the target population and achieving high intervention rates. In the early 1990's a 'pilot' mammography screening project was carried out using the data from three separate registers and self-registration, which

gave a total representative figure of 86.3% of the target population. Without a 100% accurate register of the women in the target population 13.7% were excluded from early diagnosis and treatment of breast cancer (O'Herlihy et al, 1998).

A joint study of morbidity carried out between General Practitioners and the South Eastern Health Board (SEHB) in 1998-1999 included the following problems:

- The lack of a national registration system for both General Medical Services (GMS) and private patients
- The need for a national messaging standard to enable the electronic exchange of data between General Practices and other agencies, including Health Boards
- The need for robust GP software systems that allow easy extraction of data
- Dedicated resources at General Practice and Health Board level in order to plan and track morbidity data

(O'Mahony et al, 2001).

The Primary Health Care Strategy (2001) proposed that population health services will be facilitated and that funding for screening and early intervention programmes will be given priority (Department of Health and Children, 2001). Without a National Population Register, which can be readily accessed for approved screening programmes, patients will continue to lose out on early diagnosis of diseases and preventative health interventions.

The Irish College of General Practitioners and the Irish Medical Organisation recommend a policy of Universal Patient Registration (UPR) (ICGP/IMO, 2001).

The Integrated Social Services System Report published in 1996, proposed the computerisation of the General Register Office's (GRO) data on births, marriages and deaths. The PPS Number was recommended as the system's Unique Identifier and it was proposed that the PPS Number should be allocated at the registration of birth (ISSS Report 1996).

A child's surname where the birth was registered after October 1997 can be readily changed when both parents apply to the court for re-registration (Social Welfare Act 2002).

A data link between the Health Boards and children's allowance payments has been recommended to reduce the administrative burden created by the problem of patient mobility (Oireachtas Joint Committee on Health and Children, 2001). This suggestion would be a critical link in the proposed system of this study.

The Oireachtas Joint Committee on Health and Children (2001) recommend that the Electronic healthcare records of all Health Boards be linked using recognised technology standards both for the Electronic records and for communication between the systems. The committee also recommended that each child's data be recorded at birth registration and it's Unique PPS Number be assigned at birth and that this information be passed to the Health Boards to establish the Primary Immunisation Programme's Electronic Register.

It is recommended that the Birth Registers should be linked with each Health Board and the Health Boards should be linked to the Irish Medicines Board and the GPs to the childhood immunisation record (Oireachtas Joint Committee on Health and Children, 2001).

## 2.7 The Introduction of an Immunisation Registry

Wood et al (1999) states that 'an Immunisation Registry is a computerised database of information on children (usually pre school age children) in a defined population (i.e. those enrolled in a health maintenance organisation or living in a specific geographical area), which is used to record and track all immunisations received by each child. The functional target for these Registries is to maintain records on 95% of all eligible 2 year old children in the target population and to provide an electronic immunisation record that is accessible to vaccine providers'.

The National Immunisation Programme in the United States recognise the need for Immunisation Registries to achieve high immunisation rates for vaccine preventable diseases.

The logistical challenge of vaccinating the annual cohort of 4 million babies born in the United States is threatened by:

- An increasingly complex schedule of vaccines
- Incomplete immunisation records scattered across healthcare providers
- Missed opportunities for immunisations because of the failure to use reminder/recall systems
- Inaccurate assessment of vaccine status by parents and providers
- Growing public complacency about the need for immunisation as a result of the successful elimination of vaccine preventable disease (National Immunization Program, United States, 2001)

Population Based Immunization Registries in the United States has developed rapidly due to the support of the National Immunization Program, a programme within the CDC. These Registries have been developed to comply with national standards to protect privacy, confidentially, data security and other technical functions and to develop immunisation decision-support algorithms (Simpson, 2001).

It is impossible to speak accurately of immunisation uptake in these communities or to target the parents of the non-vaccinated children and to encourage them to bring their children for immunisation because in some States in the United States, parental consent is required for the registration of their child in the vaccine register. In other States parental consent is implied and the child's data is transferred to the Immunisation Register electronically from the States Vital Record's Department. Children can move to these states following birth and be omitted from the Register (Bryant, 2002).

In order to ensure that all children are vaccinated or that their parents are offered the opportunity to have their child vaccinated requires a precise working Register. Without such a Register it is impossible to determine the precise percentage of

immunisation uptake for any community. Using electronic immunisation Registries as a tool to achieve high immunisation rates while minimising workload is recommended. The Registries would create a complete record of children's immunisations by aggregating records from different sources and thus help to minimise both under and over immunisation (Jenders et al 2000).

Accurate record keeping of vaccine products and in particular of new combination vaccines with longer generic names and novel trade names which continue to be licensed for the Primary Immunisation Programme, will require the use of new technology to avoid omissions and inaccuracies. Accurate and convenient vaccine product data capture and entry into medical records and Immunisation Registries will be essential in new improved systems (Committee on Infectious Diseases, United States, 1999).

Wood et al (1999) reported that Immunisation Registries should be used to increase the uptake of vaccines in geographical areas with low immunisation and to diminish the number of children who are given unnecessary vaccine doses. It has been shown that using a computer during consultations improves immunisation rates by 8-18% (Sullivan, 1995). Immunisation tracking with reminders and recalls has been shown to improve immunisation delivery (Lieu et al, 1998).

The current system for collation and distribution of immunisation data results in unnecessary delays. The proposed system would provide the GPs, Health Boards and other agencies with real time data allowing for early interventions where and when required. An Electronic Register, Tracking and Management System which meets international standards for compatibility with similar systems in other jurisdictions is now a pre-requisite for good clinical and audit practice by health providers responsible for mass immunisation programmes (Heijbel, 2001).

Electronic medical records should be compiled accurately so that the collected data may be used for scientific research. These records will be precise for medico-legal purposes. An electronic database will assist the tracking of defaulters, it will provide local Public Health Practitioners and the National Disease Surveillance Centre (NDSC) with real-time notice of low uptake of vaccines in particular communities.

Early interventions will help to avoid local outbreaks of infectious diseases. The tracking of defective vaccine products so that they may be withdrawn expeditiously will be facilitated by such a system (Food and Drug Administration, United States, 2001). Such a Register will also provide an early warning of possible adverse reactions. The system will automatically invoice the appropriate finance department in the Health authority for the fees due to the GP for each consultation and should allow the GP access his financial fee statement. It will provide statistical analysis for both clinical and financial audit (Office for Health Gain, 2002, Oireachtas Joint Committee on Health and Children, 2001).

## 2.8 The Automatic Data Capture Technology

Document scanning has been reported in a restricted number of clinical applications. This method whereby scanned documents with storage and display of digital images of the paper record, can improve access to clinical information. However, the information in the record cannot be efficiently searched and aggregated. It is also pointed out that illegibility is often a problem in scanned images (Shiffman et al, 1997).

Ean International is a non-profit making international association that has the task of taking a leading role in the establishment of a global multi-industry system of identification and communication for products and services based on internationally accepted and business led standards (Ean International, Belgium, 2001). It works in association with the Uniform Code Council (UCC) in the United States.

Ean International state that the use of bar codes in healthcare product identification would provide efficiencies in the healthcare supply chain and provide cost savings. Amongst the benefits would be accurate data capture at point of clinical use, consistent accuracy in the handling of logistical units, shared information on product movement, accurate maintenance of inventory and the recording of data at each inventory movement including identification code, batch number and expiry date. Ean International also states that 'if product recall becomes necessary bar coding is

the key to knowing when and to whom the product was shipped' (Ean International, Belgium, 2001).

Bar codes use parallel bars and intervening spaces of various widths which when organised in different patterns represent different alphanumeric characters. Bar code language is known as symbology and it represents the specifications used to construct different patterns. There are many different symbologies with different rules for encoding characters. Most bar codes are linear, encoding in one dimension only. Two dimensional symbologies have recently being introduced where more data has to be encoded and where space is limited. Reduced Space Symbology (RSS) and Composite Symbology are the latest development in space-constrained identification, which allow for the co-existence of symbologies already being used (Ean International, Belgium, 2001).

Unit doses can be identified using the EAN/UCC article number in the UCC/EAN – 128 symbology and also using application identifiers and EHIBCC/HIBCC supplier labelling standards. The UCC/EAN standards defined specifically the conditions of use of each bar coding unit. The EAN/UCC article number uniquely identifies all products at each level of packaging worldwide. The flexible process of uniqueness management allows healthcare suppliers/labellers a variety of options to meet their respective business environment needs (Ean International, Belgium, 2001).

Heijbel (2001) commented that in the commercial world bar code labelling had long been used to allow rapid and accurate transcription of data. He also noted that improvements in bar coding would require expensive scanners at each immunisation site. He recommended that bar coded label forms could be sent to a central scanning centre.

The Food and Drug Administration (FDA) in the United States are considering the introduction of bar coding of all drug and biological products, which would encode the National Drug Code as well as the lot number and expiry date (Food and Drug Administration, United States, 2001). In the United States Federal Register, the Food and Drug Administration (FDA) indicates that the present law allows it to make regulations requiring drug and biological manufacturers to label their products with

bar codes that would encode the National Drug Code Number, the lot number and expiry date which would comply with the FDA's regulations on the information required for good manufacturing practice. The FDA is presently examining the potential costs and benefits associated with bar coding, depending on the amount of information encoded. The current estimate is between 500 million dollars and 1.4 billion dollars over a ten year period for both medicines and biologicals. The benefit would be a reduction in medication errors and resulting mortality and morbidity, producing cost savings of 138 to 182 billion dollars (Food and Drug Administration, United States, 2001). These figures imply that there is ample potential for value for money (VFM) in the introduction of a comprehensive bar coding technology for the labelling of drug and biological products including vaccines.

Heijbel (2001) reports that the Swedish Institute For Infectious Disease Control carried out a 'pilot' study to assess the use of bar codes on vaccine products. Three vaccine manufacturers participated in the study along with sixty child health centres. Out of 21,214 immunisations the data was successfully read and transcribed utilising a hand held bar coder. The bar coded information included the six digit Nordic product number to identify the manufacturer, type of vaccine product and lot number. Two companies used a single strand bar code and the third company used a multi layered segmented label and double strand bar code with one bar code giving the Nordic product number and the other bar code giving the lot number. The expiry date was not encoded, as a more compact coding system would be required which would also require more expensive scanners.

The Committee on Infectious Diseases, United States (1999) recommended the need for convenient and accurate systems for the transfer of vaccine identification data to medical records and Immunisation Registries to avoid recording errors and ambiguities in the names of vaccine combinations. They recommend strategies for accurate vaccine identification and the development of technologies, standards and guidelines to improve the accuracy and convenience of recording and transferring information from the vaccine package or vial to a patient's medical record, which would be compatible with both manual and computerised medical record systems. They suggested standardised peel off identification stickers on vaccine packaging and standardised coding of vaccine identity, expiry date and lot number. They suggested

that bar codes that complied with the Uniform Code Council standards should be used on vaccine packages and peel off stickers to facilitate accurate electronic transfer of the specified information into computerised medical systems.

The Vaccine Identification Standards Initiative (VISI) was established in the United States by the Centers for Disease Control and Prevention (CDC) in conjunction with the biologics industry, to develop uniform guidelines for vaccine and antibody packaging, labelling and recording in order to enhance the safety of immunisation. VISI standards will increase the accuracy of transferring immunisation data into medical records and Immunisation Registries (Grabenstein J D, 2002). Grabenstein (2002) stated that accurate immunisation records make it easier to monitor the safety and side effects of vaccines, to document the percentage immunisation uptake in a community, to access the efficacy of vaccines and to facilitate the tracking of the immunisation status of individuals by Registries.

VISI recommends bar coded peel off pressure sensitive adhesive stickers affixed to vaccine unit doses for practices that retain paper based manual recording of immunisation data. It also recommends a uniform immunisation record form for use with the peel off stickers. The use of bar coding symbols and the equivalent data in alphanumeric notation should conform to the applicable standards and guidelines of the Uniform Code Council (UCC) for small pharmaceutical packages. Depending on the type of bar code used, the hand held scanners required to read them can be either expensive or relatively cheap. VISI proposes that secondary packaging containing vials or pre-filled syringes should include bar codes that encode the National Drug Code (NDC), the expiry date and the lot number. VISI also recommend the use of UCC/EAN 128 bar codes to save space on the carton. Uniform Vaccine Administration Record forms (UVAR) should include the generally accepted data requirements at present in use and should be able to accept peel off bar coded labels or manual data entry (Grabenstein, 2002).

No commercial company would attempt to track and record such a volume of product and customer data without the use of efficient technology for accurate data capture and management. The pencil and scrap of paper and the keyboard have been thrown out of the grocery shop to be replaced by scanners and bar codes. Heijbel (2001)

commented that in the commercial world bar code labelling had long been used to allow rapid and accurate transcription of data.

The use of bar coding can significantly reduce the time required to record immunisation data compared with a manual data entry. In a Milwaukee Hospital Pharmacy a comparative study was carried out between a bar-code stock ordering system and a manual paper system. The study showed that the bar code Pharmacy inventory system provided considerable time saving and accuracy compared to the manual system (Chester et al, 1989).

Adams et al (1999) states that a point of service data capture and management system used in a busy clinical practice with high patient volumes must be quick and easy to use for it to be acceptable.

With the provision of the immunisation programme free of charge in Ireland, a National Register using the Unique Identifier should be established, and an electronic data capture mechanism i.e. bar coding and scanner technology with the IMB and the FDA making it obligatory for all vaccine manufacturers to use bar coded unit dose labels should be implemented.

## 2.9 The Introduction of Agreed Standards

Medical records, which are fragmented across multiple treatment sites, pose obstacles to clinical care, research and public health efforts. Electronic Data Interchange (EDI) standards have been introduced in both the United States and the European Union (EU). In the United States HL7 (Health Level Seven) is the voluntary standards organisation for accrediting the electronic data exchange in healthcare systems. It defines standard message formats for sending or receiving patient data, which allows different health applications, such as a laboratory system and a record system to 'talk' to each other (Mandl et al, 2001). Mandl (2001) states that they should be universally accessible while at the same time protecting the patient's privacy. In Europe the CEN TC251 has been introduced by the European Committee for

Standardisation Technical Committee for Health Informatics as a preliminary standard for communication between Electronic Healthcare Records (EHCR).

In Ireland the IMO/ICGP seek an agreement on secure computer linkages across the whole health service network as a matter of urgency (ICGP/IMO, 2001). In Ireland the General Practice Information Technology (GPIT) group are developing messaging standards for electronic communication between General Practice and other areas of the Health Services. The Oireachtas Joint Committee on Health and Children recommend that electronic databases used by Health Boards to record immunisation data should be standardised and compatible with other Health Board databases, so that immunisation status data is easily retrievable and transferred between Health Board electronic health record systems. Standardisation of systems will facilitate transfer of data ensuring that each child's immunisation programme is completed and it will also provide accurate data of vaccine uptake in the community (Oireachtas Joint Committee on Health and Children, 2001).

The National Vaccine Advisory Committee of the Centers for Disease Control and Prevention in the United States recommends:

1. The protection of privacy, confidentiality for individuals and the security of information included in the Register
2. To ensure the participation of all immunisation providers and recipients
3. To ensure appropriate technical and operational functional of Registries

They state that the childhood immunisation initiative of 1993 resulted in record high levels of immunisation in pre-school children and record low levels of vaccine preventable diseases of childhood (National Vaccine Advisory Committee, United States, 1999).

## 2.10 The Present Consensus

The World Health Organisation's Children's Rights Convention stipulates the right of every child to be protected against infectious diseases (Melgaard, 2001).

Rigby et al (1998) states that 'health care is a basic human right and the most important service industry in terms of its effects on the well being and happiness of the person.

The General Directorate for Health and Consumer affairs support the 'Development of Immunisation Registers' project, the objectives of which are the description of existing and planned Immunisation Registers, to identify the areas for collaboration and harmonisation and to propose a plan of action for the introduction of Immunisation Registers (Heijbel, 2001). Heijbel (2001) concludes by stating that 'a concerted action with participation of all concerned parties including national public health agencies and drug regulatory agencies, regional and local Health authorities, providers of healthcare and vaccine manufacturers, is needed to improve monitoring of vaccine safety'.

# Chapter 3 Software Requirements Specification

## 3.1 Introduction

In this chapter the needs and requirements of the Childhood Immunisation Programme within a modular General Practice will be outlined and its inter relationship with the national programme. The role of the GP and Practice Nurse, the practice administration requirements, the vaccine supply and stock control and the data recording and management system will be delineated.

## 3.2 General Practice

General Practice is defined 'as an approach to care that includes a range of services designed to keep people well, from promotion of health and screening for disease assessment, diagnosis, treatment and rehabilitation as well as personal social services. The services provide first-level contact that is fully accessible by self-referral and have a strong emphasis on working with communities and individuals to improve their health and social well being' (Department of Health and Children, 2001).

GPs are contracted by the Health Boards and carry out a range of services to patients including the National Childhood Primary Immunisation Programme. They provide services to a mix of both public and private patients. Public patients hold a medical card, have to register with a GP and are entitled to free medical care. On the other hand, registration is not compulsory for private patients who often attend more than one GP. The Childhood Primary Immunisation Programme is free in Ireland and the GP is paid on a fee per item basis.

Prior to 1996, the Public Health Doctors in the local health centres carried out the Childhood Immunisation Programme. The programme was transferred over to the General Practitioners in 1996.

The organisation and structure of General Practice varies in Ireland. Depending on their location and the population structure of the community that they serve, they may have a significant or insignificant commitment to the Childhood Immunisation Programme. In other words, a rural practice will tend to have the full range of population whereas city practices, depending on their location can be skewed towards young family couples and children or alternatively to an elderly population. With the passage of years this can change.

There are approximately 2330 GP's practising singly and in groups, some with and some without Practice Nurses. The results of the questionnaire in chapter 4 showed the range varied from no support staff to the full compliment i.e. Practice Nurse, Secretary and Practice Manager.

## 3.3 Background to Immunisation Data

As reported there are approximately 54,000 children born in Ireland every year. By the time they reach 15 months of age these children should be given a course of immunisations by one of Ireland's 2330 GP's.

Presently, the Immunisation Schedule consists of 6 vaccines which are given at 2, 4 and 6 months in 2 injections on each occasion and a further 3 vaccines are given in 1 injection at 15 months. At the time of writing this schedule is made up of a total of 7 shots.

Each child is vaccinated on 4 different dates. Some children may not attend for immunisation or may not follow the time schedule. To add to the confusion, in any given calendar year children are being vaccinated who have been born in 3 different calendar years. In any given calendar year children from the previous two years will be completing their immunisation programme. While the children born in that calendar year will be beginning their programme. A diagram describing the overlapping cohorts is given in Appendix D.

The products are composed of 9 vaccines. This is represented below in Table 2:

| **Product** | **Vaccine Contains Antigens of** |
|---|---|
| Pentavax or Infanrix | Diphtheria<br>Tetanus<br>Pertussis<br>Polio<br>Haemophilus Influenzae Type b |
| Menjugate or MeningitecC | Meningococcus |
| Priorix or MMR2 | Measles<br>Mumps<br>Rubella |

**Table 2 Composition of Vaccines**

All these vaccines are licensed by the Irish Medicines Board for use in Ireland and are subject to regulation by the Irish Medicines Board.

The Health Boards bulk buys the vaccines and supplies them to the GPs. Each unit dose carries its own trade name, manufacturer name, batch number and expiry date. Vaccine temperature should be maintained at all times between 2-8$^0$C during storage and distribution. This is referred to as maintaining the 'cold chain', which was discussed in Chapter 2.

Whenever a child presents for immunisation, a certain amount of data must be recorded. This data should include the child's details along with the date and site administered, the product details and the doctor's details.

A breakdown of the recorded data is shown in Figure 1:

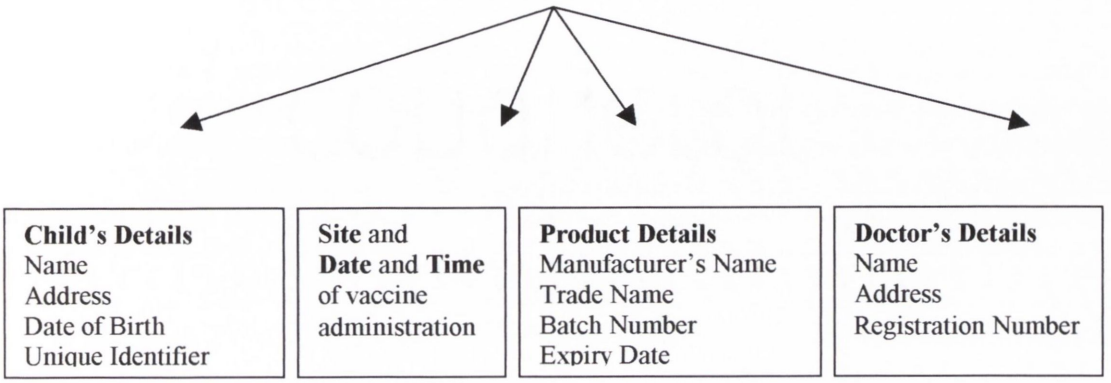


**Figure 1: Breakdown of Data Recorded**

The task of vaccinating approximately 54,000 children annually is complex. There are a significant amount of variables that are included in the management of the Childhood Immunisation Programme for each year. These variables are represented in Appendix E.

## 3.4 Current System

The pen and paper system of data recording of childhood immunisations does not give reliable, real time information on the vaccine status of individual children or of communities. This prevents early recognition of vaccine uptake, otherwise expressed as an inadequate 'herd immunity'.

As few practices are in a position to be able to establish a practice Register of children to be vaccinated, it becomes impossible to speak of percentage uptakes or to manage vaccine sessions or logistically manage vaccine product stock.

Each immunisation consultation requires the recording of the GPs details, the vaccine details and the child's details along with the site and date and time of administration. At present the recording of the vaccine product details is subject to error because of the potential of human error (Grabenstein, 2001). This data is forwarded to the relevant Health Board where it is entered manually into the Health Board computer system. The failure and delay in the returning of the forms by the GPs, mobility of parents from one practice to another and from one Health Board to another, results in distorted and poor quality statistics and consequently impaired ability of the system to provide early warning of diminished vaccine uptake.

## 3.5 Introduction to Software Requirements

It's a fundamental biological fact that the form of an organism or part of an organism is designed by nature to suit the functions required of it. The design of the eye obviously suits the functions of the eye i.e. vision. In the same way a computer system needs to be designed to suit the functions that they are required to perform. In determining the Software Requirements Specifications for a software application, the functional requirements must be clearly established and understood and described in detail unambiguously, so that the user and the analyst and the software developer understands what is required.

The Software Requirements Specification (SRS) documents the hardware, software and database requirements along with the user requirements. The production of an SRS should help the customer or stakeholder accurately describe what they want to include in the design of the computer system and also help the software supplier or developer to understand exactly the needs of the customer or stakeholder (IEEE, 1998). The following section emulates the opening section of an SRS and will help to give an overview of the system requirements and a brief description of the present environment.

## 3.6 System Overview

The purpose of the proposed Electronic Register, Tracking and Management System is to allow for the accurate recording and tracking of the vaccine information in each General Practice. The capture of a child's data and vaccine product data will be carried out by the vaccinator using a hand held bar code scanner. This will significantly improve the accuracy of data captured.

The software application system will be compatible with the present computer software applications used in General Practice. The system will have a software module to operate a bar code scanner that will meet the prescribed standards for healthcare product bar coding. This module for the purposes of this study will link to the vaccine module of the Electronic healthcare record so as to be able to enter the bar coded vaccine product data and bar coded child's data.

It will interface with the present GP software application using an open system standard. In order to link with the Health Board and the National Register, web browser technology will need to be developed. The system will be structured to meet the needs of both single user or multi user General Practices.

The software application will need to be developed using an open language, which should adhere to the necessary requirements. At present there are a number of popular software applications and each of them will need to incorporate the bar code scanning software module and be able to link to the Health Board, the National Register, the General Medical Services Payments Board (GMSPB) and other agencies.

The General Practice software application will be accessible only to approved users utilizing their username and password. The Data Protection Act will have to be complied with and data security and secure data transfer will need to be addressed.

The fundamental requirement for the development of an effective National Database Register is the allocation of a Unique Identifier to each child. The use of a Unique Identifier should be allocated to each child at birth.

## 3.7 Present Environment

A large percentage of the GPs in Ireland are partially computerised. They work however in isolation and in the main are not linked or linkable to any central Health Board computer system. All data collated by the Health Boards from the GPs pertaining to the National Childhood Primary Immunisation Programme is on paper even where the General Practice is utilizing the computer system to generate return forms. Accordingly, there is a significant time delay between the immunisation of the children and the entry of the data into the Health Board computer system. The various Health Board computer systems are not linked therefore when a child receives its first immunisation in one Health Board area and is subsequently vaccinated in another Health Board area, no linkage of the record occurs and may be represented by the original Health Board computer system as a defaulter. This distorts the percentage uptake and vaccine statistical report for that area.

All Health Board computer systems should be compatible and linked to each other. The linkage should ideally be done through the National Register computer system. This would allow the compilation and integration of immunisation data from all Health Board areas. The Unique Identifier is a pre requisite for this to function.

Such a National Register System would allow real time clinical and statistical auditing, prompt vaccine product recall, generate financial audit both for the State and the individual GP and will provide for rapid dispute resolution between the GPs and the paymaster should it arise.

The purpose of this study is to propose a system that will effectively record the data pertaining to all vaccine products used in each General Practice along with the recipient child's details and the vaccinating GP's details and or the Practice Nurse's details. To integrate these details in each child's record bar code scanner technology will be utilized. The bar coded details will be scanned into the GP's computer system and linked to the system's database. Each General Practice will link electronically with the local Health Board computer system, and the proposed National Register computer system, which in turn will link electronically to the Department of Health and Children, the Health Boards, the NDSC and other agencies.

Where a General Practice remains non-computerised, a new paper based data management system will need to be put in place using bar coded unit dose details, bar coded adhesive labels for each child's details and bar coded details of the GP on the record return forms. The forms from these General Practices will be returned to the local Health Board where they should be captured into the Health Board computer system using bar coding scanner technology. The Health Boards should then make the information available to the other agencies.

In this section the wide ranging issues and concerns relating to the development of an Electronic Register, Tracking and Management System were discussed. In the next section the domain concept will be described and analysed using the Unified Modelling Language (UML).

## 3.8 The Role of the Unified Modelling Language (UML)

The aim of this project is to propose a design for an Electronic Tracking and Management System for the Childhood Immunisation Programme utilising the UML modelling tool. Models are abstractions built to understand a problem before implementing a solution (Rumbaugh et al, 1991). It is important to note that a UML model describes what a system is supposed to do and not how to implement the system (Schmuller, 1999).

## 3.9 Requirements Analysis

An analyst's job is to understand and describe the business processes involved in a domain and to gather its requirements (Schmuller, 1999). Schmuller highlights the point that gathering the requirements is regarded as a crucial part of the development process. Investing time into this process is essential in order to fully comprehend the problems to be solved.

The key to developing a good software system is good communication coupled with a clear understanding of the user's domain.

Broadly, a system can be perceived 'as a collection of interacting components, although sometimes interest might be just in one single component. These components will often be discrete physical elements of hardware, but can equally well be functional parts of such physical components' (Schwarzenbach, 1992).

The development team should start and proceed in a structured and methodical way. The process known widely as 'the waterfall' method specifies that analysis, design, coding and deployment follow one another and each stage is completed before the next stage can begin (Schmuller 1999). See Figure 2:

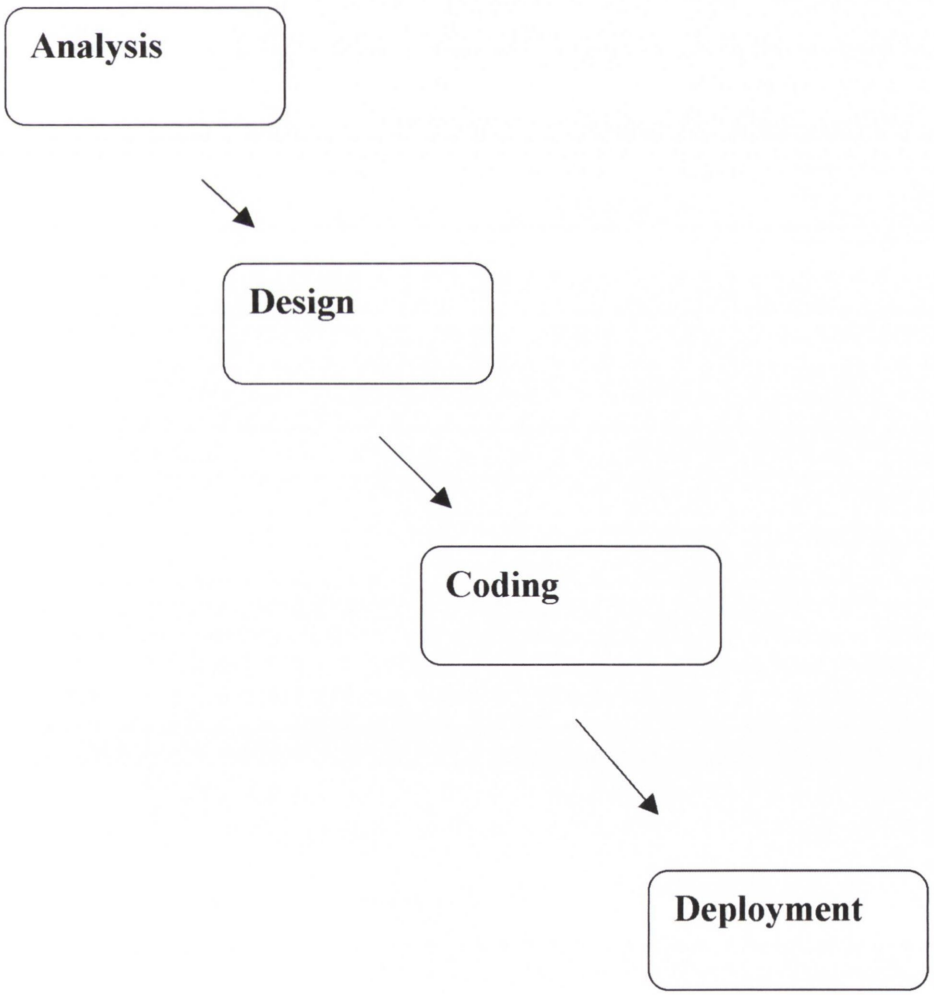


**Figure 2: The Waterfall Method**

It should be noted that this method could encourage segmentation of the different stages. Schmuller makes the point that revisiting the different stages during the development process assures a much better chance of success.

The task of gathering requirements needs to be well planned and the time used constructively. The most common requirements gathering tools and techniques employed by the analyst include:

### 3.9.1 Materials

Support materials used would include handbooks, printed forms, diagrams outlining how the current system works, and printed copies of similar systems.

### 3.9.2 Interviews

In order to gain a thorough understanding of the client's domain the interviewees would be carefully selected by the analyst. The interviewees would be selected on the basis of the analyst's information needs. Face-to-face interviews would be conducted with interviewees responsible for the day-to-day administration of the Childhood Immunisation Programme. This type of interviewing allows the analyst to gain a clearer understanding of the language used and the problems of the domain.

### 3.9.3 Personal Observation

On-site observation provides the analyst with a clear picture of how the user interacts with the system. It allows the analyst develop an understanding on the automation process and at the same time visualise the automation steps proposed in the new system.

Communication skills play an important role at this stage. Although this is a time consuming exercise, a solid rapport with the users can be built over time, which will add immeasurably to the success of the proposed system.

### 3.9.4 Questionnaires

Conducting a questionnaire on-site allows for the collection of specific data over a short period of time. Initially a pilot questionnaire would be assembled and tested for deficiencies. Fewer users are contacted in face-to-face interviewing compared to a postal questionnaire. Face-to-face interviewing is a more selective and precise method of gathering information. Specific time has to be allocated both by the analyst and the user.

The questionnaire should be structured to include both closed ended questions and open-ended questions. When precise information is needed closed ended questions are used. Open-ended questions are less structured, allow for greater detail while at the same time giving the interviewee more control.

## 3.10 Design Stage

Once the user data is collected and collated it should be evaluated and analysed. This information and analysis should then be used for the design stage of the software development process. Grimson (2001) states that 'design is at the heart of the engineering process and a key part of the design cycle is a careful and rigorous analysis of the problem being addressed'. A well structured design of the software with early detection of problems will save time later in the development process.

The design stage will show how a system will operate in terms of the hardware, software and network infrastructure. It will include the user interface, forms and reports and the specific programmes, databases and files that will be needed (Dennis et al, 2002).

A picture of the problem to be solved or the solution should be set out using the notation language known as the UML, which is a universally recognised notation standard.

## 3.11 The Unified Modelling Language (UML)

Before 1994 there were several competing visual modelling languages. The UML was the brainchild of Grady Booch, James Rumbaugh and Ivar Jacobson. Throughout the 80's and early 90's these men worked in separate organisations inventing their own methods for object orientated analysis and design. In the mid 90's they decided to come together. In 1994 Rumbaugh joined Rational Software Corporation where Booch was already working and a year later Jacobson joined them (Schmuller, 1999).

In 1996 the Object Management Group (OMG) produced a request-for-proposal (RFP) for an Object Orientated (OO) visual modelling language and UML was submitted. A year later OMG accepted the UML and the first open industry standard OO visual modelling language was born (Arlow, 2001).

The UML is a general purpose visual modelling language for systems, which provide tools for modelling every aspect of the domain for the development of the software system. The UML consists of a number of graphical elements that combine to form diagrams. Because it's a language, the UML has rules for combining these elements. The purpose of the diagrams is to present multiple views of a system and this set of views are called a model (Schmuller, 1999).

The UML begins with recording the domain of the proposed system and continues until the explicit requirements of the system are fully described. The UML can also show interactions between the proposed system and external objects using Use Case Diagrams.
It is a recognised standard for object-orientated modelling that describes classes, objects and their association with each other.

### 3.11.1 Description of a Class

A Class is a group of objects that have similar attributes and common behaviours (operations). Classes represent the vocabulary of a specific area of knowledge used

by the users of the proposed system. Interviews with the users reveal nouns that can become Classes in a model and verbs that can become operations.

Class diagrams can be used to stimulate the user to talk more about his or her area and possibly reveal additional information. See Figure 3:

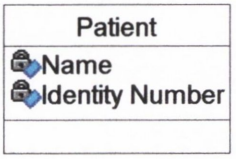


**Figure 3: Class Diagram**

### 3.11.2 Description of an Object

An Object is defined by Schmuller as an instance of a Class, which has specific values of the attributes and behaviour. An Object cannot be an instance of more than one class. It consists of attributes and operations, which together are called features.

### 3.11.3 Description of Class Associations

Relationships show how the terms in the vocabulary connect with one another to provide a picture of the slice of the world being modelled. The association is the fundamental conceptual connection between Classes. See Figure 4:

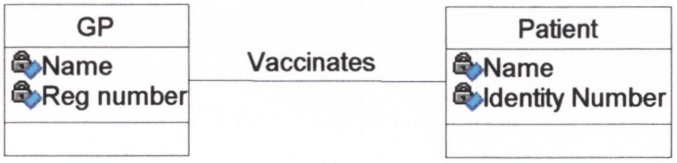


**Figure 4: Class Associations**

When Classes are connected together conceptually that connection is called an association. Associations can be more complex than just one Class connected to another. Several Classes can connect to one class.

# Chapter 4 Questionnaire Analysis

## 4.1 Introduction

The designing of the proposed Electronic Register, Tracking and Management System for the Childhood Immunisation Programme requires an in depth study of the needs of the users and of the data items to be captured by the system.

The GP and the Practice Nurse will be the key users of the system. The Secretary/Receptionist will use the system to schedule appointments. It is important to establish the requirements of the Practice staff and the administration needs of the practice. One also needs to understand the logistics and requirements of the vaccine product distribution, and storage and recording of the vaccine product details.

## 4.2 Introduction to a Problem Statement

The first step in developing a system is to state the requirements. A problem statement should be drawn up stating what is to be done and not how it is to be done. This statement is just the starting point for understanding the problem and can be ambiguous, incomplete or even inconsistent. It should be a statement of needs not a proposal for a solution (Rumbaugh et al, 1991).

### 4.2.1 The Problem Statement

The proposed software application is to be used in General Practices for the Electronic Register, Tracking and Management of the Childhood Primary Immunisation Programme.

When a patient attends a General Practice for immunisation the visit is recorded. The vaccinator (GP or Practice Nurse) opens a medical record of the patient, which is broken down into patient demographics, past medical history, past immunisation history and clinical examination. The demographics include name, Unique Identifier, date of birth, sex, parent name, parent address, telephone number and parent nationality. Every patient would have a Unique Identifier and this Unique Identifier would be used by members of the staff to search the system for patients. Only authorised staff shall use the system. A clinical examination is carried out to make sure the patient is fit for immunisation.

Between 2-15 months of age the patient will make 4 visits to the surgery as part of the Childhood Primary Immunisation Programme.

The consent form would be scanned into the patient's record and the system would confirm that the information leaflet had been explained and understood.

It should be possible to enter the vaccine product details into the stock record and the child's record using bar code and scanner technology.

The stock record would be updated automatically to record all stock as having been administered, rejected as unsuitable for use or which is accidentally contaminated.

The child's details would be entered into the system directly from the National Register or the bar coded details on the children's allowance book would be entered using bar code and scanner technology.

The vaccinator should inject the patient with the vaccine. There may be one or more than one vaccinator in each General Practice.

The product vaccine data would be recorded into the child's Electronic healthcare record and the vaccine stock updated. Each vaccine vial should have a unique code. Each vaccine product would have bar coded details including manufacturer's name, trade name, batch number and expiry date.

At the end of the visit the parent would be given an advice slip with the following a) date of the next scheduled visit and b) advice on adverse reactions and actions needed. At the end of the visit, the vaccinator would give advice in the event of any reaction stating that the patient can contact the General Practice if problems arise.

It should be possible for the authorised staff to be able to search for patient details, enter the details, delete the details, save the details or print these details.

It should be possible to automatically record details of every vaccine product given for every patient.

It should be possible to track defaulters and send out reminder letters to parents when their child's immunisation is overdue.

It should be possible to electronically send the return/invoice reports to the Health Boards and automatically generate a fee per item of service payment to the GPs.

It should be possible for the system to support backup hard copies of all reports if required.

Report forms could be sent electronically to the National Disease Surveillance Centre (NDSC) for real time statistical analysis.

Adverse reaction report forms could be sent electronically to the Irish Medicines Board (IMB) for recording purposes in the event of an adverse reaction.

In the event of a breakdown an IT support team would have authorised access to the system.

The basic management of the present system is as follows:

- Collection or delivery of the vaccine product and the storage and stock management system
- Scheduling of vaccine consultations
- Preparation of the paper-based record for the vaccine consultation including consent from the parent
- Removal of the vaccine from the fridge prior to immunisation of the child
- Checking the vaccine data and recording the vaccine data on both the child's practice chart and the official Health Board return form
- Immunisation of the child
- Recording of the site of administration
- Completion of the vaccine return form
- Mailing of the vaccine return form to the Health Board

## 4.3 Methodology

A qualitative research study was chosen in order to gather the information from the General Practices. As some aspects of the study needed to be collected by empirical

means through personal observation and other aspects were gathered using questionnaires, it was felt that this method was most suitable.

Qualitative research is an appropriate method of questioning when researchers wish to gain an understanding of their research subjects and their motivations and behaviour for doing the things they do and how they do them. According to Sam Porter, 'qualitative research is often associated with the search for reasons rather than causes' (Porter, 1996).

### 4.3.1 Support Material

Before the interviewing stage began support materials were collected and studied which helped to give a clear understanding of the amount of data that was being recorded and managed by the General Practice. The support material included the following:

- Printed forms were gathered from the most popular GP software applications which gave a clear picture of the minimal dataset used by the General Practices that were computerised

- The official Health Board return form used by both computerised and non-computerised General Practices. This form is a 5 page colour coded form, which is filled out by the General Practices and returned to the Health Board. It includes the minimal dataset for the child's details, the GP's details and the vaccine product details. The details of the vaccine recorded include the batch number, expiry date, manufacturer, dose given and date and site of administration. This form also records the consent or refusal of the parent to have the child vaccinated

- Data sheets were gathered from the various drug companies participating in the Childhood Immunisation Programme. These data sheets gave a concise record of the various antigens and ingredients used in each of the vaccine products. It also set out the strict temperature requirements of the vaccine product in order to maintain the 'cold chain'

- The Immunisation Guidelines for Ireland (2002) produced by the Immunisation Advisory Committee of the Royal College of Physicians of Ireland were studied and helped to give a thorough appreciation of the advised scheduling for the Childhood Immunisation Programme

- The Irish Medicines Board Adverse Reaction Report form was employed which helped collate the attributes used in the development process of the system

### 4.3.2 Interviews

Ten General Practices were approached and asked to participate in the study and were given a brief outline of the nature of the study. All agreed to participate. The General Practices were chosen to give a brief view of the different organisation structures and personnel variations in General Practices in Ireland and also representing different population groups.

The interviews were carried out during the morning clinic sessions. A relaxed introduction to the subject of immunisation was used prior to the introduction of the questionnaire. This helped to establish a rapport between the interviewer and interviewee. The interviewer's personal experience of working in a General Practice allowed the creation of a relaxed atmosphere for the interviewee.

### 4.3.3 Questionnaires

Creating a questionnaire for the study was an iterative process, which required tactical consideration. The 'pilot' questionnaire was developed significantly and consisted of 8 questions. Once the 'pilot' questionnaire was tested, considerable changes were made which resulted in the final copy consisting of 18 questions. A copy of the final questionnaire is included in Appendix F.

The first part of the final questionnaire consisted of 4 questions, the answers to which outlined the practice personnel organisational structure. The next 3 questions were directed towards establishing the management of the vaccine stock and the maintenance of the 'cold chain'. The next section of questions was directed towards establishing the extent of the computerisation of the practice and the utilization of the computer system to manage the Childhood Immunisation Programme with the practice. The next section established the practice approach to the administration of vaccines and indicated the extent to which the practice could establish, at any point in time, the level of immunisation activity within the practice. The final 2 questions were aimed at establishing the levels of satisfaction with the Childhood Immunisation Programme as presently structured.

A face-to- face questionnaire was chosen as it was felt it would give a more precise view of the current state of the immunisation programme and it would be easier to control the representation of the different practice types. It was felt that mailing of the questionnaire could result in a poor percentage return and that there would be no control over who replied on behalf of the practice. It was also felt that the consideration given to mailing the questionnaire would be less than that given in a face-to-face questionnaire. It was also considered possible that practices that had a heavy workload would be less likely to return the forms. However, the quantitative aspect of this process with either approach would not deliver adequate statistics.

### 4.3.4 Personal Observation

A personal observation study was carried out on 4 of the 10 practices chosen. This allowed the interviewer to gain an insight into the interviewee's working environment and the difficulties with the immunisation process were noted. This method was chosen to allow observation of the immunisation consultation.

## 4.4 Choice of Practices

There are in excess of 2330 GP's between part-time and full-time working in Ireland in 1500 or more centres of practice. Some practices have only one GP and others have mixtures of part-time and full-time GPs. Some practices have both full-time and part-time Practice Nurses. In order to obtain an overview of the different practice structures and populations served a representative sample of practices with different attributes were chosen. These practices were chosen to be illustrative of practice structures and patient populations. It is not claimed that these practices correspond exactly to the overall structure of General Practice in Ireland.

A total of 10 General Practices were contacted and face-to-face interviews were arranged at suitable times for the respondents. Personal observation of the vaccine consultation was carried out in four of the 10 General Practices.

Eight of the practices studied were located within the ERHA. Two of the practices were located in the city centre and were staffed by one GP each supported by part-time Practice Nurses and Secretary/Receptionist staff. They both served inner city communities with a significant representation of non-nationals in the practice population. A third city centre practice was a group practice with a number of GPs, Practice Nurses and support staff and served a similar practice population to the first two practices. Two other practices were located in the suburbs. One was a group practice with two GP partners, no Practice Nurse but with two part-time reception staff. The other had a single full-time GP with the support of four part-time GPs, a part-time Practice Nurse, one full-time and two part-time Secretary/Receptionist staff. Three further practices were based in a former rural town, which is now within the greater Dublin conurbation. The population served by these practices has a large number of young families including single parent families. Two of the practices were single GP practices one of which was supported by a part-time Practice Nurse. The third practice had one part-time and one full-time GP along with a Practice Nurse. The final two practices were located in the South Eastern Health Board Area. One practice was a group practice in a rural town staffed with three full-time GPs and one full-time Practice Nurse. The other practice in the SEHB was in an isolated rural area, which was staffed by one full-time GP, one part-time GP and a Practice Nurse.

There are other practices within the State with different practice structures and population however, the practices selected for this study will illustrate the needs and difficulties of General Practices overall in delivering the Primary Immunisation Programme.

## 4.5 Results

All the General Practitioners who were approached agreed to assist in the study. In six of the practices the Practice Nurse was the interviewee. All respondents were very interested in the study and gave careful consideration to the questions and their responses.

The results of the questionnaires are assembled under the following headings:

1. The Personnel in the General Practice

Three practices had 2 or more GPs. Seven of the practices had one full time GP and 4 of the practices had 1 full time GP with no part time doctor. One practice had 1 GP without the support of either a part-time GP or Practice Nurse.

Eight of the practices had a Practice Nurse either full time or part time. The Practice Nurses managed the immunisation clinics in these practices.

All of the practices had a full time or part time Secretary. Part-time Secretarial staff staffed three of the practices. There were Practice Managers in 2 of the practices, and one was practising also in 2 other practices not included in this study.

Figure 5 shows the total number of practice staff in each of the 10 General Practices.

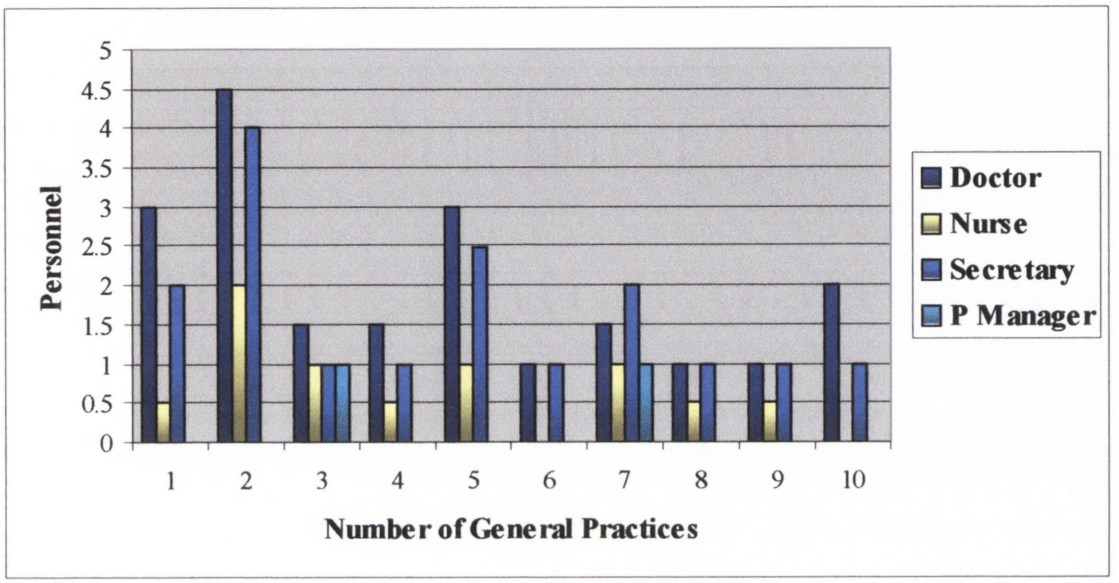


**Figure 5: Total Number of Practice Personnel**

2. The Vaccine Management Programme

In 8 practices a staff member collected the vaccines from the Health Board office. In 2 of the practices the vaccines were delivered. In 8 of the practices the Practice Nurse managed the stock control. There was a dedicated fridge for the vaccines in 9 of the practices.

3. The Computerisation Status of the General Practice

Two of the practices entered the immunisation data into the child's Electronic healthcare record and generated a paper based record and return form during the immunisation consultation. Eight practices completed the official immunisation return form manually. They also entered some or all of the data into the child's Electronic file and in some cases also recorded some of the details into the child's paper file.

Nine of the practices used computers in the clinical management of patients. Two of the practices entered the immunisation data fully into the electronic healthcare record and generated a paper-based return form and used the system to generate vaccine status reports and reminder letters to parents. Four practices entered all of the child and vaccine data, one of which generated both vaccine status reports and reminder letters to parents. Two of the remaining 3 practices with child and vaccine data recorded could generate vaccine status reports. None of the practices were able to scan the vaccine product to capture the unit dose data directly into the computer.

4. Collation and Return of Immunisation Data to the Health Board

Eight of the practices completed the official Health Board record and return form and sent it by post to the Health Board. One of the practices generated the return form from the Electronic healthcare record and then faxed it to the Health Board. The remaining practice generated the form electronically and sent it by post to the Health Board.

5. The Annual Immunisation Workload

Only 2 of the respondents were able to provide accurate figures for the number of immunisation consultations for children < 16 months of age.

Four of the General Practices organised special immunisation sessions, one of these practices also vaccinated opportunistically. The remaining 6 practices vaccinated opportunistically.

6. Opinion on Payment Management System

Eight of the respondents expressed dissatisfaction with the payment and financial management system.

7. General Opinions

Eight respondents expressed disquiet with the present administrative requirements of the Childhood Immunisation Programme because of excessive manual input of data and user unfriendly forms. They complained of difficulty in contacting the relevant Health Board office in relation to difficulties with patient records and or payments. Four respondents noted difficulty with the supply of vaccine products due to shortages. Five respondents expressed annoyance at the failure to manage change in the Immunisation Schedule in an orderly manner with adequate notice.

## 4.6 Analysis

The most noticeable finding of the study was the significant difference between the General Practices in the two Health Board areas studied. In the SEHB, both practices were computerised and used them fully in the management of the Childhood Immunisation Programme. Data was entered at point of entry and the computer allowed them to generate reports. This allowed them to create statistical records. The vaccines were delivered to both practices and the 'cold chain' was maintained. It was evident that there was a clear working relationship between the GPs and the Health Board.

In the ERHA where the computer was used for the immunisation programme limited use was made for the immunisation management. Most practices utilized both the computer and the official Health Board forms to record the vacation information. A staff member of the practice collected the vaccine product from the Health Board.

A high number had difficulty contacting the Health Board when needed and were dissatisfied with the present payment and financial management system. Table 3 below outlines these results:

| PRACTICE | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| **Parameters** | | | | | | | | | | |
| | | | | | | | | | | |
| Data at Point of Entry | - | - | + | - | + | + | + | - | + | - |
| | | | | | | | | | | |
| Create Computer Generated Reports | - | - | + | - | + | - | - | - | - | - |
| | | | | | | | | | | |
| Create Statistical Record | - | - | + | - | + | - | - | - | - | - |
| | | | | | | | | | | |
| Vaccine Delivered | - | - | + | | + | - | - | - | - | - |
| | | | | | | | | | | |
| Vaccine Collected | + | + | - | + | - | + | + | + | + | + |
| | | | | | | | | | | |
| Ease of Communication with Health Board | - | - | + | | + | - | - | - | - | - |

**Note + =Yes**

**- = No**

**Table 3: Results of Questionnaire Analysis**

The information pertaining to the number of staff in both Health Board areas contributed little to the understanding of the Childhood Immunisation Programme other than to say where there was a Practice Nurse, she took responsibility for the stock control and collection where required.

## 4.7 Limitations

This study had limitations, as the number of practices contacted was only ten. However, the practices were not selected randomly but were selected to give an overview of General Practices with different organisational structures, locations and populations. Despite the limitations, distinctive differences were noted between the practices in the two Health Boards.

# Chapter 5 The Use of the Unified Modelling Language (UML)

## 5.1 Introduction

The aim of this project is to design an Electronic Register, Tracking and Management System for the Childhood Primary Immunisation Programme using the UML. A system development is a human activity, which without an easily understood standardised notation system would have great potential for error (Schmuller, 1999). The development process is made up of a standard set of activities that must be adhered to in order to complete the development life cycle.

First, it must be shown by the analyst what the proposed system must do. This is known as the business process. It is important to note that a UML model describes what a system is supposed to do and not how to implement the system (Schmuller, 1999). The identity of the users of the proposed system is defined and the domain is analysed. Following this process, a minimum dataset will be defined and represented in Class Diagrams.

## 5.2 Introduction to Domain Analysis

The Domain Analysis is represented diagrammatically by the analyst in order to create a clear understanding of the user's business process. In the course of the interview with the user the analyst gains a working vocabulary subset of the user's terminology. This allows the analyst to communicate with both the user and the developer in a common language.

During the course of the interview the analyst becomes aware of the nouns used to describe the entities in the business. These nouns become Classes in the model while the verbs will make up the operations of those Classes. At a later stage Class Diagrams can be used to encourage the user to talk more about his domain and possibly reveal additional information.

Subsequently the Classes can be grouped with group names becoming container classes, which means they generate no instances of their own but serve as parent Classes for subclasses (Schmuller, 1999). For example, the document acts as a parent Class for return form, adverse reaction report, letter freeform, recall report and reminder letter.

By defining the classes and their relationships with each other it is possible to develop a model of the domain. Relationships show how the terms in the vocabulary connect with one another to provide a picture of the slice of the world you're modelling (Schmuller, 1999).

## 5.3 Describing Class Diagrams

Class Diagrams give a static representation of the objects in the system and allow the analyst to develop the system with the user, using the user's terminology. The Class Diagrams in turn provide the representations that the developer works from.

A Class is a category or group of things that have similar attributes and common behaviours. Each Class is represented by a named rectangle and the rectangle is divided into three separate sections. The top section contains the name of the Class, the middle section contains the attributes and the lower section contains the operations. An attribute is a property of a Class. It describes a range of values that the property may hold in objects of that Class. A Class may have zero or more attributes. An operation is something that a Class can do, or that another Class can do to a Class. These operations are not shown in the Class Diagrams in this model as they are not required at this stage (Schmuller, 1999).

## 5.4 Domain Analysis of Patient Visit

The tracking and management of the information for the Childhood Immunisation Programme is a complex task. In order to understand the process that is involved, it

is necessary to develop a clear understanding of the patient visit. The set data pertaining to the child, the GP and the vaccine product are recorded to enable the management and tracking system to function.

When a *patient* attends a *General Practice* for *immunisation* the *visit* is created and recorded. The *vaccinator* advises the child's parent on vaccine benefits and risks and obtains *consent*. A patient should have 4 visits to complete its Immunisation Schedule. The *medical record* is broken down into *demographics*, *past medical history, past immunisation history* and *clinical examination*. Prior to *immunisation*, a *clinical examination* is carried out on the *patient*. This is to ensure that the *patient* is suitable for *immunisation*. The *vaccinator* takes the vaccine dose out of the fridge, checks the details and records same including expiry date and prepares the injection. The *vaccinator* selects the site for injection and cleans the area. The *vaccinator* injects the *vaccine* type into the *patient*. One or more *vaccinator* may be involved in the *immunisation* programme.

The details of the vaccine(s) administered are recorded including the brand name, batch number, expiry date and also the site and date of administration. The vaccinator discards the syringe, needle and vaccine vial in a dedicated box for collection and incineration at a later date. The next *appointment* date is given to the *child's parent.*

Post *immunisation* the *patient* develops *immunity*. The *patient* may also develop an *adverse reaction.* At the end of the *visit*, the *vaccinator* gives advise in the event of any *reaction* stating that the *patient* can contact the *General Practice* if problems arise. See Appendix G for a description of the Domain Analysis of the patient visit.

**Note**: The nouns, highlighted in *italics* were collected during the Domain Analysis.

## 5.5 Description of Class Diagrams

Class Diagrams for the Electronic Register, Tracking and Management System were developed from the minimum data sets gathered from the GP software packages and

the official forms. The relationship of these classes to each other is demonstrated diagrammatically. See Appendix H for a brief description of relationship types.

The Class Diagrams in this study are divided into three sections, which are titled medical record, vaccine product and document. This division will allow for a clearer description while at the same time giving a complete static representation of the domain.

## 5.6 Immunisation Record System

The Class Diagram in Appendix I demonstrates the relationship between the National Immunisation Register and the child's nominated GP and its Electronic Healthcare Record immunisation module.

### 5.6.1 Patient

In this project the child should enter the GP section of the Childhood Primary Immunisation Programme at 2 months of age. Following the birth of the child it should be allocated a National Unique Identifier prior to receiving the BCG immunisation and prior to blood being taken for the National Genetic Screening Programme for inborn errors of metabolism on the fourth day of life. The child is presently allocated a Unique Identifier by the Department of Social, Community and Family Welfare when the parent applies for the Children's Allowance. At present this may not happen for up to three months of age and occasionally even later than this. To serve the Childhood Primary Immunisation Programme an Electronic healthcare record is required which will serve as the foundation of the national and personal Electronic Record (ICGP/IMO, 2001)). To this end the Unique Identifier known as the Personal Public Service Number (PPSN) should be assigned to the child either in the labour ward or within 24 hours of birth prior to leaving the Maternity Unit. Home births can readily be provided for administratively.

The details of the child will be entered into the system. The child's nominated vaccinator is also entered into the Electronic healthcare record at this time. The child has many attributes, of particular importance are the first name and surnames given to the child, its Unique Identifier, date of birth, the child's sex, parent's name, address, telephone number and the parent's nationality. The first name and surname may be changed following birth either following adoption or court approved change of surname (Department of Social, Community and Family Welfare, 2002). The date of birth and the Unique Identifier remain constant where there are changes of name or address. The child's details will be captured electronically into the practice computer either directly from the National Register or from the bar coded children's allowance book.

### 5.6.2 Immunisation Guideline

The guidelines of the Immunisation Committee of the Royal College of Physicians of Ireland recommend that children born in Ireland should be given certain vaccines between the ages of 2 and 15 months. Each child has its own guideline schedule depending on its medical and immunisation history. The first three vaccine consultations should be separated by two monthly intervals. The fourth consultation should normally be at 15 months of age but during outbreaks of Measles, Mumps and Rubella due to low community uptake, it may be brought forward to 12 months.

### 5.6.3 Practice Patient List

This list should be compiled from the National Register, which should forward to each practice the registration details of each child for which the practice has been nominated by the child's parent. This list gives the nominated GP the details of the patient due for immunisation.

### 5.6.4 Practice Vaccine Work Schedule

The work schedule of a practice will vary depending on its size and structure. In some practices immunisation consultations will be scheduled for particular times and days of the week. Where there are large numbers of children to be vaccinated they may be scheduled for different days depending on their age and vaccines to be administered. Public holidays and staff holidays for example have to be considered in the preparation of the practice work schedule.

### 5.6.5 Patient Vaccine Schedule

The child's immunisation consultations will be scheduled according to the child's date of birth and the temporal sequencing guidelines of the Immunisation Committee of the Royal College of Physicians of Ireland.

### 5.6.6 Patient Medical Record

The child's medical record will include relevant pre-natal parturition and neonatal history and details of the BCG immunisation and the results of the National Genetic Screening Programme. On the day of the first and subsequent immunisation consultations the results of the clinical examination will be entered into the record. The data pertaining to administered vaccines will also be entered on each occasion into the record. The record will also contain details of any inter current illnesses suffered by the child and drugs administered between vaccine consultations and of any adverse reactions to previous doses of vaccines. The record will be reviewed by the vaccinator prior to immunisation.

### 5.6.7 Clinical Examination

Prior to immunisation each child is examined by the vaccinator to ensure that there is no inter current illness that would preclude immunisation on that day.

### 5.6.8 Vaccine History

The details of the vaccine products administered to the child will be scanned into the Electronic Record. These details will include the manufacturer's name, the trade name, batch number and expiry date and perhaps the product licence number. At the time of immunisation the vaccinator will review the vaccine history, which at the time of the first immunisation visit to the General Practice will show only the record of the BCG. At the second and subsequent visits it will show the history of the previous visits and of any recorded adverse reactions. Where a vaccine dose is given elsewhere from the first practice i.e. on holidays, the details of the off site immunisations will be captured from the National Register.

### 5.6.9 Past Medical History

The past medical history is compiled prior to the visit by entering data forwarded to the practice from the National Register, the Maternity Unit or from a Paediatric Unit. The medical history will also include details of any consultations prior to the first immunisation visit.

### 5.6.10 Medication

The name, dose and frequency of any medication prescribed for the child and the date of such a prescription should be recorded in the medical record.

### 5.6.11 Vaccinator

The vaccinator is the person responsible for giving the vaccine and recording the product details in the child's record. The vaccinator is the main user of the system and may be either the GP or the Practice Nurse. In a number of General Practices there may be more than one GP and more than one Practice Nurse in the General Practice. Where there is more than one vaccinator it is essential that each vaccinator log on to the system using their username and password. In the case of the Practice

Nurse being the vaccinator the record will show the name of the nominated GP as well. The vaccinator's attributes will include the name, address and registration number.

### 5.6.12 Concomitant Doses

Concomitant doses are vaccine products unit doses administered separately to the child during the same visit but at different body sites. As part of the Immunisation Schedule the vaccine product commonly known as the 5 in 1 vaccine is given at the same time as the MeningitisC vaccine but at two separate sites.

### 5.6.13 Adverse Reaction

An adverse reaction is any undesirable reaction the child may develop following an immunisation, which may be either localized or generalized. Any adverse reaction should be recorded in the child's record. Where the vaccinator deems it appropriate he will inform the Irish Medicines Board of the adverse reaction. A list of the contraindicating vaccine reactions can be found in Appendix J.

### 5.6.14 Completed Vaccine Visit

The clinical portion of the visit is completed by entering the site of injection and the computer will automatically record the time and date of the immunisation with the closure of the record. The parent will be advised of the next scheduled visit and given an appointment card. The record is then closed.

## 5.7 Vaccine Product Data

The Class Diagram in Appendix K organises and displays the data pertaining to the vaccine products that should be recorded and the data pertaining to the administration of the vaccine product and of the vaccinator.

### 5.7.1 Vaccine Product

The vaccine product contains secondary ingredients, which maintain the antigen in a suitable state. The attributes include the manufacturer's name, product name, expiry date and batch number.

### 5.7.2 Monovalent Type

This vaccine contains the antigen of one infectious organism. The attributes include the name of the vaccine product and the antigen constituent.

### 5.7.3 Combivalent Type

The combivalent type consists of multiple antigens in one product. The attributes include the name of the vaccine product and the antigen constituents.

### 5.7.4 Secondary Ingredients

The secondary ingredients consist of an adjuvant or stabilizing substances and preservatives. The attributes will include the name(s) of these ingredients.

### 5.7.5 Manufacturer

The attributes of the manufacturer consists of the name, address, phone number, fax and e-mail address.

### 5.7.6 Distributor

The attributes consists of the name, address, phone number, fax and e-mail address.

### 5.7.7 Vaccine Unit Dose

The attributes of the vaccine unit dose consist of the product name, manufacturer name, batch number and expiry date.

### 5.7.8 Fridge

The fridge in the General Practice represents the end of the 'cold chain'. The temperature monitor in the fridge will be linked to the computer to provide a record of the 'cold chain'. The temperature of the vaccines should be between $2^{o}C - 8^{o}C$ at all times. The concept of the 'cold chain' has been discussed in Chapter 2.

## 5.8 Immunisation Documentation Module

The Class Diagram in Appendix L illustrates the documents, which the system will generate when required, and it also shows the attributes, which will be included in the different documents.

### 5.8.1 Document List

The document list will include the following routine reports: return/invoice report, progress report, the practice immunisation uptake report and reminder letters.

### 5.8.2 Document

The document will include the following attributes: type, doctor's details, patient's details where appropriate and the date. This represents a General Class, which includes all documents generated by the system.

### 5.8.3 Correspondent List

This list is essentially a list of the non-practice stakeholders, which include the parent, the National Register, the Health Board, the General Medical Services Payments Board, the Irish Medicines Board, the National Disease Surveillance Centre, the Manufacturers and Distributors of the vaccine products.

### 5.8.4 Correspondent

The correspondent attributes are self explanatory except for the rules of correspondence. Certain correspondents will be automatically issued certain routine reports from the document list such as the invoice and immunisation data reports and uptake reports. Other reports such as the adverse reaction reports and reminder letters to parents will be produced on the instruction of the GP.

### 5.8.5 Practice Uptake Report

At any point in time the system may be asked by the user for the percentage of the children on the patient immunisation list who are up to date with their immunisations. The system may also be asked other questions, such as the number of children who have completed their Immunisation Schedule or the percentage uptake of particular immunisations such as the MMR. The system will automatically generate the required reports at stated intervals. This report is a subclass of the 'document' class.

### 5.8.6 Adverse Reaction Report

Following administration of a vaccine(s), a child may develop an adverse reaction to the vaccine product. This information is recorded in the child's record and merged to the adverse reaction report. This report is sent to the Irish Medicines Board either by post or electronically. These reports are investigated and collated by the IMB who decide whether any further action is required. The report will also be sent to the

Health Board, the National Register and the Manufacturer. This report is a subclass of the 'document' class.

### 5.8.7 Letter Freeform

The attributes of the freeform letter will include the child's name, Unique Identifier and body of the letter. This freeform letter will be merged with the GP's details.

### 5.8.8 Vaccine Status Report

This report will show how compliant the child's immunisation status is with the Immunisation Schedule. It will relate the child's attendances to the temporal guidelines set out by the Immunisation Committee of the RCPI. It will check with the National Register for off site vaccine consultations. Taking into account the work schedule of the surgery and intermittent illnesses of the child certain tolerances will be accepted by the system. The system will automatically allow for public holidays, staff holidays and for illnesses of the child, on the instruction of the GP before listing the child as being in default of the schedule. The report will show the status of each child which will indicate which vaccine consultation scheduled date the child is next due or which scheduled date they have missed in the sequence of dates assigned to them. For example:

- A child of 6 weeks will be shown to be not yet due its first immunisation for a further two weeks
- A child of 9 weeks will be shown to have been either vaccinated or overdue its first scheduled date of its immunisation sequence

### 5.8.9 Reminder Letter

A letter will be sent to the parent where in the opinion of the GP the child is overdue a vaccine consultation. This letter may be preceded by a telephone call from the General Practice. The National Register will be informed of this action.

### 5.8.10 Return/Invoice Report

Following each immunisation the collated information pertaining to the child, the GP and the vaccine products are forwarded electronically to the Health Board. This information acts as a clinical report and invoices the Health Board for the GP's fee. This report also contributes to the statistical analysis of the vaccine uptake in the community. It may also be used to indicate to the vaccine supplier the current vaccine stock in the General Practice. This report is a subclass of the 'document' class.

### 5.8.11 Stock Control Report

The vaccine stock usage, residual stock and new stock intake will be recorded by the system and be available to both the practice personnel and the vaccine supplier. When vaccine products are used and scanned into the patient's record the system will automatically delete the used stock from the practice stock record. All new stock will be scanned into the stock record before entered into the fridge for storage. The fridge should not be opened to carry out a stock take, as this record will automatically be available by the deduction of stock usage from the stock delivery records. This usage of the stock record and avoidance of unnecessary opening of the fridge will minimise the risk of breaking the 'cold chain'. In the event of wastage including product contamination, unfit state for administration or out of date these vaccine products will be scanned and recorded as stock wastage into the stock record.

### 5.8.12 Consent Form

The GP will explain to the parent the process of immunisation and any potential risk. The consent form will be signed by the parent and witnessed by the vaccinator. This form will be combined with the Vaccine Information Statement and should be signed for each individual vaccine product given. The forms will be scanned into the child's record.

## 5.9 Introduction to Use Cases

The Use Case Diagrams describe how a system will look to potential users. The Use Case Diagram models the system at the highest level and represents the users and the main functionality of the system. The diagram consists of the actor who initiates a Use Case and the Use Case, which depicts the action of the system.

The symbol for an actor is a stick figure and the symbol for a use case is an ellipse. The initiating actor is on the left of the use case and the receiving actor is on the right. The name of the actor is entered just below the actor and the name of the Use Case may be either inside the ellipse or just below it. A straight line denotes the association between the actor and the Use Case. An actor initiates the Use Case and an actor (the same or different one) receives something of value from the Use Case. The actors, Use Cases, and interconnecting lines make up a Use Case Model. See Figure 6:

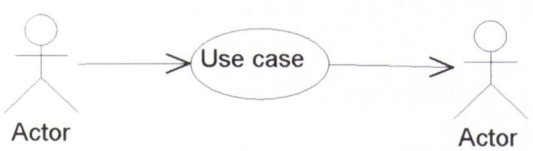


**Figure 6: Use Case Model**

## 5.10 Description of Use Case Diagrams Explaining User Interfaces with the Electronic Register, Tracking and Management System

The Use Case Diagram is used to describe the sequence of events that occur in the tracking and management system of the Childhood Immunisation Programme. The key actors represent the GP and the Practice Nurse with Secretarial staff support. The Use Cases described are the result of the information gathered at the interviewing stage. A diagrammatic representation is given in Appendices M and N.

### 5.10.1 Log On

Each user is issued with a unique username and password, which will allow the user to gain access to the system. To gain entry into the system the user clicks on an icon on the computer screen. The system will then prompt the user to enter their username and password. The username will be typed in and will be in a readable form but the password will be encrypted and made up of both letters and numbers.

### 5.10.2 Verify User

Only the user verified by the system will have access to it. The system checks the username and password before allowing access to it. This ensures that no unauthorised user has access to the data stored in the Practice Information Management System (PIMS).

### 5.10.3 Schedule Appointment

The system will allow the Secretary to schedule appointments according to the recommendations of the RCPI Immunisation Guidelines and the practice work schedule.

### 5.10.4 Capture Patient Details

Two key users have been identified who will capture the patient's clinical details, the GP and the Practice Nurse. The system will prompt the user to open a new record. However, if the patient is already entered into the system the user can access the record by entering the Unique Identifier of that patient. Where the child's parent has nominated the practice for administration of vaccines to the National Register, the practice computer will have captured the child's details. Where a child is not attending the nominated practice, the parent will produce the child's bar-coded details on the children's allowance book for capture by the bar code scanner.

### 5.10.5 Scan Unit Dose Information

Before the vaccine(s) are administered to the patient the details of the unit dose vaccine products are scanned by the bar code reader into the system. The system will alert the vaccinator where the expiry date predates the actual date recorded in the system. The product details should be checked against previous vaccine record for brand compatibility. The user will confirm the products for administration. Once verified and safe to use the vaccine product details including the manufacturer's name, batch number and expiry date are recorded in the patient's medical record.

### 5.10.6 Record Site of Administration

The site of administration will be recorded by clicking on the appropriate icon in the electronic record for the particular site utilised, for example Right Thigh or Left Thigh. As two products are frequently co-administered the site for each will be recorded separately. In the event of a localised reaction to a vaccine product the record will show which vaccine product was given on that site. The action of clicking on the site of administration will result in the vaccine details, the time and data of the vaccine administered being entered into the child's Electronic healthcare record.

### 5.10.7 Scan New Stock

The user logs onto the system and records the details of the vaccine product delivered including the number of unit doses of each product, the product name, manufacturer, batch number and expiry date. This information will be captured by the bar code scanner except for the total number of unit doses, which will be entered separately by the user using the keyboard. The fridge temperature will also be recorded at this time.

### 5.10.8 Capture New Product Details

The new product details will be captured from the National Register or will be entered into the system by the GP according to the systems requirements and instruction. The system will prompt the GP to read the product data supplied with the new product. The new details will be entered manually and the new bar code will be scanned into the system.

### 5.10.9 Capture New Schedule Guidelines

When new schedule guidelines are advised on or where new vaccines are added to the schedule these requirements will be entered into the system by the GP either from a CD from the Royal College of Physician's of Ireland or directly from the National Register.

### 5.10.10 Produce Reports

The system will allow the GP or Practice Nurse review the practice immunisation records in order to establish the vaccine status of all the children currently on the Childhood Immunisation Programme. The system will also produce a list of defaulters according to the practice protocol. For example, a child will not be deemed to be in default when public holidays or staff holidays result in the child's scheduled immunisation date being delayed. Having reviewed the vaccine status report the GP or Practice Nurse will instruct the system to generate reminder letters to the parents of the children who are deemed to be significantly overdue their Immunisation Schedule.

### 5.10.11 Print Reports

The GP or Practice Nurse can instruct the system to produce a printed report.

### 5.10.12 Send Return/Invoice Report

The system will automatically generate reports of all the children vaccinated in the General Practice, which will be automatically forwarded to the Health Board's computer system. The Health Board will use this information to record the immunisation data for each child in the National Register and monitor the uptake of the vaccines as a percentage for the community it serves. The Health Boards will alert the Public Health Doctors of the risk of local epidemics where the uptake falls below a critical level. The Health Board's computer system will on receipt of the vaccine data from the GP, invoice its financial department for the appropriate fee due to the GP, which should instantly be recorded in the GP's financial statement. The financial statement showing the fees due to the GP should be accessible to the GP at all times.

### 5.10.13 Log Off

When the GP or practice Nurse chooses to exit the PIMS the system prompts the user to save the data, which is then updated, saved and stored in the system. The user can then log off and close the system.

## 5.11 State Diagram Showing the Vaccine in Transit

A State Diagram shows the states of a single object, in this case the vaccine product and how it changes its state in response to events and to time. The state is represented by a rounded rectangle and a solid line with an arrowhead depicts a transition. It is necessary to have a State Diagram because it can help analysts, designers and developers understand the behaviour of the object (vaccine) (Schmuller, 1999). See Appendix O.

Prior to approval by the licensing authority such as the Irish Medicines Board (IMB) or the Food and Drug Administration (FDA) in the United States, the new vaccine products are rigorously tested during different stages. The only stage relevant to this

study is the post licensing surveillance programme whereby adverse reactions or possible adverse reactions are reported by the clinicians to the relevant licensing authority.

Once the vaccines are manufactured they are stored at all times within the approved temperature range between $2^0C - 8^0C$ in order to maintain the 'cold chain'. The 'cold chain' is the term used for the management of the distribution and storage of the vaccine product within the prescribed temperature range. This requirement is not peculiar to vaccines or to healthcare products. It does however place a legal responsibility on all who transport or store the vaccine products in order to show compliance with the requirements of the 'cold chain'. This data may need to be shown where a challenge is made under Product Liability Law.

Following manufacture and storage at the site of manufacture the products are transported in appropriate vehicles to the agents where they are stored by the agent prior to transfer to the Health Board's or Retail Pharmacy storage centre (Office for Health Gain, 2002). The vaccine stock is issued to the General Practice and transported to the General Practice fridge for storage.

As stated before the vaccine products should be stored in special vaccine fridges within the specified temperature range at all times and at each handover point, the relevant product data and temperature should be recorded.

The vaccinator will remove the unit dose vaccine product from the fridge immediately prior to vaccinating the child and the unit dose product data will be entered into the system prior to its administration to the child. See Appendix O.

## 5.12 Activity Diagram Showing the Vaccine from Manufacturer to Administration

An Activity Diagram is designed to be a simplified look at what happens during an operation or process. The Activity Diagram has a starting point and an endpoint represented by oval shapes. Each activity is represented by a rectangle which

impacts on the product (vaccine) represented by oval shapes. A straight arrow ended line represents the control flow. See Appendix P.

The vaccine products are manufactured by various companies and distributed by Irish agents. The drug company allocates batch numbers to their products and records the batch numbers of the products supplied to their Irish agent who in turn record the batch number of the product supplied to the Community Care Areas(CCAreas). The CCAreas record the receipt of these products and their batch numbers and in turn record the batch numbers of the vaccine products supplied to each individual GP. The CCAreas issue the vaccines on request to the General Practice and the vaccines are stored in a special fridge prior to use in order to maintain the 'cold chain'.

The vaccine is taken from the fridge immediately before use and checked. If the vaccine is up to date and does not look unusual the child is vaccinated, the vaccine details are recorded and the vaccine vial is discarded in a special incinerator. However, if the vaccine is out of date it is discarded and another vaccine is taken from the fridge. If the vaccine looks unusual a report is written and sent along with the faulty vaccine to the manufacturers for analysis.

A child could have an immediate reaction within 24 hours or a delayed reaction some time after 24 hours onwards. In either cases the reaction should be recorded and a report written and sent to the IMB.

## 5.13 Collaboration Diagram of Vaccine Administration Management in the ERHA

A Collaboration Diagram is another way of presenting the information as it helps to clarify the relationship between objects and the messages that pass from one object to another. A straight line with an arrowhead represents a message between the objects. See Appendix Q.

The Central Purchasing Section of the EHSS (Eastern Health Shared Services) acts as an agent of the DoH&C (Department of Health and Children) and purchases vaccines

for all the Health Boards in the country. It collates the vaccine requirements of the 7 Health Boards and the 3 Area Health Boards of the Eastern Regional Health Authority (ERHA) and arranges tenders for the purchase of the vaccines. It notifies the Vaccine Co-ordinator and then signs off on the vaccine contracts having advised the Health Boards of the successful tenderer(s). Contracts are then notified to the CCAreas, who arrange their own purchase orders as required and process their own payments.

At present, the CCAreas issue the vaccines to the General Practice in the ERHA. The vaccines are prepared by the vaccinators (GP or Practice Nurse) and the child is administered the vaccine(s). The GPs should record the administered vaccine(s) and return the child's details along with the GP and vaccine product details to the CCAreas.

The CCArea enters the returns onto their Child Health System and prepares a print out of the data pertaining to the immunisation returns, which is sent to the ERHA in Dr Steeven's Hospital at the end of each month. An electronic file is also forwarded to the ERHA with the same data. The ERHA use this data to calculate the payments due which is then forwarded by post to the GPs. Each Health Board maintains a Childhood Immunisation Register and at the end of each quarter the Health Boards run reports on immunisation uptake on children that were 12 and 24 months of age in that particular quarter and this information is then posted to the National Disease Surveillance Centre (NDSC) (Fitzgerald, 2002).

# Chapter 6 Functional Requirements for an Electronic Register, Tracking and Management System for the Childhood Primary Immunisation Programme

## 6.1 Introduction

In chapter 5 a detailed description of how the users interacted with the system was set out. This chapter is analogous to SECTION THREE of an SRS (IEEE, 1998) as it contains a preliminary version of the explicit user requirements for the proposed Electronic Register, Tracking and Management System.

To establish the functional requirements of the proposed system, a detailed description of all the functions of the system and how it should interact with the user is described. The functional requirements will define the fundamental actions that must be carried out by the software to capture data, process data and generate reports.

The functional requirements will also describe the user directions given by the system at different steps in the application such as, when logging on, the system will instruct the user to enter the username and password. The preparation of the SRS forces the potential users to consider rigorously all of the requirements before design begins (IEEE, 1998).

The functional requirements are set out below employing the Use Case headings in the last chapter. They are for the most part provided as "shall" statements starting with "The system shall...."

## 6.2 Login

2.1 The system shall be instructed by the main user to assign a unique username and password for each approved user.

2.2 The system shall limit the level of access of each user according to the instructions of the main user.

2.3 The system shall prompt the user on each occasion to enter their username and password when they initiate the opening of the application.

2.4 The system shall not allow entry without the correct username and password and after 2 attempts the system shall close down.

## 6.3 User Verification

3.1 Once a username and password are entered into the system, the system shall check the validity of the user and allow the level of access approved.

3.2 The system shall not allow the data stored in the Practice Information Management system (PIMS) to be accessed by unauthorised users.

## 6.4 Appoint Scheduling

4.1 The system shall allow access to the secretary/receptionist user to schedule appointments for immunisation according to the practice protocol.

4.2 The system shall adjust the schedule as set out by the RCPI guidelines to the practice scheduling requirements, which will take into account such events as public holidays and practice holidays.

## 6.5 Capturing Patient Details

5.1 The system shall capture the child's details, including the Unique Identifier assigned by the National Register within the first week of the child's life, from the National Register System.

5.2 Where a child presents for registration for immunisation prior to the first immunisation, the parent will present the children's allowance book to the vaccinator for the child, which will carry the child's details in bar-coded form.

5.3 The system shall scan the child's bar-coded details and the system shall check with the National Register the validity of the child's details and immunisation record.

5.4 The system shall check for a matching Electronic record using the data supplied on the children's allowance book bar code.

5.5 The system shall alert the user where children in the data register do not meet the scheduling target of the Childhood Primary Immunisation Programme.

5.6 The system shall scan in the parent's signed consent form and allow it to be merged with the child's electronic record.

## 6.6 Scanning Unit Dose Information

6.1 The system shall allow the user to scan the bar code of the unit dose to be administered. The details encoded in this bar code will include the manufacturer's name, the batch number, the product name and the expiry date.

6.2 The system shall prompt the user if the expiry date has been passed.

6.3 The system shall prompt the user if the product scanned is not the product brand administered to the child on the first or second visit.

6.4 The system shall record the contaminated vaccine product details into the stock record and this wastage will automatically be reported to the Health Board computer system along with the Vaccine return reports at the end of an immunisation session.

6.5 The system shall merge the vaccine data into the child's Electronic record following the administration of the vaccine when the user 'clicks' on the icon for the administration site used.

6.6 The system shall likewise merge the data pertaining to the second vaccine product administered when the icon for the second site of administration is clicked on.

## 6.7 Recording Site of Administration

7.1 The system shall prompt the user to 'click' on the icon indicating the site of injection, either the Right Thigh or Left Thigh.

7.2 The system shall prompt the user to confirm the choice of right or left site before entering the data in the Electronic record.

7.3 The system shall automatically record the date and time following confirmation of the site of injection.

7.4 The system shall allow for the possible addition of new sites of administration to be introduced in the future.

## 6.8 Scanning New Stock

8.1 When new stock is delivered to the General Practice the system shall record the number of unit doses supplied and the unit dose vaccine bar coded data.

8.2 The system shall enter these details into the stock record.

8.3 The system shall record the temperature of the new stock at the time of delivery.

8.4 The system shall record the temperature of the fridge in which the vaccine products are stored.

8.5 The system shall record the date and time of arrival of the new stock.

8.6 The system shall prompt the user to reject the new stock if the temperature recordings are either below $2^0$C or above $8^0$C at the time of arrival.

8.7 The system shall generate the vaccine orders based on the vaccine stock in the fridge and the vaccine requirements of all the children who have entered the practice Childhood Immunisation Programme according to the temporal scheduling of the RCPI guidelines.

8.8 The system shall maintain brand loyalty when ordering vaccine products where repeated doses are scheduled.

8.9 The system shall record the username and password of the staff member who will accept the new stock.

## 6.9 Capture New Product Details

9.1 The system shall capture the data of the new product introduced from the National Register OR

9.2 The system shall allow the main user to enter the barcode and matching data into the system according to the system's instructions.

9.3 The system shall check these details with the National Register for a validity check.

9.4 The system shall record the username and password of the user who enters the new product details.

## 6.10 Capture New Schedule Guidelines

10.1 The system shall capture the RCPI new guidelines from the National Register OR

10.2 The system shall allow the user download the new guidelines from a CD.

10.3 The system shall instruct the user of any adjustments necessary to comply with the practice and patient requirements.

10.4 The system shall allow for transition periods where extra immunisation consultations will be necessary in order to introduce the new vaccine to children who have already commenced or completed the Childhood Primary Immunisation Programme.

## 6.11 Produce Reports

11.1 The system shall generate an Electronic report on all the immunisation consultations carried out during that vaccine session.

11.2 The system shall include in each electronic report the GP's details, the child's details, the product details and the site, date and time of administration.

11.3 The system shall collate the information and merge it into the following reports: the invoice/return report, adverse reaction report, vaccine status report uptake report and stock report.

11.4 The system shall allow the user to produce any report type specified.

## 6.12 Print Reports

12.1 The system shall allow the user format the reports where necessary prior to printing.

12.2 The system shall allow the reports to be transferred into either a word processing package for formatting or a spreadsheet package in order to develop charts and graphs.

12.3 The system shall allow the user to print the specified reports if required.

## 6.13 Sending Return/Invoice Reports

13.1 The system shall produce a return/invoice report, which will be sent electronically to the relevant Health Board.

13.2 The system will alert the user for the proper authorization prior to sending the electronic report.

13.3 The system shall prompt the user in the unlikely event of information being omitted.

13.4 After the due date for return forms the system shall prompt the user to send in the returns.

## 6.14 Log Off

14.1 The system shall have an automatic log off after a specific length of time from when data was last entered.

14.2 The system shall prompt the user to log off before closing down the system.

14.3 The system shall maintain a log file of users, which will record both validated users and any unauthorised attempts to access the system.

## 6.15 Performance Requirements

15.1 The system shall be able to automatically backup the files at the end of each day in order to protect the integrity of the data.

15.2 The system shall provide in-built functions in order to improve data quality.

15.3 The system shall have the flexibility to accept new Immunisation Guidelines or new vaccine products in the future.

15.4 The system shall support the automatic electronic data capture from the relevant Health organisations using the appropriate security checks.

15.5 The system shall immediately alert the user by an on screen error message in the event of a system fault.

15.6 The system shall allow only one record for each child to be created and will alert the user if attempts are made to create more than one record on each child in order to prevent duplication of data.

15.7 The system shall alert the user in the event of invalid data entry and prompt the user to enter the correct data. This will ensure that the system will not be corrupted with invalid data.

15.8 The system shall adhere to the national messaging standards specifications when developed.

## 6.16 General Requirements

16.1 As a security function the system shall prompt all users to change their username and passwords at the end of each month.

16.2 The system shall allow the main user to change a user's password in the event of it being forgotten.

16.3 The system shall record all logins/logouts and alert the main user of any attempted log on by an unauthorised user.

16.4 The system shall provide for secure data transfer using a suitable encryption technology.

16.5 The system shall have an online help facility if required.

16.6 In the event of a power cut the system shall be protected using a surge protector, which is a small filter unit, designed to protect against variations in the electricity supply.

16.7 In the event of a mains failure an Uninterruptible Power Supply (UPS) which is a battery-powered back-up power supply will be on site. The system shall allow the user to save work in progress and the system shall shut down the computer properly.

In this chapter the explicit requirements were described in detail in order to give a thorough picture of how the proposed Electronic Register, Tracking and Management System should be developed so that the User Requirements can be achieved. Each General Practice has a different infrastructure and different needs which will have to be taken into account before moving onto the next stage in the development process.

# Chapter 7 Discussion

## 7.1 Introduction

The purpose of this dissertation was twofold, in the first place to review the current data management and vaccine supply and 'cold chain' management within the Childhood Immunisation Programme and secondly, to outline the requirements for a comprehensive National Electronic Register, Tracking and Management System for the National Childhood Primary Immunisation Programme.

The design of the GP module in the proposed system was illustrated using the Unified Modelling Language (UML) to demonstrate the domain and its interfaces with the proposed National Childhood Immunisation Register, the Health Authorities and other Health Agencies such as the Irish Medicines Board and the National Disease Surveillance Centre. The GP module of the system also allowed for communication with the parents in the form of Vaccine Information Statements and reminder and recall letters. The module allowed for point of service automatic data capture utilising hand held bar code scanners both in the management of vaccine administered data and in the management of the 'cold chain' storage and stock management.

The clinical challenge of vaccinating Ireland's cohort of children annually pales into insignificance when one considers the number of children born annually worldwide. The World Health Organisation aims to protect all of these children against the scourges of many infectious diseases, some of which are peculiar to particular areas of the world.

In order to manage the programme in Ireland and to create a record to scientific standards, modern data capture and management technology is urgently required. With the advent of new vaccines the volume of data to be collected will increase and

the potential for adverse reactions will also increase making an Electronic Register, Tracking and Management System even more urgent.

## 7.2 Major Findings

It has been shown in chapter 3 that the present system is manually based, labour intensive and subject to error. It has been shown in chapter 2 that there is International concern at under reporting of immunisation. In New York City it is now a legal requirement that all childhood immunisations be reported to the City Registry.

The current immunisation data management system is fragmented, is incomplete and does not support real-time statistical analysis. The present system does not allow aggregation of data automatically from different sources. The Nation's children are at real risk of both under and over immunisation due to the inadequate data management. Failure to vaccinate against Rubella in one generation may lead to unnecessary and avoidable devastation in the next generation with the birth of a child with Congenital Rubella Syndrome.

During the course of the study it became apparent that there were major differences in the vaccine management between the ERHA and the SEHB. The two practices visited in the SEHB showed that every effort was being made by both the Health Board and the GPs to improve the overall management of the Childhood Immunisation Programme. The immunisation data was recorded electronically at point of service (POS) and the computer generated the data return report. They were not in a position however, to capture the vaccine product data automatically. The immunisation data was not transferred electronically to the Health Board, but by return forms, which were posted or faxed, to the Health Board. The SEHB managed the ordering, storage and delivery of vaccine products utilising Hospital Pharmacies and a company that ensured the maintenance of the 'cold chain'. In contrast in the ERHA, few practices made limited use of the clinical software applications, for the Childhood Immunisation Programme. All practices filled out the forms manually,

which were sent by post to the Health Board. The practice staff were obliged to collect the vaccine products from non-pharmacy staff in the Health Board utilising "picnic freeze boxes" to maintain the 'cold chain' during transport. This task consumed valuable General Practice time and added further to their workload and frustration. The continuity of the supply of vaccine products and their integrity were not guaranteed.

From completing the observational study it was noted that non-nationals with difficult names created an added burden with data entry and increased the risk of transcription error. The number of non-nationals continues to increase. The labelling of vaccine products was also noted to be unsatisfactory as the unit doses only carry alphanumeric details, which can be difficult to read.

Over the past 10 years it is clear from the literature that the healthcare providers in the United States have been striving to establish standards for data capture and management for the tracking of vaccine administration and uptake with varying degrees of success. They have been handicapped by the lack of Population Based Registers, by the parental right to refuse immunisation of children and by the multiple healthcare providers in the field. It is now recognised in the United States, the EU, Australia and elsewhere that the establishment of a Population Based Register is essential for the management of Childhood Immunisation Programmes and the collation of data pertaining to adverse events.

Ireland is in a position, to provide an excellent immunisation service because the immunisation programme is provided free of charge by the State and it is in a position to establish a national population data register utilising existing administrative procedures with minimal modifications and the introduction of readily available technology and standards.

## 7.3 Present Vaccine Stock Management

The present stock management system in General Practices is haphazard for the most part. Without a defined practice list, General Practices cannot order precisely, unit

doses of vaccine products. Accordingly, either of two things can happen, the practice orders an excessive amount of stock or an inadequate amount of stock. In addition, where the staff member arrives to the Health Board to collect the requested vaccines, the required quantities may not be available, as other practices may have been supplied on a first come first served basis service. Vaccine products may be short dated which means there may be very little time left between the date of collection and the expiry date. Ordering of stock is carried out for the most part, by estimating the amount of vaccine products that will be required. Over estimation and short dated stock leads to expensive and unnecessary wastage. The Childhood Immunisation Programme cannot run smoothly without a properly structured vaccine supply chain management system that guarantees continuity of vaccine product supply, in date, with the 'cold chain' maintained to General Practices.

At present in the ERHA the vaccine product details are recorded manually onto paper forms in the General Practices and occasionally entered into the computer system. The process of transcribing the alphanumeric data of the vaccine products was observed to be slow and cumbersome. It has been found in several published articles that the transcription of alphanumeric data is prone to human error as discussed in Chapter 2. With the introduction of more new vaccines to the already complex Immunisation Schedule, there is an urgent need for the introduction of an accurate and user-friendly method of data capture.

The Eastern Health Shared Services (EHSS) and Community Care Areas should not be allowed to order vaccine products simply on the basis of financial decisions. Where a child's immunisation programme is initiated with a particular brand of vaccine it should be guaranteed its supply of that vaccine product to complete its scheduled doses as advised by the manufacturers and the NVAC.

EU Regulations for the transfer of biological products require the delivery of the vaccine products to the General Practices in vehicles that guarantee the maintenance of the 'cold chain'.

From a cost benefit point of view the proposed stock control system, both within the General Practice and the National system will allow for precise ordering of each

vaccine product so that the risk of the product going out of date will be minimised. Cost savings would be achieved from minimising the administrative workload and errors in the day-to-day management of the programme. Time and cost savings would also be made in the management of the recall of defective vaccine products and in the tracing of the recipients of defective products. It is thought that the financial savings from better management of vaccine stock will contribute to the initial expenditure involved in establishing the proposed system.

## 7.4 The Needs and Benefits of a National Register

For an Electronic Register, Tracking and Management System to be effective, there are 3 requirements for its success:

1) Each child must be given a National Unique Identifier at birth registration in the first day of life
2) These details must be electronically transferred to the National Immunisation Register
3) All data pertaining to the child, the vaccinator and the vaccine product must be captured electronically using bar code and scanning technology where appropriate

In the absence of both a National Unique Identifier and a National Register, the present system will continue to report unreliable and incomplete data with significant time lapse. Children will continue to be either under or over vaccinated. The administrative challenge of mobility of children and name changes present an unnecessary administrative workload and contribute to incomplete and segmented vaccine records. A comprehensive recall and reminder system cannot function without a properly structured Electronic healthcare record and data management system. A National Population Based Register utilising a National Unique Identifier will provide the following benefits:

- It would provide General Practices and the Health Boards with a defined population

- It would aggregate the immunisation data from different practices and different Health Boards into one complete record

- It would provide real time statistics pertaining to vaccine uptake levels in communities and within General Practices

- It would allow early intervention where uptake of vaccines is low and inadequate to protect the community

- Where data is entered and confirmed by the parent into the National Register, this information will be transferred without error to the General Practices and the Health Boards

- It would facilitate judicious and rapid management interventions when defective products require recall and parents need to be informed of the reported defect prior to publication in the general media

- It would eliminate the time consuming management procedures currently in place and provide a clear audit trail for both clinical and financial audit

In Ireland, all new cars are legally required to be registered with the local registration authority prior to leaving the garage and are issued with a car registration number i.e. its Unique Identifier. This number is recorded on the National Register and is readily accessible to all Garda (Police) and licensing authorities. It is not unreasonable to seek the creation of a similar register and an electronic tracking and management system for public health interventions for the protection of the health of the Nation's children. Cars can be recalled rapidly where common faults are suspected. It is not beyond the Nation's capacity to establish an equally effective system for recording, managing, tracking and studying public health interventions today.

The early allocation of the Unique Identifier would allow the BCG and the results of the National Genetic Screening Programme for inborn errors of metabolism (colloquially known as the 'heal prick test') to be recorded on the child's Electronic health care record held by the National Register.

In Ireland the National Immunisation Register should be compiled using the PPS number (Personal Public Service Number), an ideal Unique Identifier along with the standard data pertaining to the child recorded at birth registration. This data for each child should be sent to the nominated vaccinator by the register electronically or on paper with bar-coded self-adhesive labels. The vaccine products bar-coded data should be captured electronically at point of service (POS) using suitable scanner technology. The completed record of each immunisation consultation should also include the vaccinator's data, and the site and date of administration. Bar coding and labelling standards are a pre requisite for the collation of unit dose vaccine product data including manufacturer and product data, batch number and expiry date.

## 7.5 Benefits of Using Bar Code Technology

The use of bar coding symbology to encode the data pertaining to the vaccinator, the child and the vaccine product would significantly increase the accuracy of data capture and would increase the return of information to the Health authorities.

The benefits of bar code and scanner technology have been discussed in chapter 2. Bar-coding technology allows for easy and accurate data capture. This technology should meet the prescribed standards of the regulatory bodies and the needs of the healthcare industry. Vaccine unit doses are not yet routinely bar-coded. The introduction of bar coding of vaccine unit dose labels may require mandatory regulations from the FDA in the United States and the European Medicine Evaluation Agency.

In the design modelling the bar code scanner was referred to in the Use Case Diagram (Appendix M). The attributes of the vaccine products and the GP and child's details which would be bar coded were delineated in the Class Diagrams.

This section requires further study with the introduction of the RSS Symbology and the establishment of labelling standards by regulatory authorities.

## 7.6 Analysis of the Domain

The RCPI National Immunisation Committee recommend that each child should receive seven vaccine product doses between the ages of 2 months and 15 months. In this study it was found that the supply of vaccine product lacked logistical management and as a result the supply of vaccine product did not always match the clinical requirements of the General Practices. In the ERHA the current system did not comply with the EU regulations for vaccine and biological product's transport and storage. The documentation of the vaccine product dispersal is paper based and does not facilitate rapid recall.

In this study use was made of face-to-face interviews and questionnaires in 10 General Practices representing different practice locations, practice populations and personnel structures. This method ensured that the information collected was accurate and it allowed the interviewer to observe the depth of feeling of the interviewees. It allowed the completion of the study within a limited time frame set by the interviewer. The information derived from the completed questionnaires outlined the present state of the National Childhood Primary Immunisation Programme as operated in two Health Board areas from the GP perspective. The deficiencies illustrated in the current system in conjunction with the literature review allowed the formulation of the fundamental requirements of an Electronic Register, Tracking and Management System for the National Childhood Primary Immunisation Programme.

The Universal Modelling Language (UML) was utilized to describe the structure, needs and functions of the Childhood Immunisation Programme within a standardised General Practice and the interface of such a unit with the National Registry and with the Health authorities. Class Diagrams were utilised to precisely structure the presentation of the information required for data management of the Childhood Immunisation Programme. The Class Diagrams presented a static

representation of the data pertaining to the vaccinator, the vaccinated child and of the vaccine products administered.

The representation of the domain was progressed with a Use Case Diagram. This diagram helped to describe the functions and needs of the system within the General Practice and its interfaces with the National Registry, Health authorities, the NDSC and occasionally with the Irish Medicines Board, in the event of an adverse reaction or suspected adverse reaction. It demonstrated how the GP and support staff interacted with the system and it verified the integration of the clinical activity with data return and the automatic stock management and invoicing system. The Use Case Diagram also demonstrated how the system would communicate with the parents by producing immunisation information statements and generating reminder and recall letters.

To complete the study of the domain's interfaces with the Health Authorities and other agencies, visits were made to the local Community Care Area and to the Health authority headquarters. During these visits the data management of the immunisation return forms was studied and observed.

From the NDSC it was learnt that they received their vaccine uptake information in the form of quarterly statistical returns on the data pertaining to children who have reached twelve and twenty four months in the previous quarter.

## 7.7 Benefits of the Unified Modelling Language (UML)

The Unified Modelling Language (UML) allowed for precise documentation of the User Requirements and helped break down the complexity of the proposed system. User requirements were gathered during the course of the interviewing, questionnaires and observational stages and expressed using a set of diagrams. Each diagram played a different role in the iterative process of the development. The Use Case Diagram helped to define the sequence of interactions between the users and the system. This helped to give an understanding of how the user would use the system

and what the system would do for the user. During this study it was felt that the UML was an easy tool to use and had several benefits including:

- It broke down the complexity of the domain using simple to follow diagrams

- It allowed for amendments to be made at different stages of the development process without altering the overall design

- Each set of diagrams helped to give a clear picture of the different processes i.e. the Use Case Diagrams helped to define the interactions between the user and the system

## 7.8 Benefits of the Electronic System Proposed in this Work over the Existing System

At present the data management for the Childhood Immunisation Programme is labour intensive, disjointed and incomplete. The proposed system will compile all children's data at birth registration within 24-48 hours of birth and the child will simultaneously be issued with its National Unique Identifier. This data will be transferred electronically to the Social Welfare Agencies and to the Health Agencies. This data will be used to create the child health Immunisation Registry. The Registry will transfer the children's data electronically to the nominated General Practice vaccinators, but where necessary documentation with bar coded adhesive labels will be used for this purpose. Each GP will vaccinate the child nominated to him by its parent, according to the RCPI Immunisation Schedule and will return this information at the time of consultation preferably electronically to the National Register. The vaccine unit dose data will be captured by the GP utilising a hand held bar code scanner. In the absence of a bar code scanner the GP will use vaccine return forms carrying the GP's bar coded data, to which he will add bar coded labels carrying the child's data and bar coded unit dose labels for each product administered. These forms will be sent to the local Community Care Area office for scanning into the National Register.

This data when supplied by either method to the National Register will allow the individual's child's healthcare record to be updated and will also initiate a request for payment to the GP and a vaccine re-stocking order. This information will allow central purchasing to calculate future stock requirements according to the initial brand used and the RCPI Immunisation Schedule. The electronic database held by the National Register along with the immunisation data supplied by the GPs will facilitate reminder and recall systems. It will allow Public Health Doctors real time assessment of the level of vaccine uptake in any community, large or small. A significant advantage of this real time statistical analysis of immunisation uptake is that it will allow for early remedial interventions to increase vaccine uptake and to diminish the number of outbreaks of infectious diseases. This proposed system will allow the production of comprehensive immunisation records for individual children by aggregating data from different General Practices automatically. The stumbling block for an effective electronic data capture system has been the absence of a suitable symbology to encode the manufacturer's name, the product name along with the batch number and expiry date on standardised unit dose adhesive labels. This has now been overcome with the introduction of the Reduced Space Symbology (RSS) which was discussed in Chapter 2.

## 7.9 Limitations

This study was restricted to two Health authority areas out of eight. The number of practices studied was limited to ten but were chosen to represent the needs of practices serving different populations and to represent different staff structures within the General Practices. The limitations of the study are not thought to have affected the veracity of the observations and findings.

## 7.10 Future Work

In this study the proposed design of the General Practice segment of an Electronic Register, Tracking and Management System has been analysed using the Unified Modelling Language (UML), a standard modelling tool. This study is open to further

development and will allow the next stage of the business process to proceed with the coding and implementation of a prototype. The ultimate aim is to produce a cost effective, real time and efficient system for the Tracking and Management of the National Childhood Primary Immunisation Programme.

While this study is focused on the establishment of a Register of vaccines administered to children between the ages of 2 months to 15 months, the Register can be extended to record all future immunisations and form the basis of a patient controlled life long Electronic healthcare record.

The use of Ean/UCC standard bar codes at point of service (POS) would produce administrative and clinical benefits in other medical domains, such as drug administration especially in busy clinical environments, such as Accident and Emergency and Intensive Care Departments. There use in the logistical management of product procurement would facilitate financial audit and value for money initiatives.

## 7.11 Conclusion

The management of the National Childhood Primary Immunisation Programme in Ireland requires three tasks to be integrated so that each child of the annual cohort receives seven vaccine products during four consultations. The first task is to place the right vaccine product in the right place at the right time with its biological integrity maintained. This requires an efficient and effective supply chain management system that also maintains the environmental temperature required for vaccines during both storage and delivery. The second task is the establishment of a precise Population Based Register of children born in the State or who may subsequently enter it. To this Register is added the data pertaining to all vaccines administered to each child along with other clinical details. The third task is the clinical task of administering the vaccines.

No service or retail industry would attempt to conduct their business in today's commercial environment without the use of electronic databases and automatic data capture technologies. The introduction of an Electronic Register and Data Tracking and Management System is essential to perform the three tasks described to scientific standards. The current system is labour intensive, inefficient and wasteful of time and product. The community uptake of vaccines is unsatisfactory and results in outbreaks of infectious diseases. The present system cannot provide effective statistical returns nor can it be relied on to provide information on rare adverse reactions. The proposed system will integrate the three tasks in an efficient and effective manner producing cost and labour savings.

In this dissertation the UML was used to clearly describe the domain and the functionality of the proposed system within the domain. The Class Diagrams statically represented the different objects in General Practice in the Childhood Primary Immunisation Programme and demonstrated the structure of the objects and their relationships to each other. These diagrams were developed gradually using the information gathered from the questionnaires and other source materials. They constitute a first draft of an information model to be used in the building of an Electronic Register, Tracking and Management system.

The dynamic models , the State, the Activity and the Collaboration, demonstrated the interactions and changes to the objects and their temporal relationships.

The interfaces between the General Practice module and the National Register, the Health Authorities, other agencies and the parents were demonstrated.

It is clear from studying international literature and from studying the present management system that Ireland has two of the essential requirements for an Electronic Register and Data Tracking and Management System for the National Childhood Primary Immunisation Programme. They are the PPS Number and the Birth Register's Registration Data. The Oireachtas has recommended that the birth registration and the allocation of the PPS Number should be carried out in the first few days of life and that this data should form the National Electronic Register for the Childhood Immunisation Programme. The third requirement is dependant on the

rapid introduction of standardised bar coded and alphanumeric vaccine unit dose labels. Both the European Union and the United States authorities are approaching consensus on the need for such standards.

National authorities need to urgently activate comprehensive Population Based Registries with bar coding standards for automatic vaccine data capture in order to provide effective and safe management of the National Childhood Primary Immunisation Programmes and international exchange of suspected adverse reaction reports.

## Appendix A

References


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## Appendix B

Table 4: Introduction Dates for First Generation Vaccines for Humans

| | |
|---|---|
| **After 1796** | |
| 1798 | Smallpox |
| 1885 | Rabies |
| 1897 | Plague |
| 1923 | Diphtheria |
| 1926 | Pertussis (Whooping Cough) |
| 1927 | Tuberculosis (BCG) |
| 1927 | Tetanus |
| 1935 | Yellow Fever |
| **After 1945** | |
| 1955 | Injectable Polio Vaccine (IPV) |
| 1962 | Oral Polio Vaccine (OPV) |
| 1963 | Measles |
| 1967 | Mumps |
| 1969 | Rubella (German Measles) |
| 1981 | Hepatitis B |

(Clements, 1996)

## Appendix C

Table 5 Data Dictionary of Vaccine Preventable Diseases

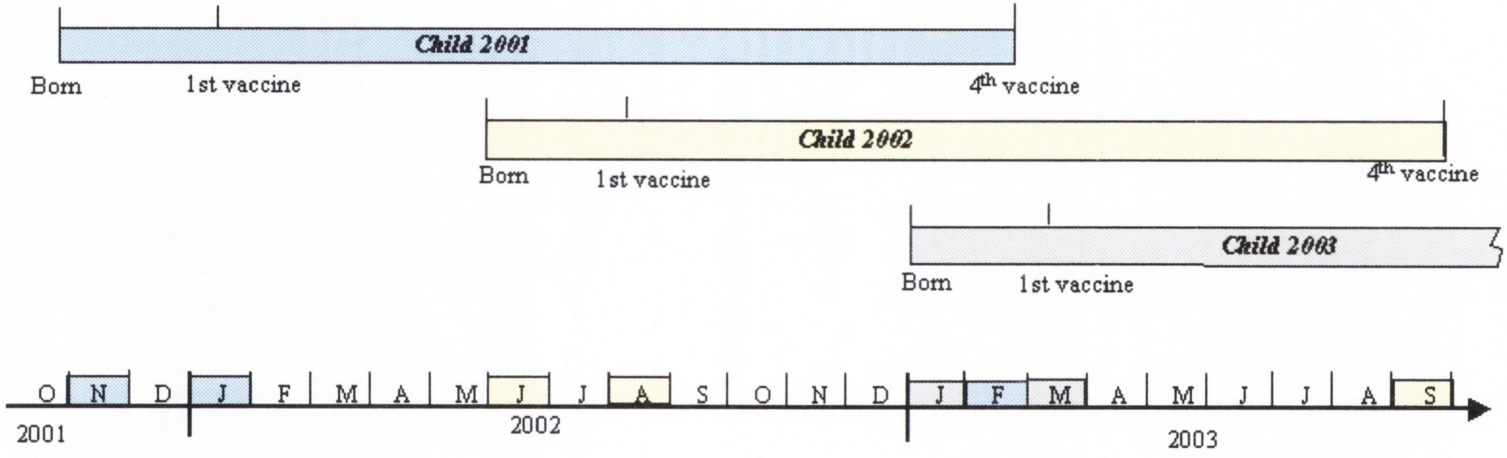
| Name of Disease | Description |
|---|---|
| Tuberculosis (TB) | A bacterial infection which primarily affects the respiratory system. Causative organism: Mycobacterium tuberculosis or rarely Mycobacterium bovis. Transmission is via droplet infection of an infected person. |
| Meningococcal Meningitis and Septicaemia | Systemic infections most common in infancy and early childhood. Causative organism: Neisseria meningitidis. Transmission is via droplet infection of an infected person. |
| Diphtheria | An acute infectious disease affecting the upper respiratory tract and occasionally the skin. Causative organism: *Corynebacterium diphtheriae.* Transmission occurs primarily from close contact with a patient or carrier. |
| Tetanus (Lockjaw) | An acute neurological disease affecting the muscles. Causative organism: *Clostridium tetani.* The organism is present in the soil and may be introduced into the body during injury. |
| Pertussis (Whooping Cough) | A highly infectious bacterial disease which occurs mostly in children less than one year of age. Causative organism: *Bordetella pertussis*. Transmission occurs by close contact via droplet infection from the respiratory tract of symptomatic individuals. |
| Poliomyelitis | An acute illness which may result from invasion of the gastro-intestinal tract. The virus has a particular affinity for nervous tissue. Causative organism: |

| | |
|---|---|
| | Polio virus. Transmission is through contact with the faeces or pharyngeal secretions of an infected person. |
| Haemophilus Influenzae type B (Hib) | The most common presentation of invasive Hib disease is meningitis, frequently accompanied by bacteraemia. The risk of complications is greatest in children aged 6 – 12 months. Causative organism: Haemophilus influenzae type B. Transmission is via droplet infection of an infected person. |
| Measles | An acute highly infectious viral illness characterised by rhinitis, inflammation of the conjunctiva of the eye, a rash and temperature. Causative organism: measles virus. Transmission occurs via droplet infection of an infected individual. |
| Mumps | An acute viral illness characterised by swelling of the salivary glands which may be unilateral or bilateral. Mumps can cause significant morbidity including permanent deafness. Transmission is by direct or droplet infection. |
| Rubella | A mild infectious disease. Maternal rubella infection during pregnancy can result in major damage to the foetus known as the Congenital Rubella Syndrome. This syndrome results in mental handicap, visual and hearing defects and congenital heart lesions. Transmission is by direct or droplet spread. |

(Immunisation Advisory Committee, Royal College of Physicians of Ireland, 2002)

## Appendix D

Figure 7: Diagram Describing the Overlapping Cohorts




Gannt Chart of Child's Progress Through the Immunisation Programme

| | | |
|---|---|---|
| **Child 2001 born November 2001** | **First vaccine given January 2002** | **4th vaccine given February 2003** |
| | | |
| **Child 2002 born June 2002** | **First vaccine given August 2002** | **4th vaccine given September 2003** |
| | | |
| **Child 2003 born January 2003** | **First vaccine given March 2003** | **4th vaccine given April 2004** |

## Appendix E

Table 6 A List of Variables in the Childhood Immunisation Programme

| **Variables** | |
|---|---|
| Births per year | 54,000 approximately |
| Total product dose to be recorded for each child | 7 |
| Total product dose per annum | 378,000 (7*54,000) |
| Total product type used | 3 |
| Total number of antigens administered | 9 |
| Total number of GP's | 2330 approximately |
| Recommended temperature of vaccines | 2-8$^0$C |
| Anatomical sites of vaccine | Left/Right Thigh |

## Appendix F

Questionnaire Design

**Tracking the Childhood Primary Immunization Programme**

**Questionnaire**

**(Circle the appropriate answer)**

1. How many doctors work in the clinic?

   Full time ☐ Part time ☐

2. How many practice nurses work in the clinic?

   Full time ☐ Part time ☐

3. How many secretaries/receptionists work in the clinic?

   Full time ☐ Part time ☐

4. Does the clinic have a practice manager? Yes/No

5. Who collects the vaccine from the Health Board?

   _____

6. Who manages the vaccine stock?

   _____

7. Does the clinic have a special vaccine fridge? Yes/No

8. Is the clinic computerised? Yes/No
(Note: if the answer is No go to question 10)

9. What Software is in use?

| | |
|---|---|
| Health One | |
| GP Clinical | |
| Medbase | |
| GP Mac | |
| Other (Please state which one) | |

10. a) Do you record the patient's details on the patient's chart? Yes/No
    b) Do you record the vaccine details on the patient's chart? Yes/No

11. If computerised:

a) Do you record the patient's details? Yes/No
b) Do you record the vaccine name and manufacturer? Yes/No
c) Do you record the batch number? Yes/No
d) Do you record the expiry date? Yes/No
e) Do you record the site of administration? Yes/No
f) Does your computer generate an electronic record of the children vaccinated and the data of the vaccines administered? Yes/No
g) Does your computer generate defaulter/recall lists? Yes/No
h) Does your computer generate a return form? Yes/No

12. Do you fill out an official Health Board return form? Yes/No

13. How do you send in the return form to the Health Board?
    a) Post
    b) E-mail
    c) Fax

14. Are your vaccinations performed in groups at a special time? Yes/No

15. Do you perform vaccinations when the opportunity arises? Yes/No

16. How many vaccine consultations are carried out each year on children less than 16 months of age?

| | |
|---|---|
| Less than 50 | |
| 50-99 | |
| 100-199 | |
| 200-299 | |
| 300-399 | |
| 400-499 | |
| 500-599 | |
| More than 600 | |
| Unsure | |

17. Is the payment management system: satisfactory/unsatisfactory?

18. Are there any other points that hinder the smooth running of the programme?

_____

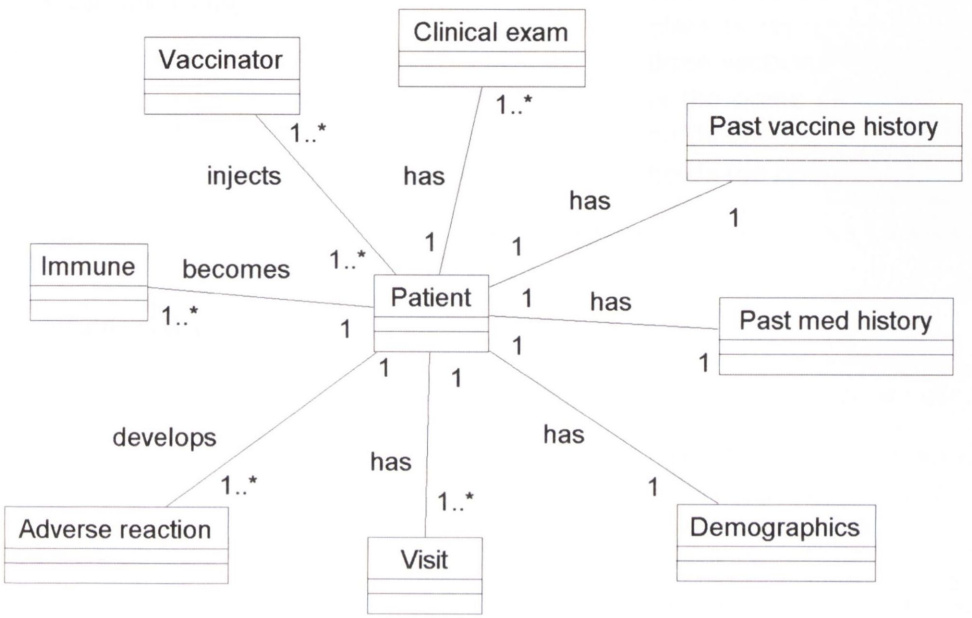
_____

_____

_____

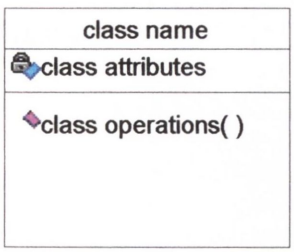
## Appendix G

Figure 8 Domain Analysis of the Patient Visit

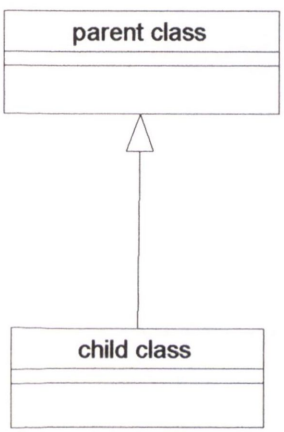


## Appendix H

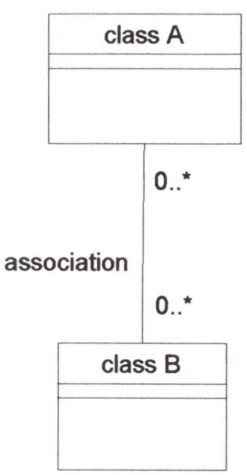
Figure 9 The UML Class Relationship Types



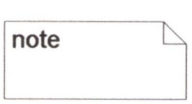

A class depicts the entities in a domain or a system and how those entities relate to each other. Each class is represented as a comprising three sections. The first from the top is the name of the class, the second holds the class attributes and the third holds the operations of the class




A child class can inherit attributes and operations from a parent class. This is represented by an arrow with a clear head that points to the parent class.



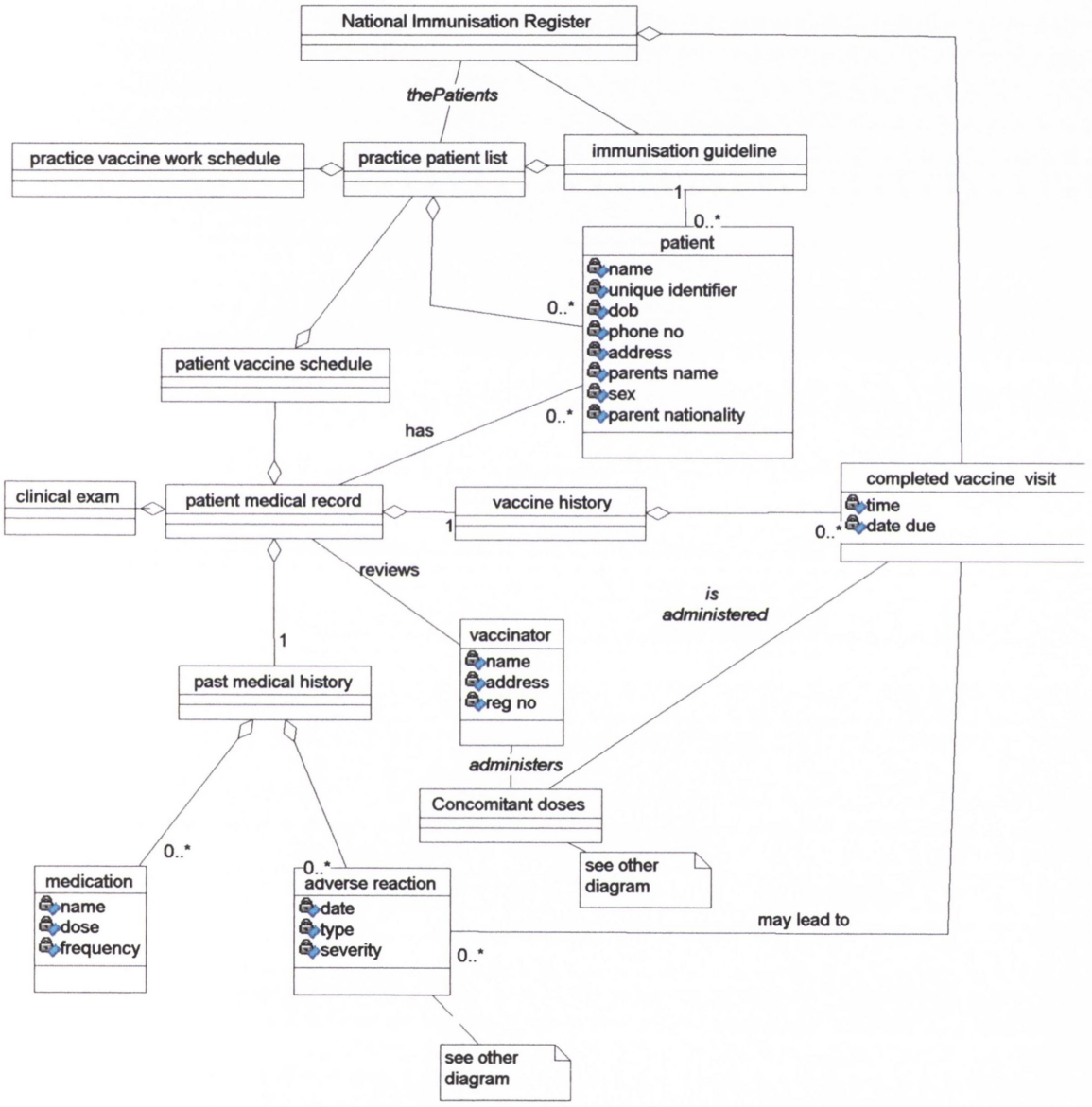

If class A is associated with class B they are connected by an arrow and the association is described in text beside the arrow. The number of objects within class A that relate to class B is represented by numbers. For example, * denotes 'more'.




An attached note provides further information about the class. It is represented by a rectangle with a folded corner. Inside the rectangle is explanatory text or graphic.

# Appendix I

Figure10 Class Diagram Illustrating Vaccination Record System



## Appendix J

Contraindicating Vaccine Reactions

### SEVERE LOCAL REACTION

An extensive area of redness and swelling which becomes indurated and involves most of the anterolateral surface of the thigh or a major part of the circumference of the upper arm.

### SEVERE GENERAL REACTION

- Anaphylaxis, bronchospasm, laryngeal oedema, generalised collapse.

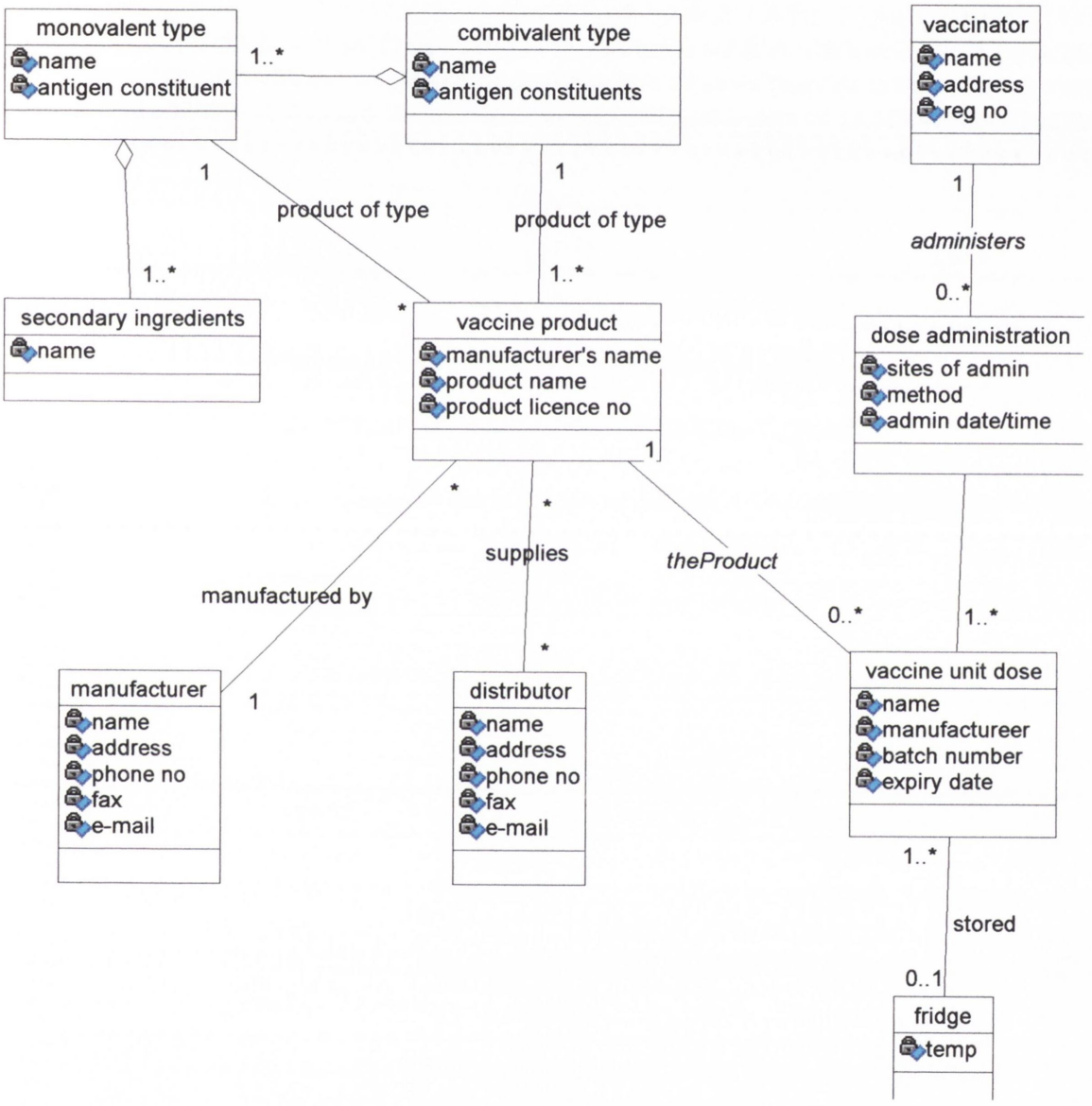
**Fever >40°C within 48 hours**

- Any of the following within 72 hours:
    - Prolonged unresponsiveness
    - Prolonged inconsolable crying
    - High pitched screaming for more than four hours
    - Convulsions or encephalopathy

(Harrington, 1998)

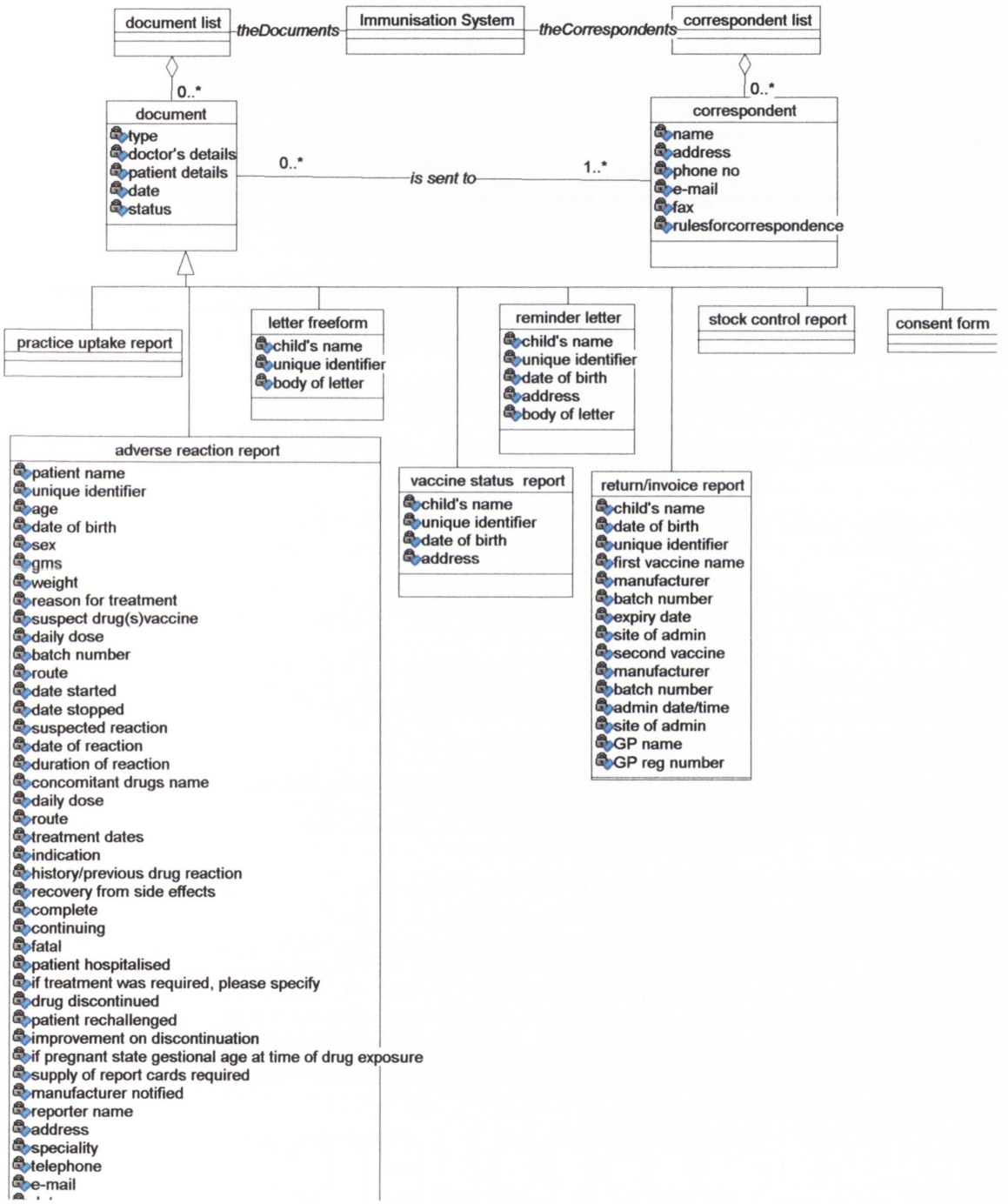
# Appendix K

Figure 11 Class Diagram Illustrating Vaccine Product Administration Data and Vaccinator



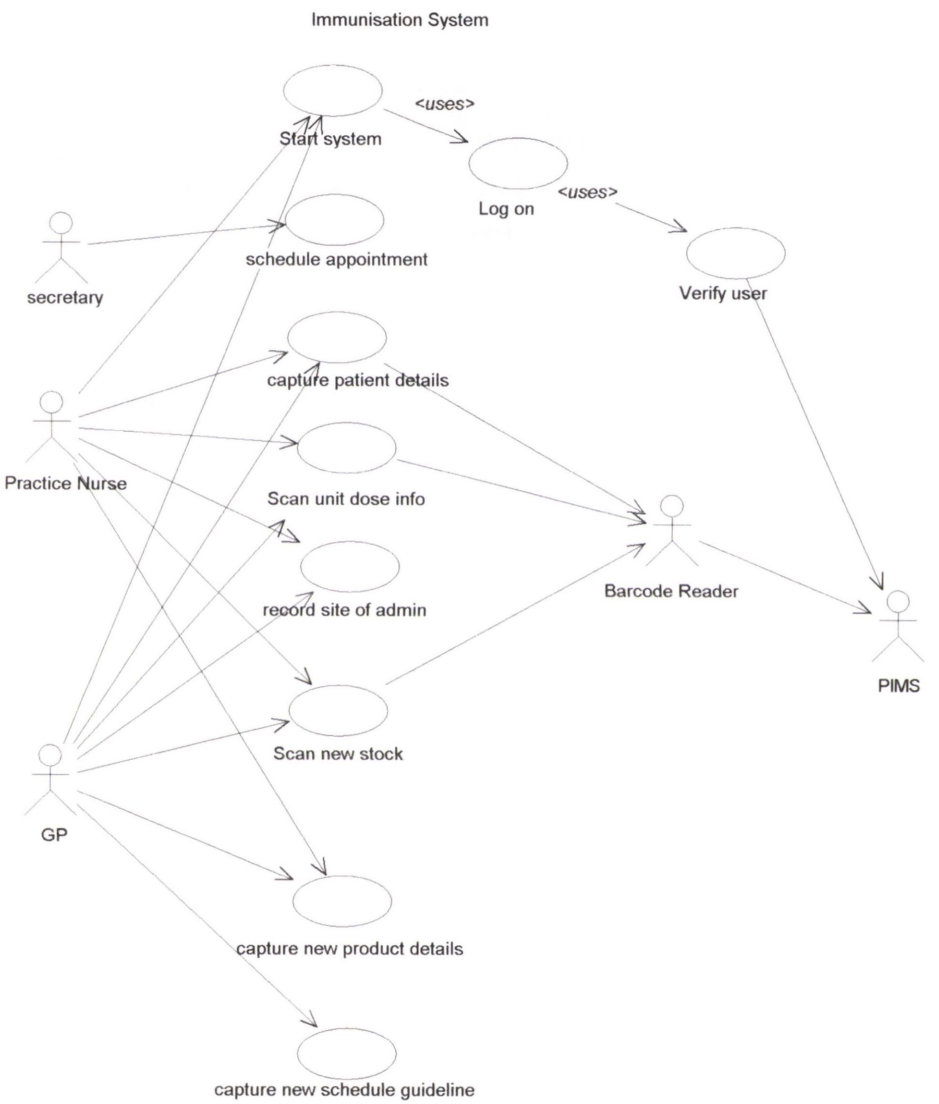
# Appendix L

Figure 12 Class Diagram Illustrating Immunisation Documentation Module



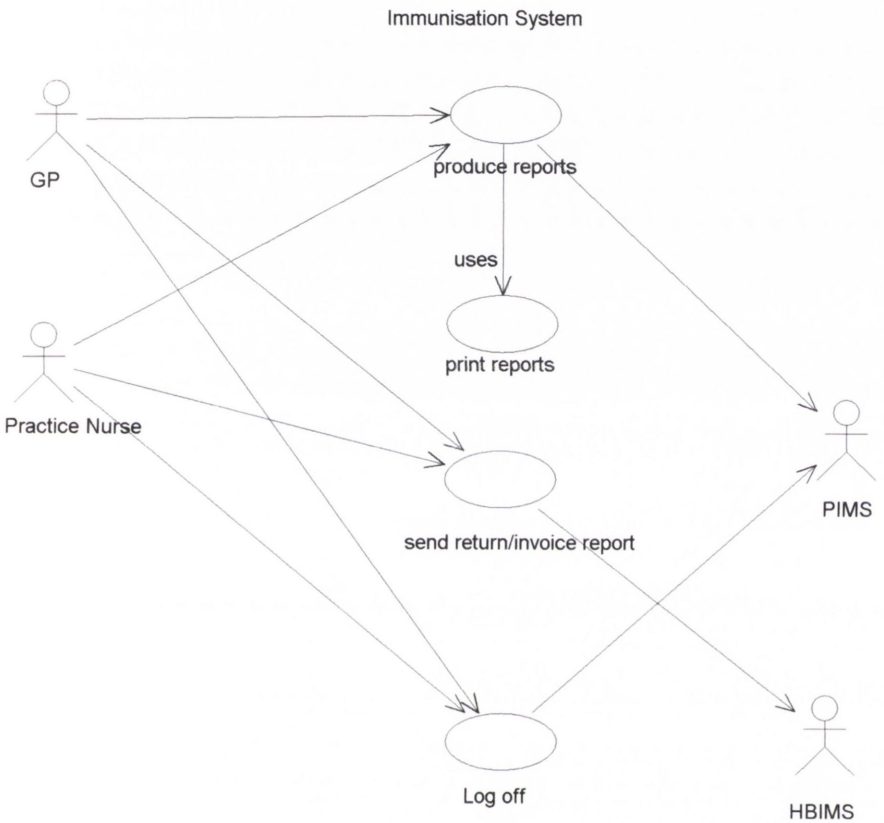
# Appendix M

Figure13 Use Case Diagram Demonstrating User Interfaces with the Electronic Tracking System



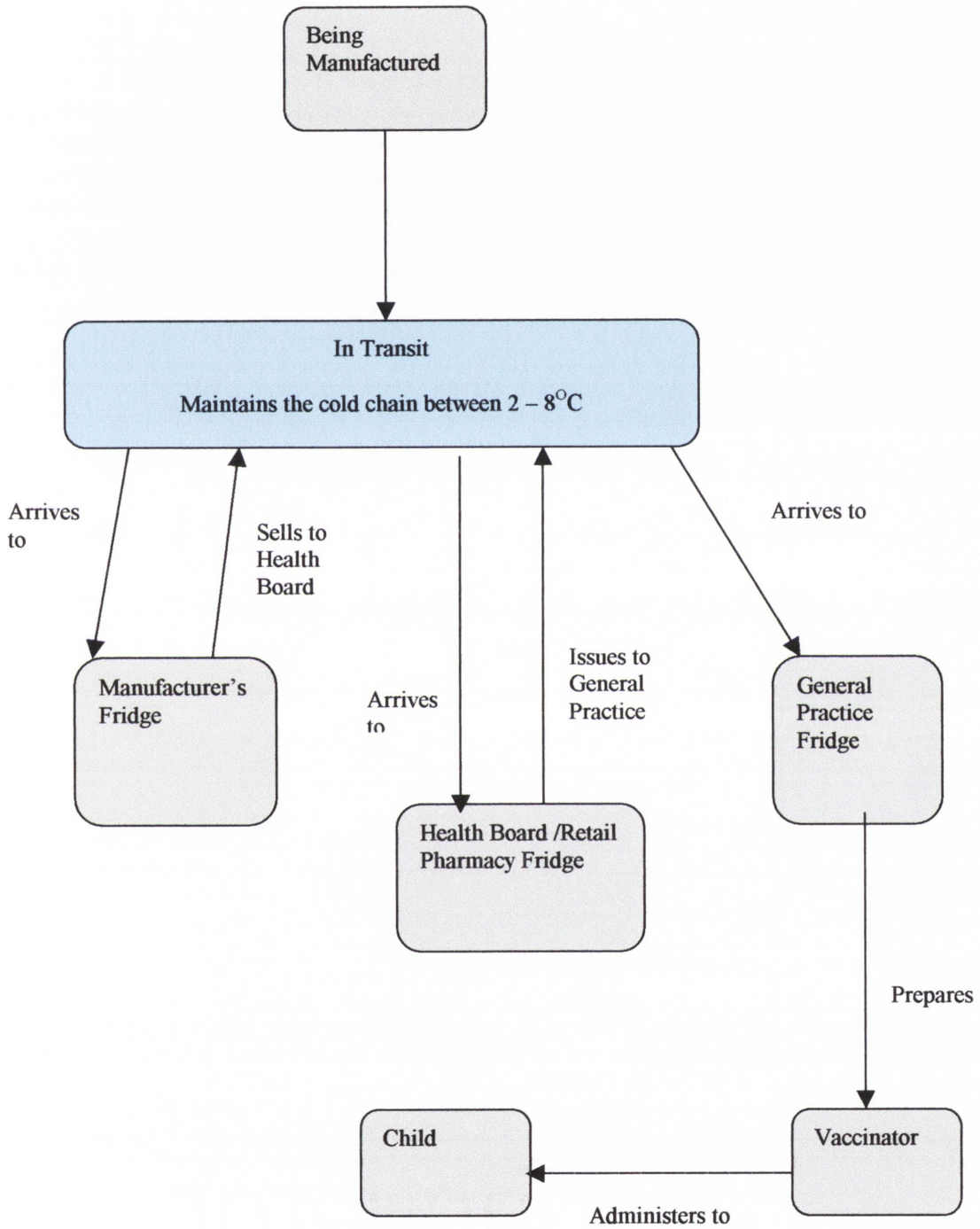
## Appendix N

Figure 14 Use Case Diagram Demonstrating User Interfaces with the Electronic Tracking System (Continued from Appendix M)



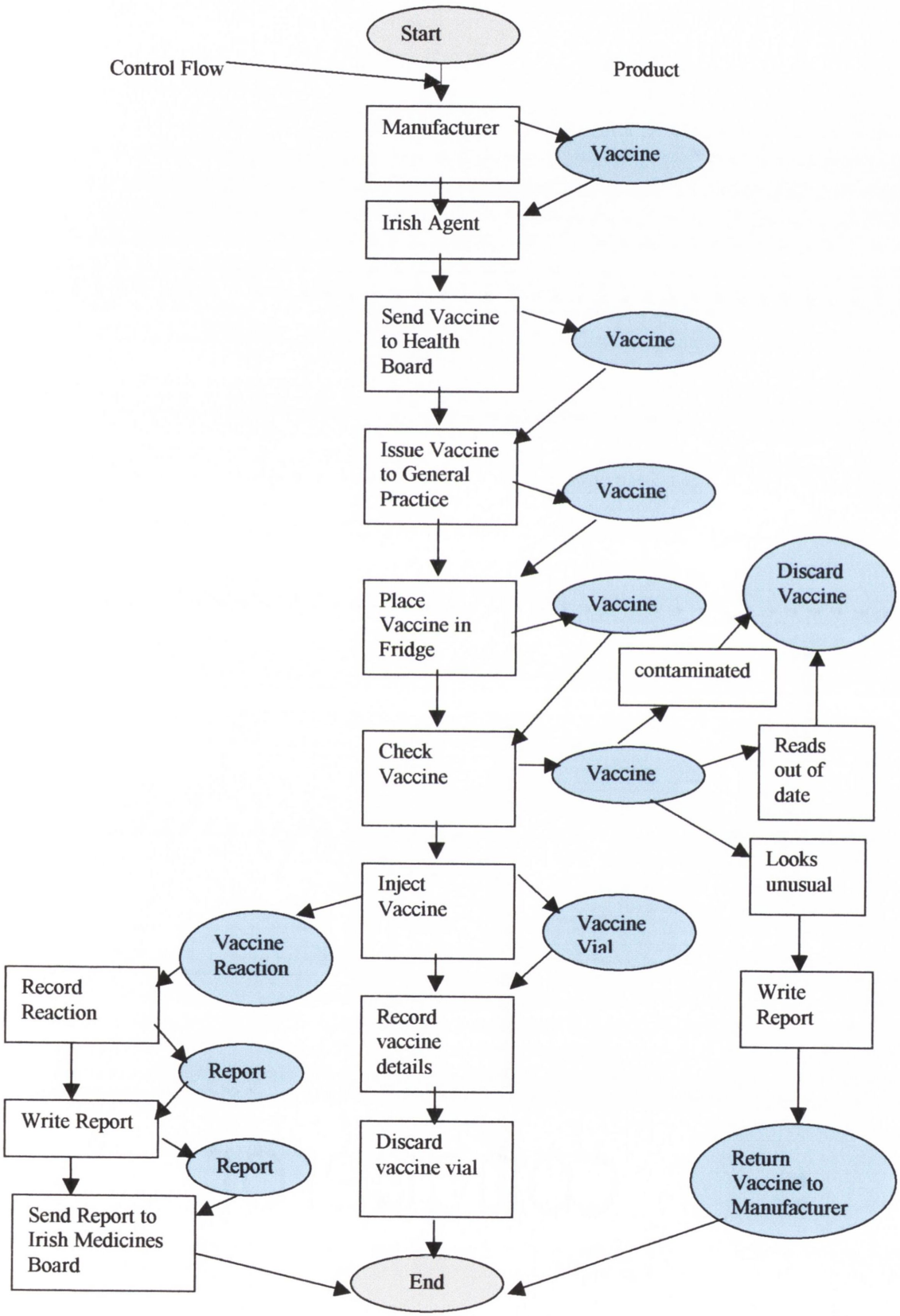
## Appendix O

Figure 15 State Diagram of Vaccine



## Appendix P

Figure 16 Activity Diagram of Vaccine Flow in the ERHA



## Appendix Q

Fig 17 Collaboration Diagram of Vaccine Administration Management in the ERHA