

Towards identifying the barriers to developing an electronic patient record (EPR) in a sexual health setting and to evaluate available systems and identify the system most suitable for use at a Sexual Health Clinic at a large Dublin public hospital

Grainne M. Courtney

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

2009

Declaration

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

Signed: _____

Grainne M. Courtney
September 2009

Permission to lend and/or copy

I agree that the Trinity College Library may lend or copy this dissertation upon request.

Signed: _____

Grainne M. Courtney

September 2009

Acknowledgements

I would like to acknowledge the excellent supervision and advice of Dr Lucy Hederman of the department of Computer Science Trinity College Dublin as this thesis would certainly not have got off the ground without her encouragement. I also thank the users of systems in other sexually transmitted disease clinics who gave valuable information about how these systems were working. My colleagues in St James Hospital were very helpful particularly Eleanor Whelton of the IMS department and my closer colleagues in the GUIDE clinic who are eternally supportive of new initiatives to improve patient care. Finally I would like to acknowledge my family, partner and soul mate Orla Howard, and daughters Clare O'Connell and Daire Courtney who have put up with the groans and weekends foregone.

Summary

This dissertation describes research on key criteria for an EPR within a sexual health clinic in a large Dublin public hospital and how potential software providers meet these criteria. The sexual health clinic is a very good setting for introduction of an EPR as the vast majority of patients fall into limited categories of presenting problems and most have the same initial assessment and investigations. It is a high volume, low complexity medical speciality which is an ideal context for an EPR. This project was undertaken because of significant problems in the Dublin based clinic with storage and retrieval of notes with large numbers of notes being stored off-site. A second driver for this project was a very significant problem in the clinic with results management where missing (positive) results have generated significant medico legal problems. All STI clinics operate under specific legislation; (Infectious Disease regulations 1981) which means that an extremely high level of confidentiality is required.

Methodology consisted of a literature review exploring existence of EPR in the sexual health area, barriers to introduction of EPR and privacy and confidentiality issues in this setting. Additionally two questionnaires were designed and administered firstly to software providers of STI patient management systems and secondly to users of these systems in different locations. Further an assessment was made as to whether the Dublin hospital preferred software provider (Cerner) could provide a software solution for this problem reducing the necessity for interfaces with existing hospital IT infrastructure.

Results reveal that there is no location in Britain and Ireland with a truly paperless EPR in the sexual health setting although a couple of locations are close to achieving it. The hospital preferred provider cannot provide a solution for reasons of confidentiality and poor functionality in results management. The critical issues for success in this project are identified and a list of software specifications from a clinical user's perspective is compiled which, if met will increase the chances of success for this project.

Abbreviations

API	Application Programming Interface
BASHH	British Association for Sexual Health and HIV
DOB	Date of Birth
EPR	Electronic Patient Record
EHR	Electronic Health Record
GP	General Practitioner
GUMCAD	Genitourinary Medicine Clinic Activity Dataset (UK NHS mandatory reporting system for all STI clinics)
HIV	Human Immunodeficiency Virus
HL7	Health level 7 (An ANSI-accredited group that defines standards for the cross-platform exchange of information within a health care organization)
ID	Infectious Disease
IT	Information Technology
LIS	Laboratory Information System
NaSH	National Sexual Health System (Scotland)
OCM	Order Communications
PAS	Patient Administration System
PPARS	Planning Permit Activity Reporting System (System purchased by Irish health service to manage human resources and payroll, implementation suspended because of massive budget overruns and poor performance)
SCI	Scottish Care Information (SCI Store and Gateway)
SHIP	Specialised Health Information Program
SSSTDI	Society for the Study of Sexually Transmitted diseases in Ireland
STI	Sexually Transmitted Infection
VRL	Virus Reference Laboratory
XML	Extensible Markup Language

Contents	Page Number
Chapter 1 Introduction	11
1.1 Electronic patient records generally	11
1.2 Barriers to introducing EPR in the sexual health setting	11
1.3 Key research question and methodology	12
1.4 Readers guide to the thesis	12
Chapter 2 Background	13
2.1 Introduction	13
2.2 The clinical setting- The hospital	13
2.3 The history of the STI Clinic and the hospital	13
2.4 The geography of the STI Clinic	14
2.4.1 STI Clinics	14
2.4.2 HIV Clinics	14
2.4.3 Infectious disease clinics	14
2.4.4 Timing of clinics	14
2.5 Medical records at the STI Clinic	15
2.5.1 STI paper records	15
2.5.2 STI registration process and STI EPR	15
2.5.3 other records used in the clinic (HIV and ID records)	16
2.5.4 Layout of paper STI records	16
2.6 Ordering tests at the STI Clinic	16
2.6.1 Laboratory tests	16
2.6.2 Radiology tests	16
2.7 Management of results at the STI clinic	17
2.7.1 Role of the Health Advisor within the STI clinic	17
2.7.2 Previous system for managing positive results	17
2.7.3 Current system for managing positive results	17
2.7.4 Cerner EPR system for electronic screening of results	18
2.8 Storage of clinic records	18
2.9 Reporting of STIs	18
Chapter 3 Key Criteria pertaining to use of an EPR in the sexual Health setting	
3.1 Introduction	19
3.2 Confidentiality	19
3.2.1 Double entry of data	20
3.2.2 Clinic guidelines for confidentiality	21
3.3 Interface between LIS and STI system	21
3.4 Interface between PAS, Cerner and new system	22
3.5 Interface between Medibridge (VRL) and new system	22
3.6 Functionality of the patient management system	22
Chapter 4 Literature Review	23
4.1 Introduction	23
4.2 Literature on Electronic records in STI setting	23
4.2.1 Patient views on IT in sexual health setting	23
4.3 Barriers to introduction of electronic records – UK NHS	24
4.4 Contrast between the implementation of IT in primary care and the hospital setting	25
4.5 US experience and barriers to progress on implementation of EHR	25
4.6 Confidentiality and electronic health records	26

4.7 European Union Data privacy directive	27
4.8 Literature: Conclusions	28

Chapter 5 Results of evaluation of available systems for use in the sexual health setting

5.1 Introduction	29
5.2 Questionnaire design and recruitment of respondents	29
5.3 The Exelicare system (Axsys Technology) NaSH Scotland	31
5.3.1 History and development of “NaSH” Exelicare system	31
5.3.2 Exelicare management of confidentiality: Provider perspective	31
5.3.3 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective	31
5.3.4 Results management in Exelicare: Provider perspective	32
5.3.5 Exelicare: User perspective	32
5.3.6 Exelicare: Is this system paperless in this location?	32
5.3.7 Exelicare laboratory ordering and results management: User perspective	33
5.3.8 Exelicare: Summary	33
5.4 The Lilie system (Blithe systems)	34
5.4.1 Introduction – provider description of system	34
5.4.2 Lilie management of confidentiality: Provider perspective	34
5.4.3 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective.	34
5.4.4 Results management in Lilie: Provider perspective	34
5.4.5 Lilie system: User perspective: Is this system paperless?	35
5.4.6 Lilie system: Laboratory ordering and results management: User perspective.	35
5.4.7 Lilie: Summary	36
5.5 TeleCare Mill systems	37
5.5.1 TeleCare description and confidentiality: Provider perspective	37
5.5.2 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective	37
5.5.3 TeleCare Results management: Provider perspective	38
5.5.4 TeleCare: User perspective: Background	39
5.5.5 TeleCare: User perspective: Is this system paperless?	39
5.5.6 TeleCare: User perspective: Laboratory ordering and results management	39
5.5.7 TeleCare: Summary	39
5.6 PreView SHE System (IMS Maxims)	40
5.6.1 PreView SHE: Provider description	40
5.6.2 PreView SHE: Provider perspective on confidentiality aspects	40
5.6.3 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective	40
5.6.4 IMS PreView SHE: Results management: Provider perspective	40
5.6.5 IMS preView SHE: User perspective: Background	41
5.6.6 IMS preView SHE: Is the system paperless?	41
5.6.7 IMS preView SHE: User perspective; laboratory ordering and results management	41
5.6.8 IMS preView SHE: Summary	42

5.7 SHIP (CaraData)	43
5.7.1 Description of SHIP	43
5.7.2 Management of confidentiality using SHIP:	
Provider perspective	43
5.7.3 Proposed interfaces with existing hospital systems:	
Provider perspective	44
5.7.4 Results management in SHIP: Provider perspective	44
5.7.5 E-triage in SHIP	44
5.7.6 SHIP system: User perspective: Location and Institutional	
Infrastructure	44
5.7.7 Is SHIP “paperless” in this location?	45
5.7.8 SHIP laboratory ordering and results management:	
User perspective	45
5.7.9 SHIP: Summary	45
5.8 Commercially available systems: Summary	45
Chapter 6 The Hospital preferred provider: Could this provider deliver an STI patient management system?	47
6.1 Introduction	47
6.2 Order Communications (OCM)	47
6.3 Display of results in Cerner EPR	47
6.4 The specific case of STI results management and Cerner EPR	48
6.5 Cerner proposed solution for STI patient management system	49
6.6 Summary	50
Chapter 7 Minimum requirements for an EPR in the sexual health clinic in this hospital from the perspective of a clinical user	51-54
Chapter 8 Conclusions and recommendations	55
8.1 Introduction	55
8.2 The critical issues	55
8.2.1 Confidentiality	55
8.2.2 The Interface with Cerner	55
8.2.3 Results management	55
8.2.4 Interface with Medibridge	56
8.3 The hospital preferred provider	56
8.3.1 Confidentiality	56
8.3.2 Results management	56
8.4 The other providers of Sexual Health Patient Management Systems	56
8.4.1 Can they provide a paperless solution?	56
8.4.2 Order communications	56
8.4.3 Results management	57
8.4.4 Software support	57
8.5 How to move this project forward	57
References	58-59

Appendices		Page No.
Appendix A	Infectious Disease Regulations 1981	60-68
Appendix B	Questionnaire for Users of STI patient management systems	69-70
Appendix C	Questionnaire for software providers	71-74
Appendix D	Ethics proposal for this study	75-85
Appendix E	Performa Patient Notes for Sexual Health Clinic	86-92
Appendix F	Legal opinion A&L Goodbody	93-98

Chapter 1

Introduction

1.1 Electronic patient records generally

It is generally accepted that the future of management of medical records lies with EPR. There are many advantages to having EPR notably rapid access to records, multiple users can access records simultaneously, legibility of records, embedded decision support, uniformity of data collection along with the obvious advantages of generation of reports, statistics, research, billing etc

This dissertation describes research on key criteria for an EPR within a sexual health clinic in a large public hospital and how potential software providers meet these criteria. The sexual health clinic is an ideal setting for introduction of an EPR as the vast majority of patients fall into limited categories of presenting problems and most have the same initial assessment and investigations. The medical speciality of sexual health and STI diagnosis and management is very protocol driven in terms of assessment and treatment, and performatives and treatment algorithms are widely used. The very large numbers of patients seen generates very large volumes of new patient notes and there are significant problems with storage and retrieval of notes, with very large numbers of notes now being stored off site and microfilmed with consequent difficulties in access to old notes.

1.2 Barriers to introducing EPR in the sexual health setting

Barriers to setting up an EPR can be divided into two categories: barriers which are common to any health setting trying to set up an electronic patient record and barriers which are specific to the sexual health setting and the most important one of these is confidentiality. Medical and paramedical personnel working in the sexual health area operate under the auspices of the Infectious disease regulations 1981 (appendix A) which are very specific about the level of confidentiality required which is very high and much higher than that required for any other patients attending the hospital. Another barrier is the sheer volume of work. STI clinics are high volume, low complexity clinical setting. Every outpatient clinic has large numbers of new patients but most clinical scenarios are straightforward. Each patient generates a minimum of 5 investigations (a significant subgroup generate 8 or more investigations) and results management is a critical issue for all sexual health clinics. All of the results of these investigations must be checked and acted upon by various health professionals in the event of a positive result as the patient does not return to the clinic unless recalled. Because patients only attend once, an absolutely robust system for the checking of results is required, especially for cervical cytology and HIV tests as, a missed positive result in either of these situations would result in likely significant morbidity for the patient and consequent major medico legal liability. Additional factors are reporting requirements - there is a list of sexually transmitted diseases which when diagnosed must be reported to public health for the purposes of monitoring outbreaks and compiling national statistics.

1.3 Key research question and methodology

There are several “off the shelf” systems on the market which purport to offer a paperless EPR for use in sexual health clinics. However to my knowledge very few clinics in the British Isles are truly paperless and many who are using these systems also maintain paper records. The object of the research described here was to investigate whether there exists an available system which would truly offer a paperless service, which would allow us to download laboratory results into our individual patient records and allow us to fulfil our regulatory requirements while at the same time maintain patient confidentiality to the level required under the infectious disease regulations. A systems requirements document for an EPR for the Sexual Health service at the hospital was prepared, prior to this research, by the hospital’s Information Systems Department (IMS) incorporating input from clinicians and other users. For this dissertation available “off the shelf” systems were evaluated using some of the criteria from this document along with other criteria suggested by the literature review and the infectious disease legislation. Software providers were then surveyed to evaluate the functionality of available systems and users of these systems in other sexual health clinics were surveyed to assess how these systems were working in other institutions. A major IT project occurred during 2005 at the Dublin hospital with the implementation of a hospital wide EPR supplied by Cerner Millennium. An exploration was undertaken to see whether the hospital’s preferred software provider Cerner could provide a solution for this problem which would reduce the need for interfaces between the STI patient management system and existing institutional software.

1.4 Readers guide to the dissertation

Chapter 2 describes the background in which this system is to operate – the STI clinic at the hospital. It is followed by a discussion of the key criteria which will determine whether a paperless electronic record for the management of STI patients will work in this setting. The literature is reviewed in chapter 4 in the areas of barriers to introducing EPR and privacy and confidentiality of records. This is followed by a description of the available systems and the results of two questionnaires, one distributed to users of available systems and one to software providers. Chapter 6 is devoted to investigating whether the current hospital preferred software provider can provide such a system within the current EPR in use at the hospital. The conclusions address the question of whether a paperless EPR can be delivered in this clinical setting in this institution and suggest measures to reduce the risk of failure for this project. Chapter 7 presents a list of minimum specifications from a clinical user’s perspective, which the procured system should meet, which will greatly enhance the chances of success from a clinical point of view.

Chapter 2

Background

2.1 Introduction

This chapter describes in detail the clinical setting in which this change is to take place. The history of the hospital and the setting up of the clinic in the 1980's is outlined. The main focus of this description will be on the STI service at the clinic which is a distinct entity within the larger clinic. HIV and Infectious disease services are referred to for the purposes of background and information about the clinical setting in which we operate.

2.2 The clinical setting- The hospital

The hospital is a large public hospital situated in Dublin 8 which is an inner city, socially deprived environment. It was created by the amalgamation and shutting down of various smaller voluntary hospitals during the 1980's and the expansion of the largest voluntary hospital on the biggest site. The Sexual Health Clinic at the hospital is the biggest sexual health clinic in Ireland, North and South, with more than 10,000 attendances per year. The catchment area of the sexual health clinic is much larger than that of the main hospital and the clinic attracts patients from all over Dublin, the East and the Midlands. For reasons of confidentiality many of our patients come from even further afield as they are reluctant to attend local services. There is a sexual health service in the North side of the city at another hospital but the capacity of that clinic is very small and most patients from the North side of the city come to the sexual health clinic herein described. The clinic is the national referral centre for sexually transmitted infections (STIs) and sexual health.

The hospital has an integrated Hospital Information System (HIS), Laboratory Information System (LIS) and Radiology Information System (RIS) and every patient attending the hospital is maintained on an Electronic Patient Record (EPR Cerner) so there is already a significant amount of information held electronically on our patients.

2.3 The history of the Sexual Health Clinic at the hospital

The sexual health clinic has operated for many years at the hospital where services were moved after the closure of 2 smaller hospitals which operated evening clinics throughout the latter half of the 20th century. Services were consolidated at the hospital in 1985 with the appointment of the first consultant in genitourinary medicine (the medical speciality which covers STIs). The HIV epidemic began at around the same time as this appointment and services expanded rapidly to cater for both STIs and HIV. The department expanded in 2000 to become a combined infectious disease (ID) and genitourinary medicine department. There are currently five consultants in the department; two in genitourinary medicine, 3 in infectious diseases and one associate specialist in genitourinary

medicine. All of the specialists treat HIV patients and the genitourinary specialists also focus on STIs while the infectious disease consultants also specialise in general infectious diseases like TB and malaria.

2.4 The geography of the Clinic

The hospital occupies a large site with many buildings, and the clinic is situated in a separate building which also houses diabetic day services, dermatology day surgery and some offices. This building is away from the main hospital with all of its radiology and other facilities. The department has its own discrete area which has a reception area, consulting rooms, day ward facilities, office space and, upstairs from the consulting rooms, an in-patient ward for admission of ill HIV and STI patients. The facilities of the clinic are not used by any other service and this allows us to keep our records separate from the rest of the hospital. The service runs clinics all day, every day, Monday to Friday in three main categories

2.4.1 STI Clinics

There are four general STI clinics and one adolescent clinic (clients aged 15-19yrs) per week. These clinics are for the purpose of diagnosis and management of STIs. There is also one nurse-led wart treatment clinic. The general STI clinics are very large clinics with approximately 30-40 new patients and up to 50 return patients per clinic. Approximately 120-140 new STI charts are created every week at the clinic.

2.4.2 HIV Clinics

There are two general HIV clinics, one HIV/Hepatitis C co-infection clinic and one new patient HIV clinic per week. These clinics provide ongoing care for patients who are already diagnosed HIV positive.

2.4.3 Infectious disease (ID) clinics

There is one general infectious disease clinic per week. Patients with infections other than HIV or STI are seen at this clinic for evaluation and ongoing treatment. An example of patient types seen at this clinic would be patients being investigated for unusual infections such as Lyme disease, malaria or other tropical infections.

2.4.4 Timing of clinics

All of these clinics operate in the same location and in general we do not operate parallel clinics, due to space constraints, although some clinics overlap (Tuesday and Thursday mornings). The clinic schedule template is as follows:

Clinic Template

	Monday	Tuesday	Wednesday	Thursday	Friday
AM	General STI	Nurses HPV	General HIV	Adolescent STI	General STI
AM		HIV/HepC Co infection		New Patient HIV	
PM	General HIV	General STI	General ID	General STI	

2.5 Medical records at the Clinic

There are currently two kinds of medical records at the clinic: (1) STI records (paper and electronic records) and (2) Other records (HIV and Infectious disease records which are treated the same way, also paper and electronic)

2.5.1 STI paper records

When a patient presents to the clinic with a sexual health problem they are registered by reception staff (see below for registration process) as an STI patient and a patient record is created which is a paper set of patient notes. This is a relatively slim volume of notes as most patients only attend once and storage is a significant issue. The notes are colour coded blue for males and pink for females (Appendix E Performa patient notes). All of the demographic information pertaining to the patient; name, address etc. is entered manually onto these notes. These notes never leave the department and are filed within the department in the reception area. If a referral to another department is required these notes may not be used and a separate set of hospital notes is set up when the patient presents to the other department. The reason that these notes are entirely different from other hospital notes is because of the legal requirement to maintain separate notes with a very high level of confidentiality on patients who attend an STI clinic (appendix A Infectious disease regulations). The same requirement for confidentiality does not pertain to HIV notes as HIV is not a notifiable disease nor is it classified as an STI under current Irish Infectious disease regulation so the level of confidentiality required for HIV records is lower than that of STI records.

2.5.2 STI registration process and STI electronic patient record

When the patient is registered by the reception staff at the clinic as well as setting up the paper STI record a hospital medical registration number (MRN) is set up and this is done electronically on the hospital Patient Administration System (PAS). This MRN is required for the purpose of ordering laboratory tests as all tests are ordered electronically by order communications (OCM) via the hospital electronic patient record (EPR provided by Cerner). The PAS "feeds" the Cerner EPR i.e. all information registered on the PAS is transferred automatically to the EPR. Because the STI patient attendance is totally confidential (see appendix A infectious disease regulations) only limited patient information which would not allow identification is entered onto PAS. Currently the following patient information is entered onto PAS: initials, Date of Birth (DOB), post code, phone number, GP name and address if given.

2.5.3 Other records used in the clinic (HIV and Infectious disease records)

HIV and other patients attending the infectious disease clinic are registered by the clinic reception staff as ordinary hospital patients i.e. all their demographic information including full name and address are entered onto PAS and thus transmitted to EPR and this information can be accessed by anyone with access to the hospital information system, depending on their access level. A paper chart is also set up in the clinic for these patients but unlike the STI record this chart can be used all over the hospital and if a HIV patient is referred to another clinic this chart is used. It is, in fact, the case that HIV is not considered to be an STI for notification purposes, and therefore does not require the same level of confidentiality as any other STI. This anomaly exists because of political pressure from HIV activists, to prevent HIV from being made a notifiable disease, at the beginning of the HIV epidemic when services were being developed, due to fear that patients could be identified and might experience the effects of stigma associated with the disease. So in effect, HIV patients are at more risk from compromise to confidentiality within the hospital than other STI patients.

2.5.4 Layout of paper STI records

The paper chart used in the STI clinic is set up as a performa pre-printed chart where the user is prompted to ask a series of questions, perform a standardised examination and request a standard panel of tests (Appendix E performa notes). Most patients attend the department once only although a significant minority are return attendees.

2.6 Ordering tests at the Clinic

2.6.1 Laboratory tests

All tests, both laboratory and radiology, are ordered via order communications (OCM) using the Cerner clinical work station to order the tests. These order comms are transmitted to the laboratory via interfaces with the laboratory system. The person who orders the laboratory test prints out a bar-coded label which is attached to the specimen – it could be a blood test, a culture plate or a swab tube. When this test arrives in the laboratory the label is scanned before the item is placed on the analyser. After the tests processed and complete the result is transmitted to the patients EPR and can be looked up by any further provider who sees this patient.

2.6.2 Radiology tests

Ordering radiology tests is different in that the request has to be screened by a doctor in the radiology department and a priority assigned. The appointment is then sent to the patient by post. Because it is required to have the patient name and address on the system to send

out the appointment, if an STI patient needs an x-ray then a new hospital number is generated different from the STI number and all of the demographic details are entered onto this record. If the patient ever attends the hospital again for anything other than STI this is the number that is used. The result of this is that radiology reports do not appear in the STI patient EPR, but in the EPR which was created on that patient to generate the X-ray order.

2.7 Management of results at the clinic

Many patients who attend the GUIDE clinic for an STI screen attend only once. They are advised that their results will be checked and that they will be called on their mobile phone if they have a positive test result. Over the years many different systems have been tried to manage results but unfortunately on rare occasions a positive result has been missed with serious consequences.

2.7.1 Role of the Health Advisor within the STI clinic

This staff member is specific to STI clinics and is not replicated elsewhere in the health service. The health advisor is specifically trained to counsel patients diagnosed with an STI and to perform partner notification or contact tracing whereby the sexual partner of the index case is brought in for screening and treatment. It is also part of the responsibility of the health advisor to deal with any positive results and to ensure that the index case and any partners are treated.

2.7.2 Previous system for managing positive results

The laboratory sends a paper copy of every result of every test done in the clinic. These results were checked by a doctor and the positive ones were given to reception staff to “pull” the notes so that the positive result could be acted upon by the health advisor. There was a major backlog in the system as more than 1000 results come into the department each week between STI and HIV results. All results, positive and negative, were filed in the notes which constituted a major burden. Using this system it is impossible to notice a test for which no result is returned – missing result.

2.7.3 Current system for managing positive results

After each STI clinic the charts are kept aside in a filing cabinet each clinic having a separate drawer. 10 days after clinic a department secretary takes this bundle of notes and prints out all of the results from Cerner EPR filing the appropriate results in each patient chart. This bundle is then given to a nurse or doctor in rotation to check that all the results are present and correct and negative. If so the notes are sent back to reception for filing. If there is a positive result the notes are sent to health advisors for action. If there has been a GP referral the notes are sent to a consultant for dictation of a letter to the GP. Using this system it takes about 4 hours per week of very senior doctor time to check the charts.

The paper results which come from the laboratory are discarded and the reason that they are not used by the secretaries is that they arrive in random order i.e. the five different results for one patient could arrive on five different days.

2.7.4 Cerner EPR system for electronic screening of results

The Cerner EPR system has a method for results management called “results to endorse”. Under this system all results are sent to a consultant to be endorsed electronically. The consultant can then delegate this function to someone else and pass the results onto that other person to endorse, however this cannot currently be done by out-patient clinic session. Also all the results come in separately from different labs and the five different test results on a typical STI patient could all come in on different days depending on which lab they came from. Under the results to endorse function it is difficult to see if the result is positive or negative so each result must be opened separately and this for more than 1000 tests per week. Because these results cannot be endorsed by outpatient clinic (an outpatient clinic groups a number of patients together who attended in the same session on the same day) the department to date have declined to move to electronic screening of results and continue to perform this function manually.

2.8 Storage of clinic records

Once the STI record is signed off after clinic and no further action is required, the notes are sent back to reception for filing. As more than 120 new sets of notes are created per week there is a significant storage problem for STI notes most of which are only used once. When the reception area is full the older notes are weeded out and sent elsewhere onsite for storage. Very old notes have been microfilmed. The hospital has a policy of retaining all patient notes on STI patients regardless of age so we have notes going back to 1987.

2.9 Reporting of STIs

There is a statutory requirement on all medical practitioners to report STIs to the local public health department. There is a list of STIs which must be reported on a timely basis, usually monthly. Currently most of the STI notifications are made by the microbiology laboratory in St James, as due to the volume of work the staff at the clinic are unable to meet this requirement. This means that the public health receive figures for infections along with data on age, gender and post code but they receive no other clinical information on STIs which is problematic. They would like to receive clinical information on patients with STI e.g. sexual orientation or numbers of partners but currently this kind of data cannot be supplied because of the volume of numbers. The only STIs which are reported clinically are genital HPV (genital warts) as there is no laboratory test for this.

Chapter 3

Key Criteria pertaining to use of an EPR in the sexual Health setting

3.1 Introduction

Key criteria crucial to the success of this project were identified from a number of sources. Firstly there was an attempt to introduce an EPR in this setting 10 years ago which failed because of lack of laboratory interfaces and the necessity to use paper notes as well as the electronic system. All patient data had to be entered onto patient notes as well as the electronic system by the same user and the system was never used. Because of this experience key stakeholders in the department have identified the necessity for a single patient management system as a key criterion. It is anticipated that all documentation pertaining to each patient including referral letters will be managed by the electronic system with no necessity for any paper records. Other key criteria were identified from the infectious disease regulations of 1981 (Appendix A). A system requirements document was prepared in relation to this system by the IMS department at the hospital with input from many stakeholders and some key criteria were identified from this document.

3.2 Confidentiality

A very high level of confidentiality is required for attendance of patients at STI clinics. Without broad confidence in the system's confidentiality the patient may not attend and may thus continue to spread the disease. If the user has no confidence in the confidentiality of the system it may lead to the existence of duplicate records or omission of information from records(Thomas 1997) and this occurs on a regular basis in family practice records. This confidentiality requirement is governed under the provisions of the Infectious Disease Regulations of 1981. The relevant section is section 20 and reads as follows.

"S.20 (2) Any records kept in pursuance of this article and any notification made to a medical officer of health under these regulations shall be treated in a confidential manner and, save as provided in sub article (5) of this article, shall not, without the consent in writing of the patient, be disclosed in such a manner as to make identification of the patient possible.

Article (5) refers to how this consent may be dispensed with in the interest of the common good.

The patient's attendance should only be accessible to the STI clinic staff and other St James Hospital staff should not have any awareness of the patient attendance at the STI clinic. Currently the STI patient notes are kept entirely separate from other hospital notes and are kept within the department. Because of the very large volume of attendances old notes are stored off site but no St James' staff other than STI clinic staff has any access to them. When the patient attends their initials, date of birth (DOB) and postcode are registered on the Hospital Patient Administration

System (PAS – iSoft) for the purpose of generating a Medical Registration Number (MRN). The MRN is required to generate order communications for ordering laboratory tests and for accessing the results of these tests via the hospital EPR (Cerner). The reason that only initials and not name are registered is so that no other employee with access to the PAS system or the laboratory can see that this person has an STI episode of care as this would breach the patients confidentiality as no person should be able to detect that a patient has had an STI attendance. However at the moment this patient record is visible to anyone who logs into the search function of the PAS or the Cerner EPR and searches under initials and DOB. So if someone with access to the system wonders if someone they know has had an STI episode at GUIDE, they can enter the initials and DOB and if the system shows a record for those details, then they might infer that that person has attended the STI clinic. They cannot open the episode in the Cerner EPR as only staff with the required access level can open those laboratory records but they can see that someone with those initials and DOB attended the STI clinic as only the STI clinic registers patients in this way under initials and DOB.

To prevent the kind of breach discussed above, it would be necessary to register STI patients on the PAS without any details whatever, and obtain an MRN for them. The STI clinic could keep a mapping between its clients' details and MRNs. However this would likely lead to errors in accessing records in the hospital EPR. If an MRN were mistyped, or a wrong one entered, there would be no details on the accessed record by which to cross check the identity. It is currently the policy that where name is not entered that it is good practice to have 2 pieces of identifying information to retrieve patient results from the laboratory to ensure that it is the correct patient for critical results e.g. HIV test results. It is unlikely that the laboratory would agree to give phoned results without 2 separate identifying pieces of information, so the current practice of entering initials and DOB into PAS is likely to continue.

During a previous attempt to introduce some electronic records at the GUIDE a legal opinion was obtained from the hospital solicitors A&L Goodbody (Appendix F) which suggested that the same standard of confidentiality should apply to electronic records as has always applied to paper notes i.e. that no patient should be identifiable as having had an STI attendance, by any St James staff outside of the GUIDE clinic or any other agency. It is possible that the current practice of patient registration on the hospital wide electronic system is not in strict adherence to this opinion as patients can be identified on the basis of initials and DOB.

3.2.1 Double entry of data

This necessity for confidentiality throws up the problem of **double entry** immediately. At the moment when a non-STI patient registers at the hospital as a new patient all of the patient information is entered onto the PAS system and the PAS system “feeds” the Cerner system which currently displays the laboratory results, discharge summaries and the radiology. As the STI patient demographic information cannot be displayed on PAS this means that this information would have to be entered on whatever system would be used to maintain the STI records as well as some data (at present: initials, date of birth and post code) being entered on the PAS system which must be used to generate the MRN. A significant amount of keying activity is done at this point even though full demographic details are not entered. At the moment if a patient attends the hospital for any reason other than an STI attendance,

the STI MRN number cannot be used for this attendance even if it is located. A new MRN is generated for another clinic or in-patient episode as the STI MRN cannot be used by any other service. Likewise if a patient attends for STI assessment that already has a hospital MRN this number is not used and a new MRN is generated for the STI attendance. Once the STI MRN is generated it is used for every attendance of that patient at the STI clinic. Likewise the hospital MRN is used for every episode in the hospital other than STI attendance.

3.2.2 Clinic guidelines for confidentiality

Under current clinic guidelines staff members need written patient consent to discuss any matter relating to that person with any other person including that patient's sexual partner, family or next of kin, the patient general practitioner (GP) or any insurance company or any agency looking for information about that patient. Even if a patient is diagnosed with a sexually transmitted disease and that patient's partner comes for screening the diagnosis may not be disclosed to the partner without the patient's express permission. If after screening the partner is diagnosed with the disease then they can be told what it is because it now their diagnosis, but they still cannot be told any of the contents of their partner's notes without permission. This very strict level of confidentiality throws up ethical dilemmas on a frequent basis particularly when dealing with couples where vital information is not disclosed between one partner and another. There are some occasions where confidentiality can be dispensed with but this is on a case by case basis. The concern that patient information could be retrieved by users of the hospital system or others is an issue of very high importance for the stakeholders. It has been shown in the literature that information which has been anonymised can be used to identify patients (Malin and Sweeney 2004).

3.3 Interface between LIS and STI system

The second key issue is the interface between the Laboratory Information System and the new system. The very large number of patients seen generates a very large volume of results. A key requirement would be that these results would download directly into the electronic patient record and that the system would automatically detect abnormal results. This function would be crucial both for the recall of patients with an infection and for the dissemination of negative results to patients where appropriate. This function would also be very important for the purpose of reporting numbers of STIs to public health agencies. If an "off the shelf" system were purchased this would require a number of interfaces. The crucial interface is between the current hospital laboratory system – Telepath - and the new STI system. Telepath currently interfaces with Cerner and it produces useful results for criteria which are numerical e.g. liver functions tests where the result is a number between certain parameters. However the interface between Cerner and Telepath is not particularly useful for microbiology results which are currently produced as a text based format e.g. "Chlamydia DNA not detected" and viewed in Cerner EPR as a "snapshot" of this text based result so in the current circumstances it is not possible to do anything useful in terms of decision support with this kind of data. For this project to deliver the required functionality for results management the

Telepath results would need to be transformed into structured data items in order to produce data which can be worked with. As over 90% of the laboratory results coming into an STI clinic are microbiology results, transforming Telepath Micro results into structured data items is a critical requirement for this project.

3.4 Interface between PAS, Cerner and new system

Some of the issues here have been covered in the section covering confidentiality. Currently an interface exists between PAS and Cerner. If an “off the shelf” system were used the demographic details would be kept on that system and the current system of having only initials, postcode and DOB on PAS and Cerner could continue. However this would necessitate an interface between Cerner and the new system, possibly PAS and the new system and would also involve double entry of demographic data. The entry requirements for PAS are already quite cumbersome so double entry would significantly lengthen the registration process. This however would be offset by the extra time available which is currently spent pulling, filing and searching for patient notes. The interface between the new system and Cerner is still a critical one because even if the “Telepath” problem outlined in the paragraph above were solved, all of the order communications are performed via Cerner and the existence of Order Communications System delivers immense value to the user in terms of results management in particular in minimising or, in fact, abolishing orphan results and locating missing results.

3.5 Interface between Medibridge (results from Virus Reference laboratory) and new system.

Currently some laboratory tests are outside of the hospital laboratory information system notably cervical cytology and virology tests which are processed by the Virus Reference Laboratory (VRL). Tests processed by the VRL currently come into St. James Hospital via a messaging system – Medibridge but these tests do not download to the EPR (Cerner) and have to be looked up separately by the provider at the consultation. Not every STI patient who attends the clinic has tests sent to the VRL but a significant minority do (approx 15%). The haemophilia service in the hospital uses a clinical information system, Clintech, which downloads results directly from the VRL via Medibridge, so it is possible to do it. This interface is a critical requirement as if this EPR were ever to be extended for HIV patient management download of virology results would be vital for success as HIV patients have a large volume of virology results.

3.6 Functionality of the patient management system

The main focus of this document concentrates on the difficult issues of managing confidentiality and crucial interfaces and it is taken as read that each system is fit for purpose i.e. can perform the day to day requirements of an STI patient management system but this issue will be addressed in the section on the individual systems.

Chapter 4

Literature review

4.1 Introduction

The literature was explored with regard to existence of electronic patient records in the sexual health setting and patient acceptance of electronic records. An analysis of the barriers to the introduction and implementation of electronic records was undertaken comparing the experience in primary care to the hospital setting and experience in the UK in comparison to the US setting in an attempt to identify possible pitfalls for this project. The areas of confidentiality, privacy and EU directives on same are particularly explored because of the relevance of these issues in the sexual health setting.

4.2 Literature on Electronic records in STI setting

There is a paucity of material in the literature relating to the specific area of EPR in the sexual health area and none in relation to Ireland. This is relevant as the legislation and regulations governing management and reporting of STDs are very different in different jurisdictions. Many sexual health units in the UK are some way along the process of introducing electronic patient records but very few are truly paperless so published experiences are limited. Brook et al.(2008) described their experience of implementation of EPR in a sexual health clinic and these mainly related to planning, training and “go-live” which was implemented on a single day. They found very significant advantages in instant access to the clinical record, no requirement for storage space, no missing notes, faster booking, and faster contact with positive results and increased scope for audit. Disadvantages identified by this group were diminished eye contact with patients, significant training requirements, high level IT support required along with some decrease in the workflow depending on the staff members typing skills.

4.2.1 Patient views on IT in sexual health setting

Ross et al.(2007) used a questionnaire to interrogate patients and community interviewees about their views on the introduction of information technology in sexual health clinics. Interviewees were asked about the acceptability of providing details of sexual history directly onto a computer and whether they thought storing of sexual health records electronically was acceptable, along with other questions about booking preferences and use of web based resources for sexual health information. They found that most patients would not mind completing details electronically, however patients with non-white ethnicity were significantly less likely to find self completion of electronic records acceptable and this group comprise a high risk group for STIs. The majority (78%) had no concerns about data on sexual health records being stored electronically. Concerns were expressed by interviewees about potential loss of confidentiality associated with electronic records along with fears

about computer viruses and loss of data through system failure. The authors referred to the NHS Care Records Guarantee (Brockley 2006) making specific commitments to patients about their electronic records including limiting access to a 'need to know' basis, allowing patients to block part of their record to prevent it being shared and an option to restrict access only to the organization that created it. Tideman et al. (2006) undertook a cross-sectional survey of 679 clients attending a Melbourne sexual health clinic and reported that 80% of clients surveyed expected that electronic records would be used in a sexual health clinic. They found that a minority were not willing to supply details using a computer and those at risk of an STI were no less likely than others to provide details using a computer-assisted-self-interview.

4.3 Barriers to introduction of electronic records – UK NHS experience

There is a wealth of literature on the introduction of electronic patient records generally and much has been written on barriers to their introduction and the reasons for the very slow progress in the hospital setting. Jones (2004) tracks the many initiatives and strategies which have taken place in the UK NHS attempt to introduce EPR, from the 1998 initiative where £56 million was invested to connect the Patient Administration System (PAS) with laboratory orders and results reporting, through to the Electronic Record Development and Implementation Programme (ERDIP 2002). He concluded that it was unclear whether the best managed hospitals were at the forefront of electronic records development, and he observed that in an environment of performance and targets it could be unclear how Information technology would help. He states that information technology is not seen as the most effective way of delivering clinical governance and audit, and cites this as the reason for slow progress along with the usual issues of competing resources and inconsistency of approach. Jones, in a wide ranging review, identifies barriers to implementation as lack of organisational change with the focus on getting systems installed, delaying and weakening organisational change which is required. Barriers to sharing of experience, Jones concluded were a significant issue for organizations and these factors which discourage organizations from seeking out and applying knowledge were identified as self perceptions and rivalries and the belief that the organisation was unique. This analysis is very relevant for this project as the information technology departments in Irish hospitals and, in particular in this institution, certainly views the institution as unique from an IT point of view and have not to date sought any information from other institutions pursuing similar projects. He pointed to delay as a significant barrier which can weaken organisational change initiatives and noted that where extended decision making, procurement and implementation were factors, that technology could be out of date before it's even introduced. He questions whether the responsiveness needed to keep up is feasible in large hospitals and health organisations like the NHS where policy changes rapidly. Looking at what is happening at the time of writing he sees no evidence that organisations implementing electronic records policy have learned from past experience and are still focused on technology procurement and implementation. For this project this offers the very important point that changes in work practices will be as important an issue as the procurement of the system if not more important as many employees notably clerical and reception staff will find their roles entirely changed by the process. Jones offers some solutions for the problems outlined above and suggests the creation of mechanisms for analysing and reporting experience. He advocates the promotion of a culture in which failure can be admitted, reported and discussed and finally he suggests alignment of electronic records with the clinical

agenda. Hendy et al. (2007) in a later review cite the problem of multiple sites, poor communication between Connecting For Health and local managers and financial deficits as the major issues and she also sees the need to support legacy systems and the delayed timetable for the implementation of PAS as stumbling blocks to progress in the NHS. Legacy systems will certainly be an issue during this project as the single biggest IT initiative in the hospital has tied the sexual health clinic into the hospital preferred provider (Cerner) and interfacing with this albeit relatively new legacy system will be a critical issue for this project.

4.4 Contrast between the implementation of IT in primary care and the hospital setting

Benson (2002) asks why General practitioners have been so successful at introducing information technology while hospitals have not. He notes that for 30 years the government have provided incentives to introduce computerisation in primary care and have helped remove barriers. In contrast in hospitals computers are seen as a management overhead and doctors have been given no incentives to get involved. He observed that in countries where payment is based on item of service there is no difference in computerisation between primary and secondary care providers. He points out that in the NHS Information technology staff are employed on clerical or administrative grades and that salaries for these posts run at 40% less than equivalent jobs outside the NHS. He concludes that differences in leadership, economic incentives and scalability are the reasons for the dramatic difference in use of IT between primary and secondary care. The sexual health clinic itself in terms of scale could be viewed as being similar to a group GP practice and in fact in one of the sexual health settings described below (SHIP, Waterford Regional Hospital STI Clinic) they have placed themselves as a "GP practice" outside of the hospital from an IT point of view, while geographically inside the hospital and not fully integrated into the hospital systems. They have thus placed themselves outside of the need to integrate with legacy systems but can benefit from the electronic results download designed originally for GP practices.

4.5 US experience and barriers to progress on implementation of electronic records

Vishwanath (2007) et al. look at the American experience and identify lack of enabling healthcare policy as a significant barrier to the introduction of EPR. They also cite the inability to achieve broad informatics standards, along with perceived complexity and resistance from physicians as the main reasons for the slow progress in the US. Do Bias (2006) states that only 25% of US physicians are using EHR and only 10% of hospitals are using CPOE and this situation is mirrored or worse in the Irish healthcare context. He points out that those providers, who see more Medicaid patients, are less likely to use EHR than those who see fewer Medicaid patients.

Jha (2009) in a wide-ranging review of the use of EHR in US hospitals examined the relationship of adoption of EHR to specific hospital characteristics and factors reported to be barriers or facilitators of adoption. They found that only 1.5% of US hospitals have EHR in all clinical areas, 7.65% having a basic system, and CPOE implemented in 17%. Larger, urban and teaching hospitals were more likely to have EHR. They found no relationship between ownership status and EHR and the prevalence of EHR was similar in private and public institutions. They found the barriers to be capital, maintenance of systems, resistance from physicians and lack of availability of staff with adequate IT experience. They point to the experience in veteran hospitals (Jha, Perlin et al. 2003) where EHR has been used for more than 10 years with dramatic associated improvements in quality. In fact including the

Veterans Administration Hospital in their analysis led to a doubling of the count of US hospitals with a comprehensive system.

Mutual transformation is described by Berg (2001) as the process by which the organization and the technology transform each other during the process and when this is foreseen patient care information systems can be intended strategically to help transform the organisation.

Ford (2006) uses a technology diffusion model to try and predict when these technologies will be widely used. He identifies innovators, first adapters, early adapters, early majority, late majority and laggards as the categories of users of new technology. He points out that general purpose technologies take long periods to reach the diffusion tipping point and do not deliver productivity gains immediately on arrival and he looks to Australia and Europe as models of significant government partnership to achieve progress. Hersh (2004) feels that those who pay do not see enough of the benefits and that most of the benefits of EHR accrue to laboratories, patients and insurers rather than physicians. Blumenthal et al. (2007) while identifying similar barriers to other sources points out that a major limitation of the literature is that most key studies in this area come from 4 institutions that pioneered Hospital Information Technology (HIT) and developed their own EHR incrementally over time and he questions the relevance of these studies to hospitals which are purchasing "off the shelf" systems. He suggests that even where capital is available that investment in IT is much lower than in other physical projects or technology and that hospitals shy away from IT investment in favour of projects more relevant to the bottom line. This would have a resonance in the Irish setting as the failure of the very large PPARS project has negatively impacted on other IT projects in the healthcare area. Privacy and confidentiality are identified as barriers in the literature (Hersh 2004) but he states that paper records are at least as insecure as electronic records.

4.6 Confidentiality and electronic health records

In a sexual health clinic setting confidentiality is of primary importance and the level of confidentiality required is much higher than that required for ordinary medical records which should be high. The literature is full of reports of how it can be breached in various ways. Malin and Sweeney (2004) developed and evaluated a general technique for re-identifying seemingly anonymous genomic data to the named individuals that the data were derived from. In a more in depth analysis of the privacy issue Williams (2008) identifies the problems which frequently occur leading to compromise of confidentiality in EHR. Firstly **trust**: meaning trust that staff responsible for security are aware of the responsibilities and possess the relevant knowledge. **Lack of knowledge** of and understanding of security issues and insufficiency of knowledge of data protection standards is a second pitfall for staff with access to medical records. **Poor implementation** of security is another cause for concern with staff at the incorrect level having access to material which they should not and that is certainly an issue at the sexual health clinic being researched where generic passwords are currently used for very sensitive information. He finds that **Attitude** can be a problem with dislike of new technologies and leading to lack of priority to security. **Inconsistency** finally is marked out as an issue with risk assessments failing to be undertaken and no clear delineation of responsibility for security leading to problems in this area. There is however consensus on the requirements (security) for an EHR (ISO/TS 2003) and Van Der Linden et al. (2009) list the elements in this standard as follows; Authentication (verify claimed ID of user), authorisation (granting of rights of access), confidentiality, consent, semantic interoperability, author responsibility, audit trail,

version control and archiving and data retention which are essential for an EHR. Anderson (2000) acknowledges public concern about security both for health care workers and patients and outlines multiple breaches of confidentiality in health care settings. He identifies secondary users of specific health care info e.g. insurers, or staff processing benefit claims as a potential risk area for breaches of privacy and states that "once data goes out of an institution there is little control over its use". One study cited by Anderson (Geller, Alper et al. 1996) found 200 instances when employers and insurance companies used information from genetic tests to discriminate against applicants. Another unpublished study cited by Etzioni (1999) found that 1/3 of fortune 500 companies had used medical information to make employment decisions. The Washington Post (O'Harrow 1998) disclosed in a series of articles how several chain pharmacies were selling patient specific information to pharmaceutical companies and these companies used this information to encourage patients to refill their prescriptions with their brand medicines. Thomas (1997) has written extensively on management of threats to confidentiality, disclosures and countermeasures to deal with same suggesting the following

- Minimum statement of institutional goals re privacy and confidentiality
- Classification of information by type
- Definition of procedures for handling abuses

This analysis suggests that an important part of this project would be a specific focus on the area of confidentiality and threats to same with a strategy to deal with it incorporating elements outlined above.

4.7 European Union Data privacy directive.

In Europe all records pertaining to people – health, banking etc are covered by the European Union Data Privacy directive of 1995, however Denley et al. (1998) ask whether large hospitals can really protect their data to the standard of this directive in practice. The EU directive sets out 8 principles governing the fair and lawful use of personal data.

1. Personal data shall be processed fairly and lawfully.
2. Personal data shall be obtained and processed for one or more specified and lawful purposes and not in any manner incompatible with those purposes.
3. Personal data shall be adequate, relevant and not excessive in comparison to the purpose that it was collected for.
4. Personal data shall be accurate and up to date where necessary.
5. Personal data should not be kept longer than is deemed necessary.
6. Personal data shall be processed in accordance with the rights of individuals as set out in the act.
7. Personal data shall have appropriate security measures in place.
8. Personal data shall not be transferred outside of the European Economic Area (EEA) unless adequate protections exist for the rights and freedoms of data subjects.

In an effort to develop an effective implementation policy on information governance policy for a Primary Care Data Quality Programme de Lusignan et Al. (2007) extensively reviewed the literature relating to data protection and privacy using a series of keywords. They identified organisational,

technological, personnel issues and professional standards as important elements for effective implementation. They concluded that even de-identified information is subject to data protection and that sound principles on data protection exist across Europe but there is a lack of information on how to implement them. They point out that most of the literature focuses on technical issues rather than organisational and personnel aspects. They propose that a code of practice for Health Informatics professionals could help with acceptance of data protection policies and trust in this area. All of the above issues are highly relevant to the area of sexual health and specifically this project as in the past names and addresses of patients have been passed to public health authorities inadvertently as part of statutory reporting requirements.

4.8 Literature: Conclusions

Reading in this area suggests that the problems of procuring and implementing EHR are common to many clinical settings and the problem of scale in hospital settings is a major issue, along with fear of failure, focus on electronic infrastructure rather than organisational change and cost. Lessons can be learned about successes in the primary care area and how this can be adapted to the sexual health setting. Abuse of patient data either intentional or accidental is widely reported and in the sexual health setting privacy and confidentiality of data would be a major priority. The EU directive on privacy sets out best practice but there is very little information in the literature on how to implement it. An organisational strategy for dealing with confidentiality and privacy issues with specific measures to deal with threats should be a priority.

Chapter 5

Results of evaluation of available systems for use in the sexual health setting

5.1 Introduction

This chapter describes the five “off the shelf” patient management systems which are currently available for use in the sexual health setting and assesses them in terms of the key criteria described in chapter 3. The evaluation of these systems is based on responses to the questionnaires described in Chapter 1 which are appended to this document (appendices B and C). There are 2 questionnaires: one to commercial providers of these systems, and one to everyday users of each system. The responses from the providers along with commercially available literature provide a description of the various systems and the responses from the users are designed to discover whether these systems are in fact capable of doing what they claim in a variety of institutions. It is assumed for the purposes of this project that the systems are “fit for purpose” i.e. have all the functionality required for an STI patient management system and most of the questions refer to crucial interfaces with existing institutional IT infrastructure and laboratory results management. The software providers are the representatives of the five companies and it is assumed that they have had significant technical input from their organisation in completing the questionnaire. The users are health care professionals working in STI clinics and using these systems. The aim was to interview two users for each system where possible and some of the users are doctors and some are data managers. An attempt was made to find a user interested in and familiar with the system.

All of these systems are suitable for both STI and HIV patient management, but this study will focus on the STI aspects of these systems.

5.2 Design of questionnaire and recruitment of respondents

There were 2 questionnaires designed, one for commercial providers, and one for users of STI patient management systems. The design of the questionnaires focused on the main objectives of the acquisition of this system namely storage and retrieval of notes and results management. It is a minimum requirement that the system would be completely paperless otherwise the storage and retrieval problem would persist. The medico-legal problem of missing results is the reason that the system will be funded by the institution; therefore results management has a very high priority in the specifications for this system. The questionnaire for providers focuses very much on results management and the ability to interface with existing institutional IT infrastructure i.e. PAS, Cerner Millennium EPR, TelePath (lab system) and Medibridge (Virus reference laboratory) as automation of results management will only be possible if these interfaces are possible. Five systems in current use were evaluated. These systems are in use in Ireland, Northern Ireland and Britain. The providers are commercial vendors of patient management systems for use in the sexual health setting. Each of the vendors has their own system which they market to sexual health clinics all over Ireland and the UK and no vendor markets any other system other than their own. The vendors are as follows 1. SHIP

System (CaraData Australia) 2. LillieSystem (Blithe Systems UK). 3. TeleCare Mill System (Mill Systems UK) 4. PreView SHE (Sexual Health Environment) System (IMS UK) 5. Exelicare (AxSys Systems) - used in the Scottish National sexual health IT project NaSH. Two of these vendors had previously contacted the hospital to market their patient management system. Two of the other vendors were identified through the British Association for Sexual Health and HIV (BASHH) IT group and the final vendor was contacted through one of the users as the original company marketing this software had been bought over and it was not easy to find who was marketing it (IMS – PreView SHE system). The companies were contacted by email and once the company had expressed an interest in providing this system the questionnaire was forwarded to the representative by email and returned via the same method.

The questionnaire for users focused on how these systems were actually working in place. An attempt was made to find 2 users for each system but in 2 cases only one user was found (SHIP and PreView SHE). An attempt was made to find a user in a location where each system was perceived to be working well and these locations were identified either from the British Association for Sexual Health and HIV website or from the commercial providers themselves (Mill system Chertsey, PreView SHE Royal London Hospital, Whitechapel). The SHIP user is the only current SHIP user in Europe although there are many users in Australia, none were contacted. One user of the Blithe system (Lillie) had published their experience of going live with this project (Brook, Davies et al. 2008) and this user was contacted via contact details in the publication. The other user for Lillie was based in Northern Ireland where there are very good links with Dublin via the national specialist society for the study of sexually transmitted diseases (SSSTD). The second user for TeleCare Mill systems was contacted because of a previous working relationship. The questionnaire for the users focused on whether the system was paperless or not, or capable of being paperless. Because of the widely differing IT infrastructure in different institutions the users were asked to identify whether problems with implementation were due to the “system”, or problems with existing infrastructure. This is not intended to be a comprehensive analysis of how these systems are in use in the British Isles as this is beyond the scope of this thesis. It is intended that the questionnaire should throw up problems which might not have been anticipated in the endeavour to introduce such a system at the hospital, and to benefit from other user’s experience. It is anticipated that most of the problems relating to full implementation of these systems will be due to local issues like interfacing with old legacy laboratory systems and patient administration systems. Some units were contacted and asked to identify the person most suitable to complete the questionnaire i.e. the person with a good working knowledge of the system. In some cases this has been a data manager (Chertsey, TeleCare Mill and Whitechapel, PreView SHE and NaSH, Scotland) and in other cases it has been a doctor with an interest in IT (Lillie NI and London, SHIP, Waterford and NaSH Glasgow). It was intended that this questionnaire would be completed in a personal capacity to give an overview of how the system is functioning in that person’s opinion, and not as a representative of the organization. Once the users had been contacted and agreed to participate, the questionnaire was administered by email. One user preferred to complete the questionnaire by phone (NaSH, Glasgow and Clyde) and a couple of users were contacted again by phone or email to clarify outstanding issues.

A proposal for ethical approval for this study was submitted to the Ethics Committee of the School of Computer Science and Statistics, Trinity College Dublin and ethical approval was received.

5.3 The Exelicare system (Axsys Technology) NaSH Scotland

5.3.1 History and development of “NaSH” Exelicare system

This system was originally developed in England as the Exelicare system to manage the population wide Chlamydia screening programme introduced in the UK NHS in 2003. Because this was a country wide programme this system had to be compatible with multiple laboratory and other systems. In 2007 as part of the National Sexual Health Strategy for Scotland a tendering process was commenced and Axsys was awarded the contract to design, develop and implement a national sexual health IT system so called NaSH (a tailored version of Axsys’ Exelicare product) across Scotland’s health board. Currently 7 out of 14 health boards have implemented NaSH with 75% of all Scottish board sexual health services accessing NaSH on a daily basis. When fully rolled out this system will support 1500 clinical and administrative staff working across 300 sexual health clinical sites treating 400,000 patients, with expected growth of 20-30% over the next 5 years. As current suppliers (of the Chlamydia system) Axsys was already integrated with crucial Scottish IT infrastructure such as the Scottish Care information (SCI) Store and SCI Gateway. A clinical modelling tool is used to build the sexual health application with data capture forms, documents and reports. The Exelicare platform behind the English and Scottish solutions is the same but each service can use the solution to develop their own priorities.

5.3.2 Exelicare management of confidentiality: Provider perspective

Security groups set up by the system administrator determines how much of the system is accessible by different users. The system allows groups to be set up on a form and control basis, so that users may only be able to view certain forms or controls within those forms. A second mechanism ‘Access control’ can be set to limit who can view a patient record. Security groups can be set as required. Access control can be applied for clinicians to individual patient records, thereby denying or allowing access to a specified record e.g. of a staff member who is also a patient. Every action taken in the system is recorded, by whom, from which PC (IP address) and when taken, so there is full audit trail for any changes to the record. Administrators can also be alerted to unusual access to a patient record. As regards double entry and management of the MRN AxSys would anticipate that patient continue to be booked into the PAS and this data fed to the Exelicare Sexual Health system to maintain a ‘real time’ copy of the PAS within the STI system.

5.3.3 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective

Exelicare has been successfully interfaced with iSOFT, PAS and Telepath in a number of sites so these interfaces would not pose a problem. The interface with Cerner is required in the Dublin hospital for the order communications, and Exelicare have not previously built an interface with Cerner but are confident that they can achieve this with cooperation from Cerner. Neither have they previously interfaced with Medibridge, but assert that interfacing with third party systems would be their major strength. This provider uses an interface engine Exeliport for data import into or export from Exelicare. It allows data to be imported into or exported from Exelicare in any format and to any

standard e.g. XML, HL7 etc. This requirement to interface with existing systems has been a major component in the Scottish setting and in the Chlamydia screening programme because of the multiplicity of laboratory systems involved and there is good evidence from the users of these systems that Axsys can deliver on this crucial requirement.

5.3.4 Results management in Exelicare: Provider perspective

Exelicare contains a full E-ordering module and depending on the accessibility of the receiving EPR system E-orders can be passed electronically. A standard report identifies by date range all results requested in a given time period. Tests or test sets are date stamped in the patient record and this information can be used to trigger a rule to highlight results requested where no results has been received within a given time period. In addition specific management protocols for certain results can be set up as follows; a first positive work list highlights all patients who have received a positive result where no previous result has existed. This would be particularly useful for syphilis and HIV but could be used for any STI. From this work list the user can drill down into the patient record and complete any required forms and diagnostic codes. Completing this information will remove the patient from the work list. The system is capable of setting algorithms against previous results and inserting patients into work lists if criteria are met. This could be used to identify syphilis reinfection which currently represents a significant workload. In addition there is a comprehensive Clinical Alerts Manager (CAM) that enables users to set up rules to create alerts which can be generated on the basis of any clinical information inserted in Exelicare including positive results. The term clinical alerts include all kinds of reminders, warnings, action and decision support flags which could be generated within the workflow process. Examples of these alerts would be adverse drug reactions, reminders re screening, disease management, guideline documents etc. The CAM module supports the concept of subscription to rules such that a user may notify the system of their interest in a rule and be notified when that rule is triggered.

There is a label wizard function which can generate a multiplicity of label types.

5.3.5 Exelicare: User perspective

The user response for the NaSH system was provided firstly by a member of the group coordinating this project with a long history of involvement in it. Secondly a clinician who was also involved in the procurement of this system for Scotland but who is using it on a day to day basis was interviewed by telephone. The system is installed as one national database for all NHS Scotland Boards. It is housed in a national data centre and access is provided via local and national networks. A system generated number is used as the primary identifier but it can be linked with the patient's NHS number if they give consent. The Scottish NHS uses a vehicle called SCI Store to store all electronic results. Each Health board has such a store and the system links with this store, although only one board is fully live with this functionality.

5.3.6 Exelicare: Is this system paperless in this location?

The system is completely paperless in Glasgow and Clyde. It is live in 6 other health boards that are at various stages of achieving a paperless system. During the implementation phase they are maintaining a paper record to handle results until such time as they can implement the SCI Store interface. Some boards are currently unable to scan referral letters and some choose to retain

consent /permission forms for a specified period and retain a paper record for this purpose. The user here identifies very significant business change process in a multiplicity of locations which need to take place for all locations to be “paperless”. The only double entry of data is for the national cervical cytology call and recall system which does not have an interface to other systems.

5.3.7 Exelicare laboratory ordering and results management: User perspective

The NaSH system does not support order communications as there is not a national product to link to and all boards operate different solutions with very few having order communications. Order Communications is on the development path and will be addressed when a solution is available as the facility for same exists within the Exelicare solution. The system does have a test ordering function which needs to be used to facilitate the electronic return of results which is operational. The system produces bar coded labels which go on individual board request forms and specimens, which are non standard between boards. All of the laboratory results download to the patient record in Glasgow and Clyde where the system is fully implemented. Currently radiology results have to be added manually. The system does alert the user to positive results but some manual intervention is required to generate recalls.

5.3.8 Exelicare: Summary

The two users who participated in this project were very high level users both having an overview of the project and both driving implementation throughout Scotland. The functionality of this system as regards STI patient management was felt to be excellent, but they would regard introduction of an order communications facility as a priority if this could be achieved. A drawback perceived by one user was the fact that the software programmers are based in Hyderabad, Pakistan, and are not easily accessible.

5.4 The Lilie system (Blithe Computer systems)

5.4.1 Introduction – provider description of system

The Lilie sexual health patient management system operates on Microsoft Windows platforms using MS Terminal Services, Citrix Metaframe or traditional client server terminal management. Lilie can also be used via VPN using secure dial up or 3G connections to the central server. Lilie is based on the MS SQL Server 2000/2005 database. This product is widely used in sexual health clinics throughout the UK and the provider claims that it is used in approximately 60% of sexual health sites.

5.4.2 Lilie management of confidentiality: Provider perspective

According to this provider comprehensive security features provide a complete audit of all changes and support selective access to patient data and system functions according to user privilege. Access levels manage rights to create, update, delete or view data. It is possible to shield data and patients by both location and episode type so that staff can restrict access to inappropriate datasets or sensitive information. For instance it will be possible to shield access to HIV data from contraceptive service staff if desired. Users may also be given access to clients groups relating to a specific service or contract needs. With reference to the MRN and avoiding double entry of data they suggest using a unique Lilie patient identifier instead of a name so that the PAS entry can be uniquely identified and matched back to the Lilie client record, this is in line with suggestions from other providers.

5.4.3 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective

This provider asserts that Blithe Computers Systems can develop interfaces to any system assuming that they have standard interface API's that utilise a standard messaging format such as HL7. Specifically with regard to Telepath, they say that text results can be absorbed into Lilie using a standard PMIP Edifact message that they know can be generated by TelePath. The Lilie laboratory link includes features to map text to coded entries so if the laboratory utilises the 'canned phrases' features on TelePath then these can be mapped as they enter the Lilie solution. Since the vast majority of STI results are microbiology items which are currently viewed in Cerner as a snapshot of a text based result rather than a structured piece of data, this sounds very encouraging. As regards the interface to Cerner for the OrderComms the provider states that this will be possible if Cerner has the standard API outlined above. As regards Medibridge the providers states that if the results can be provided in the PMIP Edifact message format or in HL7 they will download to the patient record.

5.4.4 Results management in Lilie: Provider perspective

The provider states that the Lilie Bulk communications module can extract lists of all results of a particular test and result type into a list for result notification purposes. It is then possible to send texts or letters to lists of clients according to their result notification preference. It appears that this

process is not completely automated – a list of positive results is produced with the patient contact preference displayed so that the user can use local client knowledge to adjust the list and authorise bulk generation production. Several hundred communications can be generated by one key click. This provider states that they produce all the standard reports required for the UK statutory reporting requirements which are extensive. These would have to be altered for the Irish context.

5.4.5 Lilie system: User perspective: Is this system paperless?

The users who completed questionnaires for this system were based in London and Northern Ireland. In the Northern Ireland (NI) setting the system is used in 4 different locations with different laboratory infrastructure in each location. This system operates as a “stand alone” system both in the London setting and in NI but in London they are planning to purchase a module which allows some integration with the hospital PAS. In London they still use paper for patient records and results but results are uploaded to the system and subsequently shredded. In NI the system is not paperless in any location. One clinic, Causeway, appears to be using the system well but still maintains paper records for referral letters and results from non local labs. All other sites currently only use Lilie for patient registration and use paper records for all other clinical information.

5.4.6 Lilie system: Laboratory ordering and results management: User perspective

In the London setting there is double entry of data as they do use order communications and the patients are registered on the hospital system as well as the STI patient management system. This user states that there is a module in the Lilie system which can avoid this “double entry” and that they are planning to purchase this. Tests are not ordered by the Lilie system but through the hospital Order communications (also Cerner Millennium) and the results do not download to the Lilie system. This user states that they have a good way of accessing results through the hospital browser and systems to identify positive results (browser, e-mail, paper results) which make the download of results electronically into Lilie unnecessary. The reason they do not use Lilie to notify positive results is that they fear that they will be alerted to hundreds of trivial results and that system memory will be taken up with lots of “negative results”. They do not use this STI patient management system to recall patients with positive results but use a manual system based on screening of paper results as they also found the “results to endorse” system in Cerner Millennium unsuitable for use in this setting.

In NI the Lilie system is integrated with the lab system via LabLink in the Causeway clinic and results download directly to the patient record. There are no order communications in NI and all laboratory orders are by paper request. In the Causeway clinic results from non local labs are scanned into the system but elsewhere in NI all results are managed manually. In Belfast a network upgrade is required as the current IT infrastructure will not support all of the functionality that Lilie provides and it is not currently possible for Blithe to, remotely, fully service support the system. In the Causeway clinic it is not the Lilie system but the LabLink system that alerts the user to positive results and it does it by the method of alerting “non-negative” (positive, missing and failed tests).

The NI clinics are not currently using the SMS texting function in Lillie to contact patients but are planning to introduce this functionality in the near future.

5.4.7 Lillie: Summary

The users of this system appear to be satisfied with the functionality of the system and it meets all statutory and other reporting requirements. In NI the problems with implementation appear to be related to existing IT infrastructure, upgrading and change management. In London the system appears to be working well although an entirely separate system is used for order communications and results management and this is not ideal i.e. an outsider view would suggest that if the two systems were integrated the output would be exponentially improved.

5.5 TeleCare (Mill Systems)

5.5.1 TeleCare description and confidentiality: Provider perspective

The system provides a patient record, an appointment system, a means of collecting statutory information for billing and performance reporting, and a repository of laboratory results information. The TeleCare patient database, together with the clinic management system itself, all resides on a single system server. This then allows several levels of security to maintain confidentiality. The TeleCare application is written in Progress software and not in Microsoft Sequel Server as many database applications are. According to the provider this means that the application is much less open to both virus attack and general "hacking". Any Microsoft-aware hacker who manages to bypass the network permissions will find system files that have no entry point without actually entering the application itself. Access to the system is controlled by local management. The TeleCare application is only entered with a user name and password. The password is maintained between the individual user and the system. The System Manager can issue a "passkey" password that immediately demands replacement with a new password from the user issued with the "key". Therefore, the System Manager has control over any and all of the individual users that have been given authorisation to use the system. At any time, the System Manager can revoke access, force password change, or create new users. As with the other systems described above the access for each individual user can be defined differently allowing different staff members' access to different areas of the system. The system maintains an audit of which users are connected and when and which records have been viewed.

5.5.2 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective

The provider suggests two possible options for dealing with the interfacing issue. Option 1 involves the use of lablinks which are described as flexible pathology modules capable of dealing with multiple different types of results. This provider suggests that the simplest way to deal with the interface problem is not to register the STI clinic patient on the hospital PAS system at all. Test requesting is enabled within TeleCare, with test request forms and labels (including bar codes) printed from the TeleCare system to accompany the samples going to the laboratory. The lab would use bar code scanners to assist with booking in and this would avoid the "double entry" requirement into PAS entirely, as the PAS has no function for these patients. The test results then sent back from the laboratory, can either directly, or through an Interface Engine, provide the result message stream back to TeleCare, sifted for STI/GUM data either at the Lab itself, the Interface Engine, or indeed even at the TeleCare lablink interface – whichever is deemed the simplest or most cost effective from the lab and local IT perspective. TeleCare, therefore, holds the record of what has been requested, can manage the results requested and received to ensure that results arrive in timely fashion, or to chase-up missing results against requests, and then reconciles the results that are sent back from the lab onto the TeleCare patient record. However this option relies on the laboratory being capable or prepared to accept the requirement of booking in tests manually. The laboratory currently accepts manual booking for tests sent from primary care practitioners (GPs) so this function currently exists in the laboratory but having implemented a very large project in the

hospital in 2006 to move all laboratories ordering to Order Communications moving any area back to manual ordering would be seen as a retrograde step.

Option 2 requires that the TeleCare system “pretends” to be the PAS system in an Order Comms process. The Test Request message is then transmitted to the Integration Engine, which processes the Test Requests from TeleCare such that the Laboratory “sees” the requests “as if” they were generated by the PAS/EPR system itself. The Requests would generally be “tagged” such that it can be seen that they originated from the sexual health clinic department. When Results are then transmitted back to the PAS/EPR system, they would again be processed through the Integration Engine, such that the results “tagged” as for sexual health clinic are diverted to TeleCare – and whether copies go through to PAS/Cerner EPR would be somewhat irrelevant – unnecessary according to the provider– but for the end user to determine. This provider is in the process of commissioning the first of these lablinks to be setup in this fashion, but they stress that this is both more expensive and time consuming to setup, as the creation of the messaging for test requesting is anticipated to be a very bespoke operation and this indeed must be the case for all providers. This provider has close links with TelePath and currently has two sites with operational Lablinks downloading results information into TeleCare from Telepath laboratory systems. This provider is very confident that telepath microbiology results can be converted in to useful data items for the process of results management. Management of results from the virus reference laboratory via medibridge might require the setting up of a second lablink with consequent expense.

5.5.3 TeleCare Results management: Provider perspective

The provider states that the lablink in TeleCare is created specifically for the purpose of results management and it operates as follows: for the identified major subset of tests that are used by a clinic, the TeleCare system has a Patient/Sample/Result-slot database created that closely resembles the original Laboratory result database. When a series of such tests are requested for a patient, the result-slots are opened against the patient in anticipation of the result return – transmitted from the lab. On receipt of each of these results, the TeleCare system will make a clinical interpretation of the information contained in the result message, and identify the result as a “positive”, “negative” or indeterminate according to rules that the clinicians provide. Therefore a result that comes back and is interpreted as a “negative” will be simply filed in the result slots against the patient with no further action. Where the message interpreted is indeed the last of the Test Series to be received (and where no positive result has yet been received), the system can establish that the entire Test Series have resulted as “negative” and trigger the automatic recording of a diagnosis code that indicates that negative results have been returned for all tests, and in so doing, also trigger an automatic SMS text message to the patient’s mobile phone, reporting an “All Clear” STI test result – worded to the clinic’s preference. It appears that in TeleCare this process is fully automated where the lablink is functioning, whereas with the other systems some user input is required. If at any point in the returning result stream a “non-negative” result is determined, then this result and this patient are added to an “Authorisation Queue”. (It is also placed on the patient’s record – but as an “unauthorised” result.) The provider outlines a number of steps which take place to authorise and deal with positive results including generation of automatic recall letters according to set templates.

5.5.4 TeleCare: User perspective: Background

Two users completed questionnaires in relation to this patient management system. One of the users was based at the sexual health clinic at Chertsey and this location was recommended by the provider as a location where the system is working well. The second user is located in a district general hospital 70 miles North East of London (Harlow) and is a single handed consultant in a sexual health clinic.

5.5.5 TeleCare: User perspective: Is this system paperless?

In Chertsey the system is standalone but has an integrated lablink and automatic text facilities. The system is paperless for a number of outreach clinics using a 3G connection. Referrals and clinical information are scanned into the record for all patients. However there are still paper notes for STI and HIV patients at the main clinic. It is anticipated that with the next update they will be able to go paper free for the STI clinics. They state that there is still a lot of development to be done before HIV notes can be paperless. The user states that there is no double entry of data currently but as this location is maintaining paper records for clinical information then by definition there is double entry.

In Harlow the system is standalone and paper records are still used for everything – patient registration, clinical notes, results, GP letters etc. This user feels that the major problem is with existing institutional IT infrastructure but also feels that even those elements of TeleCare that could be used e.g. GUMCAD reporting (UK NHS mandatory system for reporting activity data for STI clinics) has not been implemented and perceives this to be due to poor support on behalf of the provider.

5.5.6 TeleCare: User perspective: Laboratory ordering and results management

There is no facility for order communications at Chertsey and laboratory tests are not ordered using TeleCare. All results download directly to the STI patient record. Negative results then generate an automatic text message to the patient informing them on the result. Positive results are sent to health advisors to action and this alert is generated automatically by the system. Radiology results do not download directly as they are attached to the hospital network but can be printed and scanned into TeleCare.

In Harlow tests are requested using paper request forms. They do print labels from the system which makes things easier as previously they were filling forms manually. They can look up results on the hospital system but the results do not download to the TeleCare system at Harlow and therefore results management is completely manual.

5.5.7 TeleCare: Summary

In Chertsey, the system appears to be working well although the main clinic is still using paper notes for STI clinics. The lablink seems to be functioning well and this user is entirely satisfied with the reporting function of TeleCare. In Harlow there has been poor implementation of TeleCare and the user has found the process frustrating as they still do not have GUMCAD functioning (the mandatory reporting system for STIs in the UK). They also found that the system underreports those offered 48 hour appointments, consequently their performance is reported as poorer than it actually is, so this user has discontinued this report and does it manually.

5.6 PreView SHE System (IMS Maxims)

5.6.1 PreView SHE: Provider description

PreView Sexual Health Environment (SHE) is a browser based sexual health patient management system. The system is in use in 14 NHS trusts in England.

5.6.2 PreView SHE: Provider perspective on confidentiality aspects

The provider states that the system meets the confidentiality needs of GUM patients as set out in The NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000. Access to the system is controlled by the use of passwords and auditing. Passwords are at a minimum of 8 alphanumeric characters, stored in an encrypted list not in clear text and featuring MD5# encryption. PreView also features password expiry dates and prompts and it is possible to set automatic expiration dates forcing users to change them regularly. Security access levels are built into the system allowing staff to be allocated only the privilege level they need to undertake their work (i.e. via resource type). An audit log is maintained of access to the system.

5.6.3 Proposed Interfaces with PAS, Cerner, Telepath and Medibridge: Provider perspective

The provider states that the IMS system will interface to the Hospital's current systems using HL7 either directly or via a Hospital Integration Engine if preferred. This will provide a fast and reliable connection between the systems and will be configured so that it is capable of sending requests to, and receiving results from, each relevant department within the Hospital. The provider asserts that they have extensive experience developing HL7 interfaces and can also work with ASTM1238, Edifact and PMIP when in use (as found with some external Pathology Laboratories). This provider states that it has interfaces with iSOFT PAS in other sites and that double entry would not be required as the IMS product could either take data from PAS or in fact register the patient on PAS with data from the IMS system in whatever format required (initials and DOB). The provider asserts that it will be able to interface with Cerner to order from the STI system and also download results to the system. There is very little detail on how this will be achieved or if it has been achieved elsewhere. The provider states that IMS interfaces with DMF (Medibridge) on other sites and that this interface would not be a problem.

5.6.4 IMS PreView SHE: Results management: Provider perspective

PreView features Patient Messaging, which is designed to enable messages (i.e. more than one) to be attached to a patient's record. Messages are assigned to be read by Resource types (for example, Doctors, Health Advisors etc). Thus, if a user is registered on preView as, for example, a Doctor, then, if there is a message attached to the patient assigned to a doctor, the message will be immediately displayed on-screen as the doctor enters the patient record. If another Resource-type

(i.e. not a Doctor) were to enter the same patient record, they would not be presented with the 'Doctor-targeted' message. This method suggests that the patient record must be opened before the alert appears. If the message is not actioned it continues to appear each time the record is opened. The system can give monthly reports of positive results.

In one location the results are linked to a "Telephonetics " service. Telephonetics is a voice service whereby preView will upload patients' results data to the Telephonetics system each night. Using the Telephonetics service a patient can then dial in to that number to get their results. The Telephonetics system asks for certain patient identification details and then a voice message gives the result details to the patient. IMS preView does not currently have the functionality to send SMS text messages of results.

5.6.5 IMS preView SHE: User perspective: Background

The respondent for this system is based at the sexual health clinic at the Royal London Hospital in Whitechapel which is a large STI clinic in a London teaching hospital and this location is mentioned in the promotional material for this system. The system is standalone; there is separate patient booking system and inpatient system for the rest of the hospital (CRS – based on the Millennium software package) and there is no electronic link between that system and preView.

5.6.6 IMS preView SHE: Is the system paperless?

The system is not paperless at Whitechapel and they use paper notes for almost all of the information that they also put on the system – clinical notes, prescriptions etc. The Homerton Hospital which is in the same NHS trust is paperless with preView SHE but this user feels that the way they have done it is cumbersome – they have scanned old patient notes in and view them as an image in the system. The group at Whitechapel are looking at moving to a paperless EPR but no time frame is given. The problem of dealing with existing records is cited as the main reason that they have not moved to an EPR along with expertise and time to implement the change. Changes required are as follows: (1) appropriate pro-formas on the system (2) Clean up the data already on the system (3) Effort to scan the paper records (4) Analysis, project management, and training effort to design the solution. There is double or in fact triple entry of data as patients are registered in the paper notes, on preView SHE, and some patients are registered on the Millennium CRS (the hospital patient management system)

5.6.7 IMS preView SHE: User perspective: Laboratory ordering and results management

Requests are sent electronically from the system to the pathology system (WinPath) and (partial) results are received back electronically. This user group are in the process of getting the system implemented to get the full pathology results back automatically. In this setting the lab system returns an indicator to the STI system to say the test results are ready to view on the lab system. They are not yet uploading the full results into the STI system so the results cannot currently be

viewed there. This project has been in progress for some time according to the user but has not been fully implemented because little time has been devoted to the testing of the change. The preView system does not alert this user to positive results as the results are viewed in the laboratory system not the STI system. The results are viewed electronically and a manual SMS texting system is used to contact patients.

5.6.8 IMS preView SHE: Summary

In this setting almost all functions are done twice – i.e. there is double entry of demographic data, clinical data, diagnosis and results do not download to the EPR. The user finds that even the reporting function of this system is entirely dependent on the quality of data entered by the clinical users so that this system cannot reliably be used to fulfil statutory reporting requirements.

5.7 The SHIP System CaraData

5.7.1 Description of SHIP

The Specialised Health Information Program (SHIP) system is a Microsoft Access based system developed and widely used in Australia in sexual health clinics there. There is an add-on SHIP web based system so that clinical services which operate outlying clinics away from the main base of operation can use the system remote from the main server. The software developers and technical support staff are based in Australia and are represented by a small sales team in Europe.

5.7.2 Management of confidentiality using SHIP: Provider perspective

The SHIP system ensures that all patient identifiable data is encrypted. SHIP web makes use of the “secure sockets layer” (SSL) for transferring data from client to server. This ensures that all data transferred is heavily encrypted and therefore extremely difficult to interpret. The usual security measures are present including variable permission for access for different categories of users and full audit trail of and changes made to the record including opening and viewing of the record. The provider of this software states that because of the server-side nature of SHIP that the database is immune to many of the common problems that plague client-side software such as misbehaving client applications. A transaction-based data model is used allowing “rollback” in the event of a failure preventing data corruption caused by server-side errors. As regards double entry of data and management of the MRN and demographic data there are two options in the SHIP system, one using the STI clinics own MRN or the other involves SHIP linking to the hospital PAS system and using the hospital MRN.

5.7.3 Proposed interfaces with existing hospital systems: Provider perspective

The provider would propose to build a general purpose interfacing system which would act as a proxy for the SHIP products. Once in place, SHIP sends requests to the proxy and responds to requests from the proxy. The proxy will have plug-ins built for it to allow it to send and receive messages in various formats e.g. HL7, PAS, OCM and Medibridge. SHIP will be able to query these databases e.g. to look for patient records. The crucial question here is whether these systems would allow SHIP to connect to them. The SHIP system will be able to use the hospital MRN and accept patient details from PAS or generate a new MRN to be used for the STI system. The provider of this system asserts that these interfaces can be created to allow laboratory ordering and retrieval of results but that the ability to do this depends on the provider of the current IT infrastructure i.e. Cerner, Telepath and Medibridge. Viral load results from Medibridge are already downloading into another patient management system in the hospital (Clintech – haemophilia patient management system) which would indicate that this is feasible.

5.7.4 Results management in SHIP: Provider perspective

When an investigation record is imported, the system will check for certain values (e.g. positive).

If these values match criteria, the system will issue an alert to a staff member who will be able to view the result. The system will also alert the user to any unread results. The provider states that the program can generate reports for any test with selection of data for any timeframe. This function is required for weekly audits of positive results e.g. for Chlamydia tests. The systems can send patient results by text message and generate recall letters. The providers of this system anticipate that the healthcare provider who orders the tests will deal with the positive results, however this method will generate some issues such as (i) movement of temporary doctors to another job when their rotation in the clinic is complete leaving outstanding results (ii) dealing with results for providers on holidays (iii) currently there are a number of sessional doctors in the clinic who do not deal with results and this will be a significant change in work practice for older and more established doctors. It is possible that the function of dealing with results will be transferred to clerical staff that will have significant reduction in workload when the paper charts are no longer in use.

5.7.5 E-triage in SHIP

The provider has a partnership with another software provider in the UK who has produced an “add-on” e-triage system which can be used by the patient via the internet or by using a kiosk in the sexual health clinic waiting room. Using this facility the patient can enter clinical information and demographic information and this system can be configured to assign priority for appointments, arranging an urgent appointment when the clinical symptoms indicate it. This information may or may not be accepted into the final clinical record as the HCP can view this information at the first interview and decide whether to accept it in full, with changes, or not at all.

5.7.6 SHIP system: User perspective: Location and institutional infrastructure

The users of SHIP who participated were located in a sexual health clinic in a large regional hospital in the South East of Ireland. Although the clinic is located in a hospital the STI patients are not registered on the hospital patient administration system and the STI MRN is generated by the STI clinic. This clinic does not have order communications and the healthcare provider fills out a paper form to request laboratory tests. The user who orders the test is supposed to alert the system that the test has been ordered by ticking a box, but the user can go ahead and proceed with this test without ticking the box and in that event the system does not know that the test has been ordered. If the result subsequently goes missing there is no record on the system that the test was ordered and the user will never know. The system can generate labels for the request forms and specimens which reduces the burden of form filling. The interface to the laboratory results is currently in the testing phase. It is anticipated that the laboratory results will download directly to the STI EPR in the clinic and this will be achieved via a messaging system from the laboratory similar to that which is used for GP practices. In terms of the IT aspect this clinic will function like a GP practice outside of the hospital and will not be integrated into the hospital systems.

5.7.7 Is SHIP “paperless” in this location?

This clinic is still maintaining a paper folder as they do not currently have the ability to scan in referral letters from GPs or consent forms signed by patients. They are also using paper records in two outlying clinics in other locations. These records are entered into SHIP at a later date. All of the clinical information in the main site of practice is entered onto SHIP and there are no duplicate records of this information. It is anticipated that the ability to scan in documents will be functional shortly. They also keep paper results in this folder but anticipate dispensing with this if all audit and testing of results management shows the system to be robust. Patient medication charts are also kept in the paper record but this may be a legislative requirement as an electronic prescription is not currently legal in this jurisdiction.

5.7.8 SHIP laboratory ordering and results management: User perspective

As the electronic results download is not currently live in this location it is difficult to make an assessment of how it will perform. Two of the important aspects of results management are management of missing results and dealing with orphan results (a result for which no test appears to have been ordered). Using the SHIP system a list of missing results can be generated but only if the user ticks the box to say the test was ordered. Missing results can generate significant medico legal problems in the health area and this is one of the primary reasons for the undertaking of this entire project (in the Dublin hospital).

5.7.9 SHIP: Summary

The user of this system finds the functionality of this system good. However, it was commented that “there were a lot of tick boxes in this system” and that it might not be apparent with the use of tick boxes whether the relevant question was asked of the patient or not i.e. if the box is not ticked is that because the patient was not asked the question or because they said “no”. In answer to this the company state that they can set up the system any way that the user requires it i.e. drop down menus, tick boxes etc. Another drawback mentioned by the user was the fact that all of the technical support people were based in Australia and that it made the process of accessing technical support more difficult.

5.8 Commercially available Systems: Summary

As expected the providers of these systems assert that they can meet all the criteria according to responses in the questionnaire. As regards interfacing with existing IT infrastructure, some of the providers can demonstrate a track record in this area with existing interfaces to TelePath (Exelicare AxSys, TeleCare Mill and Lilie Blithe) however none of the providers is currently interfaced with Cerner Millennium and this is a critical interface to maintain order communications. Only two of the systems have achieved “paperless” status to date – Exelicare in Glasgow and Clyde and Lilie in West London although in London they are using another system for order communications and still

receiving paper results and uploading manually them to the STI patient management system. Two users were unhappy with the functionality or performance of the system – Mill TeleCare in Harlow and PreView SHE in Whitechapel, London. The SHIP system is not fully implemented as regards results management in Waterford so it is difficult to make an assessment of how it will perform. These issues will be discussed further in the conclusions section (Chapter 8).

Chapter 6

The Hospital preferred provider: Could this provider deliver an STI patient management system?

6.1 Introduction

A major procurement process was undertaken at the Dublin hospital in 2005 with the primary objective being the acquisition of Picture Archiving and Communication System (PACS). A tendering process ensued and the winner of the tender was Cerner Millennium. Although an EPR was not part of the original specification an EPR was provided for the hospital as part of the contract. This EPR project has been partially implemented and has delivered significant benefit to the users. The elements of the EPR which have been delivered by this project are as follows: (i) Order Communications (OCM) (ii) PACS (iii) Display of laboratory results in the individual electronic patient record (iv) discharge summaries (v) links to voice activated software programme for patient dictation (vi) referrals for consultations. An EPR is now maintained for every patient who attends the hospital which is an integrated hospital information, radiology information and laboratory information record and this hospital is the only public hospital in Ireland with this kind of integrated record.

6.2 Order Communications (OCM)

OCM have delivered significant benefits to the hospital. Orders are transmitted directly to the laboratory and all of the order information – clinical details etc are contained within the bar-coded label. This label is affixed to the specimen and scanned on arrival at the lab. Several order sets have been created to allow several tests to be ordered together; for instance a full STI screen consisting of several tests can be generated in the one order. A large panel of blood tests consisting of more than 15 different items can be ordered together for a new HIV patient. This delivers embedded decision support and ensures that all the correct tests are ordered and all the relevant clinical information is given to the laboratory when the tests are ordered, as the person ordering the test cannot generate the order without giving the required minimum dataset of clinical details for that order. The system maintains a record of the orders which can be viewed in the patient record. In the case of radiology tests where there may be a significant time lag between the ordering and performance of the test, the schedule may be viewed to ascertain the appointment date and time.

6.3 Display of results in Cerner EPR

Laboratory results which are numerical and abnormal are displayed in red in the graphical user interface in the Cerner EPR. Normal results are displayed in black. When the EPR for a particular patient is opened, in respect of numerical results the abnormal one can be seen straightaway. However most results for STI patients are microbiology results which are released by the laboratory as a text based result e.g. "Chlamydia DNA not detected". This result is displayed as "Chlamydia" on the opening page of the patient's EPR in the microbiology section but the user has to click on "Chlamydia" to open up this result and see the full message which is displayed as a snapshot of the

TelePath result. If the Chlamydia result is positive the word “Chlamydia” on the front page appears in red so the user knows it will be positive but this is just a recent change. Previously all microbiology results positive or negative appeared in black. In order to proceed with any automation of microbiology results the TelePath results would have to be converted to structured data items which when filed could be used in a rules-based mechanism to generate actions like alerts to positive results.

6.4 The specific case of STI results management and Cerner EPR

STI results management differs from every other clinical area because of the sheer volume of results generated. There is no other clinical speciality which would see a similar volume of patients in the time frame and generate a similar number of tests. Because of the volume involved it is a requirement that part of the screening of results is automated. Automatic results management is not currently possible in the Cerner EPR. Every single result generated in Cerner has to be endorsed by a clinician so this function would have to be undertaken for around 1000 results per week. Neither in the Cerner EPR, can the person (doctor or nurse provider) who ordered the test be the person who endorses the result. No test can be ordered in the hospital without an ordering consultant. This consultant does not have to see the patient, but this consultant has ultimate responsibility for the patient and all of the orders are in that consultant’s name. The proposed system for management of STI results is, that results would initially go to the ordering consultants, who would then proxy the “results to endorse” function to another named provider (not a class of provider e.g. a health advisor). Since every provider has a personal log in, in Cerner the proxy has to go to a specific person. It would not be possible for one person to endorse all of these results, as in all likelihood mistakes would be made by a person looking at similar results on a screen all day. This problem is exacerbated by the fact that STI patients (about 60% of the total results) are registered under initials and DOB and there is no identifying information to enable a provider to recognise a particular patient. There is one consultant in the hospital currently using the “results to Endorse” function in the Cerner EPR but this is in an oncology service where all of the patients are personally known to the consultant, the full names are on the screen and the number of individual tests (not patients) per week is approximately 250.

There is also the problem that the “results to endorse” function cannot be piloted for the STI service. If the service moves to “results to endorse” it has to be done for all the patients attending the service both STI and HIV. This has not happened to date because of the fear of failure due to the volume of results. Another problem with “results to endorse” in Cerner is that all the results come into the EPR separately as they arrive from the laboratories and are not grouped together for a single patient. Further using “results to endorse” method the patients cannot be grouped by “out-patient clinic” i.e. a group of patients seen at the same clinic on a particular day. There is also the added complication that all of the Medibridge results have to be checked separately as this system was never integrated with Cerner. It is however possible that if the results management function in whatever new system ultimately adopted was sufficiently robust that there would not be a requirement to screen results by clinic or by date. At the moment patients can have tests done without being registered to a particular clinic so the results management programme must cater for all eventualities, including missing and orphan results. Using the Cerner method the only way that missing results can be found is by starting with the clinic list, checking the orders and checking that

all the results are there. Orphan results would be picked up on the “results to endorse” method but missing results would not. This problem with missing results exists currently for the oncology service using the results to endorse function but they feel that it would be too onerous for them to chase up missing results and they feel it is the hospitals responsibility to produce a result for an ordered test. This is all very well but in this oncology service patients are not generally discharged and an opportunity would generally present itself later in the care episode to pick up missing tests. This is certainly not the case for the sexual health clinic where many patients attend only once and these patients completely depend on a robust results management system as there is no further opportunity to find or be notified of missing results.

The major medico legal issue which was the impetus for this project was due to missing results i.e. tests which were ordered, the results were never seen, the patient was not contacted and the test was positive.

6.5 Cerner proposed solution for STI patient management system

The team at Cerner would like the hospital to move towards a complete EPR and assert that they can provide this solution. When approached about our specific problem with the ID legislation and the confidentiality requirements their suggestion is as follows: they suggest that the patient should be registered as normal on iSOFT PAS and details thus fed to Cerner EPR. They suggest that where the relevant episode was an STI episode that the episode would be suppressed i.e. only staff with the correct level of authorisation would be able to open the episode. When the system was searched staff would be able to see that this particular person had been registered as a patient at the hospital but they would not be able to see the episode of care if there was only an STI episode. This system is currently used for attendances to the occupational health department at the hospital which are also highly confidential. However knowing that a patient has an occupational health attendance at the hospital, which would be expected for all hospital staff that undergo occupational health screening at commencement of employment, is an entirely different matter to knowing that a patient has had an STI attendance. It would only be a matter of time before staff became aware that these circumstances, of a patient being registered but no episode found meant that there was an STI episode and this would be in direct contravention of the infectious disease legislation.

In these circumstances the following scenario could ensue; a patient from outside Dublin might attend for an STI screen and thus be registered on the hospital systems but with the episode suppressed. This patient would be told that their attendance was completely confidential. Ten years later the same patient might attend with chest pain, the PAS system would be searched and the patient registration would be found although no details could be accessed. It might be mentioned to the patient that they had attended previously and an enquiry might be made as to why they had attended. This would place the patient in the embarrassing position of having to reveal that they had an STI attendance. This scenario probably occurs on a regular basis anyway as current STI patients probably book into other services at the hospital and reveal their previous attendance but that is a different matter as it is the patient revealing details of their attendance not the hospital or the STI clinic revealing it.

A legal opinion (Appendix F) secured by the hospital 12 years ago when a previous electronic system was being procured suggested that adhering to the infectious disease regulations (Appendix A) that the same conditions should apply to electronic records as currently applies to paper records i.e. no member of hospital staff outside the STI service or any other person should have knowledge of the

identity of a person attending an STI clinic. Using these criteria it seems that the Cerner proposal for “suppressing the episode” would not be adequate in terms of confidentiality in this setting. Even if Cerner would agree to have a separate MRN for STI episodes and other hospital episodes this would not work as the patient could still be found when the system was searched as the full name and address would have to be kept on this system.

6.6 Summary

A solution from the hospital preferred provider was explored because of the advantage of maintaining order communications and the fact that this system is already interfaced to hospital systems. However the hospital preferred provider cannot adhere to the strict confidentiality requirement demanded by the legislation. Further Cerner Millennium is poorly interfaced to TelePath and not at all interfaced to Medibridge and its results to endorse module is unsuitable for the needs of a sexual health clinic and therefore it is concluded that Cerner cannot provide a solution for this clinical scenario.

Chapter 7

Minimum requirements for an EPR in the sexual health clinic in this hospital from the perspective of a clinical user

7.1 Introduction

The following requirements were created using information gathered from other users of sexual health patient management systems, stakeholders in the hospital (previously prepared requirements document) and the literature review. This list of requirements reflects the importance given to the three main criteria identified as crucial to the success of this project: (i) Is the system capable of being paperless? (ii) Can it maintain order communications so that the laboratory order is placed in the STI EPR? (iii) Will the laboratory results download to the STI patient record and inform designated users of positive results?

7.2 The iSOFT PAS system is the main hospital system which feeds all other systems. The system **must** be capable of receiving the MRN from PAS such that only initials, DOB and post code are displayed in PAS (for STI patients) but all of the demographic information is held in the STI patient management system. For HIV patients all demographic information will be displayed in PAS and in the STI patient management system. PAS is a minimum requirement as it feeds the Cerner EPR which is the main system for hospital in-patients and as HIV patients are frequently admitted this is a minimum requirement.

7.3 The system **must** be capable of creating electronic orders for STI and other tests which can be passed to the hospital order communications system (OCM) Cerner using only MRN initials and DOB for STI patients and full demographic details for HIV and other patients. This could be achieved in one of two ways:

- (a) The electronic order would be created in the STI patient management system and passed through Cerner OCM to the laboratory.

- (b) The order could be created in Cerner OCM and passed from there to the STI patient management system and the laboratory creating a mirror of the laboratory orders so that results can be marked off against these orders.

This is a critical requirement and it is imperative that the recording of orders is not dependant on the user “doing the right thing” i.e. the test must NOT be capable of being ordered without it being recorded in the STI patient management system. This way the critical issue of missing and orphan results can be managed.

- 7.4 The system **must** be capable of filing laboratory results in the electronic patient record in such a way as to facilitate a certain amount of automation in results management. This requirement is critical and may involve some changes to the current laboratory reporting of results via the TelePath laboratory system.
- 7.5 The system **must** be capable of downloading results into the patient record from the Virus Reference Laboratory (outside lab generating a large number of results on STI and HIV patients) currently accessed via Medibridge.
- 7.6 The results should be structured in such a way as to make automated results management possible e.g. if a specific panel of results is completed and all results are negative, it should be possible to send an SMS text message to the patient notifying them of negative results. Some manual input to this function could be tolerated.
- 7.7 The system **must** be capable of alerting specific users to any positive results on STI patients within defined parameters to be determined by the user e.g. positive Chlamydia results should be alerted to the health advisors.
- 7.8 The system should be capable of informing certain interested users of certain results e.g. a particular user may be interested in early syphilis results and the system should be capable of informing this user when certain parameters are met.
- 7.9 The system **must** be capable of alerting the user to missing results i.e. if a test is ordered and a result is not returned within a certain time frame the user should be alerted.

- 7.10 The system **must** be capable of restricting access levels according to user profile.
- 7.11 The system **must** have full audit log for records viewed and changed.
- 7.12 The system should be capable of alerting the user to specific conditions to be defined by the user e.g. age under 16yrs, sexual assault etc.
- 7.13 The system should have embedded decision support capability to be determined by the user e.g. information on Antiretroviral (HIV) medication lists, HIV resistance mutations etc.
- 7.14 The system should be capable of generating alerts for multiple items to be determined by the user e.g. for medication allergies, drug interactions, vaccinations etc.
- 7.15 The system must be capable of distinguishing between HIV or ID and STI patients such that differing legislative requirements around confidentiality are reflected i.e. STI patient lab orders are made under initials, DOB and post code whereas HIV orders are made using full demographic details.
- 7.16 The system should be capable of generating standard letters as required by the user e.g. recall letters, GP letters etc.
- 7.17 The system must be capable of being paperless. It must have the ability to scan referral letters, prescriptions and laboratory results from outside labs into the individual EPR.
- 7.18 The system should be capable of accommodating old medical records to be scanned in or should suggest a viable method for dealing with legacy records.
- 7.19 The system **must** be able to create reports to fulfil statutory reporting requirements containing limited demographic information (enough demographic information to allow deduplication of records - as reports are also made by the laboratory, but not enough to identify patient).

- 7.20 The system should be capable of being searched under multiple criteria e.g. age, sex, sexual orientation, diagnosis, medication prescribed, date seen, episode type etc.
- 7.21 The system must be capable of managing all of the various clinics and day ward attendances and must be capable of being searched by out-patient clinic.
- 7.22 The system **must** be capable of alerting the user about patients who do not attend (DNA) for appointments.
- 7.23 The system should be capable of sending text reminders to patients about pending appointments.
- 7.24 It is expected that the system will have all the usual functionality anticipated in an STI patient management system including perform sexual history taking and examination with the ability for free text kept to a minimum.
- 7.25 The system should be capable of having separate assessment profiles for STI, HIV and ID patients.
- 7.26 The system should be capable of having a medication database containing all STI and antiretroviral medications as well as the hospital formulary. The drug database should be created by the provider according to the user requirements.
- 7.27 The system should be capable of maintaining a vaccination database and sending automatic reminders for vaccinations due including reminders to “all HIV patients” for yearly influenza vaccine.
- 7.28 The system should replace all current clinic databases e.g. HIV/HepC co infection, pregnancy, ethnic minority, syphilis, cervical cytology, vaccination etc.

Chapter 8

Conclusions and recommendations

8.1 Introduction

The objective of this research was to explore the available options for providing an EPR for the purposes of STI and ultimately HIV patient management in a large urban sexual health clinic in a large public hospital. The main issues identified in the Dublin clinic leading to inception of this project were storage and retrieval of paper records and results management which is a critical medico legal issue. The methodology consisted of firstly a literature review exploring barriers to introduction of hospital EPR systems and the specific area of confidentiality in sexual health clinics and a review of the legislation in this area. Secondly a questionnaire was administered to software providers and users of these systems to evaluate how these systems are working in other locations. An assessment was made as to whether the hospital preferred software provider, Cerner, could provide a solution.

In this section the critical issues leading to successful delivery of this project will be identified and various options in terms of provision of an electronic patient management system will be weighed up and recommendations will be made.

8.2 The critical issues are:

8.2.1 Confidentiality: All of the commercial providers of STI patient management systems can meet the requirements in the Infectious disease legislation but the hospital preferred provider (for reasons outlined below) cannot.

8.2.2 The Interface with Cerner to maintain current ability for order communications (OCM) which has delivered immense value to the Dublin institution and will facilitate results management. This interface is critical, as it is inevitable that this system will be extended to manage HIV patients, including in-patients, which will require use of Cerner EPR and OCM.

8.2.3 Results management: This is the most critical issue. Because of volume issues some automation of results is desirable. This can only be achieved if the laboratory order can be created both in Cerner and the STI patient management system. Results management would be facilitated by a change to the current lab system TelePath to convert results into structured data items rendering this data into a more useful form. The results management functionality of the system will be a major factor in evaluation of systems during the procurement process.

8.2.4 Interface with Medibridge: Since a large volume of results come from the Virus Reference Laboratory via this messaging system, these results would need to download to the patient record to allow automated and robust results management.

8.3 The hospital preferred provider

It seems as though this provider cannot provide an electronic solution in this setting for the following reasons:

8.3.1 Confidentiality: If the STI patient name is on Cerner then this patient can be found by anyone who searches the hospital system and patient confidentiality is compromised which is a direct contravention of the Infectious Disease legislation.

8.3.2 Results management: Cerner is not interfaced with medibridge, results display of microbiology test results will not allow any automatic results management and in any event there is no facility for automatic results management in the Cerner solution. The “results to endorse” results management method in Cerner is not suitable for dealing with large numbers of results from patients who attend once only. Further there is no facility to easily find missing results in the Cerner results management module which is a critical issue.

8.4 The other providers of Sexual Health Patient Management Systems

All of these providers can provide systems which are fit for purpose and are designed specifically for use in this area and all appear to have the required functionality of an STI patient management system.

8.4.1 Can they provide a paperless solution?

While all providers claim to be able to provide a paperless solution none of the five is completely paperless in any location. The nearest system to achieving paperless status is Exelicare in Scotland but they do not have order communications functionality. The Lilie system as used in West London are paperless for patient records but are still screening paper based results and uploading them manually. The SHIP, Mill and PreView SHE systems are not paperless in any location.

8.4.2 Order Communications

Exelicare, SHIP, Lilie and Telecare Mill all have the functionality for electronic ordering. None of these providers have interfaced with Cerner in any location but all

of the listed providers assert that it will be possible. One provider (Mill) acknowledges that it will be an expensive undertaking. Exelicare (AxSys) has a track record in interfacing with practically every laboratory in the UK as the provider of the IT infrastructure for the National Chlamydia Screening Program (UK).

8.4.3 Results management

The results management functionality of the Exelicare, Telecare Mill and Lilie systems appear to meet requirements. It is more difficult to assess this functionality in SHIP as the project is not fully implemented. In preView SHE results are attached to the patient record and designed to be read by resource type i.e. doctor nurse etc and there does not appear to be adequate decision support in the results management module of this solution.

8.4.4 Software support

Some providers appear to provide better software support than others. Most of the users had some issues with software support and some of the providers are very small companies. Two users (SHIP and Exelicare) mentioned distance from software support as being an issue. It is difficult to choose between providers as where one company may be strong in one area it may be weak in another critical area. It is not possible in the context of this project to decide which of these providers can meet all of the critical requirements and provide the best solution; however, there is insight to be gained from what has been achieved in other locations.

8.5 How to move this project forward

The hospital needs to produce a set of requirements which needs to reflect the above critical issues along with other criteria set by the various stakeholders. To this end, a set of requirements critical to the clinical end user has been developed (Chapter 7). If these requirements were met it would significantly reduce the risk of failure for this project.

References

- Anderson, J. G. (2000). "Security of the distributed electronic patient record: a case-based approach to identifying policy issues." International Journal of Medical Informatics **60**(2): 111-118.
- Benson, T. (2002). "Why general practitioners use computers and hospital doctors do not---Part 1: incentives." BMJ **325**(7372): 1086-1089.
- Berg, M. (2001). "Implementing information systems in health care organizations: myths and challenges." Int J Med Inform **64**(2-3): 143-56.
- Blumenthal, D. and J. P. Glaser (2007). "Information Technology Comes to Medicine." N Engl J Med **356**(24): 2527-2534.
- Brockley, L. W. o. (2006). Health Minister Sets Out Electronic Patient Record details, News Distribution Service.
- Brook, M. G., J. Davies, et al. (2008). "Implementation of electronic patient records in a sexual health clinic." Sex Transm Infect **84**(2): 155-156.
- de Lusignan, S., T. Chan, et al. (2007). "The roles of policy and professionalism in the protection of processed clinical data: A literature review." International Journal of Medical Informatics **76**(4): 261-268.
- Denley, I. and S. W. Smith (1998). "Implementing access control to protect the confidentiality of patient information in clinical information systems in the acute hospital." Health Informatics Journal **4**(3-4): 174-178.
- DoBias, M. (2006). "EHR adoption 'pitifully behind'. Study: only 10% of physicians use IT to its fullest." Mod Healthc **36**(41): 8-9.
- Etzioni, A. (1999). "Medical records. Enhancing privacy, preserving the common good." Hastings Cent Rep **29**(2): 14-23.
- Ford, E. W., N. Menachemi, et al. (2006). "Predicting the Adoption of Electronic Health Records by Physicians: When Will Health Care be Paperless?" J Am Med Inform Assoc **13**(1): 106-112.
- Geller, L., J. Alper, et al. (1996). "Individual, family, and societal dimensions of genetic discrimination: A case study analysis." Science and Engineering Ethics **2**(1): 71-88.
- Hendy, J., N. Fulop, et al. (2007). "Implementing the NHS information technology programme: qualitative study of progress in acute trusts." BMJ **334**(7608): 1360-.
- Hersh, W. (2004). "Health Care Information Technology: Progress and Barriers." JAMA **292**(18): 2273-2274.
- ISO/TS (2003). Health Informatics-Requirements for an Electronic Health Record Architecture, ISO/TS. **18308**.

Jha, A. K., C. M. DesRoches, et al. (2009). "Use of Electronic Health Records in U.S. Hospitals." N Engl J Med **360**(16): 1628-1638.

Jha, A. K., J. B. Perlin, et al. (2003). "Effect of the Transformation of the Veterans Affairs Health Care System on the Quality of Care." N Engl J Med **348**(22): 2218-2227.

Jones, M. (2004). "Learning the lessons of history? Electronic records in the United Kingdom acute hospitals, 1988-2002." Health Informatics Journal **10**(4): 253-263.

Malin, B. and L. Sweeney (2004). "How (not) to protect genomic data privacy in a distributed network: using trail re-identification to evaluate and design anonymity protection systems." Journal of Biomedical Informatics **37**(3): 179-192.

O'Harrow, R. (1998). Prescription sales privacy fears. Washington Post.

Ross, J. D. C., A. Copas, et al. (2007). "Optimizing information technology to improve sexual health-care delivery: public and patient preferences." Int J STD AIDS **18**(7): 440-445.

Thomas, C. R. (1997). "Privacy, information technology, and health care." Commun. ACM **40**(8): 92-100.

Tideman, R. L., M. K. Pitts, et al. (2006). "Client acceptability of the use of computers in a sexual health clinic." Int J STD AIDS **17**(2): 121-123.

van der Linden, H., D. Kalra, et al. (2009). "Inter-organizational future proof EHR systems: A review of the security and privacy related issues." International Journal of Medical Informatics **78**(3): 141-160.

Vishwanath, A. and S. D. Scamurra (2007). "Barriers to the adoption of electronic health records: using concept mapping to develop a comprehensive empirical model." Health Informatics Journal **13**(2): 119-134.

Williams, P. A. H. (2008). "When trust defies common security sense." Health Informatics Journal **14**(3): 211-221.

Appendix A
Legislation

STATUTORY
INSTRUMENTS.

S.I. No. 390 of 1981.

INFECTIOUS DISEASES REGULATIONS 1981.

S.I. No. 390 of 1981.

INFECTIOUS DISEASES REGULATIONS 1981.

The Minister for Health, in exercise of the powers conferred on her by sections 5 and 29 of the [Health Act, 1947 \(No. 28 of 1947\)](#) and by Section 31 of the said Act as amended by section 34 of the [Health Act, 1953 \(No. 26 of 1953\)](#) hereby makes the following Regulations:—

1. These Regulations may be cited as the Infectious Diseases Regulations, 1981.

2. In these Regulations:—

the word “carrier” means a person who, without apparent symptoms of an infectious *disease*, harbours the specific micro-organisms of such *disease* and is a probable source of infection with such *disease*;

the expression “medical officer of health” means as appropriate a Director of Community Care and Medical Officer of Health, the Dublin Medical Officer of Health, any Senior Area Medical Officer or Area Medical Officer of a health board;

the expression “infectious *disease* hospital” means a hospital provided and maintained for the treatment of infectious diseases;

the expression “infectious *disease* unit” means a unit in or attached to a hospital provided and maintained for the treatment of infectious diseases;

the expression “health officer” means an officer of a health board authorised by the health board to enforce any provisions of these Regulations;

the expression “medical practitioner” means a person whose name appears in the General Register of Medical Practitioners under the [Medical Practitioners Act, 1978 \(No. 4 of 1978\)](#) ;

“the Minister” means the Minister for Health.

3. These Regulations shall come into operation on the 1st day of December, 1981.

4. The Infectious Diseases Regulations, 1948 ([S.I. No. 99 of 1948](#)) are hereby revoked.

5. These Regulations shall, subject to any arrangement for joint action by health boards, be enforced in the functional area of each health board by that health board.

6. The diseases listed in the Schedule to these Regulations are hereby specified to be infectious diseases and the expression “infectious disease” shall be construed as meaning any disease so listed.

7. All the infectious diseases listed in the Schedule to these Regulations shall be excluded from the application of Sections 33, 34, 35 and 36 of the [Health Act, 1947](#) .

8. All the infectious diseases listed in the Schedule to these Regulations, except acute anterior poliomyelitis, cholera, diphtheria, plague, smallpox, tuberculosis, typhoid and paratyphoid fevers, typhus and viral haemorrhagic diseases (including lassa fever and marburg *disease*) shall be excluded from the application of [Section 38 of the Health Act, 1947](#) as amended by [Section 35 of the Health Act 1953](#) .

9. All the infectious diseases listed in the Schedule to these Regulations, except acute anterior poliomyelitis, diphtheria, dysentery, salmonellosis, tuberculosis, typhoid and paratyphoid fevers, typhus and viral haemorrhagic diseases (including lassa fever and marburg *disease*) shall be excluded from the application of [Section 44 of the Health Act 1947](#) , as amended by [Section 36 of the Health Act 1953](#) .

10.(1) A health board shall make arrangements for the diagnosis and treatment of infectious diseases in persons in the functional area of that health board.

(2) Subject to the provisions of sub-articles (3) and (4) of this Article, no charge shall be made by a health board for any services (including institutional services) provided by it in the performance of its duties under sub-article (1) of this Article.

(3) Where institutional services, which are provided in a private or semi-private ward or which are otherwise of a type for which it is customary to make an extra charge, are provided for a person suffering from an infectious *disease* at the request of such person or of the person in charge of him, the provisions of sub-article (2) of this Article shall not apply.

(4) Nothing in sub-article (2) of this Article shall affect any agreement with an authority in another State for the making of payments to health boards for the treatment of infectious diseases.

11. On becoming aware, whether from a notification or intimation under these Regulations or otherwise, of a case or a suspected case of an infectious *disease* or of a probable source of infection with such *disease*, a medical officer of health, or a health officer on the advice of a medical officer of health, shall make such enquiries and take such steps as are necessary or desirable for investigating the nature and source of such infection, for preventing the spread of such infection and for removing conditions favourable to such infection.

12. A medical officer of health shall take such measures as he may consider appropriate, or as the Minister may direct, with regard to the custody, transport and disposal of the body of a person which is a probable source of infection with an infectious *disease*.

13. (1) A health board may, from time to time in accordance with the advice of a medical officer of health and shall, if required by the Minister, do all or any of the following things:—

- (a) purchase and keep a supply of such agents and ancillary instruments and equipment as may be approved by the Minister for ascertaining whether or not a person is infected with an infectious *disease* or for determining susceptibility to or for increasing resistance against or for producing immunity from infection with any infectious *disease*;
- (b) make, subject to the Minister's approval, arrangements for the administration of any such agent to persons in its functional area;
- (c) supply any medical practitioner practising in the functional area of such health board with any such agent on such reasonable terms or conditions as the health board may

determine.

14. Subject to the provisions of Article 15 of these Regulations, a medical practitioner, as soon as he becomes aware or suspects that a person on whom he is in professional attendance is suffering from or is the carrier of an infectious *disease* shall—

(a) forthwith transmit a written notification to a medical officer of health and

(b) further in a case of acute anterior poliomyelitis, bacterial meningitis (including meningococcal septicaemia), cholera, ornithosis, plague, smallpox, typhus, viral haemorrhagic diseases (including lassa fever and marburg *disease*) or yellow fever, or where he is of the opinion that there is a serious outbreak of infectious *disease* in a locality, give immediate preliminary notification thereof to a medical officer of health.

15. (1) A medical practitioner who is a medical officer of an infectious *disease* hospital or an infectious *disease* unit shall forthwith transmit to a medical officer of health a notification of any case of infectious *disease* or of any carrier of an infectious *disease* occurring in his practice as such medical officer, where—

(a) the patient has been admitted to the infectious *disease* hospital or infectious *disease* unit as a suspected case of infectious *disease* or as a suspected carrier without any definite diagnosis and the *disease*, or the fact that the person is a carrier, is first definitely diagnosed after admission of the patient to the infectious *disease* hospital or infectious *disease* unit or

(b) the *disease* or the fact that the person is a carrier is diagnosed after the admission of the patient to the infectious *disease* hospital or infectious *disease* unit and such diagnosis constitutes an alteration of a definite diagnosis made before admission or the patient to the infectious *disease* hospital or infectious *disease* unit or

(c) the *disease* was contracted by a person in the infectious *disease* hospital or infectious *disease* unit.

(2) Where a medical practitioner who is a medical officer of an infectious *disease* hospital or infectious *disease* unit is required under sub-article (1) of this Article to notify a case of acute anterior poliomyelitis, bacterial meningitis (including meningococcal septicaemia), cholera, ornithosis, plague, smallpox, typhus, viral haemorrhagic diseases (including lassa fever and marburg *disease*) or

yellow fever, or where he is of the opinion that there is a serious outbreak of infectious *disease* in a locality he shall give immediate preliminary notification thereof to a medical officer of health.

(3) Where a patient is admitted as a suspected case of infectious *disease* or as a suspected carrier to an infectious *disease* hospital or infectious *disease* unit and he is found on examination neither to be suffering from nor to be a carrier of any infectious *disease*, a medical practitioner who is a medical officer in charge of such patient shall transmit a notification to that effect to a medical officer of health.

16. A registrar of births and deaths shall send to a medical officer of health such returns of deaths from infectious diseases as may be specified by the Minister.

17. (1) Where, under these Regulations, a medical practitioner

(a) sends a notification that a person is suffering from or is a carrier of an infectious *disease* or

(b) sends a notification or intimation that he suspects that a person is suffering from or is a carrier of an infectious *disease* and such suspicion is subsequently confirmed,

the health board shall pay him the appropriate fee in respect of such notification or intimation.

(2) The appropriate fee shall be determined by the Minister from time to time, with the consent of the Minister for Finance.

18. (1) A medical officer of health shall furnish to the Minister by the Wednesday of each week a return of the cases of infectious diseases notified to him in the week ending on the previous Saturday.

(2) A medical officer of health shall furnish to the Minister as soon as possible a detailed report on each case of such infectious *disease* as the Minister may specify from time to time.

19. A person who refuses to comply with a requirement or direction given or a request for information made in pursuance of any of the provisions of these Regulations shall be guilty of a contravention of these Regulations.

20. (1) A health board shall keep such records as may be directed by the Minister from time to time in relation to the exercise of its powers and the performance of its duties under these Regulations.

(2) Any records kept in pursuance of this Article and any notification made to a medical officer of health under these Regulations shall be treated in a confidential manner and, save as provided in sub-article (5) of this Article, shall not, without the consent in writing of the patient, be disclosed in such a manner as to make identification of the patient possible.

(3) When any record, report, notification or intimation or any other communication in relation to a person who is, or is suspected to be, suffering from, or is a carrier of, infectious disease is sent by post, it shall be enclosed in a sealed envelope.

(4) Nothing in this Article shall be construed as preventing the inspection by a medical practitioner authorised by the health board, or by the Minister, of the records kept in pursuance of this Article where the consent of the patient has been obtained.

(5) Where the Minister certifies in respect of records compiled under this Article in relation to any particular patient that it would not in his opinion be in the interest of the common good to seek the consent referred to in sub-articles (2) and (4) of this Article, a medical practitioner authorised by the Minister may inspect such records.

(6) Where a certificate under sub-article (5) of this Article has been given in respect of any particular records in relation to a particular patient by the Minister the patient shall be informed forthwith of the giving of such certificate.

(7) The consent referred to in sub-articles (2) and (4) of this Article may, in the case of a minor, be given by a parent or guardian.

21. A health board shall comply with any directions given from time to time by the Minister as to the exercise of its powers and the performance of its duties under these Regulations.

SCHEDULE

Diseases specified to be Infectious Diseases

Acute anterior poliomyelitis

Acute encephalitis

Acute viral meningitis

Anthrax

Bacillary dysentery

Bacterial meningitis (including meningococcal septicaemia)

Brucellosis

Cholera

Diphtheria

Food poisoning (bacterial other than salmonella)

Gastro enteritis (when contracted by children under 2 years of age)

Infectious mononucleosis

Influenzal pneumonia

Legionnaires *Disease*

Leptospirosis

Malaria

Measles

Ornithosis

Plague

Rabies

Rubella

Salmonellosis (other than typhoid or paratyphoid)

Smallpox

Tetanus

Tuberculosis

Typhoid and Paratyphoid

Typhus

Veneral diseases—gonococcal infections

—syphilis

—other (including non-specific urethritis,
chancroid, granuloma inguinale, and lympho-
granuloma venereum)

Viral haemorrhagic diseases (including lassa fever and marburg
disease)

Viral hepatitis: Type A

Type B

Type unspecified

Whooping cough

Yellow fever.



GIVEN under the Official Seal of the Minister for Health,
this 13th day of November, 1981.

EILEEN DESMOND,

Minister for Health.

The Minister for Finance consents to sub-article
(2) of article 17.

Dated this 13th day of November, 1981.

JOHN BRUTON,

Minister for Finance.

EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations declare certain diseases to be infectious diseases and require notification of cases of the diseases to the medical officers of the appropriate Health Board. The Regulations provide for the diagnosis and treatment of infectious diseases, the prevention of infectious diseases, the prevention of the spread of infectious diseases and for removing condition which favour the spread of infection. The Regulations also provide for payment of a fee to medical practitioners who notify cases of infectious diseases and for the keeping of records.

Appendix B

Questionnaire for users of standalone STI patient management systems

1. It would be very helpful to have a description of how the system works within your institution in the following terms.

Is the system standalone within the clinic or is it integrated with other hospital systems e.g. Patient Administration System (PAS) or laboratory systems?

2. Is the STI clinic “paperless”? i.e. are you also using paper records for anything? E.g. referral letters, patient registration forms, results or clinical information?

If you are completely paperless proceed to question 3. If **not** paperless please answer the following:

2. a. What do you use the paper records for?

2. b. Are you still using paper records because of a problem with the system you are using? Or is it a problem with the institution or the existing institutional IT infrastructure?

2. c. What change do you need to “go paperless”?

3. Is there **double entry** of data? i.e. do your reception staff have to enter patient demographic data into your STI system and also into any other system i.e. Hospital Patient Administration System (PAS) or lab system or paper based system?

4. Do you use order communications (**order comms**) for ordering laboratory, radiology and other tests?

4.a Can you order tests directly from your STI patient management system?

4.b If not why not?

5. Do some or all of your laboratory and radiology results download directly to the STI patient record?

5. a. Which do or do not and why?

6. a. Does your STI Patient management system alert you to positive results?

If **yes to 6.a** answer 6.b. If no to 6.a please proceed to 6.c and 6.d

6. b. If yes to 6.a. do these alerts for positive results automatically generate patient recalls (i.e. built in decision support)? For example if Chlamydia positive can the system be configured to send a recall letter or SMS text?

6. c. If you are not alerted about positive results by your STI patient management system what system do you use to find and manage positive results?

i.e. do paper results come back to the department or do you screen results electronically?

6.d. Can you explain why you do not have alerts from your STI patient management system for positive results? Is it a problem with the system? Or is it an institutional problem (e.g. can't download lab results to system)?

7. Does your system have the ability to generate **reports** for the purpose of reporting STIs – e.g. to fulfil statutory reporting requirements?

Appendix C

Questionnaire for software providers of STI patient management systems

The purpose of this questionnaire is to see if your organisation can provide a **paperless** “off the shelf” system for STI patient management to include diagnosis, treatment, laboratory and radiology investigations, prescribing and results management with clinical decision support based recall for positive tests which would be suitable for use at the STI service at St James Hospital. The individual elements of this question are dealt with in further questions below. For the purpose of this exercise I’ll assume that the diagnosis and treatment functionality of the system is “fit for purpose” in order to avoid a lengthy questionnaire.

1. Confidentiality is crucial for the operation of our service. No other user of the hospital system or user can know an STI patient identity. How is this confidentiality requirement managed in other institutions where your system is in use?

2. Interface with current hospital systems is crucial. The hospital uses the following systems for all patients. The crucial interfaces are the first 4 which are coloured red

System Name	Supplied By	Department	Function	Interface	No of Users	Platform
Millennium EPR	Cerner	Hospital – Wide	Order Comms Clinical Workstation Event Repository Interface Engine	PAS / PMI. Laboratory Internal Server (Messaging) PACS/RIS CareVue (ICU)	2000-3000	AIX / Oracle
Telepath	iSOFT	Laboratory	Laboratory Information System	PAS / OCM	120	Alpha / VMS DSM
PAS/PMI	iSOFT	Hospital Wide	Patient Administration and Billing System	OCM / LAB	700	Alpha / VMS DSM

System Name	Supplied By	Department	Function	Interface	No of Users	Platform
Virus Reference Laboratory Medibridge	DMF	Oncology Ward, GUIDE, NCHCD, Hepatology and Microbiology	Virus Results look up	No	10	Windows
ORPS	Valentia Technologies	Hospitalwide	SMS reminders for Hospital appointments	PAS	Hospitalwide	Web
PACS/RIS	Cerner	RIS: Radiology PACS: Hospital- Wide	Scheduling. Patient Tracking. Image Capture & Distribution. Doc Imaging.	EPR. Speech Recognition (Dictaphone Powerscribe). Radiology Modalities.	130	Linux / Oracle
Electronic Discharge Summary Form	Written in house	Hospital Wide	Patient Discharge Summary	SAP & PAS	450 – 500	Web
Healthlink	National Messaging Project	National	Messaging between Primary and Acute Care	Telepath	National	Web
Social Work	Written in house	Social Work	Statistics.	None	7	VB / Access
CliniScript & CliniChemo	System Solutions	Pharmacy	Dispensing / Stock Control System & Compounding Control System	EDI	60	Intel / NT Pascal

2a. The hospital MRN is generated by PAS. This hospital MRN is required for the purpose of ordering tests (order comms). Only initials, DOB, mobile number and post code are entered onto PAS to maintain patient confidentiality, as any users of the hospital PAS could look up this data. Can you outline how you would avoid the necessity for **double entry of patient data** into both PAS and the STI patient Management system?

2b. Laboratory and radiology tests are currently ordered using **Order Comms** from the Cerner millennium EPR. Could your STI patient management system interface with EPR such that laboratory tests and x-rays could be ordered from the STI patient management system?

2c. Laboratory results from the laboratory information system (Telepath) and radiology information system currently download to the hospital EPR. Telepath is a very old system which produces microbiology results in a text format. Can these **results download** to the STI patient management system?

2d. Results of certain tests come from an **external laboratory** (Virus Reference Laboratory) via a messaging system – Medibridge (DMF), currently these results are looked up separately and are not part of the patient record in EPR (Cerner). Could messages from this system be downloaded from this system into the patient record of the STI patient management system?

3. Electronic prescribing. Does your STI patient management system have a function for electronic prescribing?

3.a. Is the drug database created by the user?

4. **Results Management:** Management of results will be crucial for this system.

4.a. Can your system alert positive results i.e. is there a decision support function for management of positive results?

4. b.Can the system give monthly reports of positive results for the purposes of audit?

5. **Recalls:** Can the system be configured to generate recall letters for a variety of conditions e.g. positive Chlamydia positive cervical cytology? Can this be done automatically i.e. positive result leads to recall letter

6. **Report generation:** Can the system generate the necessary reports required to fulfil statutory reporting requirements? e.g. positive Chlamydia results by age, sex, post code, sexual orientation

Appendix D

Proposal for Ethical approval

UNIVERSITY OF DUBLIN, TRINITY COLLEGE

Faculty of Engineering, Mathematics and Science

School of Computer Science and Statistics

RESEARCH ETHICS PROTOCOL

When is Ethical Approval Needed?

Ethical approval is required before any studies involving human subjects can commence. This requirement applies to studies to be undertaken by staff, postgraduate and undergraduate students. In the case of collaborative projects involving researchers from outside the School, ethical approval obtained from an external research ethics body may suffice – evidence of same must be submitted to the SCSS Research Ethics Committee prior to the commencement of the study (see procedures below). In the absence of such external approval, approval must be obtained as per this document.

Additional ethical approval may be required if the project involves or is funded by an external body, for example, studies under FP7 automatically require such approval.

For the purpose of this document a “study” may be understood to involve a potentially staged series of different experiments to be conducted over a period of time. If substantive changes are made to a study following receipt of ethical approval, this will constitute a new study for which further ethical approval must be obtained.

Procedure

To apply for ethical approval from the SCSS Research Ethics Committee, completed application forms together with supporting documentation should be submitted in hardcopy to the School's Research Unit and an electronic copy e-mailed to research-unit@scss.tcd.ie.

The Committee will consider each application and normally provide a response within two weeks but not more than one month later. Applications that are considered not to have significant ethical implications may be evaluated by the Committee Chair without reference to the full Committee. Applications will otherwise be considered at a meeting of the SCSS Research Ethics Committee.

When approval has been obtained from an external research ethics committee, and School approval is not required, a copy of the external ethical approval must be submitted to the School's Research Unit, prior to commencement of study, for noting by the SCSS Research Ethics Committee.

Note: These procedures may be amended from time-to-time following recommendation by the SCSS Research Ethics Committee and with the approval of the SCSS Research Committee.

Before seeking ethical approval researchers should:

- identify actual and potential ethical issues that might arise;
- reflect on how these will be addressed; and
- formulate procedures to deal with all such issues.

During the research project researchers should:

- implement the ethical procedures;
- obtain continuous feedback from participants about ethical issues;
- periodically review the ethical strategy in the light of feedback received; and
- if required, update their ethical procedures.

Composition of the SCSS Research Ethics Committee

The Committee will consist of a Chairperson/Convenor appointed by the Director of Research and two other experts – a member of the School's academic staff and an external representative. The internal and external members will be selected from a panel approved by the Director of Research from time to time. Members will be selected on a case by case basis by the Chairperson subject to their availability. Researchers will be precluded from the Committee considering ethical approval for their study.

Part A

Project Title: Towards identifying the barriers to developing an electronic patient record (EPR) in a sexual health setting and to evaluate available systems and identify the system most suitable for use at the Sexual Health Clinic St James Hospital

Name of Lead Researcher (student in case of project work): Grainne Courtney

E-mail: courtneg@tcd.ie..... Contact Tel No: 0862491901

Course Name and Code (if applicable): M.Sc in Health Informatics.....

Estimated start date: Sept 2008 Estimated end date: Sept 2009

Office Use Only

SCSS Ref No.: Date Received:

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and guidelines
http://www.tcd.ie/info_compliance/dp/legislation.php;
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Tell participants that their participation is voluntary
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- Tell participants that all recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given

- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- If College students are involved in the study, I will verify that they are 18 years or older

Signed:

Date:

.....

Lead Researcher/student in case of project work

Part B

<i>Please answer the following questions.</i>		<i>Yes/No</i>
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		<i>No</i>
Will your project deliberately involve misleading participants in any way?		<i>No</i>
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		<i>No</i>
Does your study involve any of the following?	Children (under 18 years of age)	<i>No</i>
	People with intellectual or communication difficulties	<i>No</i>
	Patients	<i>No</i>

If you have answered 'Yes' to any of the questions above, details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

If you have ticked 'No' to all the questions in part B above, please complete below.

Give a brief description of participants and procedure (methods, tests used etc.)

The purpose of this study is to evaluate available “off the shelf” systems for use in the Sexual Health setting to see which system would be most suitable for use at the GUIDE clinic St James Hospital. There are 2 questionnaires; one for users of systems which are currently in place in other institutions and one for software providers. It is assumed that the systems are “fit for purpose” and most of the questions relate to crucial interfaces with existing institutional IT infrastructure and to results management.

Questionnaire for Software Providers

5 systems in current use are to be evaluated. These systems are in use in Ireland, Northern Ireland and Britain. The providers are commercial vendors of patient management systems for use in the sexual health setting. Each of the vendors has their own system which they market to sexual health clinics all over Ireland and the UK and no vendor markets any other system other than their own. The vendors are as follows 1. SHIP System (CaraData Australia) 2. LillieSystem (Blithe Systems UK). 3. Mill System (Mill Systems UK) 4. PreView SHE System (IMS UK) 5. Exelicare (AxSys Systems - used in the Scottish National sexual health IT project NaSH) . Two of these vendors had previously contacted the hospital (St James GUIDE clinic) to market their patient management system to us. Two of the other vendors were identified through the British Association for sexual Health and HIV (BASHH) IT group and the final vendor was contacted through one of the users as the original company marketing this software had been bought over and it was not easy to find who was marketing it(IMS – PreView SHE system). I am dealing with the representative of each company nominated to deal with queries of this nature from Ireland and they are completing this questionnaire on behalf of their company. I am

expecting that they will have significant technical resources at their disposal to deal with the technical questions in the questionnaire.

This questionnaire may be followed up by a face to face or telephone interview to clarify any issues. The questionnaire will be sent to the participant by email.

Questionnaire for Users of patient management systems in the sexual health setting

It hoped to interview 2 users for each system in different institutions, however one system is only in use in one location (SHIP – Waterford regional Hosp) and one system is being launched as a national project and coordinated centrally – Scottish system – NaSH -Excelicare. For the other 3 systems in use I am hoping to administer a questionnaire to 2 users for each system – one in a location where it is perceived to be working well and one in a location where it is not fully used or perceived to be not working well. Most of these systems are in use in the UK. In fact there is only one location in Ireland (Waterford). I have used previous contacts in the sexual health setting through previous work in the UK to locate some participants. I have located some participants through the BASHH IT group and one participant was located through published work on implementation of a patient management system in the sexual health setting which was published in the literature. The object of this questionnaire is an information gathering exercise for the purpose of a descriptive chapter in my thesis about how these systems are in use. Is not intended to be a comprehensive analysis of how these systems are in use in the British Isles as this is beyond the scope of this thesis. It is intended that the questionnaire should throw up problems which we might not have anticipated in our endeavour to introduce such a system at St James hospital and to benefit from other users experience. It is anticipated that most of the problems relating to full implementation of these systems will be due to local issues like interfacing with old legacy laboratory systems and patient administration systems. I have contacted some units and asked them to identify the person most suitable to complete the questionnaire i.e. the person with a good working knowledge of the system. In some cases this has been a data manager and in other cases it has been a doctor with an interest in IT. It is intended that this questionnaire will be completed in a personal capacity to give an overview of how the system is functioning in that

person's opinion and not as a representative of the organization.

The questionnaire should take about 10-15 minutes to complete and may be followed up by a telephone interview to clarify any issues. The questionnaire will be sent to the participant by email as most of the participants are in the UK.

The questionnaires are attached to this document as appendices.

I consider that this project has **no** significant ethical implications to be brought before the SCSS Research Ethics Committee.

Signed:

Date:

.....

Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external ethical approval has been received, please complete below.

External ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed:

Date:

Lead Researcher/student in case of project work

Completed application forms together with supporting documentation should be submitted in hardcopy to the School's Research Unit, Room F37, O'Reilly Institute, and an electronic copy e-mailed to research-unit@scss.tcd.ie

Application Check List

- For applications without significant ethical implications the following documents are required:

1. SCSS Ethical Approval Form
2. Participants Information Sheet
3. Participants Consent Form

Applications without significant ethical implications need to sign section A & C

- For applications with potential ethical implications for which SCSS Ethical approval is being sought the **documents listed above are required along with:**

4. Research Project Proposal

Applications with potential ethical implications need to sign section A & B

Information for participants in evaluation of “Off the shelf” patient management systems for use in the sexual health setting

Background

The GUIDE Clinic at St James is the largest sexually transmitted infection (STI) clinic in Ireland North and South and there are more than 10,000 STI patient attendances per year. Currently the clinic uses paper patient notes for all patient attendances. There is an electronic patient record (EPR) for every patient attendance but this only holds laboratory orders and results. There is very little clinical or demographic information on the EPR.

The study

The purpose of this study is to evaluate available “off the shelf” systems for use in the STI setting to see which system would be most suitable for use at the GUIDE clinic St James Hospital. There are 2 questionnaires; one for users of systems which are currently in place in other institutions and one for software providers. It is assumed that the systems are “fit for purpose” and most of the questions relate to crucial interfaces with existing institutional IT infrastructure and to results management.

The questionnaire should take about 10-15 minutes to complete and may be followed up by a telephone interview to clarify any issues. This work will be presented as a master’s thesis in part fulfilment of the M.Sc in Health Informatics TCD September 2009.

Participants referred to in any publication of this work will be anonymised as will any reference to any third party in the completion of the survey.

Many thanks for your participation in this research.

INFORMED CONSENT FORM

The researcher should retain the original of the signed form in a secure file, give one copy to the participant, and send one copy to the sponsor (if appropriate).

<p>Project title: Towards identifying the barriers to developing an electronic patient record (EPR) in a sexual health setting and to evaluate available systems and identify the system most suitable for use at the Sexual Health Clinic St James Hospital.</p>		
<p>Principal Investigators: Grainne Courtney</p>		
<p>BACKGROUND: The purpose of this study is to evaluate available “off the shelf” systems for use in the STI setting to see which system would be most suitable for use at the GUIDE clinic St James Hospital. There are 2 questionnaires; one for users of systems which are currently in place in other institutions and one for software providers. Participant’s confidentiality is assured.</p>		
<p>Participant Declaration:</p> <p><i>Tick yes or no as appropriate</i></p>		
I have read or have had the information sheet read to me and that I understand the contents.	Yes	No
I have been given an opportunity to ask questions and am satisfied with answers.	Yes	No
I consent to take part in the study.	Yes	No
I understand that participation is voluntary and that I can withdraw at any time.	Yes	No
I understand that withdrawal will not affect my access to services or legal rights.	Yes	No

I consent to possible publication of results.	Yes	No
I give my permission to: Use the data obtained from you in other future studies without the need for additional consent.	Yes	No
Researcher Declaration: <i>Tick yes or no as appropriate</i>		
I have answered questions put to me by the participant about the research	Yes	No
I believe that the participant understands and is freely giving consent	Yes	No
Participant's Statement: I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand I may withdraw from the study at any time. I have received a copy of this consent form. Participant's Name: Participant Signature: Date: Witness Name: Witness signature: Date:		