

Can a National Medical Laboratory System (MedLIS) improve the surveillance laboratory notification process of notifiable infectious diseases into the Department of Public Health in Ireland and if yes, what is needed for this to be achieved?

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

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Abstract

The importance of public health surveillance and action is summed by the Director General of WHO who states “Outbreaks are inevitable, but epidemics are preventable. If epidemics happen, it’s our mistake” (Dr Ghebreyesus, 2018).

This mixed method study aims to investigate the data collection challenges and data quality issues that exist within the current laboratory notification process of notifiable infectious diseases in Ireland. This research seeks to answer whether and how a national medical laboratory information system (MedLIS) is likely to improve the laboratory notification process of notifiable infectious diseases into the Department of Public Health in Ireland.

A literature review indicated that under-reporting, timeliness of reporting and completeness of reporting are common issues in the notification process of notifiable infectious diseases internationally and therefore these three quality measures are the focus of this study.

The research describes the laboratory notification process in Ireland using a country HSE hospital and a large voluntary hospital as examples. The inherent data collection issues, data quality issues, under-reporting issues, completeness of reporting issues and timeliness reporting issues are described and solutions proposed. The potential for real-time electronic laboratory reporting (ELR) and recommendations that the MedLIS project should consider in the design of national laboratory system are also described.

The key findings indicate that MedLIS will improve the overall laboratory notification process but will have minimal positive impact to under-reporting and timeliness of reporting and a much larger positive impact to completeness of reporting.

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Abbreviations

CDC	Centre for Disease Control and Prevention
CIDR	Computerised Infectious Disease Reporting
CSF	Cerebrospinal Fluid
EHR	Electronic Health Record
ELR	Electronic Laboratory Reporting
EMR	Electronic Medical Record
EPR	Electronic Patient Record
FSAI	Food Safety Authority
GP	General Practitioner
HIPE	Hospital In-Patient Enquiry System
HL7	Health Level 7
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
ICT	Information Communication Technology
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
MedLIS	Medical Laboratory Information System
MOU	Medical Officer
MTB	Mycobacterium tuberculosis
NEHB	North Eastern Health Board
NDSS	Notifiable Disease Surveillance System
NOS	Not Otherwise Specified
NSRL	National Salmonella Reference Laboratory
NVRL	National Virology Reference Laboratory

OEF	Order Entry Forms
PAS	Patient Administration System
SNOMED	Systematized Nomenclature of Medicine
SNOMED CT	SNOMED Clinical Terms
STI	Sexually Transmitted Infection
SSAI	Surveillance Scientist Association
TB	Tuberculosis
WHO	World Health Organisation

Chapter 1 Introduction

This chapter offers an overview of the research study undertaken, the proposed research question and an overview of the study design. The research will describe the notification issues reported in the literature in Ireland and internationally to understand what needs to be solved to improve the notification process of infectious diseases into the Department of Public Health in Ireland.

To aid in the assessment of whether a National Medical Laboratory Information System (MedLIS) will improve the notification process, the following measures underpin the review of current and the future state;

- under-reporting,
- timeliness of reporting and
- completeness of reporting

These measures as recommended by the literature, are vital to achieving a sensitive surveillance system that can detect infectious disease outbreaks. The study will, therefore, aim to understand the data collection and data quality issues that exist within the current laboratory notification process; as these have a direct impact on the sensitivity of a surveillance system.

For this dissertation, the word ‘notification’ will be used interchangeably with the word ‘reporting’ and ‘Department of Public Health’ will be referred to as ‘Public Health’.

1.1 Healthcare setting

Surveillance includes the continuous collection and reporting of notifiable infectious diseases. The reporting of notifiable diseases in Ireland includes clinical reporting of cases

that meet clinical diagnosis criteria by hospital doctors and other community clinicians and laboratory reporting of cases that meet clinical and laboratory criteria by laboratories.

In Ireland, the laboratory surveillance scientists that work in hospital clinical laboratories and the National Reference Laboratory (NVRL) are tasked with the mandatory reporting of laboratory confirmed cases of notifiable infectious diseases into Ireland's national surveillance system called 'Centre for Infectious Disease Reporting' (CIDR).

The reporting of notifiable infectious diseases into Public Health by General Practitioners (GP), healthcare officers and laboratory directors is mandatory. A regulation change in 2004 to the 1981 Infectious Disease Regulation Act, added clinical laboratories as legal notifiers.

This study is limited to assess the laboratory notification process into Public Health through CIDR, for notifiable infectious diseases in Ireland.

1.2 Background

Public health surveillance for infectious diseases is a fundamental part of delivering effective public health action, disease control and epidemiological analysis at local, regional and national level (Brabazon et al., 2008). Public health surveillance is defined as

“ the ongoing and systematic collection, analysis, and interpretation of outcome specific data for use in the planning, implementation, and evaluation of public health practice” (Roush et al., 1999).

Surveillance occurs through continuous monitoring of the frequency and distribution of notifiable infectious diseases including death and is a necessary part of infection control that aims to improve public health.

The notification of suspected and confirmed cases of notifiable infectious diseases by clinicians and laboratories provide the necessary data for this analysis and assessment of public health. In Ireland, this data is collated by Public Health in each regional health board and nationally by the Health Protection Surveillance Centre (HPSC) (Brabazon et al., 2008).

National and international research has found widespread problems with under-reporting of infectious diseases at regional and country level across the world. In Ireland, there are three main Irish studies (Tara et al., 2013, Brabazon et al., 2008, BRABAZON et al., 2015) that demonstrates that under-reporting of some infectious diseases exists in Ireland.

The most recent study ascertains that under-reporting has improved ten-fold since the introduction of CIDR and the regulation change in 2004 (BRABAZON et al., 2015). CIDR accepts clinical and laboratory notifications of notifiable infectious diseases and was developed to allow for near real-time collection of surveillance data and shared access to this data for laboratories, Public Health and the HSPC (Martin et al., 2009).

1.3 Research Question and Study Aims

Can a National Medical Laboratory System (MedLIS) improve the laboratory notification process of notifiable infectious diseases into the Department of Public Health in Ireland and if yes, what is needed for this to be achieved?

Research sub-questions:

1. Is there likely under-reporting of notifiable infectious diseases into the Department of Public Health via the laboratory notification process and if so, what are the underlying reasons and how might MedLIS address these issues when it is implemented?
2. What are the data collection issues within the current laboratory notification process, and how might MedLIS address these issues?
3. What are the data completeness and data quality issues that exist in the laboratory notification process and how might MedLIS address these issues?
4. What are the timeliness issues that exist in the laboratory notification process and how might MedLIS address these issues?

This research aims to investigate the data collection issues, data quality issues, completeness of reporting issues, timeliness of reporting issues and under-reporting issues that exist within the current laboratory notification process.

This research project will aim to:

- I. Describe the current laboratory notification process for confirmed cases of notifiable infectious disease into the Department of Public Health
- II. List the CIDR dataset requirements needed to notify a confirmed case report and assess whether MedLIS will store this dataset

- III. Categorise and list the data collection issues, data quality issues, completeness of reporting issues, under-reporting issues and timeliness of reporting issues that exist in the laboratory notification process for notifiable infectious diseases in Ireland and how MedLIS might solve these issues
- IV. Describe the potential for real-time electronic laboratory reporting in Ireland.
- V. Provide overall recommendations and findings that the MedLIS project should consider in the design of the national laboratory system to help address the issues and requirements identified.

This study will focus on confirmed laboratory notification cases for viral meningitis, tuberculosis and Influenza to help bring to life the research undertaken, with relevant practical examples.

1.4 Overview of the Research

A literature review will be conducted to establish an evidence base on how electronic laboratory reporting (ELR) can support a modern surveillance system. The pathology, prevalence and diagnosis of infectious diseases will be included to establish the importance of surveillance and the difficulties inherent in case definitions and diagnosis.

A mixed method and concurrent exploratory design will be used in which quantitative data is collected first and followed by qualitative data collection. The results will be examined individually, and then merged (Ivankova et al., 2006).

An online survey will be issued to all surveillance scientists nationwide to determine if under-reporting of infectious diseases exists currently, what data collection and data quality issues exist within the current process and how might MedLIS support the notification process in the future.

Informant interviews will be carried out with senior laboratory managers and surveillance scientists working in two hospital microbiology laboratories and the NVRL in Ireland after the results of the survey are collected. The qualitative data gathered through these interviews will help validate the results and define requirements on what is needed from MedLIS to improve the notification process.

Finally, interviews with the relevant MedLIS Project Team members will supply information on whether the future MedLIS rollout can provide a solution to these issues and requirements identified.

1.5 Overview of the Dissertation

This chapter presented the motivation for the research, the research question, study aims and an overview of the research undertaken.

Chapter 2 presents the literature review. It first addresses the pathology and prevalence of Infectious diseases and the complexity of diagnosis. An overview of surveillance systems outlines the different types of systems deployed internationally and the passive system in place in Ireland. This chapter concludes with a benefits and challenges discussion of ELR and its effectiveness for notification purposes.

Chapter 3 presents the research study design and the concurrent and sequential order of primary research. The chapter considers the chosen research design and presents the various phases and data collection methods used.

Chapter 4 presents the results of the online questionnaire and informant interviews; and aligns these results to the research study aims via coded themes identified. A description

of the current notification process in the NVRL, a Dublin and country hospital are presented. Proposed MedLIS solution(s) to resolve issues identified conclude the chapter.

Chapter 5 presents the results from the survey and interviews under each of the research sub-questions. The most common issues identified, their under-lying root cause and MedLIS solution(s) is discussed further. The overall findings and recommendations for the MedLIS project are presented.

Chapter 6 concludes the dissertation and the over-arching question on whether MedLIS might improve the laboratory notification process is answered. The limitations of the study and proposals for further study are also presented.

Chapter 2 State of the Art

2.1 Introduction

A literature review is carried out to identify the current state of the art literature. Journal articles, conference materials, public health reports and government publications about notifiable infectious diseases are reviewed.

The research focused on reported issues within the laboratory surveillance process particularly under-reporting, timeliness of reporting, completeness of reporting and general data quality issues.

Based on this review, three notifiable infectious diseases were chosen to further focus the research, namely viral meningitis, tuberculosis and emerging and/or re-emerging influenza. The review will include literature and Irish grey material on these three chosen diseases about pathology, prevalence, diagnosis and HPSC case definition that must be met before reporting a confirmed case into Public Health.

Articles about the importance of public health surveillance and evaluate the effectiveness of passive versus active surveillance systems and solutions for improving the notification process are examined. Finally, the review outlines the advantages, disadvantages and barriers of ELR.

2.2 Search Strategy

Three search strategies were employed (title and abstract keyword search, long keyword search, short keyword search) due to the high volumes of literature on infectious disease surveillance.

A shortlist of the title keywords used in the literature search included *infectious diseases* OR *notifiable infectious diseases* AND *laboratory information systems* AND *Influenza* OR *meningitis* OR *tuberculosis* OR *completeness of reporting* OR *under-reporting* OR *data collection process issues* OR *process opportunities* OR *reporting issues*.

This is a summary and the full list of title keywords used for database searches can be found in Appendix A. The long and short list of keywords including interchangeable search terms can be found in Appendix B.

Publications were limited to those written in English. All journal articles were peer reviewed. A time frame of 1998 – 2018 was added to limit the research to the last 20 years.

The following database were searched; *PubMed, Science Direct, Google Scholar, World Health Organisation and Stella*.

Table 2.1 shows there was a total of 498 articles in the search results available across these databases using the keyword searches shown in Appendix A.

Table 2.1 Summary of articles identified during the literature search

Database (s)	Keywords	Total Results
PubMed		75
Science Direct		75
Google Scholar		114
World Health Organisation		141
Stella		93
Total		498

Additional relevant articles were added based on a backward search on citations and references from key journal articles to find the original work. After evaluation for

relevancy, 171 articles and publications were downloaded into EndNote Online. See Appendix C. 83 references are included in the dissertation.

2.3 Pathology of Infectious Diseases

Infectious diseases are the “second leading cause of death throughout the world according to the World Health Organisation (WHO). In 2002, more than a quarter of approximately 57 million deaths worldwide were caused by infectious diseases” (WHO, 2014).

The causes of infectious diseases are in constant flux and involve host, environment and agent forces. These forces are “genetic and biological, environmental, social, political, and economic” (Pooter, 2014). Most emerging infectious disease are caused by new, previously unrecognised, micro-organisms and most outbreaks with pandemic potential have been of zoonotic origin (Morse, 2004). Up to 75% of human emerging infectious diseases are caused by zoonotic pathogens which are infectious agents that can be transmitted between or are shared by animals and humans as is the case with the Influenza virus and Ebola virus (Pooter, 2014).

This view is shared by the Director General of the WHO at a conference in 2018, who stated “the reality is that 70% of new pathogens come from animals ...increasing demand for food and land, and the intensive farming and transport of animals, all increase the risk of diseases spreading from animals to humans” (Dr Ghebreyesus, 2018).

An emerging infectious disease is an “infection that has newly appeared in a population or has existed but is rapidly increasing in incidence or geographic range” (Morse, 2001). According to a recent WHO report, the evolution of microorganisms and their vectors ability to adapt to new ecological niches is a continuing evolutionary battle that humans

are waging, but there is no signs of victory (The European Observatory on Health Systems and Policies, 2014).

Examples can include influenza epidemics, which appear in one part of the world and traverse entire continents within day or weeks, such as the H1N1 2009 pandemic, Ebola and severe acute respiratory syndrome (SARS) (Morse, 2004).

Re-emerging infections, on the other hand, are triggered by known infectious micro-organisms that are considered under control but now are showing an upward trend in prevalence worldwide (McCloskey et al., 2014). Human behaviour is a contributor in the re-emergence of diseases due to the increasing use of antimicrobial drugs that have brought about the development of resistant pathogens (e.g. tuberculosis) leading to the disease not responding to medications that used to work to combat the disease in the past (Almeida, 2015).

Well-known, emerging and re-emerging infectious diseases are a threat to humanity since “infectious pathogens possess an amazing common capacity to emerge and spread in unpredictable ways before they are detected by health institutions” (Abat et al., 2015). The epidemiology of recognised diseases is changing and “new and emerging infectious diseases are now being reported at the rate of about 1 per year” (Sintchenko and Gallego, 2009).

Plans to address the problem should include strategies for implementing effective disease surveillance and control and a global focus to “improving the detection of, and response to, the early stages of newly emerging infection” (Morse, 2004).

2.4 Importance of Public Health Surveillance of notifiable infectious diseases

Public health surveillance for infectious diseases is a fundamental part of delivering effective public health action, disease control and epidemiological analysis at local, regional and national level (Brabazon et al., 2008).

Public health surveillance is defined as;

“ the ongoing and systematic collection, analysis, and interpretation of outcome specific data for use in the planning, implementation, and evaluation of public health practice” (Roush et al., 1999).

Surveillance has a crucial role in infection control and takes place through the monitoring of notifiable infectious disease over time and the reporting of clinical cases or disease clusters (Gorman, 2013).

Underreporting and delayed reporting hinders public health efforts to monitor and intercept the spread of infectious diseases. When infectious disease cases are not reported, estimates of disease burden or predictions of disease trends will be incorrect (Dixon et al., 2013).

A notifiable disease surveillance system (NDSS) is needed to provide an appropriate response and public health action to prevent, detect and contain infectious disease outbreaks (Benson et al., 2017, Hopkins and M'Ikanatha, 2014, The European Observatory on Health Systems and Policies, 2014).

To identify these outbreaks and prevent the transmission of infectious diseases; accurate, complete, and timely reporting of notifiable infectious diseases is critical (Nguyen et al., 2007).

Timeliness is one of the key attributes by which NDSS's should be evaluated since prompt reporting allows for early case detection of an outbreak pandemic (Birkhead et al., 1991). Timeliness is defined "by the interval between any two steps within a surveillance system" (Cho, 2009, Hyo-Soon Yoo et al., 2009).

The public health community, particularly in Europe, needs to respond to changing patterns of diseases. The preparation for, investigation of, and response to such outbreaks require the coordination of national and international organisations which starts with the detection of events through surveillance as shown in figure 2.1 below (The European Observatory on Health Systems and Policies, 2014) See figure 2.1.



Figure 2.1 Surveillance and Notification Process

The alignment of data collection methods and systems that currently exist in Europe would improve efficiency and data quality (The European Observatory on Health Systems and Policies, 2014).

2.5 Public Health Surveillance in Ireland

CIDR is Ireland's national infectious disease surveillance system that was first piloted in 2004. It was developed to allow for near real-time collection of clinical and laboratory surveillance data by providing shared access to this data for laboratories, Public Health and the HSPC (Martin et al., 2009). By 2011, it was implemented across 37 laboratories and eight regional Public Health Departments (Cullen, 2017).

CIDR also supports infectious disease reporting to Europe and the World Health Organisation (WHO) and partners with organisations such as the Food Safety Authority (FSAI). See figure 2.2 below that highlights the flow of notification data between organisations (HPSC, 2005). See figure 2.2.

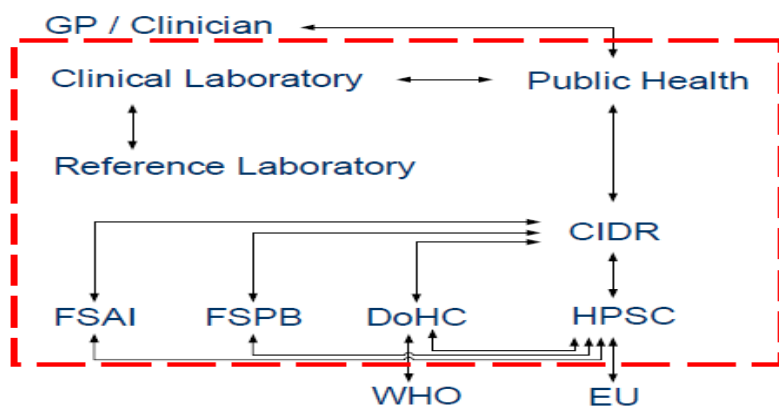


Figure 2.2 Dataflow in CIDR

CIDR accepts notifications from legal notifiers such as public laboratories, reference laboratories, GPs, public health doctors, surveillance scientists and environmental health officers.

A CIDR notification creates an event on the system which is composed of a clinical diagnosis and a laboratory test result if appropriate, for a single patient (Tara et al, 2013). These events are the source data for the majority of HPSC reports (HPSC, 2003). CIDR allows for the linking together of structured information in one single integrated repository.

A laboratory notification is based on the reporting of a causative pathogen. CIDR associates that pathogen with the correct notifiable infectious disease. See Appendix D for the full list of notifiable infectious diseases in Ireland and their corresponding causative pathogens (HSE, 2016).

Patient demographics, clinical notification and laboratory results are gathered and entered into CIDR to create an event “relating to a single episode of a disease in a single patient” as shown in figure 2.3 below (Cullen, 2004). See figure 2.3.

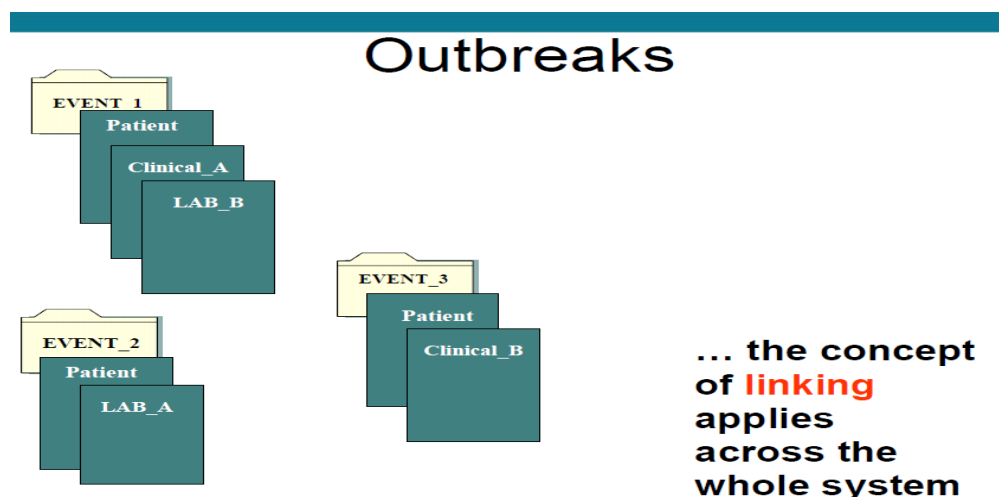
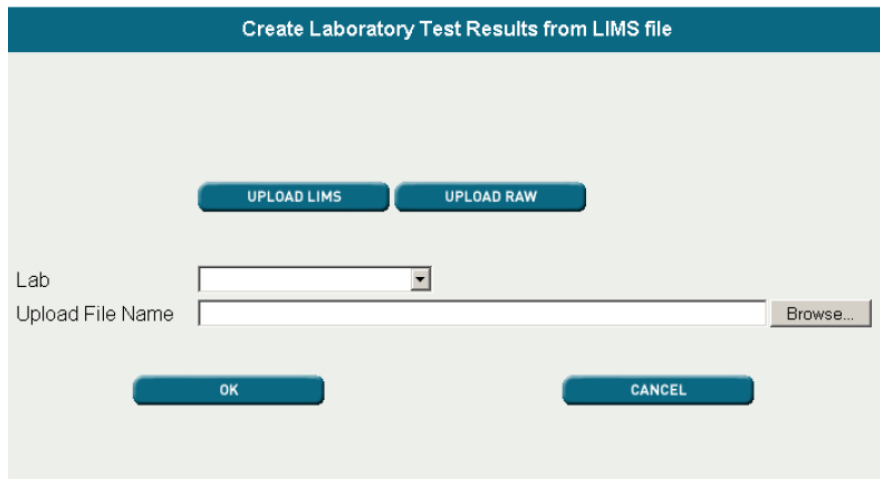


Figure 2.3 CIDR Events and Outbreaks

These single events can then be linked together across the whole system to create an outbreak and can similarly be unlinked. Users can also create an ‘outbreak’ first and then link events to it (Cullen, 2004).

Laboratory notifications may be typed manually into CIDR, or a batch file from the local laboratory information system (LIS) can be uploaded into CIDR. See Figure 2.4 of CIDR file upload screen (HPSC, 2003).



The screenshot shows a web interface for uploading LIMS files. The title bar reads "Create Laboratory Test Results from LIMS file". There are two main buttons: "UPLOAD LIMS" and "UPLOAD RAW". Below these, there is a "Lab" dropdown menu and an "Upload File Name" text input field with a "Browse..." button to its right. At the bottom, there are "OK" and "CANCEL" buttons.

Figure 2.4 CIDR File Upload

The imported data is transformed by CIDR reference tables and local laboratory codes are mapped into clinical vocabularies (SNOMED and LOINC codes) (CIDR Project Team, 2004). The adoption of clinical data dictionaries such as LOINC for lab results allows for computers and people and to understand the exact definition of data and therefore allows for meaning-based retrieval, analysis and reporting (HSE Design Authority, 2013, SNOMED International, 2018)

After successful data upload, laboratory users may review, update, deactivate, verify and, authorise the data for Public Health. Once the case is submitted, public health surveillance scientists are notified and perform another review and undertake local public health action (Brazil, 2014). At this stage, the data contains personally-identifiable health information (Brazil et al., 2003).

2.5.1 Data collection, under-reporting and data quality issues in Ireland

Data quality and completeness of data are important attributes to allow for effective public health surveillance and, Irish research suggests there is room for improvement in this area.

An Irish cross-sectional study of 416 laboratory-confirmed salmonella cases that were added to CIDR and the National Salmonella Reference Laboratory (NSRL) showed that completeness of non-mandatory fields varied significantly. For example, information on ethnicity was available for only 11% of records and the data for the onset of symptoms was missing in approximately one-third of cases (Nicolay et al., 2010).

A detailed study of 2,454 North Eastern Health Board (NEHB) patients between 1997 and 2002, showed that there were 2,758 notifiable infectious disease hospitalisations from this cohort of patients but just 2,606 cases were formally notified. This study proves that 18% of cases were not reported to the Medical Officer (MOU) (Brabazon et al., 2008).

Despite this, since CIDR was first implemented in 2004, there is a marked upward reporting trend as shown in figure 2.5 below which was bolstered by enhanced flu surveillance in 2009 and the addition of sexually transmitted infections (STIs) as notifiable diseases in 2013 (Cullen, 2017). See figure 2.5.

The Data

Trend since 2004

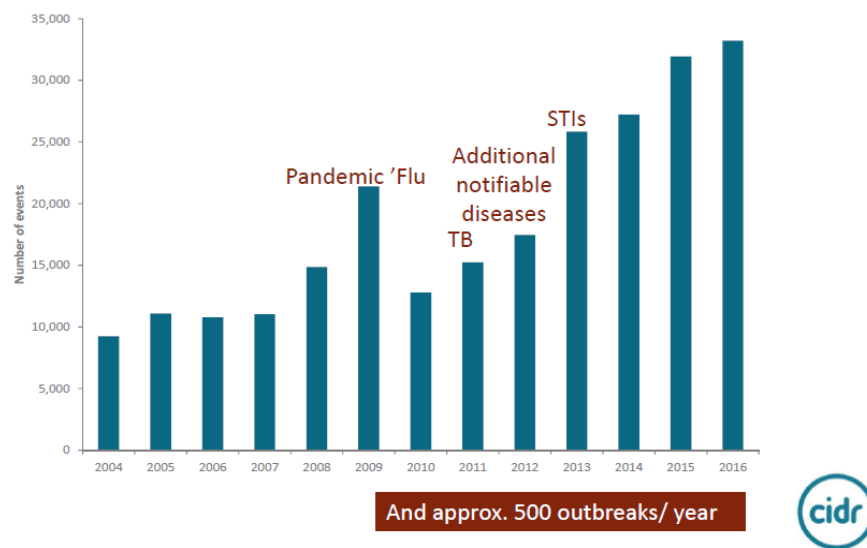


Figure 2.5 CIDR Notification Trends from 2004 to 2016

2.5.2 *Viral Meningitis Use Case*

Meningitis is a serious inflammatory disease of the brain and is characterised by meningeal inflammation, cerebrospinal fluid (CSF) pleocytosis and the absence of microorganisms on routine culture (Tapiainen et al., 2007). The brain and spinal cord are covered by layers of tissue named the meninges and certain viruses can cause an infection in these layers. This infection is called viral meningitis or otherwise known as aseptic meningitis and generally has a benign non-life-threatening course (Alan and Horn, 2014, Sanaei Dashti et al., 2017).

Viral meningitis is widely reported to result from other viruses such as enteroviruses, herpesviruses, mumps, measles, rubella, west nile virus and arboviruses (Tara et al., 2013, Alan and Horn, 2014). According to Martin, et al. (2016) enteroviruses are the leading cause of “75% of viral meningitis cases in which a pathogen is identified but in many cases of meningitis, no cause or pathogen is identified” (Martin et al., 2016).

In Ireland, the case definition of the disease as determined by the Irish Infectious Disease Regulation 2011, states that meningitis due to viruses not otherwise specified (NOS) are notifiable under the disease ‘viral meningitis’ since 2011 (HPSC, 2012).

Despite improvements in diagnostics “many cases remain without a proven viral aetiology identified” (McGill et al., 2017). Therefore, new research and lab diagnostic methods are needed to quickly and conclusively distinguish between bacterial and viral meningitis (Alkholi et al., 2011).

In Ireland’s laboratories; confirmed cases are made through detection of viral nucleic acid in cerebrospinal fluid and a clinical diagnosis which should include acute illness with meningeal symptoms and fever. The case definition criteria is shown in figure 2.6 below (HPSC, 2016). See figure 2.6.

Viral meningitis

Clinical criteria

Any person with an acute illness with meningeal symptoms AND fever

Laboratory criteria for a confirmed case

Raised cerebrospinal fluid white cell count AND one of the following three:

- Isolation of a viral pathogen from cerebrospinal fluid
- Detection of viral nucleic acid in cerebrospinal fluid
- Serological evidence of infection with a virus known to cause viral meningitis

Laboratory criteria for a probable case

Raised cerebrospinal fluid white cell count AND isolation of a viral pathogen known to cause viral meningitis from a site other than cerebrospinal fluid

Epidemiological criteria

NA

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and the laboratory criteria for a probable case but with no evidence of bacterial, fungal or parasitic meningitis

C. Confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation

Note:

Notification of viral meningitis due to a listed pathogen should be notified under the relevant disease

Figure 2.6 Viral Meningitis HPSC Case Definition

Under the 2003 case definitions; laboratory evidence and a clinical diagnosis are necessary for reporting confirmed cases. When meningitis is suspected, the infection is diagnosed by detecting IgM in serum, Cerebrospinal Fluid (CSF), or both (Tara et al., 2013).

A detailed study of Hospital In-Patient Enquiry System (HIPE) data from 265 patients that were hospitalised between 1997 and 2001 in the North Eastern Health Board (NEHB) region with a diagnosis of viral meningitis; showed there were just 38 statutory notifications (Brabazon et al., 2004).

In a later Irish study between 2005-2008 analysing hospital HIPE data, NVRL data and reported cases from the CIDR system; Tara et al (2013) concluded that there was “a 3-fold higher viral meningitis hospitalisation rate compared to the reporting rates into Public Health (Tara et al., 2013).

In the third study from 2006 to 2011 looking at all notifiable infectious diseases, there were four diseases where substantial under-reporting was evident with viral meningitis recording 1,712 hospitalised cases compared to 820 notifications which lend to potential under-reporting of 52.7% (Brabazon et al., 2015). This is despite the introduction of CIDR in 2004.

2.5.3 Tuberculosis Use Case

Mycobacterium tuberculosis (MTB) is a common and successful human pathogen (Olsen et al., 2012). Tuberculosis (TB) is caused by the pathogen or germ called ‘*Mycobacterium tuberculosis*’ that is spread from person to person through the air by coughing and sneezing and therefore most frequently affects the lungs through inhalation (Department of Public Health, 2018, WHO, 2018).

TB has been around for a millennia and is the “ninth leading cause of death worldwide ... ranking above HIV/AIDS” (WHO, 2017). It is therefore not a new infectious disease but a well-established one and one of the commonest affective diseases worldwide.

People who also have HIV are 20 to 30 times more likely to develop active TB, and in 2016, 40% of HIV deaths were due to TB which is a lethal combination (WHO, 2018). In Ireland, there were 318 notified cases out of a population of 4.7 million in 2016 of which 40% had HIV status (WHO, 2016).

This compares to 328 notified cases in 2014 and shows there remains a steady decrease in incidence levels since records began in 1952 (Department of Public Health, 2018). This is despite widespread drug resistance to TB antimicrobial treatments and increasing number of patients with both TB and HIV (National TB Advisory Committee, 2014, WHO, 2016).

The laboratory criteria for a confirmed case of TB according to Irish guidelines must include either

“isolation of *Mycobacterium tuberculosis* complex ... from a clinical specimen or detection of *Mycobacterium tuberculosis* nucleic acid in a clinical specimen and positive microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy ” as shown in figure 2.7 below (HPSC, 2016).

See figure 2.7.

Tuberculosis

(*Mycobacterium tuberculosis* complex)

Clinical criteria

Any person with the following two:

- Signs, symptoms and/or radiological findings consistent with active tuberculosis in any site
AND
- A clinician's decision to treat the person with a full course of anti-tuberculosis therapy

OR

A case discovered post-mortem with pathological findings consistent with active tuberculosis that would have indicated anti-tuberculosis antibiotic treatment had the patient been diagnosed before dying

Laboratory criteria

- Laboratory criteria for a confirmed case
At least one of the following two:
 - Isolation of *Mycobacterium tuberculosis* complex (excluding *Mycobacterium bovis*-BCG) from a clinical specimen
 - Detection of *Mycobacterium tuberculosis* complex nucleic acid in a clinical specimen AND positive microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy
- Laboratory criteria for a probable case
At least one of the following three:
 - Microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy
 - Detection of *Mycobacterium tuberculosis* complex nucleic acid in a clinical specimen
 - Histological appearance of granulomata

Epidemiological criteria

NA

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and the laboratory criteria for a probable case

C. Confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation

Figure 2.7 Tuberculosis HPSC Case Definition

This case definition shows that a confirmed case of TB requires a clinical and laboratory diagnosis.

In a detailed study by Brabazon et al. (2015) using a method of comparing HIPE data between 2006 to 2011 to national notification data entered into CIDR and the Tuberculosis Surveillance System; showed that there was potential under-reporting of tuberculosis of just 1.8% overall compared to 18% between 1997 and 2002 (Brabazon et al., 2015).

2.5.4 Emerging and/or re-emerging Influenza

The Health Service Executive (HSE) in Ireland defines Influenza as “an acute contagious respiratory illness caused by infection with an influenza virus” (HPSC, 2018). Influenza infections cause substantial morbidity and mortality every year (WHO, 2014). The H1N1 influenza pandemic in 2009 caused more than 280,000 deaths worldwide and placed an unprecedented demand on public health authorities (Barker and Snape, 2014).

In an Irish study by Cullen et al. (2009) that reviewed hospitalised cases; showed that being on medication for asthma was the most common risk factor for hospitalisation due to pandemic H1N1 influenza (Cullen et al., 2009).

The 2018 winter flu season in Ireland included a most unusual occurrence of two flu strain virus circulating which included the A(N3N2), or “ Aussie flu” and influenza B/Yamagata, or “Japanese flu” (Unknown reporter, 2018).

The Japanese flu was not included in the latest vaccine and impacted older adults and children alike which led to a reported 23,000 people being infected by the flu and is the fifth worst season since records began in 2000 (Unknown reporter, 2018).

To respond to diseases such as Influenza, “it is necessary to understand the interactions between microbial pathogens and their hosts and the impact of environmental and social factors on these interactions” (Fauci, 2006). Influenza is a recurring matrix disease that can re-emerge in a marginally different form (antigenic drift). It can also present as a newly emerging disease that is different from what has previously been experienced (Fauci, 2006).

Bacterial genomics research will seek to understand the molecular basis of human disease caused by bacterial and host-pathogen interactions which can lead to the development of new clinical tests, vaccines and therapies (Olsen et al., 2012).

In Ireland, the case definition for a confirmed laboratory case of Influenza A and B virus, is any person that meets suspected clinical criteria (must include a sudden onset of influenza-like illness and at least one out of four systematic symptoms and at least one out of three respiratory symptoms) and meets laboratory criteria as shown in the figure 2.8 below (HPSC, 2016). See figure 2.8.

Influenza
(Influenza A and B virus)

Clinical criteria
Any person with the following clinical syndrome:

Influenza-like illness (ILI)

- Sudden onset of symptoms

AND

- at least one of the following four systemic symptoms:
 - Fever or feverishness
 - Malaise
 - Headache
 - Myalgia

AND

- at least one of the following three respiratory symptoms:
 - Cough
 - Sore throat
 - Shortness of breath

Laboratory criteria
At least one the following four:

- Isolation of influenza virus from a clinical specimen
- Detection of influenza virus nucleic acid in a clinical specimen
- Identification of influenza virus antigen by DFA test in a clinical specimen
- Influenza specific antibody response (four fold or greater rise)

Subtyping of the influenza isolate should be performed, if possible

Epidemiological criteria
An epidemiological link by human to human transmission

Case classification

A. Possible case
Any person meeting the clinical criteria (ILI)

B. Probable case
Any person meeting the clinical criteria (ILI) and with an epidemiological link

C. Confirmed case
Any person meeting the clinical (ILI) and the laboratory criteria

Figure 2.8 Influenza HPSC Case Definition

This illustrates that a confirmed case cannot be made by a laboratory test alone as it also requires a clinical diagnosis.

The literature review could find no published material on influenza under-reporting issues in Ireland. There is, however, one European study that performed a detailed review during 2007-2014 of national surveillance data on the pathogen haemophilus influenza from 12 European countries which included Ireland. This study suggested the reporting incidence rates from these countries are below incidence levels owing to the passive surveillance systems operating in most of the EU reporting countries (Whittaker et al., 2017).

A comparison was made to the haemophilis influenza disease in the US which uses a different surveillance method and notifications were more than two times higher than the 12 European countries analysed (Whittaker et al., 2017).

2.6 Surveillance Systems

A surveillance system by definition “includes the functional capacity for data collection and analysis as well as the timely dissemination of these data to persons who can undertake effective prevention and control activities” (Roush et al., 1999).

Traditional health surveillance systems typically collate suspected and confirmed cases from sentinel and clinical laboratories and clinicians. One example of a sentinel laboratory or specialist laboratory for a particular disease(s) is the National Tuberculosis Surveillance System in the United States (Abat et al., 2015).

Some traditional surveillance systems rely on more manual methods of communications depending on clinical observations. Others surveillance systems do use some level of automation such as electronic laboratory test results and/or a combination of electronic laboratory and clinical observations data that is added into a national central surveillance application. Others use computer-based searches of patient medical records, and others use mathematical modelling and prediction (Gorman, 2013).

In the US, the Centre for Disease Control and Prevention (CDC) since 2002 has promoted an electronic surveillance system for the collection of notifiable disease reports based on electronic laboratory reporting (ELR). ELR is the “automated reporting of notifiable disease data via a secure, electronic connection by laboratories to ... health departments” (Hota et al., 2008).

ELR can improve the notification process into public health agencies by “automating case detection using electronic data, followed by electronic data transfer” to the relevant agency (Hota et al., 2008). According to the U.S CDC, “health departments do receive 67% of their total laboratory-based reports for notifiable diseases as electronic laboratory reports” (Dixon et al., 2017).

In the United States, ELR has become more widespread with 54 out of 57 jurisdictions receiving electronic laboratory reports as opposed to paper reports from clinical laboratories. This has resulted in surveillance officials “receiving reports more quickly, completely and accurately” although “participation of clinical laboratories in ELR, however, remains suboptimal” (Hopkins and M'ikanatha, 2014).

2.6.1 Advantages of Electronic Laboratory Reporting

The use of ICT to automate surveillance processes may “reduce paperwork; improve timeliness, completeness, and accuracy of notifiable disease reporting; and improve health care quality” (Hota et al., 2008).

Clinicians working within infection control departments and public health organisations recognise that electronic laboratory and clinical data can improve the reporting of notifiable infectious diseases to public health departments and “automated methods of infection detection improve the sensitivity of event detection” (Trick, 2008).

In a detailed study of traditional spontaneous reporting versus ELR reporting through a US health information exchange in the US; found that ELR identified 4.4 times as many cases as traditional paper-based methods and concludes that ELR improves the completeness and timeliness of disease surveillance (Overhage et al., 2008).

Dixon et al. (2013) in a recent study compared timeliness, completeness of data and reporting rates of 13,269 case reports across seven infectious diseases from the Indiana Health Information Exchange in the US that delivers laboratory results and other clinical messages to health departments. Timeliness was measured “as the difference between the date of the laboratory confirmed diagnosis and the date the report was received by the health department” (Dixon et al., 2013).

The results showed that the “laboratory reports, whether faxed or electronically sent, were received, on average 2.2 days after diagnosis versus a week for provider reports”. However, the provider reports scored much higher on the completeness of data with “all but three of 15 data fields in provider reports were more complete than those fields within laboratory reports”. Reporting rates were different per disease, but on average, the providers reported cases 19.1% of the time compared to 84.4% for laboratory reporting (Dixon et al., 2013).

ELR can result in increased timeliness, sensitivity and positive predictive value meaning there are low occurrences of incorrect, false positive results and a reduction in manual data entry errors leading to more accurate reports (Hopkins and M'Ikanatha, 2014).

2.6.2 Disadvantages of Electronic Laboratory Reporting (ELR)

While there are undoubted benefits to ELR, disadvantages and barriers have also been reported.

In a research and practice study on ELR in New York, Nguyen, et al. (2007) concluded that introducing electronic reporting into surveillance databases has its own limitations and brought new data quality errors, shifted work demands to include informatics staff skilled in data monitoring and quality assurance and could not automate reporting for certain complex diseases such as TB that require more complex clinical assessments by staff (Nguyen et al., 2007).

Nguyen concludes that raw laboratory data is not always fit for automatic uploading into surveillance databases. This can be compounded further by the introduction of a new disease and limited staff resources available to perform manual data entry and coding (Nguyen et al., 2007).

A more recent US study from Revere et al. (2017) concludes that “complete reliance on automatic electronic extraction of data requires caution and necessitates continued interfacing with clinic reporters for the foreseeable future – particularly for notifiable conditions that are high-impact, uncommon, prone to false positive readings by labs, or are hard to verify” (Revere et al., 2017).

Some international studies as reported by Wurtz and Cameron (2005) suggest that active ELR methods can result in fewer completed fields as many laboratory information systems (LIS) do not include detailed patient demographic information which is available elsewhere; however another study suggests that ELR increases the hit rate on data field completion (Wurtz and Cameron, 2005).

Transfer of electronic messages with clinical data can also introduce challenges as typically reportable data needs to be mapped to clinical vocabularies such as LOINC and SNOMED codes that are accepted by the health authorities. The receipt of non-coded data

is one of the primary reasons cited by surveillance facilities for delays in processing ELR cases (Hopkins and M'Ikanatha, 2014).

Dixon et al (2014) carried out an operational study to examine the use of LOINC and SNOMED in two health information exchanges in two US states between 2010 and 2011. The study found that very few (less than 17% in both exchanges) contained these standardised codes which led to the health departments employing staff to transform the incoming data into standardised concepts that could be used effectively by the surveillance systems (Dixon et al., 2014).

Each hospital may have their own way of describing pathology tests and results contained within their test catalogue and translating or mapping these local codes to LOINC and SNOMED is challenging and costly (Dixon et al., 2014).

2.7 Potential Solutions (Data Warehouse, EHR, Standardisation)

2.7.1 EHR and Data Warehouse

There is an increasing need to “semantically process and integrate clinical data from different sources for clinical research” including epidemiological research (Sun et al., 2015).

Laboratory information is fundamental to evidence-based healthcare and medical decision analysis (Kudler and Pantanowitz, 2010). The ability to mine data for public health surveillance of a specific disease within a specific population cohort and deliver quality reporting requires an advanced information “system that is accessible and flexible, yet secure and in compliance with regulatory requirements” (Kudler and Pantanowitz, 2010).

Since most laboratories do not include all relevant data in the reporting of an infectious disease; a data warehouse could enable the transfer of information to other systems including an electronic health record (EHR) or even directly to the national surveillance system (Trick, 2008).

EHRs are defined as “longitudinal electronic (digital format) record of patient health information generated by patient encounters in a healthcare delivery system” and typically include laboratory data that comes from the LIS, point of care testing and external reference laboratories (Kratz, 2015). Results are sent from laboratory analyser systems that process the test, then to the LIS and from the LIS to the EHR using HL7 (Health Level 7) messaging as shown in figure 2.9 (Kratz, 2015) See figure 2.9.

Messaging exchange is typically done in Ireland and internationally using HL7v2 standard that is developed by the Health Level Seven (HL7) organisation. “Messaging standards outline the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of information. The term ‘message’ refers to a unit of information that is sent from one system to another” (Health Information and Quality Authority, 2013).

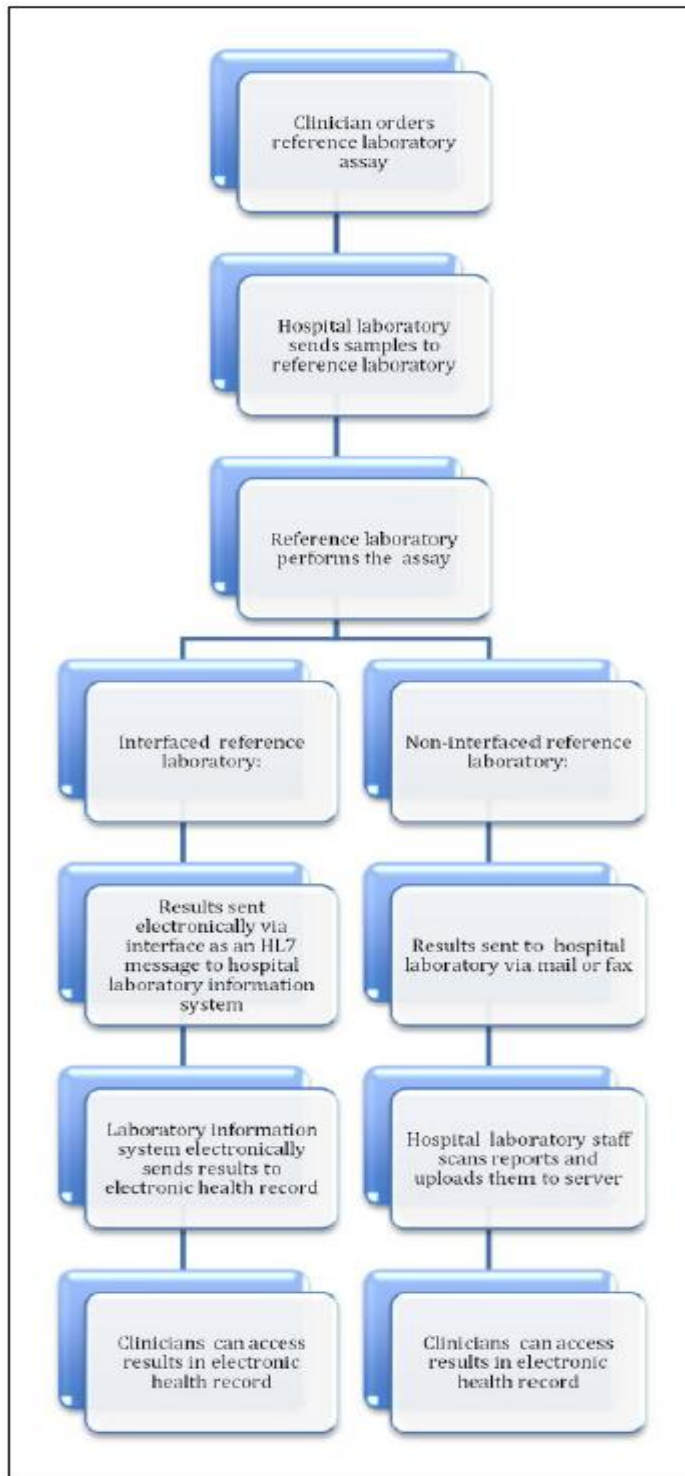


Figure 2.9 Example workflow for interfaced LIS with EHR

An interface to the external reference laboratory will remove the need to manually transcribe the result into the LIS when the test is performed externally as this can introduce the risk of transcription errors and missing relevant clinical data (Kratz, 2015).

Laboratory information can then be incorporated into the EHR for all authorised clinicians to access and display data as customised tables or graphs and access this data remotely (Kratz, 2015). Also, analytical tools can use this electronic data to detect clusters of organisms rather than depending on perceptive and sharp surveillance staff to spot an increased trend of infection (Trick, 2008).

With laboratory data included in the EMR; there is the opportunity to benefit from decision support tools (e.g. lab related e-alerts) (Kudler and Pantanowitz, 2010). Alerts that can provide information on the case count of episodes in a geographic area is shown to positively support the diagnosis process (Bellika et al., 2007).

“Epidemiological analysis of the ... results are essential to improving patient care and enhancing our understanding of disease-related processes” (Jones et al., 2014). Data warehouses will become more and more beneficial as healthcare organisations increase their use of electronic patient records (EPRs) and vendors allow non-proprietary analytical tools to interrogate data and facilitate standardised terminology mapping such as SNOMED CT (Trick, 2008).

2.7.2 Potential of standardised coding to improve sensitivity

“Standardisation is the reduction of variation in a process with the intent of improving compatibility, interoperability, repeatability, safety and other elements of quality” (Legg, 2014).

To harmonise and integrate EHR data or an electronic laboratory record from source systems, interoperability standards are needed to exchange data and provide a common syntax and representation of clinical data (Marco-Ruiz et al., 2015). Interoperability is defined as “the ability of two or more systems or components to exchange information

and to use the information that has been exchanged”(Health Information and Quality Authority, 2013).

A clinical vocabulary or terminology such as SNOMED Clinical Terms (SNOMED CT) or Logical Observation Identifiers Names and Codes (LOINC) allows the correct and exact meaning of laboratory tests and their results that can be understood universally and is essential for semantic interoperability of information (Health Information and Quality Authority, 2013).

Use of a standard vocabulary would allow for laboratories to be integrated into national and global surveillance programmes and therefore enhance further rapid alerts to infectious disease outbreaks (Cantón, 2005). It would make ELR less problematic and increase the feasibility of a health information exchange network (Overhage et al., 2008).

With standardised vocabulary coding, a modern LIS with a central database, health messaging standards such as HL7 and leveraging archetype based EHR standards and their query language; can be used to interrogate a shared database or data warehouse (Marco-Ruiz et al., 2015). The mined data can then be used to transform and aggregate population level statistics.

Semantic interoperability is central to healthcare interoperability and would allow for the EHR or other systems to be able to recognise the structure, format, units and meaning of the results sent by the LIS. To achieve this, both systems must use a common terminology or language to communicate (Health Information and Quality Authority, 2013).

2.8 Conclusion

The literature review has demonstrated the importance of an effective national surveillance system that is sensitive enough to detect infectious disease outbreaks. Early detection of outbreaks is dependent on effective, timely, accurate and full reporting of infectious diseases. The issues with passive surveillance systems such as that in Ireland that have various levels of automation and manual data entry into a surveillance system were described.

The issues reported included under-reporting due to not understanding the mandatory reporting requirements and having the right access to laboratory data. Data completeness issues such as missing clinical data from the requestor of the test, missing patient demographic data such as ethnicity were also described. Data quality issues such as manual transcription errors from external laboratories into the hospital LIS and various interoperability issues resulting from the use of local laboratory codes for orders and results were also described.

The surveillance notification issues for three infectious diseases (viral meningitis, tuberculosis and influenza) were researched and under-reporting for viral meningitis was evidenced and reported in three Irish studies.

The importance of laboratory standards was highlighted to improve interoperability, repeatability, safety and other quality measures. Standards together with an EHR and a central LIS database or a vendor-neutral data warehouse will allow for greater decision support tools, data access and mining of data to produce good quality health information reporting.

Chapter 3 Research Design / Methodology

3.1 Introduction

The question this research addresses is whether and how MedLIS can improve the laboratory notification process of notifiable infectious diseases into Public Health in Ireland.

MedLIS is due to go live with its first hospital in 2019. This research is a forward-looking analysis of the potential for MedLIS to improve the process based on (1) understanding the data quality and data collection issues in the current process, (2) the requirements from the laboratory managers and surveillance scientists that work with CIDR, (3) expert opinions from the MedLIS project team on if and how MedLIS can improve the notification process.

To answer whether and how MedLIS can improve upon the notification process; a mixed methods concurrent and sequential explanatory research design is applied. This includes a combination of quantitative and qualitative research using (1) closed statistical type questions in an online survey to all surveillance scientists nationwide, (2) open-ended questions in the same survey, (3) in-depth interviews with laboratory informants to validate and corroborate the findings of the questionnaire and define requirements and, (4) in-depth interviews with MedLIS project staff to define solutions.

This triangulation or mixed method approach provides rigour to the research given that the quantitative data collection outputs will be explored and validated by laboratory informants. The laboratory informants will include surveillance scientists, lab managers and medical scientists working in microbiology laboratories that have knowledge on

inherent issues and what is required from MedLIS to improve the laboratory notification process.

This chapter will discuss the research methodology approach and design, data collection and analysis techniques, sampling procedures, and ethical considerations. The research design will result in answers as to whether and how MedLIS will improve the current notification process against the assessment criterion of timeliness of reporting, completeness of reporting and full reporting meaning all confirmed cases are notified.

3.2 The Research Approach

Methodological triangulation is a comprehensive approach in the use of two or more methods to address the same research question and these methods can be done simultaneously or sequentially (Morse, 1991, Adami, 2005).

The traditional concept of triangulation as described by the founders of this method; was the need to measure a single problem in several ways to establish the degree to which different measures converged and so the higher degree of convergence the higher the degree of confidence in the findings. Later Denzin and Lincoln (1994) state that the use of multiple methods in a single study is an alternative to validation as it “adds rigour, breadth and depth to any investigation” (Adami, 2005) .

In this study, most of the semi-structured questions are the same for all laboratory informants, and this will add rigour by understanding the issues and root-causes from different people’s perspectives and roles. This use of (person) triangulation should result in a complete picture than if only one method from one person source is used (Adami, 2005, Zauszniewski, 2012).

Also, the quantitative data collection from the online survey was executed first and its findings discussed and validated by the qualitative in-depth interviews from the surveillance scientists. Finally, the MedLIS participants were interviewed last, and all the data from the survey and interviews were summarised and presented to them to support analysis on what MedLIS can deliver on to improve the notification process.

This approach is known as ‘sequential explanatory research design’ whereby finding from the first study approach will inform the second study and add depth to the overall study (Venkatesh et al., 2013).

3.3 Research Design

According to Attig and Winichasagoon (1998, p.85) a research design is “the logical and systematic planning and directing of a piece of research” (Rice and Ezzy, 1999) and according to Creswell & Plano Clarke (2017) is a procedure or method for “collecting, analysing, interpreting, and reporting data in research studies” (Creswell and Plano Clark, 2017).

This section will therefore outline (1) the theoretical framework that underpins the entire study, (2) the chosen research design, (3) the research method used for gathering, collecting and analysing data, (4) the study population and sampling method used and finally (5) the data collection and analytical techniques deployed.

3.3.1 Theoretical Theory

This study uses ‘grounded theory’. Grounded theory “develops an over-riding story or set of themes as grounded and “real” in any group of data” (Tracy, 2013) or in other words these themes or concepts are “inductively discovered, developed, and provisionally

verified through systematic data collection analysis of data” throughout the course of the research and not based on any existing theories or variables.

3.3.2 Research Design

This study, for the most part, followed the mixed method ‘explanatory sequential design’ in which the quantitative survey for surveillance scientists was completed first and the qualitative interviews with the surveillance scientists followed, to help understand and explain the quantitative results in more depth.

However, there is also elements of a ‘convergent design’ in which quantitative and qualitative research took place at the same time due to time constraints, with one microbiology chief medical scientist interview taking place at the same time as collection of survey results. The results and findings from the two research strands will be compared and converged in the results chapter.

The survey is a variant questionnaire in that it contains both quantitative and qualitative questions (Creswell and Plano Clark, 2017).

This study will use the constructivist and pragmatist worldviews. A constructivist inquiry is typically associated with qualitative approaches, whereby, the meaning of the phenomena is formed through participant’s subjective views moulded by social interaction with others and from their life experiences. Constructivist inquiry research is formed “from the bottom up” from individual viewpoints to broad patterns and, eventually to broad understandings (Creswell and Plano Clark, 2017). A pragmatist worldview inquiry will be employed since it is problem centred and is based on a real-life scenario as shown in figure 3.1 below (Creswell and Plano Clark, 2017). See figure 3.1.

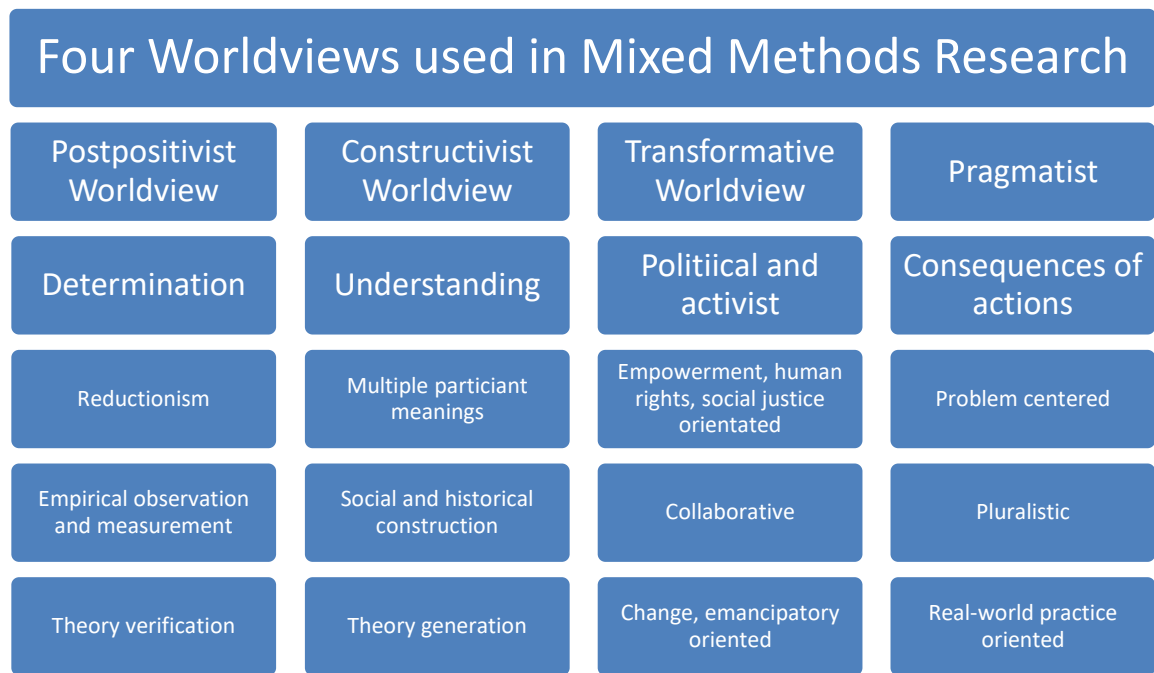


Figure 3.1 Worldview Examples of Mixed Method Research

In conclusion, exploratory sequential and concurrent design was chosen because it suits the problem statement in trying to understand both quantitatively and qualitatively what are the issues, their root-cause and potential solutions.

3.3.3 Research Methods

This study will include quantitative and qualitative research methods which will allow for a complete picture of understanding what issues exist in the current notification process and if and how these can be solved with the implementation of MedLIS.

Quantitative analysis aims to find out and count the ‘connections’ or ‘incidences’ that are more than just perceptions through the use of statistics and probability and a big enough sample size to allow for patterns of concurrences to surface and which can be confidently seen as a true and a valid representation of worldly phenomena (Venkatesh et al., 2013).

In this study, the aim of quantitative study using a survey is to determine ‘what’ data quality and under-reporting issues exist in the current notification process, ‘what’ are the

common issues that need to be solved and ‘what’ are the underlying root causes of these issues that exist nationwide.

These questions are relevant to surveillance scientists nationwide and should give a true and valid representation of what issues exist. This will provide a greater understanding of the research problem and therefore what challenges exist for MedLIS to overcome.

Qualitative research, on the other hand, is generally concerned with the ‘why’ and draws on deeper motivations and an interpretative orientation in getting under the surface (Rice and Ezzy, 1999, Venkatesh et al., 2013). This study summarises the viewpoints of the participants in a tabular format in the results chapter before creating meta-inferences.

The quantitative and qualitative results are presented separately in the results chapter (chapter 4) and second-order interpretations, i.e. the researcher’s explanations of the participants’ explanations are merged with the quantitative findings in the discussion chapter (chapter 5) (Tracy, 2013).

The participants were offered the opportunity to review and refine their feedback to ensure objectivity and subjectivity.

3.3.4 Study Population and Sampling

Sampling procedures for qualitative research are generally purposeful in nature and involve “identifying and selecting individuals or groups of individuals that are especially knowledgeable about or experienced with a phenomenon of interest” (Creswell and Plano Cark, 2011).

This study will utilise ‘criterion sampling’ as a purposeful sampling strategy which means the participants selected are drawn from hospitals that work within the current notification

process environment and are already involved in the implementation of MedLIS and therefore they possess knowledge and experience of the research phenomena.

3.3.5 Data Collection

The data collection process includes “sampling, gaining permissions, collecting data, recording the data, and administering the data collection” (Creswell and Plano Clark, 2011).

3.3.5.1 Quantitative and Qualitative Online Survey

An online survey, using Trinity College’s recommended tool “Quantrix”, was chosen as the primary method of data collection due to the population size of approximately 70 surveillance scientists nationwide. Each hospital is known to have its own unique environment (e.g. infrastructure, notification process, access rights, and LIS technologies) and therefore qualitative interview methods alone with a small population size would not provide a good overview of the notification process and inherent issues that exist nationwide.

A survey is “a method of collecting relevant descriptive data from a number of individuals, groups or representatives of groups in order to answer a research problem or question” (Neale, 2009). In this case, a variant online survey with fixed options for answers as well as open-ended questions are included; the survey can be found in Appendix E. The survey is ‘cross-sectional’ in design as the survey was sent to all 70 surveillance scientists nationwide by the secretary of Surveillance Scientist Association (SSAI) after consent was provided by the SSAI committee. Survey participants were asked to confirm consent at the beginning of survey and were sent a consent form via email.

One benefit of a survey is the anonymity of participants which should help to promote honest responses, and research bias is generally low. Data can be analysed quickly and precisely particularly with the closed end-questions and fixed response (Neale, 2009).

3.3.5.2 Qualitative Interviews

The information sheet and consent forms were exchanged, and approval was given before proceeding with data collection. Consent for ‘own views and insights’ was requested and approved in advance for all hospital laboratory staff interviews. Employer consent and individual interviewee consent was requested and approved for NVRL and MedLIS staff interviews.

The information sheet and for the hospital laboratory staff and an example consent form can be found in Appendix K. The information sheet and consent for the NVRL lab manager can be found in Appendix L. The information sheet and example consent for the MedLIS project staff can be found in Appendix M.

Chief Medical Scientist, Senior Medical Scientist and NVRL Lab Manager

Interviews

The end to end infectious disease notification process involves not just the surveillance scientists that work in the clinical laboratories, but also laboratory staff that process the tests and medical scientists that manage the operations of the department.

The Chief Medical Scientist is the most senior position in the laboratory and would have accountability for reporting of notifiable infectious diseases into Public Health. The NVRL laboratory manager will also be interviewed as the NVRL is Ireland’s reference laboratory and processes most of the infectious disease tests on behalf of other clinical laboratories and is a laboratory notifier.

The semi-structured interview questions were sent in advance via email for all interviews.

Laboratory Surveillance Scientists Informant Interviews

It was not deemed possible to interview each surveillance scientist in all the public hospitals and consequently surveillance scientists working in one large voluntary Dublin hospital, and an HSE country hospital was chosen. These informants were targeted as both hospitals are included in the MedLIS Phase 1 rollout and staff would be familiar with MedLIS and knowledgeable on what is needed from MedLIS to improve the laboratory notification process.

These laboratory informant interviews took place after the results of the online survey were collected which helped structure the questions. The semi-structured questions were sent in advance.

MedLIS Project Staff Interviews

MedLIS project staff interviews aim to understand if and how the MedLIS application can deliver solution(s) to the process issues identified from previous primary research.

Qualitative interviews took place with MedLIS project staff, namely:

- 1) Microbiology Workstream Lead
- 2) Order Communications Workstream Lead
- 3) Quality and Surveillance Workstream Lead

These interviews took place last, after the data collection of the online survey and laboratory informant interviews were complete. The questions included extracts from the results of the survey and former interviews and were sent in advance of the interview.

3.3.5.3 Recording and Administering of Data

For all interviews, notes were taken and then summarised and sent via email to the participants for review. Participants were informed the notes would be included in the appendix and were given the opportunity to edit the submission.

3.3.5.4 Analytical Analysis

The quantitative and qualitative data were analysed separately, and then meta-inferences merged in the results chapter (chapter 4). Microsoft excel was used to create the statistical analysis with the output from the survey. The development of themes and coding was applied on the output from the qualitative interviews, which can be found in the results chapter.

3.4 Ethical Consideration and Recruitment Method

Trinity College Dublin research ethics approval for this study was granted on April 20th, 2018 in the first instance. See Appendix F. Overall ethical project approval for the project was sought from the MedLIS Project Manager and Clinical Director since the subject matter of the thesis is on MedLIS and includes qualitative interviews with MedLIS project staff. See MedLIS ethics approval in Appendix G.

Employer consent was requested from the SSAI for approval to distribute the survey to the 70 surveillance scientists nationwide. The SSAI consent can be found in Appendix H. Employer consent was also requested in advance from the NVRL for the interview with the lab manager which can be found in Appendix I.

There was no employer consent requested for interview of the hospital medical scientists and surveillance scientists since there would be two hospital ethics processes involved and this was not deemed feasible within the time limitation of this study. The decision

was made to seek participants 'own views' instead. No patient data was discussed or exchanged as part of this study, and consequently hospital ethics approval was deemed not necessary.

The recruitment methods were the same for all interviewees; a work colleague reached out to a known contact via email, asked for their support in my thesis research and asked permission to share their contact details with me.

3.5 Conclusion

This research design / methodology chapter covered all the elements involved in the planning of the research study and included the approach to the research, methodology, population and sampling, data collection and analysis and ethical considerations. The results and analysis are outlined in the next chapter (Chapter 4).

Chapter 4 Results

4.1 Introduction

This chapter will present the results of the research under each of the study's aims as described below.

- I. Describe the current laboratory notification process for confirmed cases of notifiable infectious disease into the Department of Public Health
- II. List the CIDR dataset requirements needed to notify a confirmed case report and assess whether MedLIS will store this dataset
- III. Categorise and list the data collection issues, data quality issues, completeness of reporting issues, under-reporting issues and timeliness of reporting issues that exist in the laboratory notification process for notifiable infectious diseases in Ireland and how MedLIS might solve these issues
- IV. Describe the potential for real-time electronic laboratory reporting in Ireland.

4.2 Laboratory Notification Process

Understanding the laboratory notification process from the perspectives of a country hospital laboratory, Dublin hospital laboratory and the NVRL will help to identify process weaknesses that could benefit from the implementation of MedLIS.

4.2.1 Country Hospital Notification Process

The laboratory notification process outlined below was obtained during three qualitative interviews with the Laboratory Surveillance Scientist, Chief Medical Scientist, and Senior Medical Scientist working in the microbiology department of a country HSE hospital. The interview notes can be found in Appendix N, O and P respectively. Figure 4.1

describes the current high-level workflow of the reporting process, from receipt of papers orders to notification into CIDR. See figure 4.1

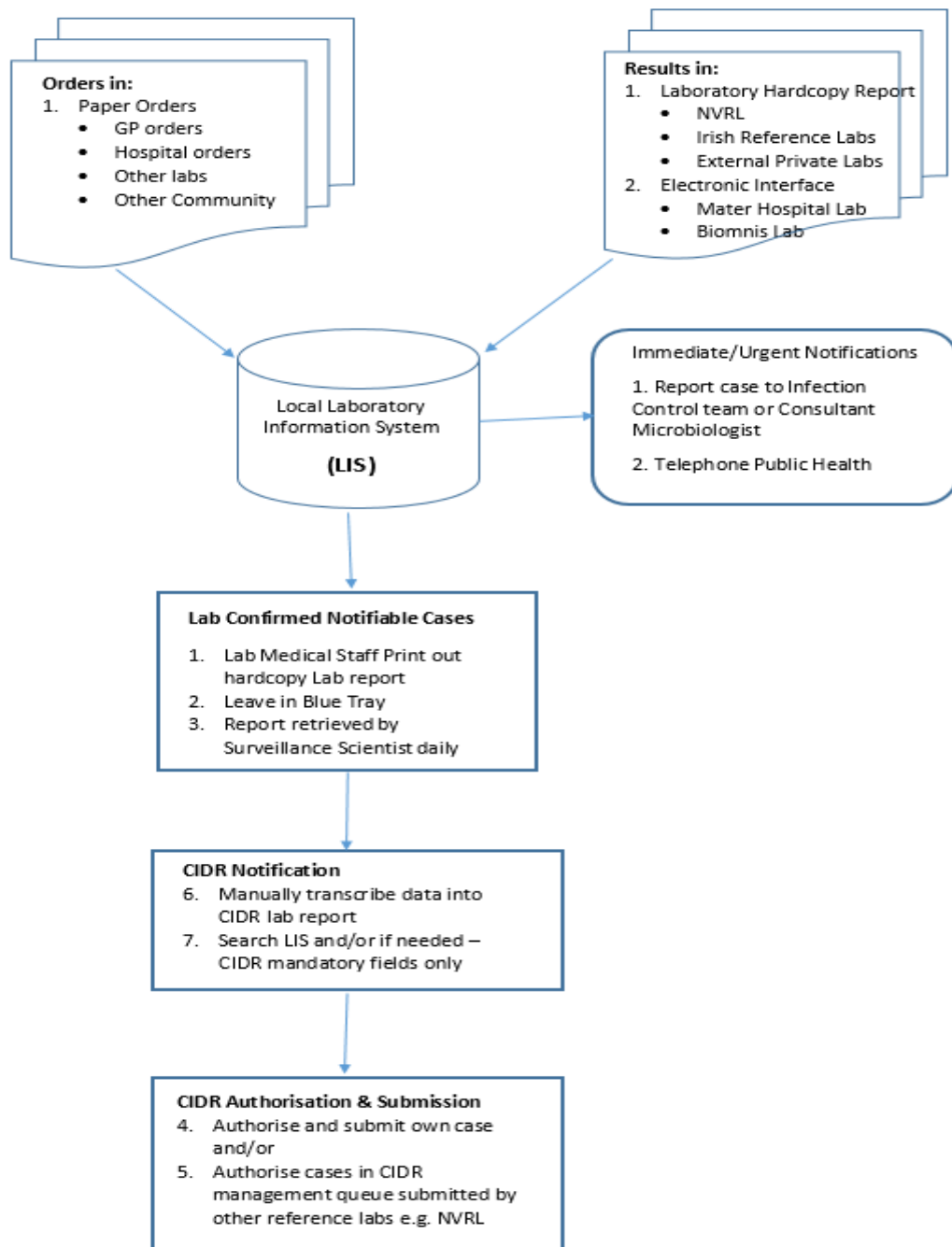


Figure 4.1 Country Hospital Laboratory Process into CIDR

Most of the pathology orders received from GP's, inpatient wards and other community organisations are in paper format. Data is manually transcribed from the paper order

forms into the LIS by laboratory administration staff. Notification into Public Health through CIDR is completed by the laboratory surveillance scientist working in the microbiology laboratory, or a nominated laboratory staff in their absence. Only finalised, authorised laboratory reports are reported into CIDR.

When medical staff receive a confirmed diagnosis of a notifiable infectious disease, a copy of the hardcopy laboratory report is printed out and filed in a blue paper tray in the microbiology lab. The surveillance scientist processes these notifications daily by transcribing the data from the laboratory report into CIDR on a case by case basis. There are typically approximately 10-20 notifications made each week into CIDR.

Also, preliminary notifications awaiting authorisation in the CIDR management queue are authorised and submitted. These cases in the management queue are CIDR notifications entered by external specialist laboratories, e.g. NVRL, for positive laboratory results obtained on behalf of the referring hospital. The referring hospital needs to review and authorise the case in the management queue, before the notification is submitted and made to Public Health.

Where there is an urgent case or a suspected outbreak, a phone call is made to Public Health, infection control nurses or the consultant microbiologist in addition to the routine reporting on CIDR.

For some diseases that have a complex case definition and require a laboratory diagnosis and a clinical diagnosis, there is a weekly meeting with the microbiology consultant and infection control team where the case is reviewed, and a decision made as to whether the case is notifiable or not.

Many tests for notifiable diseases are referred on to an external laboratory for processing; for example, all TB tests go to the Mater Hospital laboratory. If the Mater gets a positive result, then the sample is sent from the Mater to St James TB reference laboratory where further tests are run. In this scenario, the St James surveillance scientists will do the notification into CIDR if there is a confirmed case of TB.

For tests sent to the NVRL and external labs, a hardcopy laboratory report with the results are returned, and this is scanned into the country hospital local LIS.

4.2.2 Dublin Hospital Notification Process

The laboratory notification process described below is from a large Dublin voluntary hospital as described during an interview with a senior surveillance scientist. The interview notes are in Appendix Q. Figure 4.2 below is authored by the same surveillance scientist and describes the end to end process from receipt of pathology orders, processing of orders in the LIS, extraction and validation of notifiable data from the LIS, upload of data into CIDR and authorisation of confirmed cases in CIDR. See Figure 4.2.

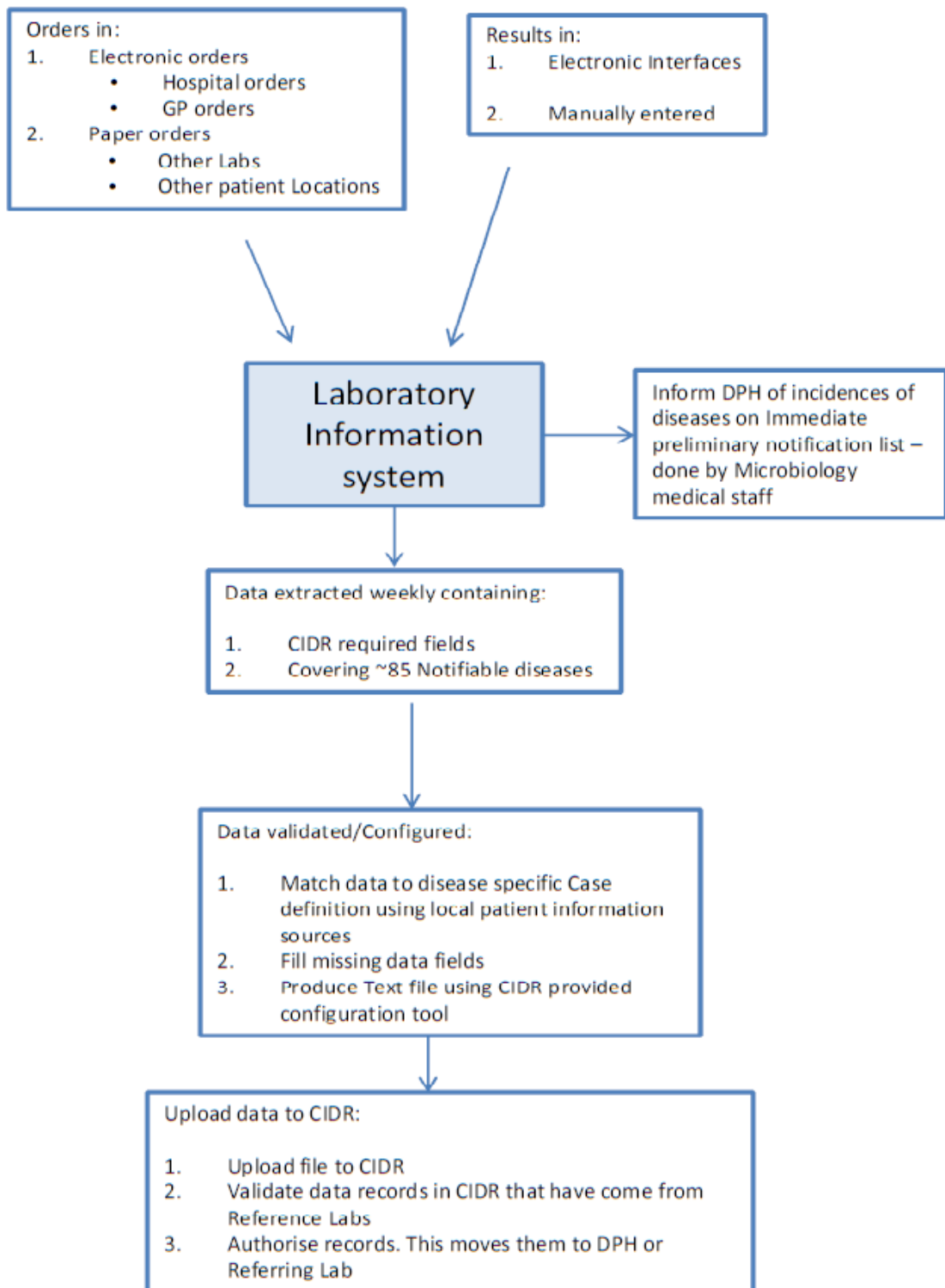


Figure 4.2 Dublin Hospital Laboratory Notification Process

Pathology orders are received in handwritten format from some GPs and referring hospital clinical laboratories. Most of the orders are in electronic format originating from the order communication system used within the hospital by doctors on the wards and

from some GPs who send in electronic orders from Healthlink. Healthlink is Ireland's messaging broker that sends data such as pathology results from hospitals to GPs practice systems.

Once a week, a complex custom Microsoft access query is run against various data source systems including the LIS, EPR, Patient Administration System (PAS), data warehouse and microbiology clinical notes system. All the notification data is gathered for all confirmed notifiable cases and then run through a CIDR tool to transform it into the correct text file format.

This batch text file is uploaded into CIDR, and all data fields are populated. The cases are then authorised and submitted. Once submitted, the cases are visible to public health surveillance scientists from Public Health. There are typically 150 notifications a week reported into Public Health. There is no manual data entry into CIDR. If there are pending cases in the CIDR management queue that have come from other reference laboratories, e.g. NVRL, these are also validated and submitted once a week.

For some cases that require a clinical diagnosis in addition to the laboratory diagnosis, the process is the same as at the country hospital. There is a weekly meeting where the case is reviewed, and a decision made as to whether it is notifiable or not.

4.2.3 NVRL Laboratory Notification Process

The NVRL laboratory notification process is as described during an interview with a laboratory manager working in the NVRL. See Appendix R for a summary of the interview notes. The NVRL is a screening and referral lab and receives specimens and test requests nationally from hospitals, GPs and other clinics as shown in figure 4.3 below.

The notification process is largely the same as the Dublin hospital and notifiable data is uploaded into CIDR in batch file format. See figure 4.3.

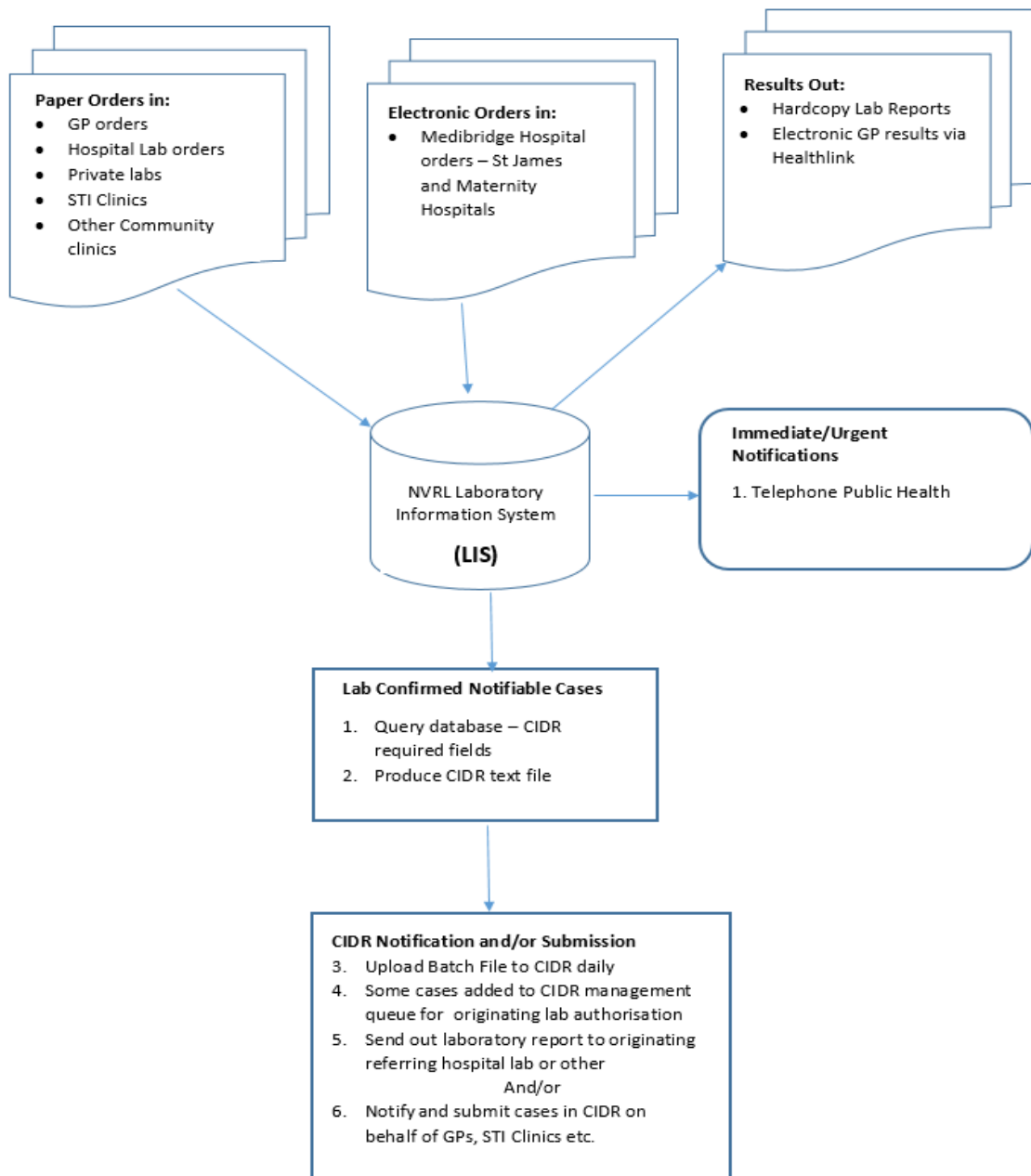


Figure 4.3 NVRL Laboratory Notification Process

The NVRL processes over 900,000 tests per year covering approximately 320,000 samples. Less than 20% of these tests originate from GPs. Notifiable infectious diseases are a subset of this figure, and CIDR notifications are in the region of 250-300

notifications per day during October to February and 20-40 per day during March to September. Sexually Transmitted Infections (STI's) are the largest cohort of notifiable tests that get reported into CIDR.

The NVRL receives pathology orders from multiple sources and in various non-standardised formats including:

- Handwritten request forms from GPs
- 2D barcoded printed forms from maternity hospitals
- Medibridge order communications from a couple of Dublin hospitals
- Printed or handwritten order requests from other HSE originating labs and clinics.

The patient demographic and clinical test data is extracted from the request forms and entered manually or uploaded into the NVRL LIS. The test is processed. The positive laboratory cases are extracted from the LIS using an automated query, transformed into the CIDR text format and uploaded in batch into CIDR daily by the NVRL surveillance scientists. There is no manual data entry into CIDR.

4.2.4 Summary

The notification processes are similar for the Dublin hospital and NVRL. Both are reference laboratories, have a mixture of electronic order requests and paper order requests to process in high volumes; and offer batch notification processing into CIDR. The country hospital does not have a data extraction query and transcribes data off a hardcopy laboratory report into CIDR on a case by case basis. Routine cases are entered daily into CIDR by the country hospital and NVRL and once a week by the Dublin hospital.

4.3 CIDR Dataset

This section highlights the mandatory and optional dataset requirements required to notify a confirmed case into CIDR. This dataset will help to understand what data MedLIS needs to collate and store and whether MedLIS is likely to help improve data completeness in the laboratory notification process.

The ability of MedLIS to store and extract this data will also help to form a view as to the possibility of a real-time electronic reporting interface between MedLIS and CIDR. ELR would remove the need for surveillance scientists to enter data into CIDR and manually authorise and submit notifiable cases as described in the process above.

The dataset information is recorded in the CIDR file import specification document authored by an HPSC surveillance scientists (Grogan, 2005).

The following table 4.1 outlines the complete list of notifiable fields together with comments provided by MedLIS project staff (Order Communication Lead and Microbiologist Workstream Lead). See Table 4.1.

Table 4.1 CIDR Data Set Specification

CIDR Specification	Mandatory or Optional for CIDR notification	Stored in MedLIS Y/N	Comment
Patient Surname	Mandatory	Y	PAS will remain the Master. Patient data will continue to be updated from each hospital's PAS or GP Practice Systems if the patient does already exist in PAS.
Patient First Name	Optional	Y	Same as above
Date of Birth	Optional	Y	Same as above
Patient Gender	Optional	Y	Same as above
Patient health board of residence	Mandatory	N	Not stored currently in all hospital PAS or GP Practice Systems so cannot extract from MedLIS
Address 1	Optional	N	Not stored currently in all hospital PAS and GP Practice Systems so cannot store in MedLIS and extract from MedLIS. Yes, if we can standardise and agree on a minimum patient data set
Address 2	Optional	N	Same as above
Address 3	Optional	N	Same as above
Address 4	Optional	N	Same as above
Address 5	Optional	N	Same as above
County	Mandatory	N	It will not always be filled as not all hospital PAS have 'County' as a separate field item. The County could be in Address Line 3 as an example. All PAS and GP Practice systems would need to be upgraded and standardised to store this field
Patient Type	Optional	Y	
Patient Age	Optional	N	Could be possible to generate the age from the DOB in the PAS but not a current requirement. MedLIS just stores date of birth
Patient Identifier (hospital number, mrn)	Optional	Y	MedLIS will store new Individual Health Identifier (IHI) and will also store hospital MRNs and GP electronic patient record identifiers
Referring Lab	Optional	Y	Yes, assuming referring originating lab is a MedLIS lab
Referring Lab Specimen Received Date	Optional	Y	Yes, assuming referring originating lab is a MedLIS lab
Specimen Type	Optional	Y	

Specimen Collected Date	Optional	Y	Yes, for electronic order requests but no for paper order requests. MedLIS will continue to have some level of hardcopy requests, and this data may not be recorded on the form. Even if it is on form, it may not be re-typed in MedLIS by specimen reception staff as it's not essential data for the lab to process the test.
Lab Specimen Identifier	Mandatory	Y	
Referring Lab Specimen Identifier	Optional	Y	
Specimen Received Date	Optional	Y	
Reported Results Date	Mandatory	Y	
Comments	Optional	Y	Include free-text lab comments and automated comments depending on diagnosis rules built into the system
Lab Notifier (microbiologist, pathologist, lab director)	Mandatory	N	This has not been submitted as a requirement. MedLIS cannot control which surveillance scientist do the notification as MedLIS and CIDR will not be integrated
Referrer	Optional	Y	
Referral Source	Optional	Y	Yes, if referral source such as GP Practice System or Hospital, or Clinic is signed up to MedLIS and uses electronic order communications to send in the pathology request
Organism	Mandatory	Y	
Lab Test Name	Optional	Y	MedLIS will provide an Order Catalogue that all tests need to be ordered from
Lab Test Result	Optional	Y	
Susceptibility Test Name	Optional	Y	
Susceptibility Test Result	Optional	Y	
Susceptibility Test Interpreted Results	Optional	Y	

As can be seen from the table above, there is a minimum mandatory dataset. This minimum dataset is required for a successful upload of a file into CIDR.

MedLIS, as indicated in the orange shading in the table above, will not be storing the patients' Health Board of Residence, County of Residence or the Lab Notifier, i.e. surveillance scientist who made the notification into CIDR. These missing data items cannot be included in an automated extract report and will need to be entered into CIDR by the surveillance scientist. The other data fields as indicated by the Y column can be included in the data extract query and then uploaded automatically into CIDR.

4.3.1 Conclusion

The majority of the CIDR dataset fields will be stored in MedLIS and could easily be added in the data extract query for notifiable data. A robust automated data query would lead to improved completeness of reporting since the current notifications into CIDR from the country hospital only add mandatory fields and this is probably indicative of most laboratories nationwide.

4.4 Data Collection, Data Quality and Reporting Issues in the current process

This section categorises and lists the data collection issues, data quality issues and under-reporting issues that exist in the laboratory notification process for confirmed cases of notifiable infectious diseases as discovered during primary research.

4.4.1 Online Survey Results

There were 20 responses out of a total of 70 possible responses returned by surveillance scientists nationwide in Ireland which represents a 29% response rate. The types of respondents are shown in Figure 4.4 below. See Figure 4.4.

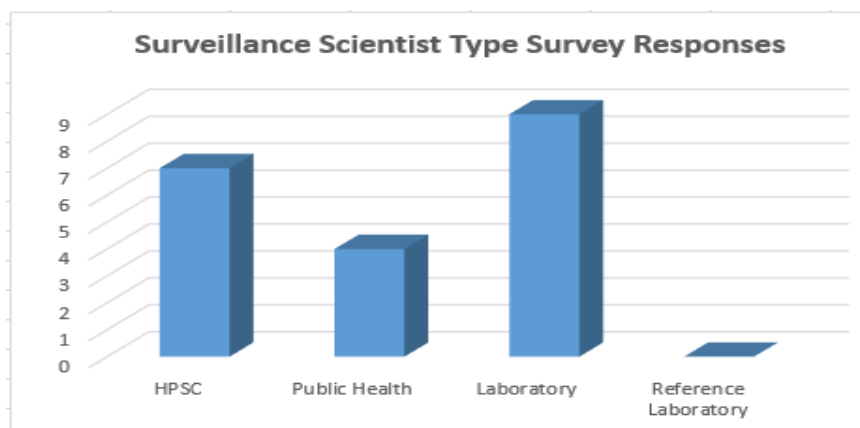


Figure 4.4 Count of responses to Online Survey by Surveillance Scientist Type

As described in the notification process in Section 4.1 both hospital and NVRL laboratory surveillance scientists perform the laboratory notifications into CIDR. Regional public health surveillance scientists then validate the CIDR notifications and anonymise the data before it is submitted it to HPSC surveillance scientists who aggregate CIDR data and HIPE data to create national or regional surveillance reports.

Do you believe there to be under-reporting of laboratory confirmed cases of notifiable infectious diseases into the Department of Public Health?

There were 19 responses to this question and as shown in figure 4.5 below; most respondents said that under-reporting happens ‘sometimes’ which is somewhere between never and half the time. Only one HPSC surveillance scientist believes that under-reporting happens all the time. See figure 4.5.

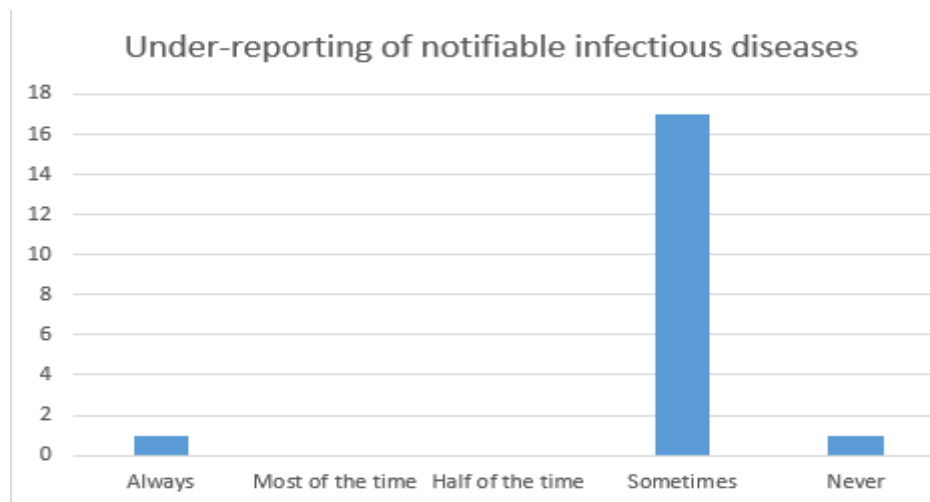


Figure 4.5 Under-reporting of notifiable infectious diseases

What may contribute to under-reporting of laboratory confirmed notifiable infectious diseases? Tick all that apply

There were 20 individual responses to this question, and only three respondents indicated more than one underlying reason. The majority selected only one root cause of under-reporting which was ‘other’. See figure 4.6.

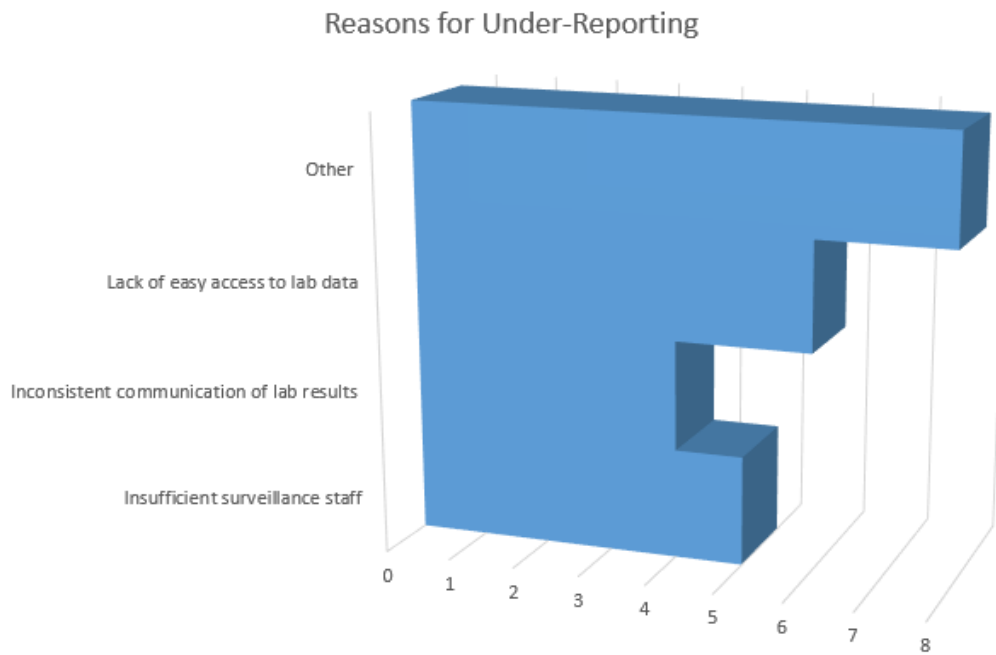


Figure 4.6 Underlying reasons for laboratory under-reporting of notifiable infectious diseases

The ‘other’ free-text other reasons were as follows:

- I. Lack of automated extracts from LIS
- II. Lack of clinical information on request forms
- III. Testing done externally or in private lab and therefore not uploaded into CIDR
- IV. Lab tests are updated or modified or added
- V. Codes may not be captured in CIDR extract

What data quality errors, if any, do you regularly encounter when collating appropriate data for notification into the Department of Public Health? Tick all that apply

This question was only open to laboratory surveillance scientists. There were nine responses, all from hospital laboratory surveillance scientists. 45% believe there to be no data quality errors, and the remaining 55% believe there is data quality issues such, as ‘missing clinical notes’ that was cited most frequently by 22% of respondents. See Table 4.2.

Table 4.2 Data quality errors in laboratory notification process

Data Quality Issues	Sum of Number of responses
correct lab results wrong pat	0
erroneous test results	1
false positive lab result	1
illegible handwritten data	0
missing clinical notes	2
Missing patient data	1
none	4
other	0
Grand Total	9

What do you think is the most common data quality error? Please elaborate on the underlying reason for the issue if known?

There were only three responses to this open-ended question which was only open to laboratory and reference laboratory surveillance scientists. Due to the small number of responses, no meaningful statistics or indications of most common data quality error and underlying route cause can be established.

The free-text answers are as follows:

- I. Data error problems are very rare in my experience
- II. Location (i.e. GP/hospital) data entry. This does not affect CIDR reporting too much but more infection control and possible clinical risk when the report goes to the incorrect location. Reasons: human error and illegible GP codes
- III. Data not supplied by referrer

What sources of information do you have easy access to in order to collate the relevant data and raise a confirmed case of a notifiable infectious disease into the Department of Public Health? For each source, please select Yes, No or Not applicable

100% of all nine laboratory surveillance scientist respondents said that they have easy access to their LIS and 77% of same respondents also have easy access to their Patient Administration System (PAS). 33% also have access to an EPR which is only available at the Mater and St James hospitals in Ireland. Hardcopy laboratory reports and patient records are also used as sources of information. See Figure 4.7.

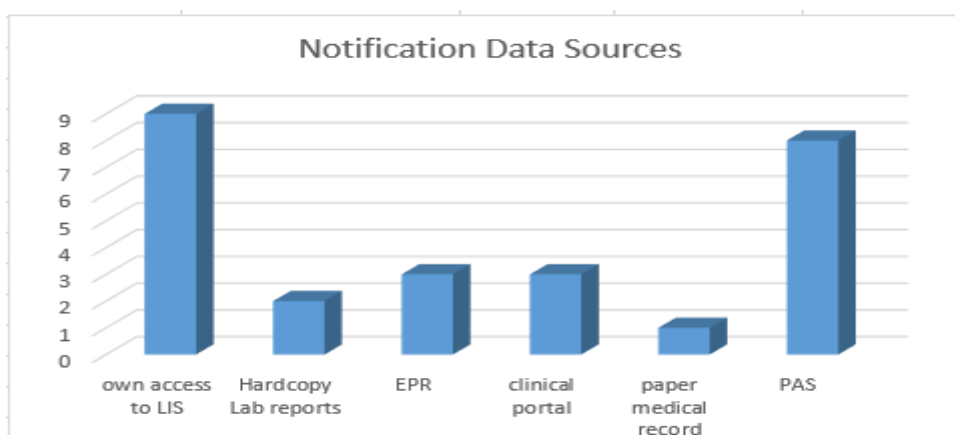


Figure 4.7 Regular data quality errors in laboratory notification process

Do you agree or disagree that you have easy access to laboratory results data that you need in order to raise a confirmed case of a notifiable infectious disease into the Department of Public Health?

This question was only open to laboratory and reference laboratory surveillance scientists and a very decisive results states that 100% laboratory surveillance scientists agree that they have easy access to laboratory results which is needed to raise a laboratory notification. See Figure 4.8

Easy Access to Laboratory Results Data

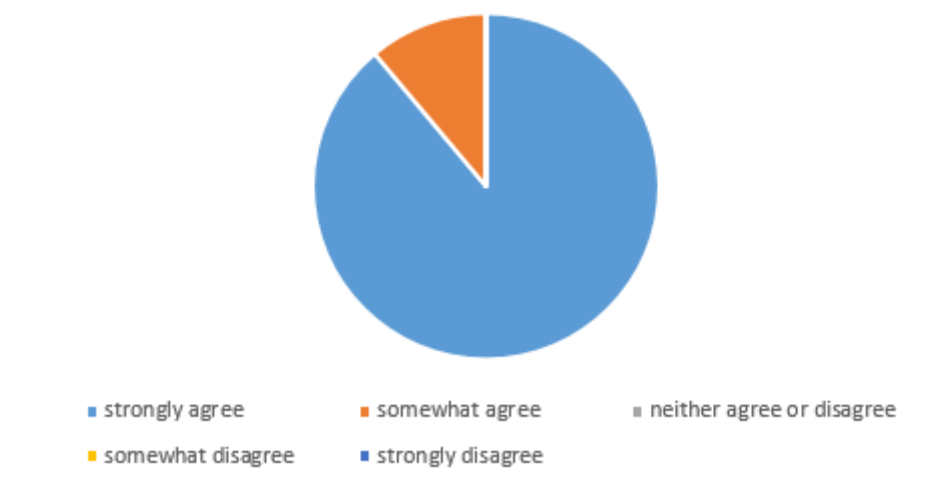


Figure 4.8 Easy access to laboratory results data

What prevents you from raising timely routine cases of notifiable infectious diseases into the Department of Public Health?

This open-ended question was only open to laboratory surveillance scientists, and all nine provided a free-text response which is summarised below. See Table 4.3.

Table 4.3 Reasons for delay of notified cases into Public Health

Number of Responses	Theme	Description
2	Case Definition Complexity	Some cases need to be examined clinically to see if they meet case criteria, and there isn't time to do so. Case definition discussion of cases, sometimes delays reporting. Cases are usually discussed at weekly Infection Control Team meetings to see if particular cases meet the criteria for reporting. If a case does meet the criteria, then it is subsequently reported, but this could be a minimum of 3-4 days after a positive result is identified.
1	Waiting on test results	Waiting on confirmation from reference labs
1	Communication of test results	Communication delays of positive results from lab staff to surveillance staff
4	Nothing causes delays	2 * Nothing should delay reporting of results 1 * Routine notification of notifiable infectious diseases is always timely 1* 99% of time reporting is easy. There is the odd occasion when the clinical notes don't tie in with the isolate being notifiable and requires help/feedback from the Consultant
1	annual leave/time off	annual leave/time off

The results imply there is rarely any delays to notifications into CIDR as put forward by four out of nine respondents. The complexity of case definition and the need for cases to be reviewed clinically was mentioned by over 20% of respondents as the main reason for delayed notification.

4.4.2 Laboratory Informant Interview Results

The following informant interviews took place with the intention of (1) validating the survey results and (2) to understand in more depth the reasons data and process issues within the laboratory notification process.

4.4.2.1 Validation of Survey Results

In response to the question “Do you believe there is under-reporting of laboratory confirmed cases, most of the survey respondents said that under-reporting does exist ‘sometimes’ which is somewhere between never and half the time. Do you agree?”

All four-laboratory staff that were posed this question, responded that they agreed that under-reporting does exist sometimes.

In response to a question about reasons for under reporting, most of the laboratory surveillance scientists cited lack of easy access to laboratory data’ and ‘other’ as the main reasons for under-reporting when it does sometimes occur. What is your experience and are there any additional reasons you think are valid?

Three out of the four laboratory staff were posed this question responded that they agreed that one or more of the reasons listed for under-reporting originating from the survey was valid. Only the NVRL lab manager said the reasons listed were not relevant for them.

There was a couple of comments made on ‘lack of easy access to laboratory data’ in which the interviewee thought that the problem is not access to lab data but the extraction of data from the lab database tables and the need for specialist IT skills to extract the data you need.

The survey respondents indicated a variety of data quality errors and four laboratory surveillance scientists said there are no data quality errors within the notification process to CIDR. What is your experience?

Three out of four laboratory staff agreed that data quality issues exist within the process. One of the informants who also responded to the online survey re-iterated that there are no data quality errors as these are caught and fixed earlier in the specimen check-in process.

A summary of data quality errors cited by interviewees are:

- I. Anonymous patient demographic data
- II. Missing GP information
- III. Missing patient data on John Doe, i.e. date of birth
- IV. Illegible handwritten data
- V. Transcription errors into CIDR
- VI. Missing clinical details
- VII. Poor quality of data on paper request forms

All laboratory surveillance scientists in the survey responded that they have easy access to their LIS and 7/9 have access to their PAS. Only 3/9 have access to an EPR. What is your experience, and do you have easy and direct access to all systems that you need to gather the case data?

All four laboratory informants stated they have easy access to all the systems they need. However, one informant did state that retrieving data is time-consuming.

Four laboratory scientists in the survey responded that there is rarely or no delay in notifications. Do you agree?

Three out of the four laboratory informants stated they agreed there is rarely or no delay. One respondent did not agree and said the answer would depend on the definition of delay and this is not audited. Delays can occur due to manual steps.

4.4.2.2 Root cause analysis of notification issues

In your experience, what data quality issues exist in the notification of infectious diseases and what do you think is the root cause of these issues?

See Appendix V for the detailed collection of results from interviews on data quality issues and root causes. See a summary of these results in the table below. See Table 4.4.

Table 4.4 Root Cause of Data Quality Issues

Data Quality Issue	Root Cause
Illegible Order Request Forms	Handwritten GP order requests Handwritten inpatient order requests
Transcription Errors into CIDR	Manual data entry
Missing Specimen Collection date and timestamp	Not added to paper order requests Clinicians don't complete request forms to a high standard
Ambiguous what test is requested	Sometimes just viral screen is added instead of the name of the virus to test for Missing clinical details
Incorrect patient data	Difference between the patient name on the specimen tube and the paper request
Anonymous patient data	Patient surname, address etc. can be anonymised by STI clinics
Missing Clinical Details	Clinical details are not mandatory and not needed to process the test
Incomplete Data on CIDR	Don't have time to go looking for data for optional fields

Many of the data quality issues including missing data, anonymous data and ambiguous test requests seem to all stem from handwritten GP and inpatient ward pathology requests.

In your experience, are all laboratory confirmed case of notifiable infectious disease reported into the Department of Public Health? If not, why?

Three out of five laboratory informants stated that yes, all laboratory notifications are reported. The responses of interviews are presented in Table 4.5.

Table 4.5 Indication of full reporting into Public Health

Y/N Response	Why	Informant
Mostly Yes	NVRL notifies for both hospitals and GPs and we are the primary testing laboratory. Under-reporting has been an issue in the past but it has got a lot better	1 * NVRL Lab Manager
Mostly Yes	Occasionally find the very odd thing and cannot say you never make a mistake but we have all angles covered	1 * Dublin Surveillance Scientist- Dublin Hospital
Mostly Yes	Under-reporting only occurs in non-laboratory notifications if there is a reliance on a clinical notification by a doctor. All lab cases are pretty much all reported but there can be ambiguity sometimes on who does the notification between hospital labs	1 * Chief Medical Scientist – Country hospital
No	There are occasions when not reported due to the manual system/process in place. It is possible that lab staff do not print out the laboratory reports for a confirmed case.	1 * Senior Medical Scientist – Country hospital
No	Majority of notification processes nationwide have a human manual element and dependent on medical staff to come across a positive case and communicate that with surveillance scientist.	1 * Surveillance Scientist – Country Hospital

These results suggest that laboratory under-reporting into Public Health is rare and happens only because of the manual steps in the notification process and ambiguity on which laboratory is doing the notification into CIDR.

In your experience, can you offer a view as to why some infectious diseases according to research (e.g. viral meningitis) have been greatly under-reported into Department of Public Health and other such as tuberculosis is not?

The interview responses to this question are presented in Table 4.6.

Table 4.6 Viral meningitis versus TB under-reporting reasons

Viral meningitis	Tuberculosis	Informant
<p>Testing for viral meningitis via lumbar puncture does not always work, and it can detect a virus or not. Therefore, there can sometimes be a clinical diagnosis only without a laboratory diagnosis, and symptoms would need to match the case definition.</p>	<p>For a TB diagnosis, it is a much simpler test with TB culture, and it's either one way or the other. TB is better known and garners more attention from clinicians and lab staff.</p>	<p>Chief Medical Scientist- Country Hospital</p>
<p>Viral meningitis is a clinical paper notification, so laboratories do not notify, and you will not get the level of buy-in from clinicians. Clinicians are reluctant to diagnosis viral meningitis as the diagnosis is too ambiguous and there could be other co-morbidities and clinical factors involved that contribute to an overall diagnosis.</p>	<p>Compared to TB, you can't deny its TB, it is, or it isn't.</p>	<p>Surveillance Scientist – Country hospital</p>
<p>With viral meningitis, the pathogen cannot always be identified. The problem is we don't always get the correct sample type or specimen collection date and clinical details. This makes the diagnosis more difficult.</p>	<p>We don't test and notify for TB</p>	<p>1 * NVRL Lab Manager</p>
<p>When you test for viral meningitis on CSF, it does not always work, and it can detect a virus or not.</p> <p>Also, viral meningitis can sometimes be a clinical diagnosis only and not always accompanied by a laboratory diagnosis.</p>	<p>TB is a much simpler diagnosis using TB culture test. Historically, TB was always the scary infection and gets more attention.</p>	<p>1 * Senior Medical Scientist – Country Hospital</p>
<p>Difficult to get a laboratory-confirmed diagnosis.</p>		<p>1 & Surveillance Scientist – Dublin Hospital</p>

The central theme from the results presented in the table is that due to the nature and complexity of the viral meningitis disease and reaching a diagnosis; a confirmed case of viral meningitis into Public Health can only be made by a clinician and is not reported by laboratory surveillance scientists.

TB on the other hand, although also quite a complex disease since a confirmed case requires a laboratory and clinical diagnosis; the laboratory diagnosis is much simpler and on the whole garners much more attention from hospital staff due to bed management isolation reasons.

4.4.2.3 Root cause analysis of timeliness issues

The literature has indicated that timeliness of reporting is a big issue internationally? What in your experience, what impact notification timeliness in the current setting?

The interview responses to this question are presented in Table 4.7.

Table 4.7 Timeliness of Reporting reasons for delay

Timeliness statement	What impacts timeliness?	Responder
There is no set time that you need to report on, and so there is no benchmark to measure against. HPSC would like us to report as quickly as possible, but there are no rules	The complexity of the case definition such as Cdiff requires a clinical review meeting to determine if it meets notifiable criteria. These meetings take place once a week. It could be a week before a case gets notified.	Senior Medical Scientist – Country Hospital
Timeliness cannot be quantified as there are no HPSC guidelines.	There is only one surveillance scientist per hospital generally so all types of leave impact laboratories across the country.	Senior Medical Scientist – Country Hospital
Surveillance Scientist Priorities	How busy the surveillance scientist is as notification into CIDR is only a small fraction of their overall role and not high on the priority list.	Senior Medical Scientist – Country Hospital
HPSC don't give us rules; we do as much as we can.	CIDR is a tiny amount of what we do. Don't have time to do things manually and do things on the fly.	1 * Dublin Surveillance Scientist
Case reporting can be slow	Hospitals have different lab systems, and they mostly upload into CIDR one case at a time. At the NVRL, we can do batch uploads into CIDR	1 * NVRL Lab Manager
CIDR System is not good for identifying an emerging outbreak promptly	Even though we do the notification on behalf of the originating lab; the originating lab still needs to review and authorise the case on CIDR themselves and this delays notification.	1 * NVRL Lab Manager
There is a list of immediate notifications that must be reported immediately, but this can be interpreted differently by different labs.	Routine cases would generally be the same day unless a routine case is notified on a Friday evening or weekend, then it is following Monday.	1 * surveillance hospital – Country Hospital

Yes, we meet HPSC criteria. We notify daily.	But when sending tests out to another lab for processing, we can't control the timeliness. Some diseases such as Cdiff are handled differently and require a clinical decision on meeting case definition	1 * Chief Medical scientist – Country Hospital
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The results show that timeliness is not an issue for routine cases in the current process and is not measured as there are no HPSC timeliness rules. The main reasons for delays when they do occur are due to the complexity of case definition and availability of the surveillance scientist.

4.4.3 Conclusion

Data Collection Issues

The survey results showed all laboratory surveillance scientists have easy access to notifiable data in their LIS and their PAS systems to raise a notification into CIDR. This was validated by the interviewees but with a comment from one informant stating it is time-consuming.

Data Quality Issues

A slim majority of survey respondents stated there are data quality issues in the notification process. The results were inconclusive on the most common data quality error. However, missing clinical notes was ticked the most by two out of nine survey respondents. The informant interviews validated that there are always data quality errors and most of the errors are introduced by the requestors of tests mostly regarding missing patient and clinical data on the paper request forms and the presence of anonymised patient data.

Under-Reporting Issues

The survey results showed that all respondents believe that under-reporting takes place sometimes. The reasons for under-reporting include the lack of an automated extract of notifiable data from local LIS, testing done by external labs are not notified in CIDR and issues with missing codes when new tests are added or modified by the lab. The interviewees agreed with these findings and concluded that all or most laboratory cases are reported into CIDR. Under-reporting reported in the literature (e.g. viral meningitis) is due to clinical under-reporting and not laboratory under-reporting.

Timeliness of Reporting Issues

Four out of the nine responses stated that nothing causes delay and generally reporting is easy apart from the odd occasion. The remaining respondents cited the complexity of case definition, waiting on test results from reference laboratories, communication of test result and annual leave as reasons for notification delays. The interviewee results agreed with the survey respondents that delays to reporting are rare and there are no delays. However, it was stated that timeliness could not be quantified as there are no HPSC guidelines.

4.5 MedLIS Opportunities

This section will describe and outline (1) what the laboratory managers and surveillance scientists need from MedLIS to improve the notification process (2) whether and how MedLIS is likely to overcome the issues and meet the requirements identified.

4.5.1 MedLIS Requirements to improve the notification process

Online Survey Results

An open question on what all surveillance scientists hope to gain from MedLIS was included in the online survey. Responses are summarised thematically per surveillance scientist type in Table 4.8 below. There were sixteen usable responses with three responses saying they did not know enough about MedLIS to be able to answer the question.

Table 4.8 MedLIS requirements from the perspective of Surveillance Scientists

Surveillance Scientist Type	Theme and count of responses	Description of what they hope to gain from MedLIS to support surveillance scientist role
Laboratory	2 * Alerting functionality	MedLIS needs to deliver an over-arching, catch-all system that can highlight all specimens that are notifiable. Better tracking of patients with multi-drug resistant organisation (MDRO)
Laboratory	2* Easy data extraction	Easier and more flexible extraction of data Data extraction should be made very simple in MedLIS
Laboratory	2 * Hospital results lookup	Option to check follow up results in other hospitals when the patient is transferred. Gaining access to patient results from other sites
Laboratory	1* Replicate existing LIS and data validation system functionality	That MedLIS is as good as APEX and a separate validation system independent of APEX can validate data and run reports as is currently the case. The APEX system we have is very good.

Laboratory	3 * unsure of any advantage of MedLIS	I cannot see any advantage over the current LIS system that I use; Unsure that MedLIS will improve disease notifications I don't believe it will be too much more helpful
Public Health	1* Standardised method of reporting	A standardised timely method of reporting
Public Health	3 * more data completeness	Access to a broader set of laboratory results More completed data More comprehensive data
HPSC	2 * Full reporting	Improved reporting of surveillance data. That all cases of notifiable viral meningitis, specified or otherwise, are reported to CIDR and their causative organism identified
HPSC	1* Standardised method of reporting	Consistency, time-saving, standardised.
HPSC	1 * Improved Data Quality	Improved quality of reported surveillance data.

There is a broad set of requirements outlined in the table above. From the perspective of the laboratory surveillance scientists, the most frequently requested requirements were the ability to extract data easily from the MedLIS database and an alerting mechanism that highlights positive laboratory results that are notifiable. The Public Health and HPSC surveillance scientist requirements are more focused on wanting better data quality, better completeness of data, and standardised method of reporting and full 100% reporting into CIDR.

Informant Interview Results

Laboratory interviewees were asked a different question, to assess the likeliness of MedLIS to improve the notification process. In answering this question, they went to specify more MedLIS requirements. The detailed results of this assessment can be found in Appendix W. Their overall conclusion is that, yes, MedLIS will improve the process but with some caveats. A summary of the caveats to improve the notification process include:

- Standardised electronic order request forms
- Custom extract query that can extract notification data from MedLIS but that also meets local hospital data needs
- Robust extract query that works for all hospital labs
- MedLIS extract query that can pull mandatory and optional notification data and can be transformed and uploaded into CIDR
- MedLIS audit and surveillance report that can compare confirmed lab cases for notifiable infectious diseases and compare to what was notified into CIDR.

The delivery of a robust data extract query featured very heavily in the interviews and is the major requirement that MedLIS needs to deliver for the surveillance scientist stakeholder group.

4.5.2 MedLIS Solution(s)

The following interviewees as shown in the table below hold senior positions in the MedLIS project team.

1 * MedLIS Microbiology Lead with laboratory knowledge of a different large Dublin voluntary Hospital	See Appendix S
1* MedLIS Order Communication Lead with laboratory knowledge of large Dublin voluntary hospital	See Appendix T
1 * Quality MedLIS lead with laboratory surveillance scientist knowledge in a country hospital	See Appendix U

This section aims to consolidate common issues and MedLIS requirements identified by the online survey and laboratory interviewees and present proposed solutions next to each.

4.5.2.1 Process Improvement Evaluation

Improve data collection issues

MedLIS will take away the reliance on medical staff in the laboratory to have to print out a copy of the laboratory report for the surveillance scientists' attention. A national data extract query will be provided to all MedLIS hospital laboratories that can extract notifiable data from MedLIS which then can be uploaded to CIDR in the correct format. The extract query should improve the ease of getting the data from the database but also getting the data in a more standardised format.

However, it will not completely automate the process. An interface between MedLIS and CIDR to allow for real-time notifications will not be delivered as no requirement has been submitted for it by Public Health or any other stakeholder group. Such an interface would be possible in a later phase should it be requested and would remove manual intervention

as all the CIDR dataset requirements could be stored within separate fields in the MedLIS database assuming a patient dataset is agreed and implemented.

There will be no more need to scan results into the local LIS that are sent back from other laboratories such as the NVRL. Results will automatically populate the flowsheet in the central MedLIS database making data collection of all results easier.

Improve Completeness of Reporting

The NVRL are requesting more specific information in the electronic order forms (OEFs) from requestors that order electronically through MedLIS. Clinical details will be a mandatory field for all electronic ordering of microbiology and virology tests. MedLIS will deliver a laboratory record that is much more complete than what we have now. Each laboratory patient record will be allocated with an individual health identifier (IHI) for every patient that has a pathology test processed within the Irish public health service. However, a minimum patient data set policy is required to get an IHI match.

Improve Data Quality

MedLIS will most certainly improve data quality as shown through the various solutions that will help reduce common data quality issues that exist nationwide. A Yes, No, or Maybe score is added by the researcher based on an assessment as to whether MedLIS is likely to solve that issues or meet the requirement based on the combined responses of the MedLIS staff interviewees. See Table 4.9.

Table 4.9 Data Quality Solutions

Data Quality Issue	MedLIS Solution	Yes/NO/Maybe
Illegible Order Request Forms	Electronic ordering solutions for all hospital inpatients, outpatients and GPs order requests	Yes
Transcription Errors into CIDR	National MedLIS data extract query will extract the notifiable data from MedLIS which can then be transformed and uploaded into CIDR.	Yes
Ambiguous what test is requested	MedLIS will implement a national Laboratory Order Catalogue for all electronic orders only and will include NVRL tests. But cannot prevent non-MedLIS paper orders going directly into NVRL.	Maybe
Incorrect patient data	MedLIS will implement new 2D specimen tube labels for every electronic order that will remove mismatch in patient spelling errors between handwritten order requests and handwritten labels on specimen tubes. MedLIS driven by the IHI is likely to implement a minimum patient data set to uniquely identify patients.	Yes
Anonymous patient data	Anonymous patient data for STI clinics is likely to continue. MedLIS is likely to process the anonymised data as we cannot stop it but MedLIS will not perform anonymisation of data. MedLIS will have no responsibility to link an IHI patient record with their anonymised record so conceivably a patient can have two or more records If the HSE policy decision is for MedLIS to accept and process anonymised data than the goal of having one longitudinal ELR for a patient with an IHI will not be met.	NO

MedLIS will improve data quality through the delivery of electronic order communications and mandatory clinical details in the OEFs, a national order catalogue,

minimum patient dataset, easier extraction of notifiable data from central database and barcode labels. Electronic information is much more accurate than transcribing handwritten requests.

Improve Under-Reporting

MedLIS will improve under-reporting. MedLIS will be a great benefit to surveillance scientists as some of them are still manually drilling through their laboratory results to find the notifiable diseases. However, there will be no alerting type functionality to assist laboratory staff in recognising a confirmed case that should be notified. This decision support functionality is more suited to an EHR than a laboratory information system such as MedLIS.

MedLIS has not yet designed or built a report to extract all national laboratory confirmed cases of known pathogens out from the MedLIS database. No requirement for this has been submitted by Public Health. You can only pull national data if there is a legitimate reason to do so and authorisation is in place. There is currently no such authorisation in place.

4.6 Conclusion

Can a National Medical Laboratory System (MedLIS) improve the surveillance laboratory notification process of notifiable infectious diseases into the Department of Public Health in Ireland and if yes, what is needed for this to be achieved?

Four laboratory interviewees were asked to assess the likelihood of MedLIS to improve the laboratory notification process against each of the assessment criteria. The result is that ‘completeness of reporting’ and ‘full case reporting’ into CIDR is likely to improve, but most interviewees were unsure if ‘timeliness of reporting’ would improve.

The results show that there will be improvements to data collection issues within the notification process, but this is very much dependent on the delivery of a robust extract query.

The delivery of an electronic laboratory interface is needed to eliminate under-reporting and deliver ELR but unfortunately, this is not in scope of the project.

The delivery of electronic order communications and an order catalogue for all hospital and community pathology test requesters is needed to achieve realistic and substantial improvements in data quality and therefore data completeness of reporting into CIDR.

A detailed discussion of the results of this chapter will be provided in the next chapter (chapter 5).

Chapter 5 Discussion

5.1. Introduction

“It is the effective presentation, analysis, and interpretation of data and indicators that results in correct health information” (The European Observatory on Health Systems and Policies, 2014).

This chapter will draw on the primary research, and the literature review to (1) assess the ability of MedLIS to improve the notification process into Public Health based on and (2) provide overall recommendations for the MedLIS project to help address the issues and requirements identified.

5.2 Notification process improvements assessment

From the outset, the process assessment criteria were established to help assess the likelihood of MedLIS improving the laboratory notification process of infectious disease into Public Health via Ireland’s national surveillance system CIDR. The process improvement criteria includes full case reporting, completeness of reporting, and timeliness of reporting; each of these is addressed in the research sub-questions which will now be discussed in turn.

Full case reporting assessment criteria is measure of the % of true incidences that are reported into Public Health. In literature this is known as the sensitivity of the surveillance system and refers to the proportion of case of disease detected by the surveillance system (German et al., 2001).

Data quality reflects the completeness and validity of the data recorded in a public health surveillance system. Data quality issues includes missing data in its scope and falls under the ‘completeness of reporting’ assessment criteria. “Examining the percentage of

“unknown” or “blank” responses to items on surveillance forms is a straightforward and easy measure of data quality”(German et al., 2001).

Timeliness of reporting reflects the speed between each step in the notification process of a public health surveillance system. For example, the time between the ordering of the test and the notification into Public Health could be measured which in turn would have an impact on the identification of an outbreak and public health action (German et al., 2001).

1. Is there under-reporting of confirmed cases of notifiable infectious diseases into the Department of Public Health via the laboratory notification process and if yes what are the underlying reasons and how might MedLIS help address these issues when it is implemented?

The primary results revealed that under-reporting occurs ‘sometimes’ but that it is difficult to quantify how much under-reporting occurs since this metric is not audited by the hospital laboratories and the interviewees admit that there is ambiguity sometimes on which lab does the notification into CIDR.

Also, the reliance on the laboratory medical staff to print out a hardcopy of a laboratory report for the surveillance scientists’ attention is prone to human error. If this manual process exists in many hospital laboratories nationwide; there could be consistent under-reporting into CIDR that the surveillance scientists and Public Health would not even be aware of it.

The reasons for under-reporting are wide-ranging in the survey results with no singular contributing reason as most of the survey respondents chose ‘other’ as their response.

Lack of easy access to automated extracts from their local LIS and inconsistent communication of notifiable laboratory results to surveillance scientist staff to report a case to CIDR; featured most heavily in the survey and informant interviews overall.

MedLIS will not deliver a real-time notification interface to CIDR. The reasons for the decision to supply a national extract query that does not fully automate the notification process instead of a real-time interface is not known to the researcher.

The informant interviews did offer some insights as to why this could be. The HPSC case definition is too complex and wide ranging as some infectious diseases require both laboratory and clinical criteria to meet the definition of a confirmed diagnosis. A perfect example of this is viral meningitis which has been proven to be under-reported in three previous Irish studies.

There were many clinical reasons given for the difficulty of a laboratory test to isolate the causative antigen for viral meningitis through a CSF sample which can be further hampered by the timing of the test and therefore give an inconclusive laboratory result. The very nature of the disease and the fact that many different viruses can cause viral meningitis makes it difficult to diagnosis.

However, from a notification perspective, the main reason for under-reporting is that a confirmed case of viral meningitis requires a clinical diagnosis to be made by a clinician such as a consultant microbiologist or GP. Even if there is a confirmed laboratory test, it is insufficient for the surveillance scientist to make a notification into CIDR.

A clinical notification is generally made outside of CIDR, and typically clinicians are not known to be good at submitting formal notifications as they are either unaware of reporting guidelines or are too busy to do so. This conclusion is also backed up by literature which suggests that under-reporting is at the clinical notifier level and not the laboratory notifier level. MedLIS will not improve or positively impact on the clinician reporting levels into Public Health.

2. What are the data collection issues within the current laboratory notification process, and how might MedLIS address these issues when it is implemented?

The results from the survey and informant interviews conclude that although most surveillance scientists and laboratory managers may have easy access to their local LIS to view laboratory data; the issue is the mining and extraction of laboratory data. There is a plethora of different laboratory systems nationwide (see Appendix X), and surveillance scientist informants suggest that notification processes can vary widely between public laboratories. There is bound to be manual steps in the process and reliance on the medical staff to print out a hardcopy of the report and leave it for the attention of the surveillance scientist.

Reliance on the LIS vendor to mine laboratory data was also mentioned as a barrier as many vendors will not allow hospital staff to run their queries against the database but instead charge for the creation of standard reports. This is standard behaviour from vendors that is unlikely to change with MedLIS vendor, Cerner. Unless the MedLIS back-office employ skilled business analysts with SQL knowledge and they are granted sufficient access rights, this practice is unlikely to change.

The sophisticated data mining techniques of the Dublin hospital and the NVRL with the ability to extract notifiable data in a usable format that is batched and uploaded into CIDR; is unlikely to be repeated nationwide. CIDR will not accept an uploaded file unless certain mandatory fields are completed, and consequently most laboratories are thought to enter case data manually into CIDR on a case by case basis.

This manual intensive process may not impact under-reporting but would have an impact on timeliness of reporting if the volumes of cases suddenly spike and surveillance staff are on leave and the task of notification is then transferred to other busy laboratory staff.

The main deliverable that MedLIS should deliver is a robust data extract query that can be supplied to all 43 HSE and voluntary laboratories. This query needs to extract both mandatory and optional notifiable data from MedLIS in a CSV format which can then be easily manipulated by surveillance staff and uploaded into CIDR with minimal manual data entry. This national database query needs to be fit for purpose, accommodate the CIDR data field specification and must handle the fact that not all laboratories notify on the same tests.

The confidence is quite low currently that the database query will be robust enough, will work across all labs and can be simply customised and maintained as new tests are added to the notifiable list of diseases.

3. What are the data quality issues that exist in the laboratory notification process and how might MedLIS address these issues when it is implemented?

The online survey offered no indication as to the most common data quality issue, but missing referral information was mentioned in two out of the three free-text responses. In a closed survey question, ‘no’ data quality errors was the most ticked option and accounted for 45% of responses with ‘missing clinical notes’ coming in second with two out nine responses.

Illegible handwritten data which features heavily in literature as a data quality error surprisingly only got one tick in the survey response as did erroneous lab results and lab results that are reported as negative (false positive) incorrectly. These three data quality issues were not mentioned, hardly mentioned or dismissed by informants during the interview.

What did feature heavily in the informant interviews but did not come across in the survey was the presence of anonymised patient data and the multiple non-standardised ways of sending order requests into reference laboratories by GPs, clinics and referring hospital laboratories. This, in turn, contributes to ‘missing clinical information’ and ambiguity on what test is requested or should be run based on limited clinical information provided.

Hopkins et al. (2014) states that to enable “surveillance and epidemiological investigations... laboratory reports should include first and last name, data of birth, sex, home address and additional information ... type of specimen (e.g., stool, urine blood), collection date, test performed, and results. Details about the submitting provider (e.g., name and address) are also required” (Hopkins and M'Ikanatha, 2014).

These data fields mentioned by Hopkins are included in the standardised pathology request forms given to GP (Appendix Y) and clinics by hospitals and in the NVRL paper request form as shown in Appendix Z. The underlying reason for missing correct patient identifier data and missing clinical and GP details is the low standard of completion of the order test forms by requestors.

Without a doubt, the survey and informant results indicate that MedLIS will improve data quality errors mainly through the delivery of electronic order communications for both GPs and clinicians in inpatient and outpatient hospital setting. Electronic ordering will include both mandatory and optional data fields in the order entry form (OEF), and clinical details for all microbiology and NVRL orders will be mandatory. NVRL orders, which account for most of the notifiable list of diseases, will include some custom questions to support the NVRL in ensuring the right scope of tests are run on the samples.

However, the anonymised patient data is an issue that MedLIS is unlikely to solve as this anonymisation of data originates from the test requestor and mainly comes from STI clinics that want to protect the privacy of their patients. MedLIS cannot enforce and prevent the entry of anonymised data into the central database.

The inclusion of anonymous data has continuity of care consequences as MedLIS will have no responsibility regarding linking the anonymised data with the real patient's laboratory record, and consequently the patient's complete medical picture will not be available for future care visits and in the case of a medical review.

4. What are the timeliness issues that exist in the laboratory notification process and how might MedLIS address these issues when it is implemented?

An open-ended survey question requesting reasons for preventing a timely notification into Public Health resulted in most respondents citing there is no delay.

This finding that the current notification process has no timeliness issues was validated by the laboratory informants and concludes that routine and urgent cases are all reported in a timely fashion and within HSPS expectations. The only consideration is that there are no HPSC reporting rules for routine cases and so timeliness is not benchmarked and measured. The only HPSC rule is that urgent cases must be reported ‘immediately’ and this is generally done by a telephone call into Public Health as opposed to an immediate notification into CIDR.

Nevertheless, reasons cited for a delay in notifications for those rare cases, include the complexity of case definition and the need to wait for a weekly infection control meeting to confirm that the case meets clinical diagnosis criteria. The complexity of case definition and the requirement to have a clinical diagnosis was the highest scoring reason in the survey and talked about most and in-depth by all laboratory informants.

The key finding is that Ireland’s national surveillance system does not allow for real-time notifications and is therefore passive and is not capable of detecting an outbreak by itself. MedLIS will not solve this issue, and no requirement is submitted to MedLIS to support real-time notifications. This could end up being a missed opportunity when and if, in the future, Ireland does have an outbreak of an infectious disease that is spread rapidly from human to human and has high morbidity rates.

5.3 MedLIS Recommendations and Findings

This section will focus on the researcher's recommendations for MedLIS considering the literature review and primary research. The study aim to “describe and outline and the potential for real-time laboratory-based surveillance in Ireland”, was introduced in the results chapter and will be expanded upon in this section.

Many of the MedLIS solutions and recommendations to overcome issues and improve the notification process has already been discussed above in section 5.2 but will be summarised in this section.

Electronic Order Communications and Standardisation of Ordering Processes

The implementation of electronic order communications towards replacing inpatient and GP paper order requests will go a long way to addressing the data quality issues identified which in turn will impact positively on the completeness of reporting.

The MedLIS project will need to put a lot of effort and time into systematically removing paper requests from all the community patient care settings that place pathology orders. There are nursing homes, prisons, dentists and private clinics that will continue to send in paper orders to HSE and voluntary hospital labs which in turn may have a positive case report and need to be notified into Public Health. These organisations need to use the MedLIS electronic order solution or data quality issues, and transcription errors will continue to exist as they do now.

GPs and these community organisations will be able to continue to send in paper requests to the NVRL directly since the NVRL laboratory will not be replaced by MedLIS and offers no electronic ordering solution. There will be an interface between MedLIS and

the NVRL, but this will not stop GPs and these organisations continuing to send in paper orders and specimens directly to the NVRL.

The MedLIS project should deliver an electronic ordering solution that will make it very easy for GPs and other community organisations to register their patients in MedLIS and order NVRL tests through MedLIS and the national order catalogue. This will streamline and standardise the requesting process into the NVRL which processes most of the notifiable diseases.

There needs to be a minimum patient data set that is mandated by the HSE to allow MedLIS to begin conversations with hospital PAS vendors, GP practice system vendors and other patient registration system vendors to ensure that the same mandatory patient dataset is captured in all healthcare settings. An example of this minimum patient dataset can be seen in figure 5.1 below. See figure 5.1.



Surname	McCarthy
Forename	Patricia
Date of birth	01/01/1970
Place of birth	Cork
Sex	Female
All former surnames	Flaherty
Mothers surname at birth	O'Brien
PPSN - Personal public service number	1234567A
Address	20 New Street, Clonakilty, Co. Cork
Nationality	Irish
Date of death	N/A
Signature	
Photograph	
SAFE Level of Registration	2

Figure 5.1 Patient Dataset Example

This will not only help with an Individual Health Identifier (IHI) match but will help with improving patient data quality within the laboratory notification process and allow for

more automated reporting whether that is via the MedLIS extract query or real-time notifications from MedLIS into CIDR in the future. This will then realise the benefits expected from better data quality and removal of transcription errors

MedLIS Data Mining

The ability to extract laboratory data and more specifically notifiable patient demographic and disease results from the MedLIS database has featured very heavily in the primary research. The research findings suggest that the extraction query that will MedLIS will deliver, will not have any measurable impact on the timeliness of reporting and under-reporting. However, it is very likely to positively impact data quality by removing transcription errors into CIDR and completeness of reporting for optional fields. The MedLIS project and Cerner vendor need to restart their efforts into getting this script to work and to meet usability, customisability and maintenance requirements.

Surveillance scientists should be provided with the tools and means to extract and interrogate laboratory data. Some hospitals labs already offer these capabilities, and the surveillance scientists that work for those labs want MedLIS to be as good as what they have now. Other laboratories probably don't have this type of access and rely on their local LIS vendor to create reports for a fee and are expecting that MedLIS will improve upon this situation.

The demand for management reports and secondary use of national laboratory data will only increase once MedLIS is live. The HSE and each hospital should consider a vendor-neutral data warehouse, as recommended in the literature. This will facilitate data mining without interfering with the live database and will also allow interfacing with other clinical systems such as an EHR or an EPR which in turn could interface with CIDR.

Real-time Laboratory-Based Surveillance in Ireland

The research has shown that there is no potential for real-time notifications of laboratory cases of notifiable infectious diseases into Public Health in Ireland, at least not in the short and medium term.

The international literature review has described all the potential benefits including increasing sensitivity of the surveillance system to identify potential epidemics through timeliness of reporting and other cited benefits such as improved completeness of reporting.

Although there are epidemiological and surveillance benefits to real-time reporting, there is no requirement submitted from Public Health to build an interface between MedLIS and CIDR or any other surveillance application. If the main stakeholder that would benefit from real-time reporting has not requested it, then there is no mandate for MedLIS to build it. It also suggests there are solid reasons why real-time laboratory reporting will not work in the Irish context. This is backed up by literature that states the ELR should not replace traditional provider reporting but should be used in combination with it.

The complexity of the case definitions for different infectious diseases and the lack of standardised reference ranges across the 43 laboratories would make such an interface, in the short term, very complex to implement. This is backed up by the literature which states that automated reporting is not always possible or recommended for more complex diseases.

Nevertheless, a real-time interface between MedLIS and CIDR could be possible in the longer term if CIDR is upgraded to handle the intake of HL7 messages and the case definitions can be simplified to allow for laboratory results only. This could be deployed in addition to the passive surveillance system in place for those more complex case

definitions. Another solution could be to wait for the implementation of either a hospital EPR or a national EHR and create an interface between that system and CIDR as shown in figure 5.2 below. This would allow for the continued reporting of clinical and laboratory data in a single episode and use of existing case definitions.

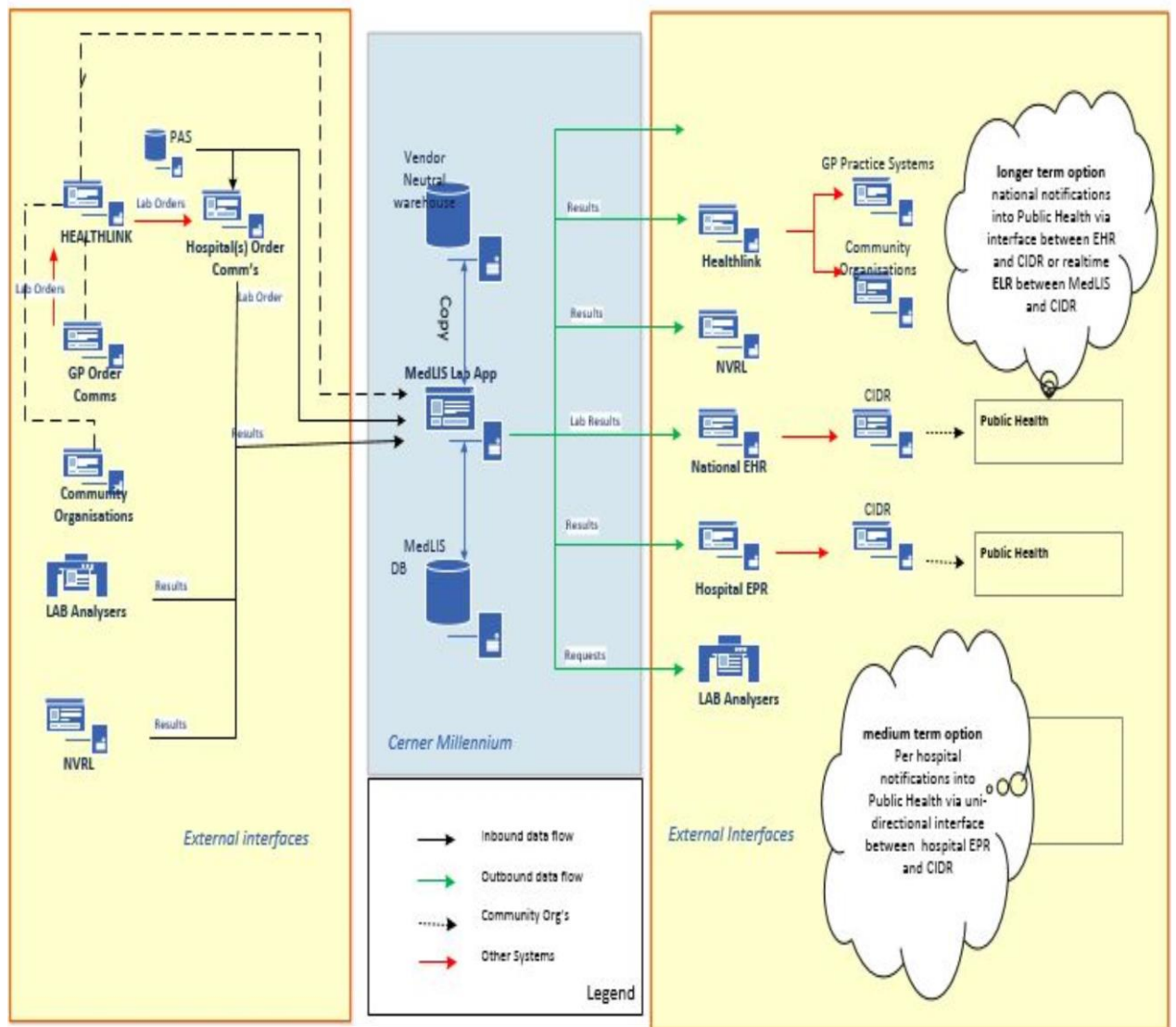


Figure 5.2 MedLIS Future Architecture ELR Options

5.4 Conclusion

The requirements and/or improvement opportunities that MedLIS should consider are:

- Rollout electronic orders communication to all GPs and community organisations that submit pathology requests to public laboratories. The electronic order catalogue should include all NVRL tests, and these organisations should only order NVRL tests via MedLIS which in turn will send the tests to the NVRL directly.
- Deliver a robust data extract query that will accommodate all the CIDR data-set requirements and can be easily and quickly customised and maintained as new tests are added.
- All patient registration systems such as MedLIS, hospital PAS systems and GP practice systems should implement a standard and minimum patient dataset mandated by the HSE.
- MedLIS should accommodate the HSE Policy on anonymised data when that is decided.
- The laboratory surveillance scientists should be given the tools they need to create their surveillance reports. A national surveillance report should be designed and built which can be used by HPSC to cross-reference against CIDR notifications.
- A vendor-neutral warehouse should be implemented at each hospital location to allow for effective data mining using the hospitals own analytical tools. This will remove the reliance on a third-party vendor to create standard and custom reports and pave the way for implementation of an EHR to extract the data from this data warehouse.
- MedLIS should be implemented with the IHI in place which is linked to the correct patient laboratory record. The IHI and MedLIS will pave the way for the

EHR and promote safer use of patient data and sharing of patient data between systems.

- MedLIS should map the order catalogue and pathology tests results to LOINC and SNOMED CT. This is not essential since CIDR maps all tests and results to these terminologies post data upload, but it will pave the way for the creation of surveillance reports generated from MedLIS and the future implementation of an EHR.

Chapter 6 Conclusion and Future Work

6.1 Introduction

This chapter will first summarise the findings of the study under each of research sub-questions. It will describe the strengths and limitations of the study and give recommendations for future research. Finally, the over-arching research question will be answered in the conclusion section.

6.2 Strengths and Limitations of the Study

A mixed-methods research methodology using an online survey followed up by informant interviews with senior laboratory managers, and surveillance scientists brought validation and rigour to the results and description of the laboratory notification process and its inherent issues. MedLIS is not yet implemented, and therefore the informant interviews with the MedLIS staff were invaluable in understanding what MedLIS is likely to deliver to solve the issues identified and brings new information and knowledge that is not yet published.

The main limitation of the study is the fact that the nationwide picture of the laboratory notification process is based on what information could be found on the internet and from a detailed description of the process from interviewees working in only a Dublin and a country hospital. The reality is that the process is most likely different in each laboratory and therefore it is difficult to assess whether MedLIS will improve the current process or not.

6.3 Summary of Findings

Yes, there is sometimes under-reporting of notifiable diseases into Public Health in Ireland. The passive and manual nature of the notification process and the lack of local and nationwide audit reports make it impossible to state there is no under-reporting and impossible to verify how much under-reporting does exist.

The primary research has concluded that the amount of under-reporting of laboratory cases is very low and MedLIS is unlikely to make any sizeable impact on this since there will be no real-time notification interface between MedLIS and CIDR. Also, there is currently no requirement submitted for a national surveillance report that could be used to cross-reference positive laboratory results for notifiable diseases against actual CIDR notifications and in doing so verify where under-reporting exists and introduce process improvements as needed.

The research has concluded that surveillance scientists have easy access to source systems such as their local LIS and PAS. The real issue reported is the reliance on LIS vendors to mine and extract the data from the local LIS and therefore the inability for surveillance scientists to run their queries against the database and run custom reports and extracts.

The assumption is that this problem is nationwide and as a direct result there are multiple manual steps in the laboratory notification process resulting in the need to print out hardcopy laboratory reports and manually transcribe data into CIDR on a case by case basis.

MedLIS has committed to delivering a custom extract query for use across all 43 MedLIS labs that can mine laboratory notification data from the central Oracle database using Cerner's data analytics tool. This extract query, if it works, will greatly improve data

collection for a lot of laboratories and enable them to do batch case upload into CIDR and remove all or most of the manual data entry into CIDR.

There is a vast array of data quality issues in the current notification process but nothing surprising given the largely manual nature of pathology order requests and laboratory to laboratory order and result transfers between Ireland's HSE and voluntary hospital laboratories. Only two voluntary hospitals in Ireland (St James and Mater Public) have in-house electronic order communications, and only three hospitals (St James, Mater Public and Cavan hospitals) have some level of GP electronic order requests via Healthlink which means that the remaining 40 laboratories must rely on paper order processes.

This is important as most of the data quality errors mentioned such as missing clinical and patient data, illegible handwriting, anonymised patient data are all introduced at the very beginning of the order request workflow, mainly via hardcopy request forms from GPs and hospital inpatient wards.

MedLIS will deliver electronic order communications modules for hospital clinicians in the inpatient and outpatient setting and community order requesters such as GPs and hopefully other community organisations such as nursing homes, private clinics etc.

Because timeliness is not measured, there are no timeliness issues reported, and the underlying reasons for rare cases of notification delays are outside of the control of MedLIS. Therefore, there is no role for MedLIS to improve timeliness in the laboratory notification process.

6.4 Recommendations for Future Research

Most of the studies found in the literature compared cases notified into CIDR against hospital HIPE data and registries to form a view and conclusion on the levels of under-reporting of certain diseases into Public Health. These sources of information are unlikely to be completely accurate and are often updated retrospectively. Future studies should compare CIDR notification levels against a national surveillance report or hospital specific report produced from the central MedLIS database instead.

6.5 Reflections on the Study

A factor in the success of this study was the help and assistance of the Surveillance Scientist Association (SSAI) that reviewed and critiqued my survey and published it to all surveillance scientists nationwide on my behalf. This action helped with achieving an almost 30% response.

Another success factor was that the survey was also published to Public Health and HPSC surveillance scientists. These survey participants allowed for more rigorous results as Public Health and HPSC surveillance scientists benefit from, and are the receivers of, laboratory notifications added to CIDR. Therefore, they have sight of data quality and other issues from their perspectives giving a more rounded view.

The only real difficulty was the very broad nature of the research question(s) and the many project aims I set for myself. This made it challenging to structure the results and discussion chapters in a way that answered all the questions, met the aims of the research and did not overly repeat information.

6.6 Conclusion

Can a National Medical Laboratory System (MedLIS) improve the surveillance laboratory notification process of confirmed cases of notifiable infectious diseases into the Department of Public Health in Ireland and if yes, what is needed for this to be achieved?

Yes, MedLIS can improve the laboratory notification process as proven by the primary research results shown against each of the assessment categories. The impact to under-reporting and timeliness of reporting is likely to be minimal given the omission of real-time notifications into Public Health. However, there should be a sizeable positive impact to improving data collection and data quality issues within the process which in turn will improve the completeness of reporting; once MedLIS is implemented across all 43 laboratories.

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Appendices

Appendix A: Title Search Keywords

PUB Med – 75 results-- title and abstract

((((((((((((((((((((((((Infectious Diseases[Title/Abstract]) OR Notifiable Infectious diseases[Title/Abstract]) AND National Laboratory System[Title/Abstract]) OR Laboratory Information System[Title/Abstract]) OR Electronic Lab record[Title/Abstract]) OR Electronic Surveillance System[Title/Abstract]) OR electronic laboratory reporting[Title/Abstract]) OR Laboratory notification[Title/Abstract]) OR Surveillance System[Title/Abstract]) AND Emerging infectious diseases[Title/Abstract]) OR FLU[Title/Abstract]) OR INFLUENZA[Title/Abstract]) OR Meningitis[Title/Abstract]) OR Tuberculosis[Title/Abstract]) OR TB[Title/Abstract]) OR Flu pandemic[Title/Abstract]) OR completeness of reporting[Title/Abstract]) OR under-reporting[Title/Abstract]) OR under-reporting of infectious diseases[Title/Abstract]) OR data collection process issues[Title/Abstract]) OR process issue[Title/Abstract]) OR process opportunities[Title/Abstract]) OR reporting issues[Title/Abstract]) OR notification issues[Title/Abstract] AND under reporting of Tuberculosis[Title/Abstract]) OR under-reporting of flu[Title/Abstract]) OR under-reporting of flu pandemic[Title/Abstract]) OR under-reporting of meningitis[Title/Abstract])

Science Direct – 75 results

"Infectious Diseases" OR "Notifiable Infectious diseases" AND "National Laboratory System" OR "Laboratory Information System" OR "Electronic Lab record" OR "Electronic Surveillance System" OR "electronic laboratory reporting" OR "Laboratory notification" OR "Surveillance System" AND "Emerging infectious diseases" OR FLU OR INFLUENZA OR Meningitis OR Tuberculosis OR TB OR Flu pandemic OR "completeness of reporting" OR under-reporting OR "under-reporting of infectious diseases" OR "data collection process issues" OR "process issues" OR "process opportunities" OR "reporting issues" OR "notification issues" AND "under reporting of Tuberculosis" OR "under-reporting of flu" OR "under-reporting" OR "flu pandemic" OR "under-reporting of meningitis"

Google Scholar – 114 results

allintitle: infectious disease AND OR "Infectious Diseases" OR "Notifiable Infectious diseases" OR "National Laboratory System" OR "Laboratory Information System" OR "Electronic Lab record" "Infectious Disease Surveillance"

The screenshot shows the Google Scholar search interface. The search bar contains the query: "ation System" OR "Electronic Lab record" "Infectious Disease Surveillance". Below the search bar, it indicates "Articles" and "About 114 results (0.22 sec)".

On the left side, there are filters for "Any time", "Since 2018", "Since 2017", "Since 2014", and a "Custom range..." option with a date range from 1998 to 2018. There is also a "Sort by relevance" and "Sort by date" option, and a checkbox for "include patents".

The search results are displayed in a list. The first result is titled "[HTML] Surveillance Sans Frontiers: Internet-based emerging infectious disease intelligence and the HealthMap project" by JS Brownstein, CC Freifeld, BY Reis, KD Mandl, published in PLoS medicine, 2008. It has 294 citations and is available on plos.org. The second result is titled "[HTML] Structure and performance of infectious disease surveillance and response, United Republic of Tanzania, 1998" by P Nsubuga, N Eseko, W Tadesse, published in Bulletin of the World Health Organization, 2002. It has 91 citations and is available on scielosp.org.

Stella Title keyword search- produced 93 results

Infectious Disease reporting or surveillance accuracy OR reporting of infectious diseases or prevalence of infectious diseases or notifiable infectious disease reporting

Advanced Search [Basic Search](#)

t(("Infectious Disease reporting") | ("surveillance accuracy") | ("reporting of infectious diseases") | ("prevel:

Title	▼	"Infectious Disease reporting"	
OR	Title	▼	"surveillance accuracy" X
OR	Title	▼	"reporting of infectious diseases" X
OR	Title	▼	"prevelance of infectious disease reporting" X
OR	Title	▼	"notifiable infectious disease reporting" X

Add boolean:

Year: to

Appendix B: Keyword Search Terms

World Health Organisation Key Word Search

With all words: notifiable infectious diseases notification under-reporting surveillance
laboratory

with the **exact phrase** Infectious Disease surveillance

with at least one the words : "Notifiable Infectious diseases" OR "National Laboratory System"
OR "Laboratory Information System" OR "Electronic Lab record" OR "Electronic Surveillance
System" OR "electronic laboratory reporting" OR "Laboratory notification" OR "Surveillance
System" AND "Emerging infectious diseases" OR FLU OR INFLUENZA OR Meningitis OR
Tuberculosis OR TB OR Flu pandemic OR "completeness of reporting" OR under-reporting OR
"under-reporting of infectious diseases" OR "data collection process issues" OR "process issues"
OR "process opportunities" OR "reporting issues" OR "notification issues" AND "under reporting
of Tuberculosis" OR "under-reporting of flu" OR "under-reporting" OR "flu pandemic" OR "under-
reporting of meningitis"

notifiable infectious diseases notification under-reporting sur

Refine your search

WHO regional sites

[Global](#)

All sites

[Africa](#)

[Americas](#)

[Eastern Mediterranean](#)

[Europe](#)

[South-East Asia](#)

[Western Pacific](#)

Content format

[PDFs \(.pdf\)](#)

[Flash \(.swf\)](#)

Search results

1-10 of 141 results

[Influenza health topic](#)
<http://www.who.int/topics/influenza/en/>

[Tuberculosis health topic](#)
<http://www.who.int/topics/tuberculosis/en/>

[Pandemic \(H1N1\) 2009](#)
<http://www.who.int/csr/disease/swineflu/en/>

Mission report: [↓ pdf](#)
 ... H5N1), cholera, plague) and newly emerging infectious diseases, laboratory confirmation is ... 54 in the reporting of notifiable diseases. ... guidelines is available for five zoonotic diseases. ...
<apps.who.int/iris/bitstream/10665/255037/1/WHO-WHE-CPI-2017.21-eng.pdf> - 682k

Mission report: [↓ pdf](#)
 ... Two electronic notifiable infectious disease reporting systems are in place in Abu Dhabi ... A unified electronic notification system is not ... and ecosystems reduces the risk of diseases at the ...
<apps.who.int/iris/bitstream/10665/259456/1/WHO-WHE-CPI-REP-2017.57-eng.pdf> - 569k

Generic Long Keyword Search – modified slightly depending on database

Infectious Diseases OR “Infectious Disease burden” OR “Notifiable Infectious diseases” OR “Notifiable Infectious disease reporting” OR “Infectious Disease Surveillance” OR “Epidemiology of Infectious Diseases” OR “Epidemiology” OR “Infectious Disease surveillance” OR “Infectious Disease Notification” OR “Infectious Disease Statistics” OR “Public Surveillance” OR “Public Health Surveillance” AND “Computerised Infectious Disease Reporting System” OR CIDR OR “National infectious Disease Surveillance System” OR “national lab system” OR “National Laboratory System” OR “Laboratory Information System” OR LIS OR “Medical Laboratory Information System” OR MedLIS

OR "Electronic Laboratory Record" OR "Electronic Lab record" OR "Surveillance System"
OR "Electronic Surveillance System" OR "Infectious Disease Surveillance System" AND
"Infectious Disease Under-Reporting" OR "Infectious Disease Notification" OR
"accuracy of Infectious Disease Reporting" OR "Infectious Disease Reporting Issues" OR
"Under-Reporting of Infectious Diseases" OR "Occurrence of Infectious Disease
reporting" OR "Infectious Disease Reporting Process Improvements" OR "Process
Improvement Infectious Disease Surveillance" OR "process opportunities" OR "process
issues" OR "Laboratory Legal Notifiers" OR "legal notifiers" OR "legal notification of
Infectious Diseases" OR "Timeliness of Infectious Disease reporting" OR "Completeness
of Infectious Disease reporting" AND "Infectious Disease" OR "Influenza A Virus" OR
H1N1 OR "Influenza outbreak" OR "Emerging Flu pandemic" OR "Emerging Flu" OR "Flu
pandemic" OR "Pandemic Influenza" OR "Re-emergent Flu" OR "Emerging Influenza" OR
"Viral Meningitis" OR "Bacterial Meningitis" OR Meningitis OR Tuberculosis OR TB

Shorter Generic Keyword Search

"Infectious Diseases" OR "Notifiable Infectious diseases" OR "Infectious Disease
surveillance" AND "National Laboratory System" OR "Laboratory Information System"
OR "Electronic Lab record" OR "Electronic Surveillance System" OR "electronic
laboratory reporting" OR "Laboratory notification" OR "Surveillance System" AND
"Emerging infectious diseases" OR FLU OR INFLUENZA OR Meningitis OR Tuberculosis
OR TB

Keyword Search – interchangeable keywords

Infectious Diseases
Infectious Disease burden
Notifiable Infectious Disease
Infectious disease monitoring
Notifiable Infectious disease reporting
Infectious Disease Surveillance
Epidemiology of Infectious Diseases
Infectious Disease Epidemiology
Infectious Disease Notification
Infectious Disease Statistics
Public Surveillance
Public Health Surveillance
Computerised Infectious Disease Reporting System
CIDR
National infectious Disease Surveillance System
National lab system
National laboratory system
Laboratory Information System
Laboratory Notification
Clinical microbiology
Clinical microbiology informatics
Clinical microbiology infectious diseases
LIS
Medical Laboratory Information System
MedLIS
Hospital Electronic Patient Record
EPR

Electronic Medical Record

EMR

Electronic Health Record

EHR

Electronic Laboratory Record

Electronic Lab Record

Surveillance System

Electronic Surveillance System

Infectious Disease Surveillance System

Electronic laboratory reporting

Infectious Disease Under-Reporting

Infectious Disease Notification

Accuracy of Infectious Disease Reporting

Infectious Disease Reporting Issues

Infectious Disease Process Reporting Issues

Under-Reporting of Infectious Diseases

Occurrence of Infectious Disease reporting

Infectious Disease Reporting Process Improvements

Process Improvement Infectious Disease Surveillance

Laboratory Legal Notifiers of Infectious Diseases

Timeliness of Infectious Disease reporting

Completeness of Infectious Disease reporting

notifiable infectious disease reporting

Appendix C: EndNote Reference Groups and Number of References

EndNote™ basic My References Collect Organize

Manage My Groups

Manage My Groups

My Groups↑	Number of References
EMR	7
epidemiology	6
Infec Diseases Stats Methods	5
Infectious Diseases	20
Influenza	19
Interoperability	6
LIS	37
meningitis	16
methodology	21
Notification Process and Guidelines	5
surveillance systems	21
TB	11

[New group](#)

Appendix D: List of Notifiable Diseases in Ireland

Notifiable Diseases and their respective causative pathogens		Notifiable Diseases and their respective causative pathogens	
specified to be Infectious Diseases under Infectious Diseases (Amendment) Regulations 2016 (S.I. No. 276 of 2016) (May 2016)		specified to be Infectious Diseases under Infectious Diseases (Amendment) Regulations 2016 (S.I. No. 276 of 2016) (May 2016)	
Disease	Causative Pathogen	Disease	Causative Pathogen
Acute anterior poliomyelitis	Polio virus	Measles	Measles virus
Ano-genital warts	Human papilloma virus	Meningococcal disease	<i>Neisseria meningitidis</i>
Anthrax	<i>Bacillus anthracis</i>	Mumps	Mumps virus
<i>Bacillus cereus</i> food-borne infection/intoxication	<i>Bacillus cereus</i>	Non-specific urethritis	
Bacterial meningitis (not otherwise specified)		Noroviral infection	Norovirus
Botulism	<i>Clostridium botulinum</i>	Paratyphoid	<i>Salmonella</i> Paratyphi
Brucellosis	<i>Brucella</i> spp.	Pertussis	<i>Bordetella pertussis</i>
<i>Campylobacter</i> infection	<i>Campylobacter</i> spp.	Plague	<i>Yersinia pestis</i>
Carbapenem-resistant <i>Enterobacteriaceae</i> infection (invasive)	Carbapenem-resistant <i>Enterobacteriaceae</i> (blood, CSF or other normally sterile site)	<i>Pseudomonas aeruginosa</i> infection (invasive)	<i>Pseudomonas aeruginosa</i> (blood or CSF)
Chancroid	<i>Haemophilus ducreyi</i>	Q Fever	<i>Coxiella burnetii</i>
Chickenpox – hospitalised cases	Varicella-zoster virus	Rabies	Rabies virus
Chikungunya disease	Chikungunya virus	Respiratory syncytial virus infection	Respiratory syncytial virus
<i>Chlamydia trachomatis</i> infection (genital)	<i>Chlamydia trachomatis</i>	Rotavirus infection	Rotavirus
Cholera	<i>Vibrio cholerae</i>	Rubella	Rubella virus
<i>Clostridium difficile</i> infection	<i>Clostridium difficile</i>	Salmonellosis	<i>Salmonella</i> spp. other than <i>S. Typhi</i> and <i>S. Paratyphi</i>
<i>Clostridium perfringens</i> (type A) food-borne disease	<i>Clostridium perfringens</i>	Severe Acute Respiratory Syndrome (SARS)	SARS-associated coronavirus
Creutzfeldt Jakob disease		Shigellosis	<i>Shigella</i> spp.
variant Creutzfeldt Jakob disease		Smallpox	Variola virus
Cryptosporidiosis	<i>Cryptosporidium parvum, hominis</i>	Staphylococcal food poisoning	Enterotoxigenic <i>Staphylococcus aureus</i>
Cytomegalovirus infection (congenital)	Cytomegalovirus	<i>Staphylococcus aureus</i> bacteraemia	<i>Staphylococcus aureus</i> (blood)
Dengue fever	Dengue virus	Streptococcus group A infection (invasive)	<i>Streptococcus pyogenes</i> (blood, CSF or other normally sterile site)
Diphtheria	<i>Corynebacterium diphtheriae</i> or <i>ulcerans</i> (toxin producing)	Streptococcus group B infection (invasive)	<i>Streptococcus agalactiae</i> (blood, CSF or other normally sterile site)
Echinococcosis	<i>Echinococcus</i> spp.	Streptococcus pneumoniae infection (invasive)	<i>Streptococcus pneumoniae</i> (blood, CSF or other normally sterile site)
Enterococcal bacteraemia	<i>Enterococcus</i> spp. (blood)	Syphilis	<i>Treponema pallidum</i>
<i>Escherichia coli</i> infection (invasive)	<i>Escherichia coli</i> (blood, CSF)	Tetanus	<i>Clostridium tetani</i>
Giardiasis	<i>Giardia lamblia</i>	Toxoplasmosis	<i>Toxoplasma gondii</i>
Gonorrhoea	<i>Neisseria gonorrhoeae</i>	Trichinosis	<i>Trichinella</i> spp.
Granuloma inguinale	<i>Klebsiella granulomatis</i>	Trichomoniasis	<i>Trichomonas vaginalis</i>
<i>Haemophilus influenzae</i> disease (invasive)	<i>Haemophilus influenzae</i> (blood, CSF or other normally sterile site)	Tuberculosis	<i>Mycobacterium tuberculosis</i> complex
Hepatitis A (acute) infection	Hepatitis A virus	Tularemia	<i>Francisella tularensis</i>
Hepatitis B (acute and chronic) infection	Hepatitis B virus	Typhoid	<i>Salmonella Typhi</i>
Hepatitis C infection	Hepatitis C virus	Typhus	<i>Rickettsia prowazekii</i>
Hepatitis E infection	Hepatitis E virus	Verotoxigenic <i>Escherichia coli</i> infection	Verotoxin producing <i>Escherichia coli</i>
Herpes simplex (genital)	Herpes simplex virus	Viral encephalitis	
Human immunodeficiency virus infection	Human immunodeficiency virus	Viral haemorrhagic fevers	
Influenza	Influenza A and B virus	Viral meningitis	
<i>Klebsiella pneumoniae</i> infection (invasive)	<i>Klebsiella pneumoniae</i> (blood or CSF)	West Nile fever	West Nile virus
Legionellosis	<i>Legionella</i> spp.	Yellow fever	Yellow fever virus
Leprosy	<i>Mycobacterium leprae</i>	Yersiniosis	<i>Yersinia enterocolitica, Yersinia pseudotuberculosis</i>
Leptospirosis	<i>Leptospira</i> spp.	Zika virus infection	Zika virus
Listeriosis	<i>Listeria monocytogenes</i>		
Lyme disease (neuroborreliosis)	<i>Borrelia burgdorferi</i>		
Lymphogranuloma venereum	<i>Chlamydia trachomatis</i>		
Malaria	<i>Plasmodium falciparum, vivax, knowlesi, ovale, malariae</i>		

Please refer to the case definitions for the above diseases. The up-to-date list of diseases and case definitions are available on the HPSC website at www.hpsc.ie/notifiablediseases

Surveillance Scientists

Start of Block: Default Question Block

Q1 I would like to invite you to participate in this research, which is being undertaken as part of the requirements for an MSc in Health Informatics at Trinity College Dublin. I am conducting this research on my own behalf for the purposes of my studies at TCD, and not on or behalf of my employer, HSE and the MedLIS project that I am currently working on.

Research Question: I have undertaken to complete a dissertation on:

An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve laboratory surveillance of notifiable infectious diseases in Ireland.

What is this research about?

This research aims to investigate the data collection challenges, data quality issues and under-reporting issues that exist within the current laboratory notification process of notifiable infectious diseases in Ireland. This research seeks to answer what can be gained from a National Medical Laboratory System (MedLIS) to improve the surveillance laboratory notification process of confirmed cases of notifiable infectious diseases into the Department of Public Health in Ireland. This study will focus on confirmed laboratory notification cases for viral meningitis, tuberculosis and emerging and re-emerging Influenza.

Why was I chosen to take part?

You have been chosen based on your current role working for the CIDR team, Department of Public Health and your expert knowledge of the infectious disease notification process and inherent data quality issues. Your views and insights will be sought on identifying data collection issues, data quality issues and under-reporting issues and their underlying root causes and what solutions you expect to see from MedLIS to improve the notification process and reduce those issues identified.

What is involved?

If you chose to participate, you will be invited to take an online questionnaire that will take from five to ten minutes approximately and contains 11 questions in total of which two are related to consent.

The answers you provide will be summarised and included in my dissertation and I may quote your responses directly in the body of my document with your consent. Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised.

Participation in this research will be voluntary and you may refuse to answer any question and may withdraw at any time without penalty. Permission from your employer will be sought first to carry out the questionnaire. In the unlikely event, illicit activity is reported to me during the study, I will be obliged to report it to appropriate authorities.

Is the research confidential?

In accordance to the Data Protection Act, the data will be stored securely and appropriately. The final dissertation will be submitted to the examination board at Trinity College and, if successful, will be posted on TCD's Intranet website for future reference by students and academic staff. Your answers to the questionnaire is anonymous in the sense that the researcher will not know from whom the answer came from. Your participation is not fully anonymous as your title (i.e. Surveillance Scientist) and organisation you work for (i.e. Department of Public Health) will be mentioned to give context to the data, and in doing so, you could be identifiable. However, no personal details or specific hospital names that may work with will be mentioned.

Where can I get further information?

If you need any further information now or at any time in the future, please contact:

Adrena Keating at 0873490520 or keatinad@tcd.ie

Yes (1)

No (2)

Display This Question:

*If I would like to invite you to participate in this research, which is being undertaken as part of... =
Yes*

Q2 What is your Surveillance Scientist position type?

- Public Health (1)
- Laboratory (2)
- Reference Laboratory (3)
- HPSC (4)

Display This Question:

*If I would like to invite you to participate in this research, which is being undertaken as part of... =
Yes*

Q3 Do you believe there to be under-reporting of laboratory confirmed cases of notifiable infectious diseases into the Department of Public Health?

- Always (1)
- Most of the time (2)
- About half the time (3)
- Sometimes (4)
- Never (5)

Display This Question:

*If I would like to invite you to participate in this research, which is being undertaken as part of... =
Yes*

Q4 What may contribute to under-reporting of laboratory confirmed of notifiable infectious diseases? Tick all that apply

- Insufficient surveillance staff to report cases (1)
 - Inconsistent communication of laboratory results for confirmed cases to surveillance staff (2)
 - Lack of easy access to laboratory data to report the confirmed case (3)
 - Other, please specify (4)
-

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

Q5 Previous research studies have found under-reporting of viral meningitis in Ireland. Why do you think this under-reporting occurs?

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

And What is your Surveillance Scientist position type? = Laboratory

Or What is your Surveillance Scientist position type? = Reference Laboratory

Q6 What data quality errors, if any, do you regularly encounter when collating appropriate data for notification into the Department of Public Health? Tick all that apply

- Missing patient demographic data (73)
 - Erroneous/inconsistent laboratory data about the test result (74)
 - Missing needed clinical notes from attending clinicians (75)
 - False positive lab result (76)
 - Illegible handwritten data (77)
 - Correct lab result but for incorrect patient (78)
 - Other, please specify (79)
 - None (80)
 - Not Applicable to my role (81)
-

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

And What is your Surveillance Scientist position type? = Laboratory

Or What is your Surveillance Scientist position type? = Reference Laboratory

Q7 What do you think is the most common data quality error? Please elaborate on underlying reason for issue if known

Display This Question:

*If I would like to invite you to participate in this research, which is being undertaken as part of... =
Yes*

And What is your Surveillance Scientist position type? = Laboratory

Or What is your Surveillance Scientist position type? = Reference Laboratory

Q8 What sources of information do you have easy access to in order to collate the relevant data and raise a confirmed case of a notifiable infectious disease into Department of Public Health? For each source, please select Yes, No or Not applicable

	Yes (1)	No (2)	Not applicable (3)
Own access to Laboratory Information System (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hardcopy Laboratory reports only (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Electronic Patient Record (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Own access to clinical portal that stores lab results (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paper Medical Records (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient Administration System (PAS) (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

And What is your Surveillance Scientist position type? = Laboratory

Or What is your Surveillance Scientist position type? = Reference Laboratory

Q9 Do you agree or disagree that you have easy access to laboratory results data that you need in order to raise a confirmed case of a notifiable infectious disease in the Department of Public Health?

- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)
- Not applicable to my role (6)

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

And What is your Surveillance Scientist position type? = Laboratory

Or What is your Surveillance Scientist position type? = Reference Laboratory

Q10 What prevents you from raising timely routine cases of notifiable infectious diseases into the Department of Public Health?

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

Q11 What do you hope to gain from the implementation of a national medical laboratory information system (MedLIS) to help you in your role?

Display This Question:

If I would like to invite you to participate in this research, which is being undertaken as part of... = Yes

Q12 Do you consent to submit these answers? Once these answers are submitted, they cannot be withdrawn as this survey is anonymous and I will not know which answers are yours.

- Yes (1)

- Exit without submitting answers (2)

Display This Question:

If Do you consent to submit these answers? Once these answers are submitted, they cannot be withdraw... = Yes

Q13 Thank you for taking the time to complete this survey. Your answers have been recorded.

Display This Question:

If Do you consent to submit these answers? Once these answers are submitted, they cannot be withdraw... = Exit without submitting answers

Q14 Thank you. Your decision to not submit your answers has been recorded.

End of Block: Default Question Block

Appendix F: Trinity Ethics Approval

----- Forwarded message -----

From: <rec-app-help@tchpc.tcd.ie>

Date: Thu 19 Apr 2018 at 13:01

Subject: TCD REC WebApp: The status of 'An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve the surveillance of notifiable infectious diseases in Ireland' (445) has been updated by the Committee

To: <keatimad@tcd.ie>

The status of 'An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve the surveillance of notifiable infectious diseases in Ireland' has been updated by the Committee.

Title: 'An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve the surveillance of notifiable infectious diseases in Ireland'

Applicant Name: Adrena Keating

Submitted by: Adrena Keating

Academic Supervisor: Lucy Hederman

Application Number: 20180301

Result of the REC Meeting: Approved

The Feedback from the Committee is as follows:

All issues have been addressed, we wish you the best with your study.

The application can be viewed here:

https://webhost.tchpc.tcd.ie/research_ethics/?q=node/445

If amendments are required, please use the following link to edit the application and upload the changes:

https://webhost.tchpc.tcd.ie/research_ethics/?q=node/445/edit

Appendix G: MedLIS Project Manager Ethics Approval

MedLIS Project Manager- Overall Ethics Approval

TRINITY COLLEGE DUBLIN
ETHICAL APPROVAL FORM FOR MEDLIS PROJECT MANAGER and CLINICAL
DIRECTOR

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver.

ETHICAL QUESTIONS AND ANSWERS

<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)?		No
Will your project involve photographing participants or electronic audio or		No
Will your project deliberately involve misleading participants in any way?		No
Does this study contain commercially sensitive material?		No
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).		No
Does your study involve any of the following?	Children (under 18 years of	No
	People with intellectual or communication difficulties	No
	Patients	No

PROCEDURES OF THIS STUDY:

Semi-structured interviews of approximately 40 minutes will take place over the phone or in person to gain insight into the views of key informants whom have working knowledge of the laboratory notification process of notifiable infectious diseases. Key Informant interviews include Chief Medical Scientist from two hospitals, Surveillance Scientist from two hospitals, CIDR Team, NVRL Team, HPSC, MedLIS project manager and staff. Participation in this research will be voluntary and participants may refuse to answer any question and may

withdraw at any time without penalty. Employer consent will first be sought from Department of Public Health, CIDR, NVRL, HSPC and MedLIS organisations. With permission from the participants, meeting notes will be made with the main points summarised and quotes transcribed to text accordingly. An online questionnaire will be sent to all surveillance scientists working in HSE and voluntary hospitals with prior employer consent from CIDR. The questionnaire can be found at:
https://scssted.eu.qualtrics.com/jfe/preview/SV_eeOZBLoyFC90MQZ?Q_CHL=preview


In accordance with the Data Protection Act, the data will be stored securely and appropriately. All participants will be given a participant information sheet which will ensure the participants in the research are fully informed. Participants will also be asked to sign an 'informed consent form' that includes a note that states that permission has been obtained from the participant's employer to carry out the interview.

PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

MedLIS PROJECT MANAGER NAME: Miriam Griffin, National Clinical Director & Project Manager, MedLIS Programme

ORGANISATION NAME: MedLIS Programme, Health Service Executive

SIGNATURE:  X
DATE: 31/05/2018

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that my employer/MedLIS project manager understands my explanation and has freely given informed consent and overall ethics approval to proceed with the study.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating email: keatinad@tcd.ie Telephone: 087 - 3490520

INVESTIGATOR'S SIGNATURE: 
DATE: 31/5/18

Appendix H: SSAI Employer Approval

SURVEILLANCE SCIENTIST ASSOCIATION CONSENT FORM

TRINITY COLLEGE DUBLIN CONSENT FORM TO SEND SURVEY TO SURVEILLANCE SCIENTISTS

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver.

PROCEDURES OF THIS STUDY:

An online questionnaire that will take from five to ten minutes approximately and contains 12 questions in total of which two are related to consent. Therefore the participant consent is part of the online questionnaire and there is an opportunity at the beginning and end of the survey to agree or not agree to take part and a consent question at the end relating to submission of answers

The answers provided will be summarised and included in my dissertation and if appropriate some quotes will be added directly to the body of my document with your consent.

Participation in this research is voluntary and participants may refuse to answer any question and may withdraw at any time without penalty.

In accordance with the Data Protection Act, the data will be stored securely and appropriately. All participants will be given a participant information sheet which will ensure the participants in the research are fully informed.


PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

DECLARATION

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my employees' data is used for scientific purposes and I have no objection that this data is published in scientific publications in a way that does not reveal their personal identity but does mention their title and organization they work in.
- I understand that if my employees make illicit activities known, these will be reported to appropriate authorities.
- I understand that my employees may stop at any time, and that at any time, even subsequent to their participation have such electronic field notes destroyed (except in situations such as above).
- I freely and voluntarily agree to my employees being part of this research study, though without prejudice to my legal and ethical rights.
- I understand that my employees may refuse to answer any question and may withdraw at any time without penalty.
- I have received a copy of this agreement.

AUTHORISED CONSENT NAME: MARRITA MAHON

SIGNATURE: 

ORGANISATION NAME: SSAI Committee

DATE: 01/05/18

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the employer understands my explanation and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating

email: keatinad@tcd.ie

Telephone: 087 - 3490520

RESEARCHERS SIGNATURE: 

DATE: 21/5/18

Appendix I: NVRL Employer Approval

NVRL CONSENT FORM

TRINITY COLLEGE DUBLIN
INFORMED CONSENT FORM FOR EMPLOYER TO INTERVIEW

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver.

PROCEDURES OF THIS STUDY:

Semi-structured interviews of approximately 40 minutes will take place over the phone or in person to gain insight into the views of key informants whom have working knowledge of the laboratory notification process of notifiable infectious diseases. Participation in this research will be voluntary and participants may refuse to answer any question and may withdraw at any time without penalty. With permission from the participants, meeting notes will be made with the main points summarised and quotes transcribed to text accordingly. In accordance with the Data Protection Act, the data will be stored securely and appropriately. All participants will be given a participant information sheet which will ensure the participants in the research are fully informed. Participants will also be asked to sign an 'informed consent form' that includes a note that states that permission has been obtained from the participant's employer to carry out the interview.

PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

DECLARATION

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my employees' data is used for scientific purposes and I have no objection that this data is published in scientific publications in a way that does not reveal their personal identity but does mention their title and organization they work in.
- I understand that if my employees make illicit activities known, these will be reported to appropriate authorities.
- I understand that my employees may stop at any time, and that at any time, even subsequent to their participation have such electronic field notes destroyed (except in situations such as above).
- I freely and voluntarily agree to my employees being part of this research study, though without prejudice to my legal and ethical rights.
- I understand that my employees may refuse to answer any question and may withdraw at any time without penalty.
- I have received a copy of this agreement.

EMPLOYER NAME: *Coastal Resources Ltd*

ORGANISATION NAME: NVRL *North West River Lough*

EMPLOYER SIGNATURE: *[Signature]*

DATE: *31/5/18*

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the employer understands my explanation and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating

email: keatinad@ted.ie

Telephone: 087 - 3490520

INVESTIGATOR'S SIGNATURE: *Adrena Keating*

DATE: *31/5/18*

Appendix J: Online Survey Information Sheet and Consent Form

Information Sheet

Online Questionnaire Information Sheet (Surveillance Scientist)

Re: MSc in Health Informatics – Online Questionnaire for Dissertation

Dear Surveillance Scientist,

I would like to invite you to participate in this research, which is being undertaken as part of the requirements for an MSc in Health Informatics at Trinity College Dublin. I am conducting this research on my own behalf for the purposes of my studies at TCD, and not on or behalf of my employer, HSE and the MedLIS project that I am currently working on.

Research Question: I have undertaken to complete a dissertation on:

An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve laboratory surveillance of notifiable infectious diseases in Ireland.

What is this research about?

This research aims to investigate the data collection challenges, data quality issues and under-reporting issues that exist within the current laboratory notification process of notifiable infectious diseases in Ireland. This research seeks to answer what can be gained from a National Medical Laboratory System (MedLIS) to improve the surveillance laboratory notification process of confirmed cases of notifiable infectious diseases into the Department of Public Health in Ireland. This study will focus on confirmed laboratory notification cases for viral meningitis, tuberculosis and emerging and re-emerging Influenza.

Why was I chosen to take part?

You have been chosen based on your current role working for Department of Public Health and your expert knowledge of the infectious disease process and inherent data quality issues. Your views and insights will be sought on identifying data collection issues, data quality issues and under-reporting issues and their underlying root causes and what solutions you expect to see from MedLIS to improve the notification process and reduce those issues identified.

What is involved?

If you chose to participate, you will be invited to take an online questionnaire that will take from five to ten minutes approximately and contains 12 questions in total of which two are related to consent. If you are public health or HPSC surveillance scientist the number of questions will be less and will not include notification type questions.

The answers you provide will be summarised and included in my dissertation and I may quote your responses directly in the body of my document but no personal details nor the hospital that you work with will be mentioned, only your surveillance scientist role and type.

Participation in this research will be voluntary and you may refuse to answer any question and may withdraw at any time without penalty. Permission from your employer will be sought first to carry out the questionnaire. In the unlikely event, illicit activity is reported to me during the study, I will be obliged to report it to appropriate authorities.

Is the research confidential?

In accordance to the Data Protection Act, the data will be stored securely and appropriately. The final dissertation will be submitted to the examination board at Trinity College and, if successful, will be posted on TCD's Intranet website for future reference by students and academic staff. Your answers to the questionnaire are anonymous in the sense that the researcher will not know from whom the answer came from. Your participation is not fully anonymous as your title (i.e. Surveillance Scientist) and organisation you work for (i.e. Department of Public Health) will be mentioned to give context to the data and in doing so, you could be identifiable. However, no personal details or specific hospital names that you work with will be mentioned.

Where can I get further information?

If you need any further information now or at any time in the future, please contact:
Adrena Keating at 0873490520 or keatinad@tcd.ie

Sincerely


Adrena Keating

TRINITY COLLEGE DUBLIN
ONLINE QUESTIONNAIRE INFORMED CONSENT FORM

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver and the future of electronic laboratory reporting.

PROCEDURES OF THIS STUDY:

Participation in this research is voluntary and participants may refuse to answer any question. Permission has been sought from the Surveillance Scientist Association to carry out the survey. Your consent is requested at the beginning and end of the online questionnaire, this document is just for information purposes. In accordance with the Data Protection Act, the data will be stored securely and appropriately.

PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

DECLARATION

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.

- I understand that I may stop at any time, and that I may at any time, even subsequent to my participation have such electronic field notes destroyed (except in situations such as above).
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I have received a copy of this agreement.

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation, and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating

email: keatinad@tcd.ie

Telephone: 087 - 3490520

INVESTIGATOR'S SIGNATURE: 

DATE: 30/4/2018

Appendix K: Hospital Laboratory Staff Information Sheet and Consent Form

Key Informant Information Sheet (Surveillance Scientist)

Re: MSc in Health Informatics – Key informant Interview for Dissertation

Dear [Name],

I would like to invite you to participate in this research, which is being undertaken as part of the requirements for an MSc in Health Informatics at Trinity College Dublin. I am conducting this research on my own behalf for the purposes of my studies at TCD, and not on or behalf of my employer, HSE and the MedLIS project that I am currently working on.

Research Question: I have undertaken to complete a dissertation on:

An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve laboratory surveillance of notifiable infectious diseases in Ireland.

What is this research about?

This research aims to investigate the data collection challenges, data quality issues and under-reporting issues that exist within the current laboratory notification process of notifiable infectious diseases in Ireland. This research seeks to answer what can be gained from a National Medical Laboratory System (MedLIS) to improve the surveillance laboratory notification process of confirmed cases of notifiable infectious diseases into the Department of Public Health in Ireland. This study will focus on confirmed laboratory notification cases for viral meningitis, tuberculosis and emerging and re-emerging Influenza.

Why was I chosen to take part?

You have been chosen based on your current role working for the CIDR team, Department of Public Health and your expert knowledge of the infectious disease notification process and inherent data quality issues. Your organisations views and insights will be sought on identifying data collection issues, data quality issues and under-reporting issues and their underlying root causes and what solutions you expect to see from MedLIS to improve the notification process and reduce those issues identified.

What is involved?

If you chose to participate, you will be invited to take part in a semi-structured interview that

will last approximately 40 minutes in a location that is convenient to you or over the phone depending on your availability. The questions will be sent to you in advance of the interview. With permission, field notes will be made and then transcribed to text accordingly. There will be no audio recordings made of the meeting.

The answers you provide will be summarised and included in my dissertation and I may quote your responses directly in the body of my document with your consent. Before submitting the final document for examination, I will provide you with a copy of the appropriate section for final review and will make any required changes based on your feedback.

Participation in this research will be voluntary and you may refuse to answer any question and may withdraw at any time without penalty. Permission from your employer will be sought first to carry out the interview. In the unlikely event, illicit activity is reported to me during the study, I will be obliged to report it to appropriate authorities.

Is the research confidential?

In accordance to the Data Protection Act, the data will be stored securely and appropriately. The final dissertation will be submitted to the examination board at Trinity College and, if successful, will be posted on TCD's Intranet website for future reference by students and academic staff. Your participation is not fully anonymous as your title (i.e. Surveillance Scientist) and organisation you work for (i.e. Department of Public Health) will be mentioned to give context to the data, and in doing so, you could be identifiable. However, no personal details or specific hospital names that may work with will be recorded.

Where can I get further information?

If you need any further information now or at any time in the future, please contact:
Adrena Keating at 0873490520 or keatinad@tcd.ie

Please can you confirm by return email if you are willing to participate in the interview?

Sincerely

Adrena Keating

TRINITY COLLEGE DUBLIN
INTERVIEWEE INFORMED CONSENT FORM FOR OWN VIEWS AND INSIGHTS

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver and the future of electronic laboratory reporting.

PROCEDURES OF THIS STUDY:

Semi-structured interviews of approximately 40 minutes will be conducted in person or over the phone depending on availability to gain insight into the views of key informants. These are the views of the individual and not those of the organisation that the informant works in. Participation in this research is voluntary and participants may refuse to answer any question and may withdraw at any time without penalty. With permission from the participants, meeting notes will be made and summarised and then transcribed to text accordingly. In accordance with the Data Protection Act, the data will be stored securely and appropriately. All participants will be given a participant information sheet which will ensure the participants in the research are fully informed.

PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

DECLARATION

- I am 18 years or older and am competent to provide consent.
 - I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
 - I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
-

- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may stop at any time, and that I may at any time, even subsequent to my participation have such electronic field notes destroyed (except in situations such as above).
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I have received a copy of this agreement.

PARTICIPANT'S NAME : *Adrena Keating*

PARTICIPANT'S SIGNATURE : *Adrena Keating*

DATE : 18/05/2018

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation, and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating email: keatinad@tcd.ie Telephone: 087 - 3490520

INVESTIGATOR'S SIGNATURE: *Adrena Keating*

DATE: 18/05/18

Appendix L: NVRL Lab Manager Information Sheet and Consent Form

Key Informant Information Sheet (NVRL)

Re: MSc in Health Informatics – Key informant Interview for Dissertation

Dear **Dr. [Name]**,

I would like to invite you to participate in this research, which is being undertaken as part of the requirements for an MSc in Health Informatics at Trinity College Dublin. I am conducting this research on my own behalf for the purposes of my studies at TCD, and not on or behalf of my employer, HSE and the MedLIS project that I am currently working on.

Research Question: I have undertaken to complete a dissertation on:

An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve laboratory surveillance of notifiable infectious diseases in Ireland.

What is this research about?

This research aims to investigate the data collection challenges, data quality issues and under-reporting issues that exist within the current laboratory notification process of notifiable infectious diseases in Ireland. This research seeks to answer what can be gained from a National Medical Laboratory System (MedLIS) to improve the laboratory notification process of confirmed cases of notifiable infectious diseases into the Department of Public Health in Ireland. This study will focus on confirmed laboratory notification cases for viral meningitis, tuberculosis and emerging and re-emerging Influenza.

Why was I chosen to take part?

You have been chosen based on your current role working for the National Virus Reference Lab (NVRL) and your expert knowledge of the infectious disease notification process and inherent data quality issues. Your views and insights will be sought on identifying data collection issues, data quality issues and under-reporting issues and their underlying root causes from NVRL's perspective and what solutions you expect to see from MedLIS to improve the notification process and reduce those issues identified.

What is involved?

If you chose to participate, you will be invited to take part in a semi-structured interview that

depending on your availability. The questions will be sent to you in advance of the interview. With permission, field notes will be made and then transcribed to text accordingly. There will be no audio recordings made of the meeting.

The answers you provide will be summarised and included in my dissertation and I may quote your responses directly in the body of my document with your consent. Before submitting the final document for examination, I will provide you with a copy of the appropriate section for final review and will make any required changes based on your feedback.

Participation in this research will be voluntary and you may refuse to answer any question and may withdraw at any time without penalty. Permission from your employer will be sought first to carry out the interview. In the unlikely event, illicit activity is reported to me during the study, I will be obliged to report it to appropriate authorities.

Is the research confidential?

In accordance to the Data Protection Act, the data will be stored securely and appropriately. The final dissertation will be submitted to the examination board at Trinity College and, if successful, will be posted on TCD's Intranet website for future reference by students and academic staff. Your participation is not fully anonymous as your title and organisation you work for (i.e. NVRL) will be mentioned to give context to the data and in doing so, you could be identifiable. However, no personal details or specific hospital names that you work with will be mentioned.


Where can I get further information?

If you need any further information now or at any time in the future, please contact:

Adrena Keating at 0873490520 or keatinad@tcd.ie

Please can you confirm by return email if you are willing to participate in the interview?

Sincerely


Adrena Keating

TRINITY COLLEGE DUBLIN
INTERVIEWEE INFORMED CONSENT FORM FOR OWN VIEWS AND INSIGHTS

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver and the future of electronic laboratory reporting.

PROCEDURES OF THIS STUDY:

Semi-structured interviews of approximately 40 minutes will be conducted in person or over the phone depending on availability to gain insight into the views of key informants. These are the views of the individual and not those of the organisation that the informant works in. Participation in this research is voluntary and participants may refuse to answer any question and may withdraw at any time without penalty. With permission from the participants, meeting notes will be made and summarised and then transcribed to text accordingly. In accordance with the Data Protection Act, the data will be stored securely and appropriately. All participants will be given a participant information sheet which will ensure the participants in the research are fully informed.

PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

DECLARATION

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.

-
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
 - I understand that I may stop at any time, and that I may at any time, even subsequent to my participation have such electronic field notes destroyed (except in situations such as above).
 - I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
 - I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
 - I have received a copy of this agreement.

PARTICIPANT'S NAME : Deirdre Burke

PARTICIPANT'S SIGNATURE : 

DATE : 17/05/2018

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation, and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating

email: keatinad@tcd.ie

Telephone: 087 - 3490520

INVESTIGATOR'S SIGNATURE: 

DATE: 17/05/2018

Appendix M: MedLIS Staff Information Sheet and Consent Form

Organisation Key Informant Information Sheet (MedLIS)

Re: MSc in Health Informatics – Key informant Interview for Dissertation

Dear _____,

I would like to invite you to participate in this research, which is being undertaken as part of the requirements for an MSc in Health Informatics at Trinity College Dublin. I am conducting this research on my own behalf for the purposes of my studies at TCD, and not on or behalf of my employer, HSE and the MedLIS project that I am currently working on.

Research Question: I have undertaken to complete a dissertation on:

An analysis of whether and how a National Medical Laboratory System (MedLIS) can improve laboratory surveillance of notifiable infectious diseases in Ireland.

What is this research about?

This research aims to investigate the data collection challenges, data quality issues and under-reporting issues that exist within the current laboratory notification process of notifiable infectious diseases in Ireland. This research seeks to answer what can be gained from a National Medical Laboratory System (MedLIS) to improve the laboratory notification process of confirmed cases of notifiable infectious diseases into the Department of Public Health in Ireland. This study will focus on confirmed laboratory notification cases for viral meningitis, tuberculosis and emerging and re-emerging Influenza.

Why was I chosen to take part?

You have been chosen based on your current role working for the MedLIS project and your previous laboratory background. Your views and insights will be sought on analysing the data collection, data quality and under-reporting issues identified by primary and secondary research and what solutions MedLIS can provide to improve the notification process and reduce those issues identified.

What is involved?

If you chose to participate, you will be invited to take part in a semi-structured interview that will last approximately 40 – 60 minutes in a location that is convenient to you. The questions will be sent to you in advance of the interview. With permission, field notes will be made and then transcribed to text accordingly. There will be no audio recordings made of the meeting.

The answers you provide will be summarised and included in my dissertation and I may quote your responses directly in the body of my document with your consent. Before submitting the final document for examination, I will provide you with a copy of the appropriate section for final review and will make any required changes based on your feedback.

Participation in this research will be voluntary and you may refuse to answer any question and may withdraw at any time without penalty. Permission from the MedLIS project manager will be sought first to carry out the interview. In the unlikely event illicit activity is reported to me during the study, I will be obliged to report it to appropriate authorities.

Is the research confidential?

In accordance to the Data Protection Act, the data will be stored securely and appropriately. The final dissertation will be submitted to the examination board at Trinity College and, if successful, will be posted on TCD's Intranet website for future reference by students and academic staff. Your participation is not fully anonymous as your title and team you work for (i.e. MedLIS project) will be mentioned to give context to the data and in doing so, you could be identifiable. However, no personal details or specific hospital names that you work with will be mentioned.

Where can I get further information?

If you need any further information now or at any time in the future, please contact:

Adrena Keating at 0873490520 or keatinad@tcd.ie

Please can you confirm by return email if you are willing to participate in the interview?

Sincerely|

Adrena Keating

TRINITY COLLEGE DUBLIN
INTERVIEW INFORMED CONSENT FORM FOR MedLIS ORGANISATIONAL VIEWS

RESEARCHER: Adrena Keating

RESEARCH STUDY: An analysis of how a National Medical Laboratory System (MedLIS) can improve surveillance of notifiable infectious diseases in Ireland.

BACKGROUND OF RESEARCH:

This research is an exploration of the current laboratory notification practice with a view to providing valuable insights on what is needed from MedLIS to improve the current process and what MedLIS is likely to deliver and the future of electronic laboratory reporting.

PROCEDURES OF THIS STUDY:

Semi-structured interviews of approximately 40 minutes will be conducted in person or over the phone depending on availability to gain insight into the views of key informants. Participation in this research will be voluntary and participants may refuse to answer any question and may withdraw at any time without penalty. With permission from the participants meeting notes will be made and then transcribed to text accordingly. In accordance with the Data Protection Act, the data will be stored securely and appropriately. All participants will be given a participant information sheet which will ensure the participants in the research are fully informed.

PUBLICATION:

The primary purpose of this research is to fulfill the research dissertation requirements for the MSc in Health Informatics, Trinity College Dublin. The final dissertation will be submitted to the examinations board at Trinity College and, if successful, will be posted on TCD's intranet for future reference by students and academic staff.

DECLARATION

- I am 18 years or older and am competent to provide consent.
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 - I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
-

authorities.

- I understand that I may stop at any time, and that I may at any time, even subsequent to my participation have such electronic field notes destroyed (except in situations such as above).
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is not fully anonymous but that no personal details about me will be recorded. My specific title (i.e. surveillance scientist) and the name of the organisation or department that I work for will be used to describe my data input but my name will not be mentioned nor will the specific hospital that I previously or currently work in will be mentioned.
- I have received a copy of this agreement.

PARTICIPANT'S NAME : ...

PARTICIPANT'S SIGNATURE :

DATE : 31.5.18

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I have sought and received permission from the participant's employer to undertake the interview. I believe that the participant understands my explanation, and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS:

Adrena Keating

email: keatinad@tcd.ie

Telephone: 087 - 3490520

INVESTIGATOR'S SIGNATURE:

DATE: 31.5.18

Appendix N: Surveillance Scientist Interview – Country Hospital

Interview Date: May 24th, 1.30pm, 2018

1. What is your role with respect to the laboratory notification of notifiable infectious diseases? Senior Surveillance Scientists working for Country Hospital. Main person that puts the notifications on CIDR.
2. In your experience, what data quality issues exist that you are aware of in the notification of infectious diseases and what do you think is the root cause of these issues? Can include issues introduced by GP and in-house order forms and data collection issues.

Data Quality – This hospital has a uniform controlled request form that is the same for GP and inpatients. If there is missing clinical information such as no date and timestamp; the specimen reception would check this and reject those requests. If there is an issue, it does not get as far as being tested. If the quality system is adhered to, there should be no data quality issues and should not have passed specimen reception who types the handwritten orders into the LIS. It's true that handwritten requests may not include clinical details. If there are clinical details then the secretarial staff would enter them into the LIS, but often they are absent. This does not prevent the processing of the test.

For CIDR notifications DOB, Surname, Specimen Site, Pathogen, Specimen ID and hospital number is mandatory if the patient is an inpatient. For anything else and other patient demographic information, I would need to access the PAS system, but this is too time consuming.

Anonymised Data: We don't do any in-house STI type tests. We do send those types of tests out to NVRL and we do get a report back with the results, but we don't have other involvement. We authorize the notification via our CIDR management queue but clinically, we don't record anything on our LIS other than the order going out. We don't do anything the results. There is a unique Specimen ID that in the end would link the result to the anonymised patient. In CIDR, you can add initials, just need to add at least one character. But the other patient demographic data i.e. DOB would be correct.

3. In your experience, are all laboratory confirmed cases of notifiable infectious diseases reported into the Department of Public Health? If not, why?

No. But we now have a new process that is being validated now.

There is notifiable list of pathogens and we have built a new query search for that. Prior to that, we were depending on the medical staff printing off a laboratory report and leaving it for the surveillance scientist and there is bound to be issues with that.

I'd say that most laboratories nationwide have some level of manual processes. The accessibility to mine data would be different across Labs. For example, iSOFT would be reluctant to give you access to their database and mine information directly. I'd say most of notification processes nationwide have a human element where you are dependent on medical staff to come across a positive case and communicate that with the surveillance scientist.

I would think that most people would have access to the system but to be able to write a query is different. Somebody in iSoft would have to write the query for you and then you might need the majority of iSoft sites in Ireland asking for the same thing before you get that new report. I have worked in different places in Dublin and often you are waiting a long time to get anything done or updated in the LIS. But in this hospital, we have a custom and open-ended system that can be mined with MS Access queries. But you need to know what you're doing as could end up corrupting the database so it's a double-edged sword.

4. In your experience, can you offer a view as to why some infectious diseases according to research i.e. viral meningitis has been greatly under-reported into the Department of Public Health and others such as tuberculosis is not?

Talked to and asked our Consultant microbiologist on this. Because it's a clinical paper notification you will not get the same buy-in from clinicians. It's a clinical notification only, so laboratories do not notify these cases into CIDR. Clinicians can be reluctant to diagnosis viral meningitis as just because the test was negative, depending on the way the test was done and when it was done; it does not mean it is not viral meningitis. Clinically, the diagnosis is too ambiguous and there could be other co-morbidities involved. Compared to TB, you can't deny its TB, it is, or it isn't.

It's so broad but even if you got a positive lab test for enterovirus, this is not enough as need to get the clinical feedback as well. Clinicians would be reluctant to hang their hat on any one diagnosis as there are many other clinical factors that contribute to an overall diagnosis. There is a broader frame for viral meningitis diagnosis.

5. The literature has indicated that timeliness of reporting is a big issue internationally. What in your experience, what might impact notification timeliness in the current setting?

There is a list of immediate notifications from CIDR that are in the interest of public health that should be notified immediately once there is a positive lab test i.e. verotoxin producing e.colie -2 children in same crèche. Then there are infections like Cdiff that take a few weeks to notify because you could get a positive lab result but then need to wait to discuss it at a clinical meeting with microbiology and infection control team that could take one or two weeks depending on staff availability. 'Immediately' could be interpreted differently by different labs as the guidelines does not say less than 24 hours or anything like that. Routine cases here would generally be notified the same day between 8am – 5pm or next day. If a test comes up positive on a Friday evening, it would get notified the following Monday for routine cases.

Our lab processes between 10-20 notifications into CIDR a week. Stomach bugs, faeces samples, Verotoxin producing ecoli would be the main staples.

6. Do you perceive that a national laboratory information system such as MedLIS will be able to support and improve upon the notification process in relation to the following categories? Yes, well aware of MedLIS.
 - a. Data quality issues data – yes, hopefully and hope it is as good as we have now. If there are data quality issues; they will exist for all sites and so MedLIS should help in this regard.
 - b. Collection issues- Not sure. Could be worse, at the very least it needs to be the same as we have now. Currently, I can build and write my own database queries but if we are given a box of generic queries; I would be concerned if it is fit for purpose for what we need here. Once MedLIS can get a data set that can be exportable into excel and it is the data we are looking for, then it will suffice. For us, it could be worse, but it depends on the robustness of the script. We have a bespoke system

and data is easily accessible. Need same level of access and data querying capabilities as we have now.

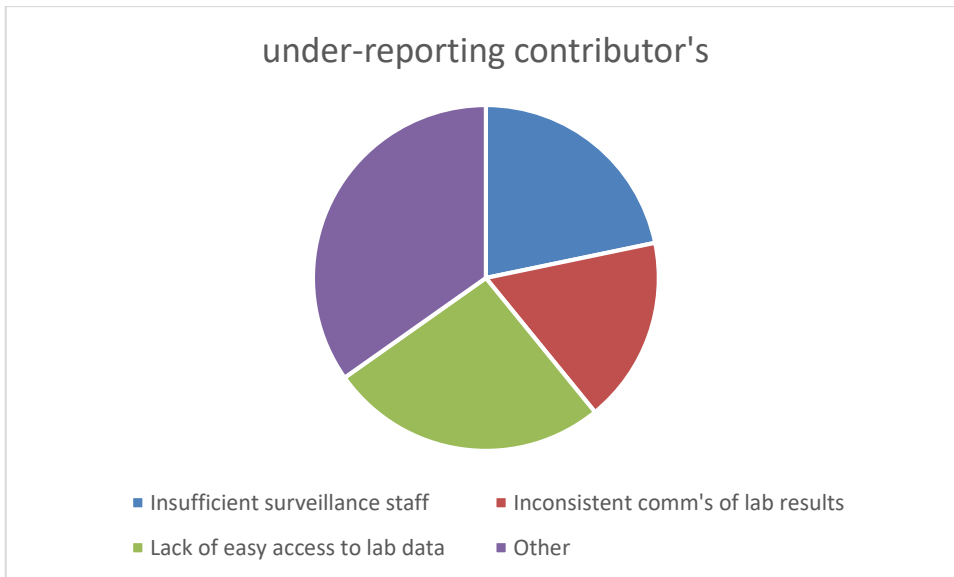
- c. Completeness of reporting (mandatory and optional data fields). Yes, for optional data if we can get this query working. We currently only add mandatory data into CIDR. Could CIDR and MedLIS ever be interfaced together? That would be a nice quality initiative to automatically populate the fields in CIDR and this is where we should be moving towards. An interface would remove the issue of under-reporting and remove reliance on laboratory surveillance scientists to notify. But this has its problems too, not a simple solution.
 - d. Timeliness of reporting – Yes
 - e. full reporting (all confirmed diagnosed tests notified into CIDR) Yes if integrated and we get this query working.
7. Is there anything specific you need from MedLIS to help with the categories listed in question 8 above? Any barriers that MedLIS will need to overcome to realise this?
- Ease of access to the data
 - Alerting would be good element to join up your laboratory process with notification process. It would nice, as soon if there is positive result on the notifiable lists, that an alert is generated.

Survey Results

8. In response to the question “Do you believe there is under-reporting of laboratory confirmed cases” most of the survey respondents said that under-reporting does exist “Sometimes” which is somewhere between never and half the time.
Yes, I agree

9. Reasons for under-reporting

In response to a question about reasons for under reporting, most of the laboratory surveillance scientists cited lack of easy access to laboratory data’ and ‘other’ and as the main reasons for under-reporting when it does sometimes occur. What is your experience and are there any additional reasons you think are valid? See free-text other reasons listed below that were provided.

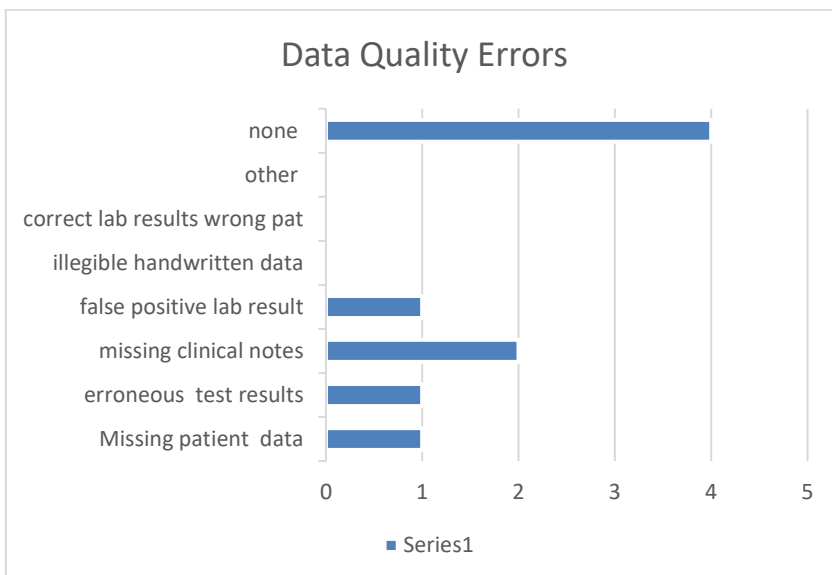


Other (lack of automated extracts from LIS, lack of clinical information on request forms, testing done externally or in private lab and therefore not uploaded into CIDR, lab tests are updated or modified or added and codes may not be captured in CIDR extract.

Poor notification communication from medical staff to laboratory surveillance scientist would be the main issue in my experience

10. Data Quality Error in current process

The survey respondents indicated a variety of data quality errors and four laboratory surveillance scientists said there are no data quality errors within the notification process to CIDR. What is your experience?



I would have said no data quality errors

11. Easy access to necessary data to undergo the complete notification

All laboratory surveillance scientist respondents say that they have easy access to their Laboratory Information System (LIS) and 7/9 have easy access to their Patient Administration System. Only 3/9 has access to an electronic patient record. What is your experience, do you have easy and direct access to all systems that you need to gather the case data?

Yes, I agree – have access to LIS and PAS. But could be different nationwide. The respondents might all have easy access to the data but would question if the data is easily mined and appropriate for what you really need.

13. Reasons for possible delay of notifications into CIDR Four laboratory scientists

responded that there is rarely or no delays in notifications. Do you agree?

Some of the free-text reasons cited for delays were the following:

- I. Waiting on confirmation from external reference laboratories
- II. Communication delays of positive results from lab staff to surveillance staff
- III. Annual leave/time off

Do these match your experience? Yes, I answered there could be a delay due to needing clinical input before it is notified. Cdiff example.

Appendix O: Chief Medical Scientist Interview – Country Hospital

Interview Date: May 17th, 11am, 2018

1. What is your role with respect to the laboratory notification of notifiable infectious diseases? Chief Medical scientist - joint approach together with lab consultant microbiologist. Day to day administration and management of department is more my role. Surveillance scientist has also reporting relationship into micro consultant. When no surveillance scientists than notification would fall to other micro staff. Medical staff can also do notifications provided they have had CIDR training.
2. When you provide laboratory notifications into CIDR, do you just provide the laboratory criteria case data and notification and/or also the clinical criteria case data? Send on documents. What is the trigger for confirmed case /lab test positive? The medical scientist that result/organism will know it is a notifiable disease and issue a second/copy of that lab report. Hard copy of the lab report is filed in blue paper tray. No system alert or reminder that it's a notifiable disease. Relies on people to have an understanding that it is notifiable disease. Unless people are aware, yes it could be missed in theory. All laboratory reports are double checked and microbiology chief would ensure that a copy is also provided to the surveillance scientist.
Our LIS is available to all hospital staff to view results only. Only lab staff can generate reports. Once we get a notified disease, it is phoned to the ward. We also add results to a list which is viewable to the consultant microbiologist. Hard copy result is sent to the ward also – clinical team made aware by many routes. Doctors can also then look up reports in LIS. The lab always does the notification to CIDR and don't rely on ward doctors.
3. In your experience, what data quality issues exist that you are aware of in the notification of infectious diseases and what do you think is the root cause of these issues? Can include issues introduced by GP and in-house order forms and data collection issues.
 - Wrong patient demographic data
 - Transcription errors into CIDR
 - Incomplete data into CIDR

Data quality would be very variable. With MedLIS and order communications it will do away these types of issues. Issue it notification is that we must transcript data from LIS

and request form into CIDR manually, if we could extract notification data from MedLIS system, it would mean better data integrity. The LIS takes the demographics from the previous reports so if there is a change needed; we need to make the change to the LIS. But if the request form has a change then we need to update our LIS ourselves as there no automated update between PAS and LIS.

Relating to hardcopy request form from ward – we assume those details are correct on the form has the most current information. There are two rounds of patient demographic data entry into LIS and then again into CIDR. Hope that MedLIS would provide auto upload of patient demographic and lab data. Therefore, no transcription errors.

We have a minimum data set that we must have i.e. data and time of collection, surname, address 1 and DOB. It would be helpful if we had more info but not necessarily missing details. That said if we had wider clinical details than might widen scope of testing i.e. if we know there was recent foreign travel.

Other data quality errors – match result to wrong patient – don't think so, never came across this. We operate from a sample and request form – as long as details match – we assume we have the correct patient. Always risk that sample may come from another patient but we would not be aware of it. We put measures in place (belts and braces) for things we can control and not things we cannot control.

4. In your experience, are all laboratory confirmed cases of notifiable infectious diseases reported into the Department of Public Health? If not, why? Where there is a reliance on clinical notification, it is certainly under-reported. i.e. non- laboratory notification by doctor or GPs. All stuff that tested here, confident they are fully reported. TB for example goes to the Mater, if Mater get a positive and then SJH has the responsibility for reporting. We don't take responsibility for reporting as we don't get results back in meaningful way directly into our LIS. We get hardcopies back and we scan them in. The understanding is that they do the notification and we assume that is done. There could be some under-reporting by ourselves i.e. liver abscess fluid which gets referred to Great Ormond street but there is ambiguity on who does the notification? Its grey area for a lot of people. HPSC said to add a note and say it was tested abroad.

The gray area is we didn't come across it before, it is on notifiable list but should we report it even though we didn't grow anything. New departure, unclear, potentially could have been under-reporting for a period – CIDR does not have a line/row for liver. All labs cases in generally are pretty much all reported.

5. In your experience, can you offer a view as to why some infectious diseases according to research i.e. viral meningitis has been greatly under-reported into the Department of Public Health and others such as tuberculosis is not?

TB and influenza appear at ward level to be much more significant from the point of view of cross-infection and get more attention from ward staff, bed management but viral meningitis does not create the same level of consciousness. Could be something to do with the time lag between specimen collection and getting results back. Viral meningitis could be week to 10 ten days before you get result back and patient could be discharged by then.

6. The literature has indicated that timeliness of reporting is a big issue internationally. What in your experience, what might impact notification timeliness in the current setting?

When sending to another lab, we can't control timelines.

Generally, we are not waiting on data from clinician's. Once we get a positive test, we report. We don't wait unless it's a cdiff as that is handled differently and is subject to meeting with the clinical control team to decide on case definitions and they get back with decision as to report or not – time lab there. For most others we notify on daily basis as soon as we get the positive results.

Our current manual process – yes does meet timeliness criteria. Our notifications every day- are generally less than recommended 48 hours. There is arrangement in place if VTEC or bacterial meningitis in crèche; we can phone public health at the weekend as they don't access their CIDR at the weekend. But in these two cases, we do phone over weekend. Our lab is 24 * 7 for routine and on call lab services so we do notify at weekend also. We meet HPSC criteria and do not have timeliness issues.

7. Is there anything specific you need from MedLIS to help with the categories listed in question 8 above? Any barriers that MedLIS will need to overcome to realise this?

- I. Help with getting correct patient demographic data

- II. Data transcription errors.
- III. Not from under-reporting as there is no issue, but yes for clinician reporting.
- IV. List of notifiable diseases is growing all the time, amount of drug resistant organisms that we are seeing will only increase. Getting harder to carry notifiable list of diseases in our heads.

MedLIS Barriers – don't think so. CIDR is quite simple from lab point of view. Just a series of fields. MedLIS should be well capable to uploading data extract into those fields. Once this is in place, notifications should be more streamlined and more secure. MedLIS should try including feedback at ward level on what is notifiable. Can MedLIS have an alert similar to LIS on MRSA that says this patient has X disease from a previous confirmed diagnosis? This would make a difference at ward level and could be part of triage system at A&E, especially CPE status – very useful for bed management, Similar for notifiable disease – especially if something exotic. Would be useful if there is a popup alert that says patient has X disease previously and would prompt to cover this and look for certain pathogen when ordering new tests.

Appendix P: Senior Medical Scientist – Country Hospital

Interview Date: May 18th, 11am, 2018

1. What is your role with respect to the laboratory notification of notifiable infectious diseases?

Snr medical scientist working in microbiology lab. Perform notifications into CIDR in absence of surveillance scientist. Always try to notify them in timely fashion.

We don't discriminate between GP and inpatients. If it is a case that is notifiable (isolation of organism or molecular test results). We notify both inpatients and GPs equally. GPs have obligation to perform clinical notification, but the laboratory must do the laboratory notification – regardless of the source.

The process is designed to capture all notifiable diseases, but it does have drawbacks. There are instances where we can miss things because of the manual interventions we have. We have never had an electronic upload into CIDR system

Current working on plan and draw up an extract table of all notifiable and run that once a week and that would circumvent any issues with missing notifiable cases.

2. When you provide laboratory notifications into CIDR, do you just provide the laboratory criteria case data and notification and/or also the clinical criteria case data?
It depends, some cases are straightforward and require a laboratory confirmed test and laboratory criteria only and others must be laboratory and clinical criteria. There is a weekly meeting attended by infection control team, surveillance scientist and consultant microbiologist to review more complex clinical cases like TB and Cdiff to confirm that they meet clinical notification criteria.

Repeat cases may not be deemed to be notifiable. But others are added without clinical intervention. For TB, all the notification will be done via mater, they will notify and it will come on our management queue and we verify the case. There is no trigger that there is something in the management queue. We look at it on daily basis and part of our notification process to check and notify accordingly.

GP have obligations to do a clinical notification and laboratories will do a lab notification on behalf of GP.

3. In your experience, what data quality issues exist that you are aware of in the notification of infectious diseases and what do you think is the root cause of these issues? Can include issues introduced by GP and in-house order forms and data collection issues.

The CIDR has minimum data set before you can save and authorise and that will always be there. All the other data may not be required, and we don't go looking to fill optional data – don't have resources to do that. Clinician when requesting generally don't complete request forms to a high standard and specimen timestamp invariable is not included. For inpatient requests, we make them complete it but for GPs we don't have that in place. For NVRL, we label up the samples, so we can track them and then send them out to NVRL.

Inpatient Order Request – handwritten request form that goes with specimen. We record that info on our system with accession number and send on to NVRL. Sometime our system uploads data to their LIS system and then we can get back results back electronically.

- Transcription Errors from LIS into CIDR – since CIDR is manual data entry for us, you can select the wrong organism via the dropdown and therefore report a case against the wrong notifiable infection – it has happened.
- Illegible handwriting from GP paper requests, can be mismatch on patient demographics details between request form patient and patient demographic details on specimen label and requests can be rejected on that basis. If the patient does not exist on the LIS system, then a new patient record will be added. If the patient name was spelt slightly differently and the patient has had a previous test and does exist, then there could be two patient records in the LIS for the same patient which means you don't have a single unique patient laboratory record for a patient which can impact quality of care.

- Date and time stamp of specimen collection is not always present. On the inpatient wards it is a mandatory field and data quality is better, but it is missing more often with GPs pathology tests.
- Not always clear what viral test is requested on GP paper requests.
- The original handwritten requests from inpatient ward or GP requests are sent with the specimen to the referral reference lab i.e. SJH or NVRL if our hospital does not process that test in-house.
- Can be ambiguity on the test that GP is asking for. In micro, it is generally just culture and sensitivity that is requested. But for viral meningitis might be non-specific on what test they want done as there are so many to choose from. Viral screen or named virus for instance and if handwritten not clear what they are looking for so do get issues like that sometimes.
- Sometime problems matching patient demographic data and if mismatch the test will not be processed- process for rejection. Hospital don't need address but the MRN must be present.

Electronic Order Communications will bring traceability and standardisation. Taking away the handwritten request form will be huge benefit. It will help with problems with transcription errors particularly from GPs who handwrite a lot of request forms. The GP do use our designed form that we send out to them. Name, DOB and address are mandatory and there is a process for rejection if that is not met.

4. In your experience, are all laboratory confirmed cases of notifiable infectious diseases reported into the Department of Public Health? If not, why? Intent to report them but there are occasions when not reported due to manual steps. No, they are not, they are notified as timely as possible but you cannot stand over and say they are all notified given the manual process that is in place. It is very difficult to quantify but it is possible that the laboratory staff do not print out the lab reports for confirmed case and leave them in the correct tray for the surveillance scientists to pick up and process.
5. In your experience, can you offer a view as to why some infectious diseases according to research i.e. viral meningitis has been greatly under-reported into the Department of Public Health and others such as tuberculosis is not? Viral meningitis can sometimes be a clinical diagnosis only and not always accompanied by a laboratory

diagnosis. Patient would need a lumbar puncture and test may not always work. For clinical notification, the symptoms would need to match the diagnosis. When you test for viral meningitis on CSF, it does not always work, and it can detect a virus or not. For a TB diagnosis, it is much simpler to test via TB culture and it's either one way or the other. Historically TB was always the scary infection and gets more attention, on people minds more. With TB there is symptoms is also much more well-known and garners more attention. To a certain extent the lab and clinical notifications would always marry.

6. The literature has indicated that timeliness of reporting is a big issue internationally. What in your experience, what might impact notification timeliness in the current setting?

There are certain diseases that Public Health likes to be made aware of outside of CIDR system notification i.e. via telephone case. There is no set time that you need to report on. If you get a diagnosis on Friday evening, that may not get reported until Monday. There are no criteria set out; you cannot measure it as there is no benchmark to measure against.

All manner of leaves impact laboratories greatly across the country.

The complexity of the case definition might impact timeliness. Cdiff is a good example as that requires a case review meeting that takes place once a week on a Tuesday to determine if it meets notifiable criteria. If there is a suspected case, made known on a Wednesday than it could be a week before it gets notified.

Timeliness cannot also not be quantified since there is no reporting guidelines. HPSC would like us to report as quickly as possible but there is no rules as such. Sometimes cases are timely and sometimes not. How busy the surveillance scientist is another factor. Notification into a CIDR is only a small fraction of their overall role and notification into CIDR is not highest on priority list considering all the disease reporting work that needs be done outside of notifiable diseases. There is only one surveillance scientist per hospital generally and maternity leave, paternity leave, sick leave, annual leave can all impact on timeliness. The cases will still get reported by other staff i.e. snr medical scientists but will not be as timely. Surveillance scientists

have a lot of work to do with data notifications, i.e. do a lot of work for micro consultant who want stats. Lots of work outside of notifications.

7. Do you perceive that a national laboratory information system such as MedLIS will be able to support and improve upon the notification process in relation to the following categories?
- f. data quality issues Yes, especially if have order communications and standardise request process. There should not be any request forms anymore if GP do electronic ordering. The fields will dictate the data that will be on the system which should help.
 - g. data collection issues, - Yes, assuming we have a custom query that can extract the notification data and be able to upload into automatically into CIDR. MedLIS should streamline this lot and automated upload would be massive benefit. We need automated electronic data.
 - h. Completeness of reporting (mandatory and optional data fields) yes if the MedLIS data extraction also pulls more data on optional fields – but otherwise no as cannot save and authorise a submission into CIDR unless the minimum mandatory fields are added. MedLIS upload should complete all those fields. Can use the mouse wheel to select an organism and easy to select the wrong one and LIS upload would solve this. Won't be depending on people filling in optional fields so that can only help, particularly for Public Health.
 - i. Timeliness of reporting – Possibly not as there will still be mandatory process steps. If the automated data extract is in place it should speed the data entry part but still need to authorize cases via mandatory steps and some cases will need to wait for the weekly case review meeting for those more complex cases. Somebody still needs to click a button to upload the data so depends on the process that is designed in each hospital.
 - j. full reporting (all confirmed diagnosed tests notified into CIDR) – yes assuming we have an alert/trigger that confirms a positive laboratory case and we have an audit report we can run that pulls out all the confirmed case over a period of time and we can compare that to what was notified in CIDR

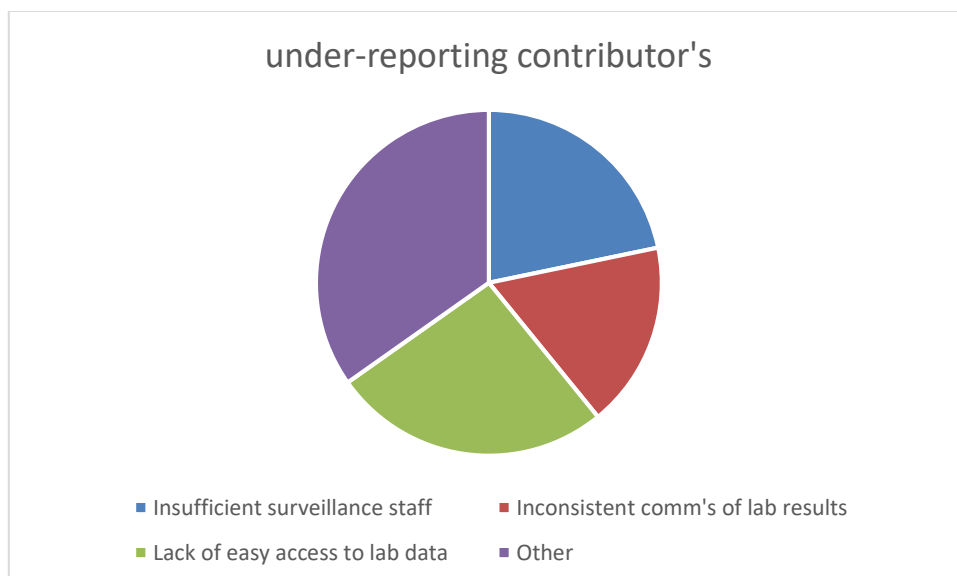
8. Is there anything specific you need from MedLIS to help with the categories listed in question 8 above? Any barriers that MedLIS will need to overcome to realise this?
- I. Alert/trigger that tells the laboratory staff that the organism that has a positive result is a notifiable infectious disease and should be reported.
 - II. Custom data Extract query that can pull the necessary and correct data we need from the LIS in a format that can be uploaded into CIDR
 - III. Audit/Stats reports that can be run on MedLIS to check the number of confirmed cases etc.
 - IV. Order Communication will be a big help

Survey Results

9. In response to the question “Do you believe there is under-reporting of laboratory confirmed cases” most of the survey respondents said that under-reporting does exist “Sometimes” which is somewhere between never and half the time. Do you agree? Yes, difficult to quantify if closer to never but sounds right.

10. Reasons for under-reporting

In response to a question about reasons for under reporting, most of the laboratory surveillance scientists cited lack of easy access to laboratory data’ and ‘other’ and as the main reasons for under-reporting when it does sometimes occur. What is your experience and are there any additional reasons you think are valid? See free-text other reasons listed below that were provided.



Other (lack of automated extracts from LIS, lack of clinical information on request forms, testing done externally or in private lab and therefore not uploaded into CIDR, lab tests are updated or modified or added and codes may not be captured in CIDR extract.

I think most labs have easy access to lab data on the front-end including ourselves that use a custom LIS system. The problem is not access but the extraction of data from the tables etc. as need to IT knowledge specifically in MS access queries to extract data you need.

Need to be very savvy with MS access. The frontend is no problem. But we all are not be able to pull out raw data. Its easily accessible if know how to use it.

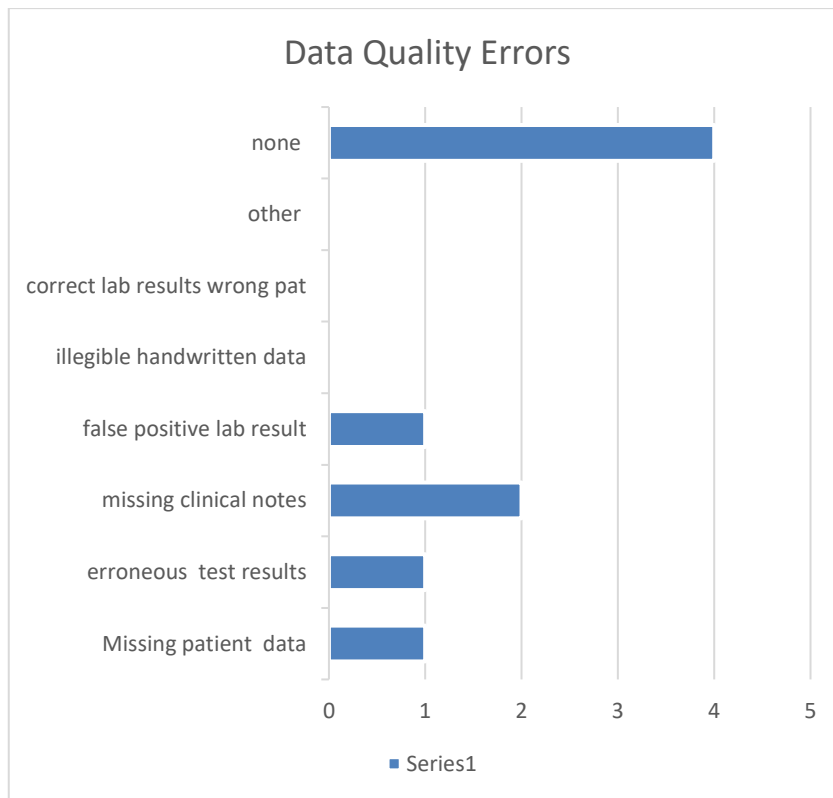
All the reasons mentioned here are valid. Because of the manual process, if the lab staff do not print out duplicate copy of the hardcopy lab report and leave it out for the surveillance scientist, then it will not get reported.

Insufficient surveillance staff – yes had that for couple of years which would have impacted the timeliness of notifications but not actual reporting.

The hospital employs the surveillance scientist.

11. Data Quality Error in current process

The survey respondents indicated a variety of data quality errors and four laboratory surveillance scientists said there are no data quality errors within the notification process to CIDR. What is your experience?



Yes, overall would agree with most of that. Clinical notes would not have much on effect. Transcription errors is missing. If have positive result but incorrectly typed as negative – we would not know about that. From my experience, always be data quality errors, just the nature of laboratories and the work we do. It would be next to impossible to have no data quality errors. Data quality issues are inherent in the nature of the work we do in the labs.

Missing patient demographic data i.e. initials instead of surname, address information and anonymised patient demographic data would be higher on list of data quality issues. Also missing GP referral practice information is another one as this data is supposed to be included in notification. Transcription errors due to manually typing and selecting data into CIDR is another.

12. Easy access to necessary data to undergo the complete notification

All laboratory surveillance scientist respondents say that they have easy access to their Laboratory Information System (LIS) and 7/9 have easy access to their Patient Administration System. Only 3/9 has access to an electronic patient record. What is your experience, do you have easy and direct access to all systems that you need to gather the case data? Yes, easy access on the front-end but time consuming and don't have an EPR.

We have an interface between LIS and PAS. Our LIS downloads patient demographics from the PAS. This is used for inpatient requests – we enter in MRN into LIS and that does a lookup from PAS i.e. address, DOB – no issues with patient matching on inpatient.

For GPs, do search on LIS first – add DOB – search – bring up history of all patients and then we select the appropriate patients – that helps. Then we copy the patient details onto the current test. Then do comparison on patient on screen against request form – patient match. If patient does not exist, then enter a new record into LIS but that does not get copied to PAS.

You could mistakenly create a second patient entry on LIS so you have duplication and two records for same patient i.e. Anne Byrne with and without an E. MedLIS should reduce the instance of that happening.

All patient search lookups done on LIS first.

13. Reasons for possible delay of notifications into CIDR

Four laboratory scientists responded that there is rarely or no delays in notifications. Do you agree? Disagree. There are delays in notification but depends on definition of delay. We make effort to do notification in timely fashion as possible, but delays can be occurred for manual steps mentioned. This is not audited but historically speaking there will be no delays.

Some of the free-text reasons cited for delays were the following:

- Waiting on confirmation from external reference laboratories
- Communication delays of positive results from lab staff to surveillance staff
- annual leave/time off
- Communication delays of positive results from lab staff to surveillance staff

Do these matches your experience? Yes, I come across the free-text reasons mentioned.

Appendix Q: Surveillance Scientist Interview - Dublin Hospital

Interview Date: May 16th, 3pm, 2018

1. What is your role with respect to the laboratory notification of notifiable infectious diseases? Senior surveillance scientist – working with MedLIS and Cerner to create a DB query that can be used to extract data from MedLIS and upload notified cases automatically into CIDR. I process approx. 150 notified cases into CIDR once a week via bulk upload. I have my own custom access database that I use to manage the data. I query the LIS and supplement the extract with data from EPR, PAS and the data warehouse to retrieve the case data I need and get into the correct format that I can then upload automatically into CIDR. I don't do any manual data entry into CIDR. Don't do the high urgent ones- Microbiology clinicians will ring and I follow up with the CIDR record. Do a lot of data extraction /audit and make sure that all cases were notified into CIDR.

2. Do you provide notifications on TB, Influenza and viral meningitis into the Dept of Public Health? Please elaborate on current notification process and role of NVRL in that process?

Yes, on TB and Influenza. No on viral meningitis – the NVRL do that.

In, some diseases e.g. Hepatitis B and C we do some parts of the testing and the NVRL do other parts. In this instance we consolidate both parts of the testing and do the notification. When the NVRL process all the tests and have a confirmed case, they do the notification into CIDR, but we still need to review and authorize it in our CIDR management queue. For GP cases, we do the laboratory notification and GP should do the clinical notification.

3. Are any requests for tests that are referred on to NVRL sent on paper or electronically?

Not paper. We send an extract from our LIS that extracted by DMF system and they send to NVRL and we send specimens over.

4. In your experience, what data quality issues exist that you are aware of in the notification of infectious diseases and what do you think is the root cause of these issues? Can include issues introduced by GP and in-house order forms and data collection issues.

Handwritten forms are worst thing to get but this is the minority of requests. We do get printed or handwritten forms from referral labs and some GP and so some data is still manually entered into the LIS.

5. In your experience, are all laboratory confirmed cases of notifiable infectious diseases reported into the Department of Public Health? If not, why? Yes, as far as possible. Occasionally find the very odd things but cannot say never made a mistake but try to ensure that all cases are notified.
6. In your experience, can you offer a view as to why some infectious diseases according to research i.e. viral meningitis has been greatly under-reported into the Department of Public Health and others such as tuberculosis is not? In the example of viral meningitis, it is difficult to get a lab confirmed case, so most diagnoses are made clinically. Clinical notifications are not done as comprehensively as Lab notifications so under reporting is likely. When we send a report to a clinician there is always a comment at the end – this is a notifiable disease please report it to public health. STI Clinics in this facility do send clinical notifications and they will be matched with lab notifications in local DPH. They do the reporting.
7. The literature has indicated that timeliness of reporting is a big issue internationally. What in your experience, what might impact notification timeliness in the current setting?

Timeliness of notifications will depend on resources available locally. This varies widely from Lab to Lab. The more electronic the process is the better. What are your expectations on timeliness? Urgent is as soon as the disease is identified. Diseases on the immediate preliminary notification list are phoned to DPH by Microbiology medical staff. This will be followed up by a notification in CIDR. Most labs try to be as timely as possible. I extract data from LIS, go through each line and see what should be notified. Everywhere that has a lab system should do an extract but some labs may not have the facilities to do that. Hard to say what other labs do and everyone has to work within their capability, no two labs are the same. We have EPR, PAS, LIS, data warehouse and loads of other systems such as ‘patient notepad’ and bring data together all the time. I built access query that pulls all the data together and maintains a local record of all notifications. This file is then transformed into text file which can be uploaded into CIDR. We have medics who do ward rounds that add micro data to patient notepad. We could not run infection management in the hospital without that.

8. Do you perceive that a national laboratory information system such as MedLIS will be able to support and improve upon the notification process in relation to the following categories?

This would be the expectation of a new laboratory national system

- k. Data quality issues data – it should when everybody gets order communications. And labs get a standard extract. It should help with missing data
 - l. Collection issues, - yes – via the extract but a lot of work to be done on this and not confident that what we have been given by MedLIS is robust enough. Microbiology has changed hugely in last few years and a lot of work moved into machine testing/molecular testing.
 - m. Completeness of reporting (mandatory and optional data fields) – yes if all data fields required are available in DA2 MedLIS and included in extract that is reliable and robust
 - n. Timeliness of reporting –depends on how often you run that query.
 - o. full reporting (all confirmed diagnosed tests notified into CIDR) – should facilitate complete reporting.
9. Is there anything specific you need from MedLIS to help with the categories listed in question 8 above? Any barriers that MedLIS will need to overcome to realise this?

It will be great benefit to see the patient's previous history and test results as recorded in the referral lab e.g. all test results from NVRL. Labs will have a notional expectation that MedLIS will be better than what they have now. Depends on what you can do now. Yes, MedLIS is a new lab system but new is not always improved. We need to make it do what we need it to do and it should improve on quality and not reduce it.

When MedLIS is introduced, CIDR will have one upload specification/configuration instead of 43 currently. This will improve upload configuration maintenance for the CIDR team. MedLIS maintenance will be difficult as labs change tests, methodology and platforms as developments in new technology come to market. MedLIS will need to track and update every test for every lab. CIDR queries have to cover every test and method for every disease as used in every Lab. The hospital lab has a very different requirement of a lab system than a national view. It is not realistic to have

the same test done in the same way across all labs. Labs do tests in different ways for many different reasons i.e. resources, expertise, clinical specialties, and consultant requirements This variation across labs could be a barrier to continued maintenance of MedLIS.

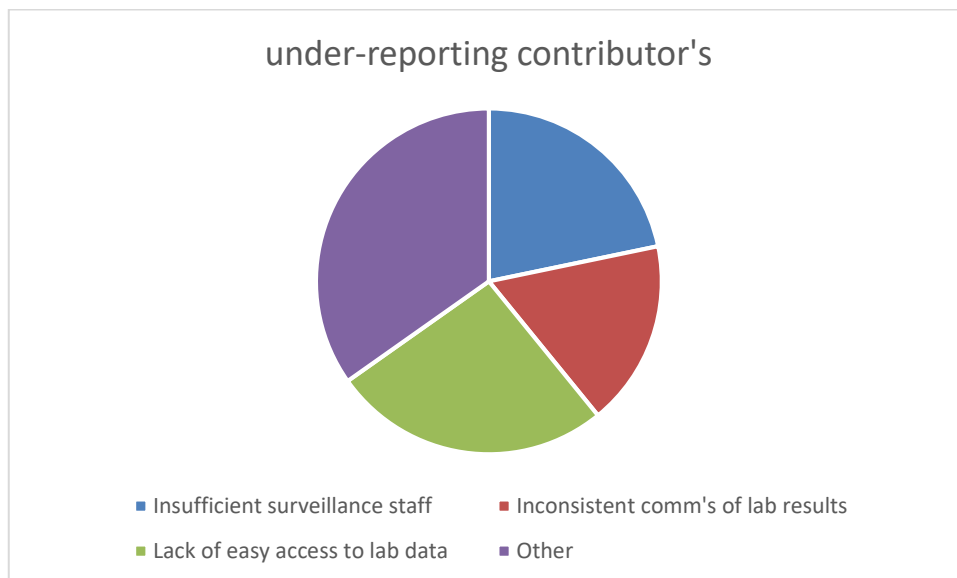
Survey Results

10. In response to the question “Do you believe there is under-reporting of laboratory confirmed cases” most of the survey respondents said that under-reporting does exist “Sometimes” which is somewhere between never and half the time.

Yes, I agree, lower end of sometimes but can never say never. If the LIS does not have cross checking audit reports than yes it can be higher end of sometimes. Every lab is different.

11. Reasons for under-reporting

In response to a question about reasons for under reporting, most of the laboratory surveillance scientists cited lack of easy access to laboratory data’ and ‘other’ and as the main reasons for under-reporting when it does sometimes occur. What is your experience and are there any additional reasons you think are valid? See free-text other reasons listed below that were provided.

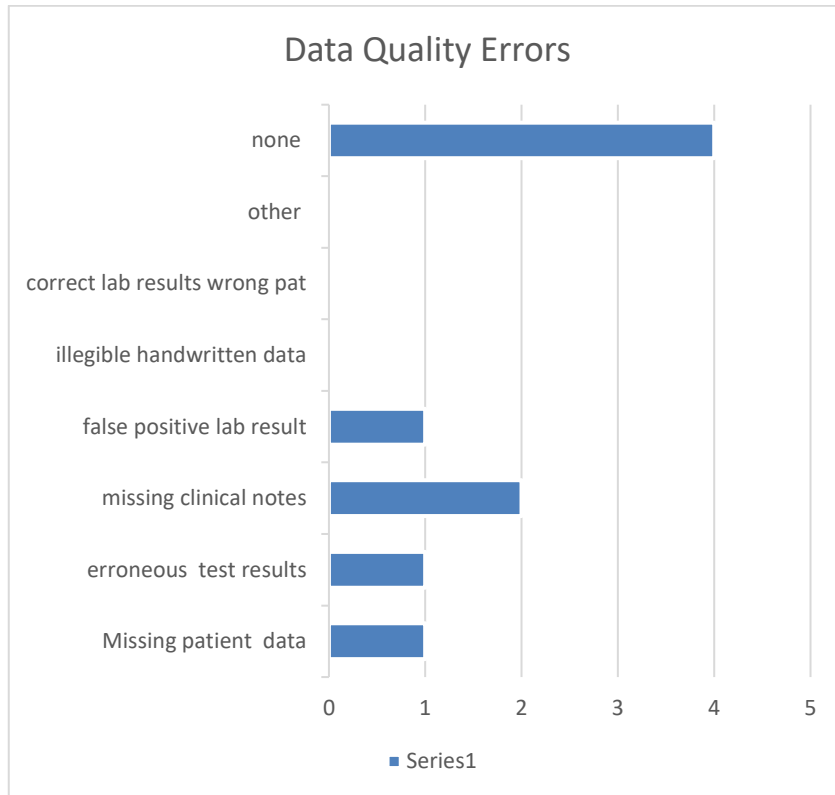


Other (lack of automated extracts from LIS, lack of clinical information on request forms, testing done externally or in private lab and therefore not uploaded into CIDR, lab tests are updated or modified or added and codes may not be captured in CIDR extract.

I think the respondents were thinking of lack of easy extract of LIS. For testing done externally, you are responsible to notify so yes that could happen.

12. Data Quality Error in current process

The survey respondents indicated a variety of data quality errors and four laboratory surveillance scientists said there are no data quality errors within the notification process to CIDR. What is your experience?



Can't be no data quality errors— there must be some illegible handwritten data

False positive lab results. Not sure what this is.

No data sets are perfect. Most data need to be cleaned and validated before being analysed. Data received in the lab whether electronically or on paper is taken as correct and this is what is contained in LIS. In some hospitals the patient demographics in LIS are updated automatically by PAS, this facilitates the accuracy of LIS data particularly with name changes or missing DOB. Any errors are corrected, and audits of data input quality are undertaken to improve quality

DPH validate the data when they receive it in CIDR and they will ask for clarification i.e. gender does not match the test that was done.

Data errors are more along the missing data.

Illegible handwriting on forms can be a problem. Missing clinician notes is also common

Erroneous lab results: Any lab result problems should be sorted out before the data goes to CIDR.

We audit everything end of every month to make sure everything appropriate was notified and to check that the queries are still working correctly.

13. Easy access to necessary data to undergo the complete notification

All laboratory surveillance scientist respondents say that they have easy access to their Laboratory Information System (LIS) and 7/9 have easy access to their Patient Administration System. Only 3/9 has access to an electronic patient record. What is your experience, do you have easy and direct access to all systems that you need to gather the case data?

Yes – In this Lab we have easy access to a wide range of data

14. Reasons for possible delay of notifications into CIDR

Four laboratory scientists responded that there is rarely or no delays in notifications. Do you agree?

Some of the free-text reasons cited for delays were the following:

- I. Waiting on confirmation from external reference laboratories
- II. Communication delays of positive results from lab staff to surveillance staff
- III. Annual leave/time off

Do these match your experience?

What does delays really mean? I'd say that is right, yes agree.

If you are sending it out to a different lab it will always take longer than if you do that test yourself

Timeliness is different for different diseases.

Other Notes

Laboratory scientists sends notifications to local public health. HPSC also include public health surveillance scientists.

150 cases processed once a week – which in a way is better than occasional cases – tried and tested process that improves over time.

Local DPH can view the records when they are authorised in CIDR. The data is sorted, validated and then anonymised. The data then moves from patient-based data to disease based data. This data is analysed both locally and nationally.

Appendix R: NVRL Lab Manager Interview

Interview Date: May 17th, 10am, 2018

1. What is your role with respect to the laboratory notification of notifiable infectious diseases?

We help with creating line listings for the HPSC when they request it in times of a suspected outbreak of a notifiable infectious disease. A line listing is extracted from the LIS but takes quite a bit of work and provide stats on confirmed laboratory cases.

The NVRL processes approx. 900K tests per years on approx. 302K samples. Less than 20% is from GPs. These stats include all tests, not just notifiable diseases.

Our CIDR notification is as follows:

October to February: 250- 300 per day

March to September: 20-40 per day

NVRL is a screening and referral lab and receives specimens and test request nationally from hospitals GPs and other clinics.

2. Do you provide notifications on TB, Influenza and viral meningitis into the Department of Public Health? Please elaborate on current notification process and role of NVRL in that process?

NVRL performs mainly viral investigations which includes, testing and notifications for viral meningitis and influenza but not TB. We have our own LIS system and IT department and do bulk uploads into CIDR for confirmed cases. There is no manual data entry into CIDR. We do not test for TB.

3. Are any requests for tests that are referred on to NVRL sent on paper or electronically?

- GP send in a lot of handwritten forms either directly or via their catchment hospital. Mainly issues with patient demographic – missing data,
- 2D barcodes on printed forms from hospitals such as maternity hospitals. The barcode which contains the patient information is scanned and the data uploads directly into the LIS
- Get Medibridge requests from Dublin hospitals but still need to do a manual search for the patient data on our LIS and select the correct patient
- Get paper request forms from drug clinics and STI clinics - anonymized data

4. In your experience, what data quality issues exist that you are aware of in the notification of infectious diseases and what do you think is the root cause of these issues? Can include issues introduced by GP and in-house order forms and data collection issues.

The main data quality issues stem from the various non-standardized request forms that we get from all the different sources

Issues include:

- Missing clinical details which can mean that not always clear what tests should be run
 - Missing patient demographics i.e. patient surname, address – data is anonymized from STI clinics
 - Missing specimen type
 - Missing sample collection date, onset of symptoms
5. In your experience, are all laboratory confirmed cases of notifiable infectious diseases reported into the Department of Public Health? If not, why? Yes, the NVRL notifies patient results for both hospitals and GPS when we are the primary testing laboratory. We also notify confirmatory results on patient samples that are new to us but had the initial test performed by the requesting site. We have the staff and resources to do it. Under-reporting has been an issue in the past, but it has got a lot better due to:
- HPSC reviews and updates to clinical laboratory diagnosis criteria
 - General information and awareness on notifiable diseases is much improved
 - Notifications and who is responsible for notifications has got much better
6. In your experience, can you offer a view as to why some infectious diseases according to research i.e. viral meningitis has been greatly under-reported into the Department of Public Health and others such as tuberculosis is not?

With viral meningitis the pathogen cannot always be identified. We test for herpes 1 & 2, varicella zoster, enterovirus and if it's a child specimen (under 3yrs) we include Parechovirus and Herpes 6. The problem is we don't always get the correct sample type, or information such as sample collection date /clinical details. This makes diagnosis more difficult.

7. The literature has indicated that timeliness of reporting is a big issue internationally. What in your experience, what might impact notification timeliness in the current setting?

I think the hospitals have different lab systems and mostly upload into CIDR one case at a time. We have our own IT staff at NVRL and we can do batch uploading into CIDR which a bit can still be slow, but it has got a lot better. I think the delays came from the fact that even though we do the notification on behalf of a referral lab for example, the originating hospital still must review and authorise that case in CIDR themselves before it is sent and notified to public health and HPSC. Therefore, the system is not good for identifying an emerging outbreak in a timely manner. This is where the line listings are invaluable. Public Health (request can come from anywhere) will contact the NVRL director with a suspected outbreak and ask for line listing e.g. a measles or influenza suspected pandemic.

8. Do you perceive that a national laboratory information system such as MedLIS will be able to support and improve upon the notification process in relation to the following categories?

p. data quality issues data **Yes, it should**

q. collection issues, - **Yes**

r. Completeness of reporting (mandatory and optional data fields) **Yes**

s. Timeliness of reporting - **Yes**

t. full reporting (all confirmed diagnosed tests notified into CIDR) **Yes**

9. Is there anything specific you need from MedLIS to help with the categories listed in question 8 above? Any barriers that MedLIS will need to overcome to realise this?

It will be great benefit to see the patient's previous history and diagnosis as recorded in the referral lab and from other sites. E.g. viral load for a HIV patient. The standardization of data fields that electronic order communications will bring will be a huge benefit to us and remove any data quality issues and will mean less manual checking work for missing data etc. The streamlining and standardization of the requesting process would be extremely beneficial.

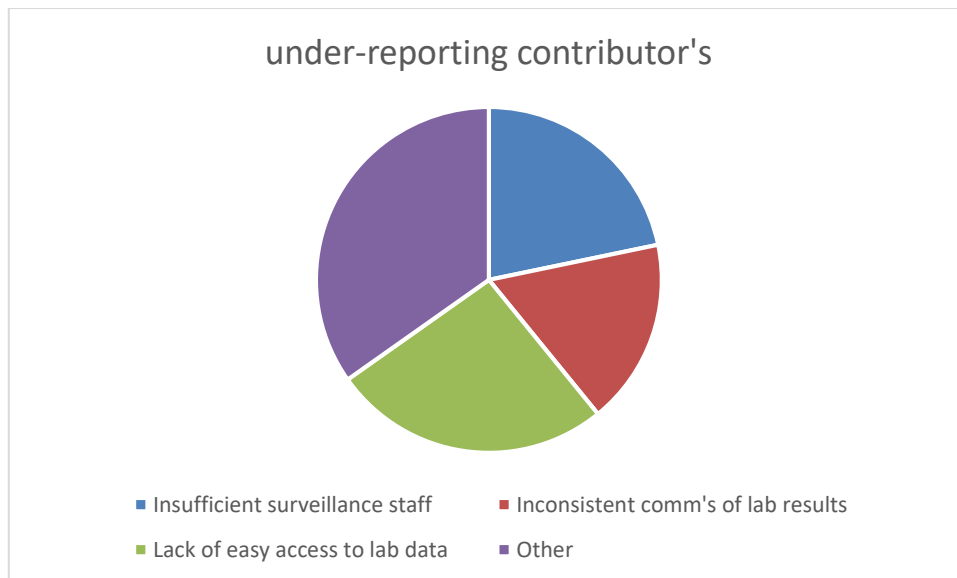
MedLIS should make it easier for all public labs overall including the NVRL.

Survey Results

10. In response to the question “Do you believe there is under-reporting of laboratory confirmed cases” most of the survey respondents said that under-reporting does exist “Sometimes” which is somewhere between never and half the time. Yes ‘sometimes’ - agree

11. Reasons for under-reporting

In response to a question about reasons for under reporting, most of the laboratory surveillance scientists cited lack of easy access to laboratory data’ and ‘other’ and as the main reasons for under-reporting when it does sometimes occur. What is your experience and are there any additional reasons you think are valid? See free-text other reasons listed below that were provided.

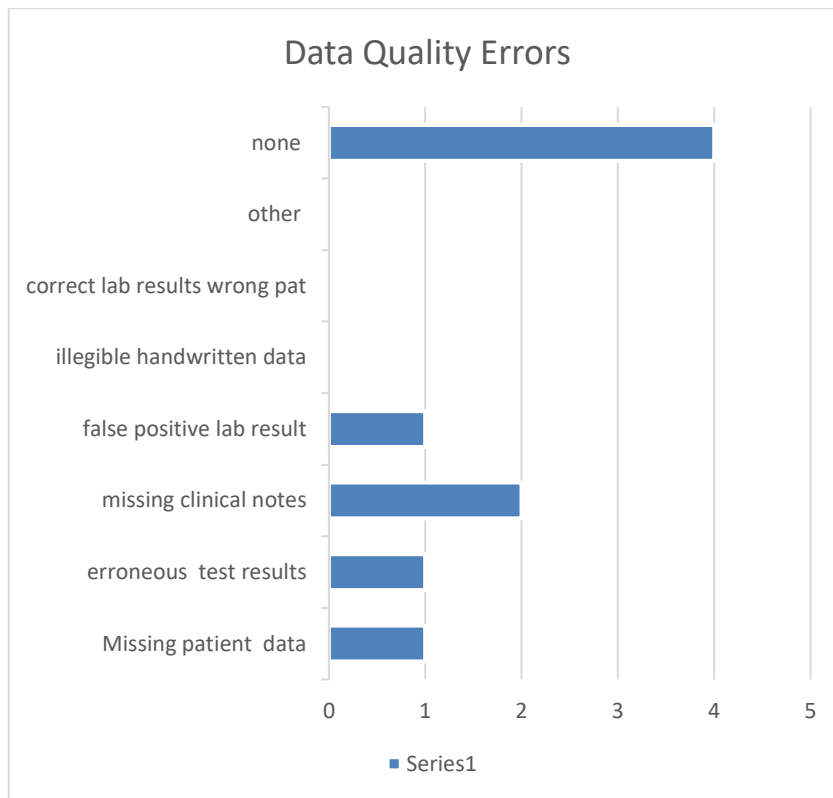


Other (lack of automated extracts from LIS, lack of clinical information on request forms, testing done externally or in private lab and therefore not uploaded into CIDR, lab tests are updated or modified or added and codes may not be captured in CIDR extract.

Not very relevant for us, we have a standalone lab and great IT support.

12. Data Quality Error in current process

The survey respondents indicated a variety of data quality errors and four laboratory surveillance scientists said there are no data quality errors within the notification process to CIDR. What is your experience?



There is, of course data quality errors. Missing clinical details and quality of data on paper and electronic request form are the most common issues.

13. Easy access to necessary data to undergo the complete notification

All laboratory surveillance scientist respondents say that they have easy access to their Laboratory Information System (LIS) and 7/9 have easy access to their Patient Administration System. Only 3/9 has access to an electronic patient record. What is your experience, do you have easy and direct access to all systems that you need to gather the case data?

Yes, I agree, we have a standalone LIS system.

13. Reasons for possible delay of notifications into CIDR

Four laboratory scientists responded that there is rarely or no delays in notifications. Do you agree?

Some of the free-text reasons cited for delays were the following:

- Waiting on confirmation from external reference laboratories yes, they are right, they do need to wait on us to process test

- Communication delays of positive results from lab staff to surveillance staff- not relevant for us
- annual leave/time off – yes relevant for here too

Does this match your experience? Yes

Appendix S: MedLIS Microbiology Lead Interview

1. Is there planned alerting functionality of any kind in MedLIS to alert the medical staff when there is a confirmed pathogen diagnosis of a notifiable infectious disease? And if a patient had a previous confirmed diagnosis of a disease; could that appear as a pop up or alert in some way on the patient record similar to MRSA patient?

No, there is nothing planned. This decision support functionality is more suited to an EHR than a laboratory information system such as MedLIS. We are going to create a visual type of alert that will be added to the patient's electronic laboratory record (ELR) if the patient has a confirmed diagnosis for a selection of infectious diseases such as MRSA, VRE, CPE, ESBL etc. These diseases are important for awareness to stop the spread of infection in the hospital but will not be expanded to include notifiable diseases.

The thing about notifiable diseases is that they can come from anywhere. The microbiology laboratory report will always have a comment included on the nature of the pathogen and although this is not an alert, the laboratory report will state that "this is a notifiable disease and should be notified".

2. Is there a standard audit report that can be run in MedLIS, to provide a list of all the confirmed notifiable pathogens over a custom time? Can this report be customised easily and by whom?

Yes, there will be surveillance reports that will provide this information. The report can be easily customised in terms of changing date filters etc. but adding a new pathogen to the report will not be so easily customisable as it will need to be changed by probably only one or two people that will be trained in the Cerner query language and will probably sit in the MedLIS back office support team.

3. The MedLIS data extract that can be automatically uploaded into CIDR has been cited by microbiology staff as one of the key MedLIS deliverables that will:
Can you please comment on each one of these categories and provide a view as to if you believe based on your current knowledge, if MedLIS is likely to deliver on expectations for this script?
 - I. improve data collection issues as some labs rely on hardcopy lab reports that require manual data entry in CIDR. Yes, MedLIS should improve data collection as a

national data extract query will be provided that will extract the notifiable data from MedLIS and which then eventually can be transformed and uploaded into CIDR.

- II. completeness of reporting in terms of being able to extract more LIS data on more optional fields especially if more good quality data is added and stored in MedLIS due to electronic order communications by hospital staff and GPs.

The quality of data going into MedLIS should improve and MedLIS should make it more standardised. For example, the NVRL are requesting more specific information from the people that are ordering the tests such as:

- I. Date of onset of symptoms
- II. Foreign travel
- III. Type of respiratory cough

This will help in determining the scope of tests to be run.

With regards to missing clinical information.

- the specimen collection timestamp will be added automatically as part of the electronic ordering process in MedLIS
- The onset of symptoms is more significant for viral infections, so it would not be appropriate to routinely ask for this clinical information on the wards
- Anonymous patient data for STI clinics is likely to continue. For example, the 'Guide clinic' is part of SJH and their results are hidden from most of SJH other than the staff who are processing the test.

- III. Improving any under-reporting that might exist by removing the dependency on medical staff to report a confirmed case to the surveillance scientist. No, if this is the current process in some labs, then MedLIS will not remove this dependency. There will be no alerting type functionality. This is more for EHR.

Primary Research Background: The literature has stated there is wide variability on non-mandatory data that is entered in CIDR. For example, information on ethnicity was available for only 11% of records and the data for the onset of symptoms was missing in approximately one third of cases (Nicolay et al., 2010).

Survey and interview results have all cited missing clinical and patient demographic information such as specimen collection timestamp, foreign travel, anonymised patient data, missing GP contact information as some of data quality and completeness of reporting issues.

4. The NVRL receive lab specimens and pathology order requests in many different formats including
 - GP handwritten request forms directly from GPs – will be replaced with standardised electronic ordering
 - 2D barcoded printed forms from maternity hospitals - not sure
 - Medibridge requests from some Dublin hospitals – Medibridge facilitates orders from other hospitals coming into the lab. It is a product that produces a printed order request form for orders entered by SJH or Tallaght LIS or Midland hospital LIS. These hospitals use Medibridge to transfer order requests between them and to NVRL. MedLIS will replace Medibridge.
 - Paper requests forms from drug and STI clinics. The intention is that external clinics such as these will be able to order electronically similar to the GPs but this is still to be worked out.

Is MedLIS likely to streamline the ordering process and introduce standardised electronic ordering across all or most sources of pathology requests? What knock-on benefits do you think it will have to the overall laboratory notification process into CIDR?

Yes, it will streamline the overall process.

5. Will there be an automated lab messaging interface between MedLIS and NVRL and is this likely to improve the current process (LIS extract) of sending over notification data into NVRL? Yes, there will be an automated interface but don't know much about it and if it will improve the current process.

Primary Research Background: For tests that are sent on to the NVRL via Dublin hospital, there is a LIS extract that is created by a third-party vendor.

6. Some hospital labs that refer tests to reference labs; do not receive back the reference lab result automatically into their LIS and need to scan in a hardcopy of the lab result into their LIS? Is this likely to change with the introduction of MedLIS and will HSE and voluntary hospitals see the lab results and patient history as recorded in the NVRL lab as an example?

Yes, this will change for NVRL and all MedLIS labs but not for UK reference lab as that is an external lab and not on MedLIS. There will be no more need to scan results into the local LIS. Results will automatically populate the flowsheet in the central MedLIS database.

7. Is there anything else you would like to add on how MedLIS might improve the laboratory notification process and any barriers it will need to overcome to realise this?

MedLIS will deliver an electronic laboratory record that is much more complete to what we have now. Each laboratory patient record will be allocated with an individual health identifier (IHI). This will benefit laboratory surveillance scientists. For example, if a patient has a hepatitis C test done and is treated in three different hospitals, it will now be possible to identify that there are in fact duplicate tests and therefore there is no need to notify again.

Public Health will not be given access to MedLIS.

Barriers: There is no user-friendly front-end solution for extracting data in the right format from MedLIS. The front-end tool for extracting data is very complicated and means a lot of maintenance and experience to run the tool in the first place.

Appendix T: MedLIS Order Communications Lead

1. The MedLIS data extract that can be automatically uploaded into CIDR has been cited by microbiology staff as one of the key MedLIS deliverables that will:

Can you please comment on each one of these categories and provide a view as to if you believe based on your current knowledge, if MedLIS is likely to deliver on expectations for this script?

- I. Improve data collection issues via extraction of data from MedLIS – Yes, I agree if we can get this MedLIS extract to work as it would improve the ease of getting the data from database but also getting the data in a more standardised format.

We will be taking all this patient demographic that is required by CIDR from the PAS. If it's recorded there in PAS than yes, we can also store this data in MedLIS. If CIDR requires ethnicity, then the labs should be asking for and recording this but we don't request ethnicity information currently. Ethnicity can be important for some labs tests so yes, we could potentially include this. PAS will be master and there will be a uni-directional interface, so we pull data patient data from PAS into MedLIS. Most existing LIS would already have a uni-directional interface to PAS. We should not update patient data in MedLIS, only in PAS. The only exception is that we will have to create new patient records directly in MedLIS for paper pathology orders such as GP orders that won't use the electronic ordering module and this patient information will not be copied to the PAS. We will need to think about impact of this.

- II. Improve data quality i.e. missing GP contact information, missing clinical details

Yes, if we can standardise and agree on a minimum patient data set. This is important to get a hit on an IHI match and to add an IHI to electronic laboratory record. This is very important to get a comprehensive and complete electronic laboratory record. In order to get an IHI hit, you need:

- a. first name, surname, Gender, DOB
plus, one other
- b. first line of address or Eircode or PPS or Mother Birth Surname.

Missing Clinical Details

For the tests that go to the NVRL and NVRL want specific data than the NVRL Order Entry forms (OEFs) will request that. Of course, you will get some nonsense data added to the OEF with full stops etc but cannot prevent this.

Yes, we would hope that the data quality will improve as relevant clinical details in the OEF will be added by the GPs. We will more easily collect this patient demographic information from MedLIS electronic order requests, but the challenge will be trying to collect these details from paper order requests.

We can request that this sort of data is being gathered in the order entry forms in terms of a mandatory clinical detail free text field. There will be mandatory clinical detail data field on all microbiology orders. The NVRL will also be requesting some custom information requests on the order entry form. Microbiology order entry forms – there will be mandatory clinical details on microbiology OEF and probably for the NVRL OEF too. Clinical data comes from the requestor and so this is where this data needs to be captured and recorded.

For missing GP details, nearly every patient entry into a PAS system has a GP attached to it and we store this in MedLIS too. Even for GP paper requests, we will have that GP data on the form and a copy of this will be kept in MedLIS. If the lab is a MedLIS lab than we should have the GP information, if it is not a MedLIS lab than it might not be included. Non MedLIS sites that refer tests into a MedLIS site; would not necessarily have GP information included. If for example, Cappagh is sending a reference lab test, Cappagh don't include this GP data and the testing lab does the notification into CIDR without this information as that information is only available in Cappagh. So yes, in the future there is still likely to be some notifications without a GP when the originating referring lab is not on MedLIS. In this scenario, the MedLIS lab would send the positive result to non-Med lab but if it's tested by the MedLIS lab than the MedLIS lab do the notification. Except in the case of a TB test and then it is the responsibility of the originating lab to do the notification.

Primary Research Background: The literature has stated there is wide variability on non-mandatory data that is entered in CIDR. For example, information on ethnicity was available for only 11% of records and the data for the onset of symptoms was missing in approximately one third of cases (Nicolay et al., 2010).

Survey and interview results have all cited missing clinical and patient demographic information such as specimen collection timestamp, foreign travel, anonymised patient data, missing GP contact information as some of data quality and completeness of reporting issues.

2. Please review of CIDR List and let me know if there is any data fields that MedLIS will not store

Patient Healthboard of Residence– Might come across on interface from PAS and could store on Millennium but does not exist currently on PAS

County– don't think this is stored as a separate field in our PAS.

Patient Age Type – could take the DOB that generates the age but don't think this is there in PAS currently

Specimen Collected Date: Yes, for electronic order requests. However, if this is included on paper order request forms, we are unlikely to transcribe and enter into MedLIS. It really will depend on volumes and workload. I think it should be included on the form and the MedLIS lab will keep the form but that does not mean that it will get entered MedLIS. It is something we can look to in the future, but it will depend on the number/volumes and the hospital site if they have the resources to type that in.

For some tests the specimen collected date matters but for others it does not. If the test has an unusual result, the lab staff might look up the specimen collected date to check if it very old specimen. Labs don't confirm the collection date before processing. For some bio-chemistry test this would be more important as some tests need to be processed within a matter of hours of taking the specimen. Microbiology and virology tests however are less time dependent. It would be a

nice thing to record especially for INAB but not something we record currently all the time.

Lab Notifier: This reads as the person responsible for notification or person who did the notification. Not sure where that would be recorded in the MedLIS as surveillance scientists are not an authoriser on the result and therefore not set up on the system as a user. Maybe it could be possible to default in the consultant microbiologist name and add that to automated CIDR extract.

3. Do think it would be difficult to do a real-time automation of notifications into CIDR?

If P2 Sentinel does what it is supposed to do but don't know a lot about it. I assume this would be possible and would not require manual intervention as most of the needed CIDR data will be stored in fields in MedLIS. If the healthboard is recorded in PAS but is needed by surveillance scientists and rather than surveillance scientists having to manually add that into CIDR, then we can look at this and aim to store this healthboard data field in MedLIS. There is nothing too complicated on this CIDR specification list of data items that MedLIS cannot handle and a solution created. For example, perhaps PAS could automatically convert the patient address into an appropriate health board of patient and then we can extract it from PAS into MedLIS and from there into CIDR.

This in the end, could remove the reliance on a surveillance scientist person doing a manual update of data into CIDR. Not for initial phase, but as a next phase MedLIS should be able to deliver an interface between MedLIS and CIDR if that is a requirement.

Now If you have an automated script and/or interface how would we make sure that the case is not reported twice into CIDR i.e. once by the originating lab and again by the processing lab? This would all have to thought about in more detail.

4. The NVRL receive lab specimens and pathology order requests in many different formats including:

Is MedLIS likely to streamline the ordering process and introduce standardised electronic ordering across all or most sources of pathology requests? What knock-on benefits do you think it is likely to have?

- GP handwritten request forms directly from GPs- should decrease but MedLIS cannot stop this
- 2D barcoded printed forms from maternity hospitals – Yes, as soon as that hospital is on MedLIS
- Medibridge requests from some Dublin hospitals – Yes, will be replaced by MedLIS
- Paper requests forms from drug and STI clinics – No, MedLIS cannot stop this

No not completely. There will not only be MedLIS electronic orders going into NVRL. There will either be MedLIS electronic orders or non-MedLIS paper orders. If the GP chooses to not use MedLIS electronic ordering and sends in paper forms instead to their local catchment MedLIS lab, then there is a decision to be made as to whether the MedLIS lab will turn that paper order into an electronic order i.e. register that patient in MedLIS and create an electronic order in MedLIS on the GPs behalf.

There may be some resistance from the labs to do this and do data entry into MedLIS for handwritten GP forms as the GPs should be using the MedLIS electronic ordering solution. This resistance is likely to be greater for notifiable tests that the lab will send on to the NVRL anyway.

If the order is only an NVRL test, then maybe the MedLIS lab won't transcribe and enter that order into MEDLIS and will just send the specimen by courier to the NVRL with the original GP paper order form.

If the paper order however includes one or more tests that are to be processed by our own MedLIS lab and maybe one of the four tests needs to be sent on to the NVRL; than the lab is more likely to process that entire paper order request and register the patient and all those orders into MedLIS.

For Drug and STI Clinic paper requests that go directly to NVRL, then there is nothing MedLIS can do about that and this may continue.

Medibridge requests. What Medibridge does is lift the information out of your LIS into a format that is batched once a day as Medibridge charge per transaction. This batch order request is batched at a certain time of day and only then would be sent to the NVRL, once a day. Yes, the new MedLIS interface to the NVRL will negate and replace Medibridge and therefore requests will be sent to the NVRL in real-time as they happen via the new interface.

Whatever information is in MedLIS and whatever data the NVRL want can be sent across the interface. The medibridge requests currently only include mandatory data. With the assumption that we will now have more information in MedLIS coming from PAS and GPs, then yes would assume we can send extra data fields to the NVRL, whatever they need.

5. Is there anything else you would like to add on how MedLIS might improve the laboratory notification process and any barriers it will need to overcome to realise this?

Think there needs to be a minimum patient data set strategy from the HSE and this needs to be led by the HSE. This is important for an IHI match, but it also helps other downstream systems and any national system should have a minimum dataset. Then we can go to our PAS vendors and GP Practice system vendors and say we need to have a separate field for Eircode and ‘mothers birth surname’ as an example. We need to have this mandate to tell our vendors that this is what we need, this is our minimum national standard, so we can discuss and agree a plan to work towards. We don’t have that today, but we need this policy decision, so we can plan for next upgrade etc. Then we can also insist to have this same minimum dataset information on paper pathology order forms.

The IHI will probably drive this.

Barriers

Anonymisation of patient data is another key barrier for MedLIS. MedLIS needs to have a policy decision on anonymization and this decision needs to come from the HSE. There is no legal requirement for us/MedLIS to anonymise data as it is medical health data, and this is backed up by the GDPR. Having said that, STI type patients in the Guide clinic in

St James for example, may not use this service if we can't maintain patient privacy and handle anonymised patient data. But this anonymization of patient data is historical, and we need to figure out what is the correct thing to do now.

MedLIS is likely to process the anonymised data as we cannot stop it but MedLIS will not perform anonymisation of data. MedLIS cannot be the enforcer of a policy decision. If the decision is for MedLIS to accept and process anonymised data then we are not going to reach our goal of having one laboratory record for a patient with an IHI as this anonymised data will be outside of that. Our preference would be that we don't have anonymised data. This is something we need to figure out.

For example, why do we notify CIDR about an infectious disease if we don't have the correct patient data? Then CIDR does not have the correct patient information. Ironically, it's many of the notifiable diseases that are anonymised. We need the HSE to recommend a policy that we should follow.

Appendix U: MedLIS Quality and Surveillance Scientists Lead

1. Is there a standard audit report that can be run in MedLIS, to provide a list of all the confirmed notifiable pathogens over a custom time period? Can this report be customised easily and by whom?

If there is a requirement, then yes MedLIS can provide that and we would just need to know what the reporting requirements are.

Currently, we have not provided for a report that will pull cases for laboratory confirmed cases of all known pathogens nationwide out from the MedLIS database. But we plan to run a standard report that can be run locally at each hospital site and that can extract notifiable case data from the MedLIS database which then can be uploaded to CIDR in the correct format.

The surveillance scientists will be the only people authorised to pull this information and run this type of report. If there is a new pathogen to be added, it will be legislated for in all hospitals that test for that pathogen.

This new pathogen would need to be added to the report centrally by the back office MedLIS team and would be more complicated if it is a new pathogen that we have never heard of before as the test for that pathogen would first need to be built out in the system. On the other hand, if there is an existing known pathogen i.e. foot and mouth, that has been added to the notifiable list of disease, then it would be a relatively easy change to simply flag this pathogen has a notifiable disease.

The creation and maintenance of the extract report will be easier if we can standardise what the tests are called across hospital sites i.e. Cdiff, C-difficile or something similar. It would be easier to process a change to the report if all the tests are called the same. It does depend on the naming of the pathogens across sites. MedLIS needs to overcome this and there needs to be more discussion between microbiologists on standardisation.

MedLIS will bring in some standardisation but we can't enforce it. It's not the job of MedLIS to enforce standardisation. It would be preferable from an ordering perspective too, Hep B, surface ant. It would be preferable for everyone if tests were called the same

thing across sites. How easy the maintenance of the extract report will depend on the degree of standardisation.

From an overall surveillance report perspective; there would be a benefit if an extract query could be pulled for all notifiable cases for the entire country as you could map the confirmed laboratory cases and find out clusters in certain locations etc. But currently nobody has requested or is authorised to do that as public health the way it is organised, only looks at regional health data. I'm not aware of anyone who has the authority to pull country wide laboratory data. You can only pull that data if you have a legitimate reason to do so.

2. The MedLIS data extract that can be transformed and uploaded into CIDR has been cited by microbiology staff as one of the key MedLIS deliverables that will:

Can you please comment on each one of these categories and provide a view as to if you believe based on your current knowledge, if MedLIS is likely to deliver on expectations for this script.

- I. Improve data collection issues as some labs rely on hardcopy lab reports that require manual data entry in CIDR. *Yes, MedLIS will improve data collection issues.*

Yes, MedLIS will cut out that manual step of notification and take away the reliance on medical staff in the lab to have to print out a copy of result for the surveillance scientist. However, it will not completely automate the process. A surveillance scientist will need to scan through the MedLIS extract report as sometimes a diagnosis is there for a few days and you should only report once. For example, a doctor could have sent in a second sample for testing and so there can be multiple confirmed results for the same patient but only one of these should be notified.

- II. Completeness of reporting in terms of being able to extract more LIS data on more optional fields especially if more good quality data is added and stored in MedLIS due to electronic order communications by hospital staff and GPs. *Yes, agree that the new extract report would pull additional optional fields i.e. admitted date and discharge date. Also, because most of this data will now be generated from*

electronic ordering; data like clinical details should be more complete. Also, existing hardcopy laboratory reports do not have the space required for all the data details within the fields and so this limits the notifiable data that can be added to a report. MedLIS will solve this, and more notifiable data can be stored in the electronic record as it will be easier to capture any amount of that data.

- III. Improving any under-reporting that might exist by removing the dependency on medical staff to report a confirmed case to the surveillance scientist. It will definitely improve under-reporting. It will also be much easier to audit the information in CIDR and be able to run a cross-check report.

From my own experience, the queries I would have run for the infection control department would be more for hospital acquired notifiable diseases i.e. Cdiff and MRSA, meningitis but there is a lot more on the notifiable list. Based on the limitations of the LIS, I would need to have setup a query based on how many tests were ordered for a specific notifiable disease and only then could I do further investigations to see what was resulted. I was unable to run a query on resulted tests, only on tests ordered. Running a query to check all confirmed results is not possible, as not all results come back electronically into the local laboratory information system. Some results would come from different sources in different formats i.e. on paper.

Now, with MedLIS you will be able to run a query and confirm on what was resulted instead of what was ordered.

Not in all cases would the other lab have raised the notification i.e. not in the case of TB. There are gaps in the current notification process.

3. Can you provide a view as to whether and if MedLIS might improve upon data quality issues within the current notification process? See below issues cited by primary research.

Primary Research Background: The literature has stated there is wide variability on non-mandatory data that is entered in CIDR. For example, information on ethnicity

was available for only 11% of records and the data for the onset of symptoms was missing in approximately one third of cases (Nicolay et al., 2010).

Survey and interview results have all cited missing clinical and patient demographic information such as specimen collection timestamp, foreign travel, anonymised patient data, missing GP contact information as some of data quality and completeness of reporting issues.

I do think that electronic info is much more accurate than transcribing handwritten requests.

4. Do you think an electronic messaging interface between MedLIS and CIDR would be beneficial and work in the Irish context given the current notification process?

Don't believe we are there yet due to:

- I. Complexity of case definitions
- II. Lack of standard terminology and variability of the test names
- III. Ireland does not have infectious diseases that are spread easily have severe outcomes such as death in a matter of days i.e. Ebola or SARS. We don't really need it yet.

Irish reference labs are the place where most of these things are tested. The NVRL is the main notifier for most of the tests and their terminology is standardised and all hospitals will use that. Within hospitals, there is variations on the names of the tests. We need all the laboratory notifiers to be using one standard terminology.

5. Is there anything else you would like to add on how MedLIS might improve the laboratory notification process and any barriers MedLIS will need to overcome to realise this?

MedLIS will be a great benefit to surveillance scientists as some of them are still manually drilling through their laboratory results to find the notifiables. Some labs are very dependent on medical staff to communicate to them a confirmed case. In this case, you would not know as a surveillance scientist if you have missed one.

MedLIS will have a challenge on the extract query as there are three laboratory modules within MedLIS which are microbiology, helix and gen lab. This is important

because some microbiology results are across all three and aren't gathered in one location in the database. This might make it difficult to extract all necessary data and complicates the query. This is a current problem in existing LIS system and MedLIS will not solve this.

Barriers

Test names need to be standardised across hospital sites and it's a pity this was not done before the build as now we have a microbiology build per site as opposed to one national microbiology catalogue.

Anonymised data is a barrier that MedLIS cannot overcome. MedLIS will have no responsibility to link patients record with their anonymised record so conceivably a patient can have two or more records. With multiple records, you cannot see the progress of the disease as there will be no IHI added and therefore records cannot be linked.

Anonymisation impacts continuity of care but also impacts Public Health as the role of Public Health in infectious diseases is to provide guidance to those people who have these diseases and provide national guidance on an outbreak. So anonymised data is a complication in the process and just delays things. It would be good to understand what public health do in the case of anonymised data. – check Andrea King. The real patient name is so important so even if a patient has been given a unique Patient ID, there might still be a mistake i.e. typo.

Public Health also create CIDR notifications themselves for notifications that are made outside of CIDR i.e. clinical notifications. You would never just use a number to uniquely identify a patient, always use multiple things i.e. surname, DOB, address.

Also, with anonymised data, you can never understand linkage as it prevents the possible identification of an outbreak within a family cluster of people. Normal outbreaks are normally location based so anonymization would not prevent location-based cluster identification.

Appendix V: Detailed collation of data quality issues and root cause analysis

Data Quality issues	Root Cause	No. of Responses
Handwritten forms Handwritten inpatient order requests Handwritten GP request forms	Need to type in the data manually into our LIS	1 * Surveillance Scientist 1* Chief Medical Scientist 1 * Senior Medical Scientist
Transcription Errors into CIDR	Easily to select wrong organism via long dropdown list in CIDR Must transcribe data from request form into CIDR manually	1* Chief Medical Scientist
Illegible handwriting from GP paper requests		1 * Chief Medical Scientist
Date and timestamp of specimen collection is often missing from GP requests.	Clinicians don't complete request forms to a high standard	1 * Chief Medical Scientist 1* Senior Medical Scientist 1 * NVRL Lab Manager
Not clear what test is requested by GP	Can be ambiguous as many viral tests for GP to choose from. They often request a viral screen instead of a test for a named virus. Requests are missing clinical details so it's not always clear what tests are to be run i.e. onset of symptoms, foreign travel	1* Senior Medical Scientist 1 * NVRL Lab Manager
Wrong patient demographic data resulting in duplicate patient records or LIS or rejection of test	Mis-match of patient demographic details on specimen tube label versus	1 *chief medical scientist – country

	paper request. Test would be rejected	1 * senior medical scientist
Incomplete CIDR data	CIDR requires a minimum dataset (DOB, Surname, Specimen Site, Pathogen, Specimen ID and MRN if inpatient) but we don't have the resources to go looking to fill optional data. Too time consuming	1 * Senior Medical Scientist 1 * Surveillance Scientist
Clinical details are often absent from handwritten order request	Clinical details are not mandatory and does not prevent the processing of a test. Yes, they would be helpful and might widen scope of testing but they not necessarily missing details	1 * Chief Medical Scientist
Anonymised Patient Data that ends up getting entered in CIDR	Typically requests from STI Clinics only include initials for the name to protect patient's privacy but DOB would be correct. Patient Surname and address is often anonymized from STI clinics	1 * Surveillance Scientist (country hospital) 1 * NVRL Lab Manager
Missing specimen type	Main issues stem from various non-standardised request forms we get from different sources	1 * NVRL Lab Manager
Not many to no Data quality errors Match result to wrong patient - never get this	Data quality errors are caught and fixed before getting to the lab/surveillance scientist. Test requests with errors are rejected by specimen collection lab staff and do not get as far as being tested	1 * Surveillance scientist (Dublin Hospital) 1 * Surveillance scientist (Country Hospital)

Appendix W: Laboratory Interviewees Notification Improvement Assessment

Evaluation Category	Yes/No/ Other	Comment
Data Quality Issue	Yes (snr medical scientist (country hospital))	Yes, especially if have standardised electronic order request forms. These order entry fields will dictate the data we have on MedLIS.
Data Quality Issue	Yes (Surveillance scientist, Country Hospital)	If there are data quality issues, they exist for all sites and so MedLIS should help
Data Quality Issue	Yes (NVRL Lab Manager)	
Data Quality Issue	Yes (Surveillance scientist, Dublin Hospital)	It should when everybody gets order communications
Data Collection Issues	Yes (snr medical scientist (country hospital))	Assuming we have a custom extract query that can extract notification data from MedLIS
Data Collection Issues	Not sure (Surveillance scientist, Country Hospital)	It could be worse and depends on robustness of extract query to get data from MedLIS database. Currently, I can build and write my own queries and our bespoke database is easily accessible.
Data Collection Issues	Yes (NVRL Lab Manager)	
Data Collection Issues	Yes, but not confident (Surveillance scientist, Dublin Hospital)	Yes, assuming the data extract is robust enough but don't have confidence it will work. If it all worked, and every lab was the same and did the same tests and all notified, than yes

		MedLIS would help data collection.
Completeness of reporting (mandatory and optional fields)	Yes (snr medical scientist (country hospital))	If query can pull more data on optional fields and MedLIS upload into CIDR completes all those fields.
Completeness of reporting (mandatory and optional fields)	Yes (Surveillance scientist, Country Hospital)	Yes, if we can get this query working and if in future we had an interface between CIDR and MedLIS. We currently only add mandatory data in CIDR.
Completeness of reporting (mandatory and optional fields)	Yes (NVRL Lab Manager)	
Completeness of reporting (mandatory and optional fields)	Yes (Surveillance scientist, Dublin Hospital)	
Timeliness of reporting	Not sure (snr medical scientist (country hospital))	Somebody still need to click a button to upload the data into CIDR. Still need to wait for weekly clinical review meeting for those more complex cases.
Timeliness of reporting	Yes (Surveillance scientist, Country Hospital)	
Timeliness of reporting	Yes (NVRL Lab Manager)	
Timeliness of reporting	Not sure (Surveillance scientist, Dublin Hospital)	Depends on how often labs run their query now
Full case Reporting	Yes (snr medical scientist (country hospital))	Assume we have an audit surveillance report that can compare confirmed lab cases to what we notified into CIDR

Full case Reporting	Yes (Surveillance scientist, Country Hospital)	Yes, if integrated and we get this query working
Full case Reporting	Yes (NVRL Lab Manager)	
Full case Reporting	No Change	There should be full reporting now

Appendix X: Count of existing laboratory information systems nationwide

Laboratory Information System (LIS) Name	No of hospital labs per LIS
CSC APEX/iLAB	20
CSC Telepath	6
Custom S/W Netacquire	7
Clinisys Winpath	7
Sunquest Copath	2
Lifeline	1
Total	43 labs

Appendix Y: GP Paper Order Request to Hospital Example

GP Request for Laboratory Services
MICROBIOLOGY DEPARTMENT
 C. P. L., St. James's Hospital, Dublin 8.
 Tel: 4162941 / 4162966 / 4162967

010421

Patient Details: Surname, First Name, Date of Birth, Sex (Male/Female), Ethnicity (if relevant)

Patient's Address:

Doctor's Name, Practice address or practice stamp here, Practice Telephone Number:

Clinical Details: *Upper FU*, Drug / Antibiotic Therapy, Date Taken: *10/01/2018*, Time Taken: *11am*, Date/Time Received:

SPECIMENS (Please Tick): Blood Urine Stool Swab Other

General Microbiology		
Culture & Sensitivity <input type="checkbox"/> Urine <input checked="" type="checkbox"/> Swab <i>Query Influenza</i> <input type="checkbox"/> Fluid Site: <i>Oropharyngeal</i>	Fungal Culture <input type="checkbox"/> Nail Clippings <input type="checkbox"/> Hair <input type="checkbox"/> Skin Scrapings Site: _____	STI Molecular Investigations <input type="checkbox"/> CT/NG (Endocervical Swab) <input type="checkbox"/> CT/NG (Vaginal Swab) <input type="checkbox"/> CT/NG (First Void Urine) <input type="checkbox"/> CT/NG (Pharyngeal Swab) <input type="checkbox"/> CT/NG (Rectal Swab)
<input type="checkbox"/> Sputum C/S <input type="checkbox"/> Sputum TB <input type="checkbox"/> MRSA Screen Swab (Nasal/Throat/Groin)	<input type="checkbox"/> Stools Investigation <input type="checkbox"/> Stools Ova & Parasites** ** performed only when relevant clinical details are provided.	Viral Molecular Investigations (Green Top Viral Swab) <input type="checkbox"/> Herpes Simplex Virus (HSV) <input type="checkbox"/> Varicella Zoster Virus (VZV) Site: _____


Serology (Order either profiles or individual investigations as appropriate)

PROFILES	INDIVIDUAL INVESTIGATIONS	
<input type="checkbox"/> STI Screen (Syphilis, HIV, Hep B sAg) <input type="checkbox"/> Measles / Mumps / Rubella Screen IgG <input type="checkbox"/> Viral Hepatitis B & C Screen (Hep B sAg, Hep C Ab) <input type="checkbox"/> Hepatitis B Infection Status (Hep B sAg, Hep B cAb) <input type="checkbox"/> Current Hepatitis C Infection (Hep C core Ag)	<input type="checkbox"/> Syphilis <input type="checkbox"/> HIV <input type="checkbox"/> Hep B sAg <input type="checkbox"/> Hep B sAb (Post-vaccination) <input type="checkbox"/> Hep B core Ab <input type="checkbox"/> Hep C Ab <input type="checkbox"/> Other (please specify): _____	<input type="checkbox"/> Hep C core Ag <input type="checkbox"/> Measles <input type="checkbox"/> Mumps <input type="checkbox"/> Rubella <input type="checkbox"/> Hep A IgG <input type="checkbox"/> VZV IgG

Specimen requirements and other information are available on www.sjames.ie by clicking on the "Lab Services" Tab. For further information on ordering hepatitis screens please refer to "Viral Hepatitis Testing for General Practitioners" in the Laboratory Policies & Guidelines section.

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Appendix Z: GP Paper Order Request Example to NVRL

	National Virus Reference Laboratory University College Dublin Belfield, Dublin 4	Tel General Enquiries: 01 7164401 Web: nvrl.ucd.ie Email: nvrl@ucd.ie
GENERAL REQUEST FORM		
PATIENT DETAILS		
Forename: <input style="width: 100%;" type="text"/>	DOB: <input style="width: 100%;" type="text"/>	
Surname: <input style="width: 100%;" type="text"/>	Sex: <input type="checkbox"/> F <input type="checkbox"/> M	
Address: <input style="width: 100%; height: 40px;" type="text"/>		
SPECIMEN DETAILS		
Specimen Type(s): <input type="checkbox"/> Serum <input type="checkbox"/> Plasma	Specimen Date & Time of collection: <input style="width: 100%;" type="text"/>	
Other: <input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	
CLINICAL DETAILS	INVESTIGATION REQUIRED	
<small>Clinical details aid the selection of an optimal testing strategy. Please include duration of illness and relevant vaccination/travel history</small> Date of onset of symptoms: <input style="width: 100%;" type="text"/>		
DOCTOR / SURGERY DETAILS/REQUESTING HOSPITAL DETAILS		
Name: <input style="width: 100%;" type="text"/>	Surgery Address / Hospital Address/Stamp <small>N.B. Please note that the sample will not be processed without address of surgery or hospital</small>	
Signature: <input style="width: 100%;" type="text"/>		
IMC No: <input style="width: 100%;" type="text"/>		