TITLE: AN EVALUATION OF THE PERFORMANCE OF THE HEPATITIS B SURVEILLANCE SYSTEM AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL FOR 2017 – 2018

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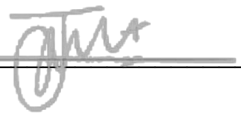
Candidate's Declaration

I, Dr. Jesne Kistan, declare that this dissertation is my own, unaided work. It is being submitted for the degree of Public Health Medicine at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Jesne Kistan (electronic signature)

SIGNED: 

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__31st_ day of ____August_____ 2020_____ in _____University of Witwatersrand

Abstract

Background

Infection with Hepatitis B virus is a public health priority globally due the transmissible nature of the virus and the subsequent complications of Hepatitis B related disease. Public health surveillance systems are necessary to manage public health priorities such as Hepatitis B virus as these systems detect public health threats and inform public health actions. Surveillance systems need to be functioning appropriately to effectively inform public health responses. Therefore, it would important to assess the functioning of a surveillance system.

Methods

We conducted a cross-sectional study of the performance of the attributes of the Hepatitis B virus surveillance system at Charlotte Maxeke Johannesburg Academic Hospital between 2017 – 2018. We performed a retrospective record review of the completeness and timeliness of the Hepatitis B virus positive case notification. We further conducted a survey of the healthcare worker (doctors and infection prevention and control nurses) perceptions of the attributes (i.e. simplicity, acceptability, timeliness, flexibility and usefulness) of the HBV surveillance system.

Results

Overall, 45.2% (n=238) of positive Hepatitis B virus cases were reported from Charlotte Maxeke Johannesburg Academic Hospital to the City of Johannesburg district office. Of 83 matched cases, 44.6% (n=37) of cases were found to be reported timeously. Health care workers (n=82) largely perceived the HBV surveillance system at CMJAH to be unacceptable (45.0%, n=36), untimely (37.8%, n=31) and not useful (74.1%, n=60). They were equivocal regarding the simplicity and flexibility of the surveillance system.

Conclusion

Dysfunction of the HBV surveillance system directly impacts on South Africa's ability to prevent infection with Hepatitis B virus and disease-related morbidity and mortality. Staff training, roll out of electronic reporting systems and routine feedback and monitoring of the HBV surveillance system could improve functioning of this system.

Acknowledgements

I would like to recognize the following people for their importance with regards to my dissertation, my ongoing studies and my everyday life:

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- My friends for love, laughter and sympathetic ears.

Table of Contents

List of figures

List of Tables

Acronyms

CDC	CENTER FOR DISEASE CONTROL
CMJAH	CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL
COJ	CITY OF JOHANNESBURG
GHSS	GLOBAL HEALTH SECTOR STRATEGY
GIS	GEOGRAPHICAL INFORMATION SYSTEM
HBV	HEPATITIS B VIRUS
HIV	HUMAN IMMUNODEFICIENCY VIRUS
IHR	INTERNATIONAL HEALTH REGULATIONS
LIS	LABORATORY INFORMATION SYSTEM
NHA	NATIONAL HEALTH ACT
NICD	NATIONAL INSTITUTE OF COMMUNICABLE DISEASE
NMC	NOTIFIABLE MEDICAL CONDITION
TB	TUBERCULOSIS
WHO	WORLD HEALTH ORGANIZATION
REDCAP	RESEARCH ELECTRONIC DATA CAPTURE

List of Appendices

1. Chapter 1: Introduction

1.1 Background

Hepatitis B virus (HBV) is a public health concern due to the transmissible nature of this viral infection and its' association with liver cirrhosis and liver cancer. The World Health Organization (WHO) estimates that 15-20% of adults with chronic HBV infection will die from HBV associated liver cirrhosis or liver cancer (World Health Organization, 2017a). In 2016, 194 countries (including South Africa) undertook to implement health care strategies that would eliminate viral hepatitis by 2030 (World Health Organization, 2017a). Infection with HBV remains a challenge with the prevalence of HBV in South Africa ranging anywhere between 1-15% (Kew, 2008).

Hepatitis B virus prevention and control requires information regarding the infection to be accurate, valid and timeous to inform prompt action. In South Africa, reporting of positive HBV cases forms part of the passive surveillance system whereby acute and chronic infection with HBV is a medical condition which is notifiable by legal mandate (South African National Department of Health, 2017).

Public health surveillance systems are necessary to detect public health threats and to inform public health actions timeously. Globally, there are challenges with the performance of these surveillance systems which prevents effective prevention and control measures being employed. Furthermore, there are great variations in completeness of reporting of notifiable medical conditions (NMC). Underreporting varies between 22-96% complete in some countries. Completeness of reporting also differs by disease with more commonly known diseases such as Tuberculosis (TB) and Human Immunodeficiency Virus (HIV) being reported better (Doyle et al., 2002). Challenges also exist with timeliness of reporting of diseases. Reporting of notifiable diseases in a timely manner also differs by country and by disease (Reijn et al., 2011, Garcell H G, 2014). Cases reported outside the required time-period pose a threat to public health safety as prompt action to prevent person-to-person transmission of diseases is reduced.

In South Africa, reporting of NMCs by health care establishments, of diseases which pose a public health threat are mandated by law under the National Health Care Act and regulations relating to the surveillance and the control of notifiable medical conditions (NMC) (South African National Department of Health, 2003, South African National Department of Health, 2017). Infection with HBV is required to be notified within seven days of clinical suspicion or diagnosis of disease.

The National Institute of Communicable Diseases (NICD) in South Africa is responsible for the analysis and interpretation, as well as dissemination of health-related notifiable diseases which inform action to reduce morbidity and mortality and to improve health in the population. The collection and reporting of this data begins at a facility level (i.e. primary health care facility, hospital or private practitioner) and information flows from the bottom-up to district, provincial and national levels of government. For surveillance systems to work effectively, it requires information to be collected, analyzed and interpreted in an accurate, valid manner. An evaluation of public health surveillance systems should be conducted to ensure that public health issues are being monitored effectively and efficiently.

Few studies have looked at HBV Surveillance systems. One study conducted approximately 30 years ago noted huge discrepancies in reporting of HBV (Karim and Dilraj, 1996). Since then, dual methods of reporting (electronic and paper-based) were introduced in South Africa in 2017. The performance of the HBV surveillance system in South Africa has not yet been assessed since the commencement of the new reporting system. Other studies in South Africa evaluating surveillance systems of other diseases such as Malaria have shown variation in reporting of disease, poor timeliness of disease reporting and a view of the surveillance system being perceived as useless by stakeholders (Weber, 2007).

Our study was conducted in a central hospital in Gauteng. It consisted of a retrospective record review of facility based reports (line lists), quantitative data analysis of the reported HBV cases from laboratory tests to the NICD provided from 2017 – 2018 and a cross-sectional survey of health care workers (medical doctors and infection, prevention and control (IPC) nurses) to assess health care worker perceptions of the HBV surveillance systems.

1.2 Problem Statement

Infection with HBV is a public health threat that requires a well-functioning surveillance system to inform rapid response to prevent and control further infection. In South Africa, we are unable to state if the HBV surveillance system is performing well or not, as there is a gap in the knowledge of the performance of HBV surveillance systems. Furthermore, the last study performed on HBV surveillance systems was conducted 30 years ago. There is a need to evaluate the HBV surveillance system as well as identify end user perceptions of surveillance systems to understand and inform improvements of the surveillance system.

1.3 Justification of study

In South Africa, accurate figures of the prevalence of acute viral hepatitis (including HBV) are difficult to obtain. Although the disease is notifiable, most cases are not reported (Kew, 2008). Moreover, the quantification of underreporting is unknown. Evaluation of disease surveillance systems in South Africa largely focus on TB and HIV. As a result, there is a lack of information regarding other notifiable diseases such as HBV public health surveillance systems. Hepatitis B virus is an important public health infection that requires monitoring of new cases and its' sequelae. This communicable infection is also preventable by vaccination. Therefore, the surveillance system also contributes to monitoring the effectiveness of HBV prevention strategies. Effectiveness and efficiency of HBV prevention programmes in South Africa including immunization and burden of disease are largely unknown.

Although there are national and provincial data on prevalence, there are no published data on the performance of surveillance systems for HBV in South Africa. Quantification of reporting of disease is necessary as it establishes potential gaps in baseline data as well as identifies areas for improvement for surveillance systems. Under reporting of HBV may lead to underestimation of disease burden and hindering of appropriate prevention and control strategies (Braz et al., 2016). In South Africa, areas of improvement in prevention of HBV, threats to HBV related transmission and efficiency of programmes are uncertain as the effectiveness of our notification system has not been evaluated at facility level.

There remains a need for an evaluation on performance of HBV surveillance systems in South Africa. An evaluation of completeness and timeliness of HBV surveillance systems at CMJAH will contribute to assessing the effectiveness surveillance systems in South Africa. Our study will attempt to fill the gap in knowledge by being one of the few studies to quantify the reporting completeness and timeliness of HBV notification in patients seen and tested at a central hospital in South Africa. We also aim to understand health care worker perceptions of the HBV surveillance system which may affect performance of the HBV surveillance system at a facility level.

1.4 Research Question

How did Charlotte Maxeke Johannesburg Academic hospital (CMJAH) HBV surveillance system perform when reporting HBV from 2017 to 2018?

1.5 Aim

To evaluate the performance of HBV surveillance system at Charlotte Maxeke Johannesburg Academic Hospital from 1 January 2017 to 31 December 2018.

1.6 Objectives

1.6.1 To determine completeness of reporting of positive HBV cases at CMJAH

1.6.2 To determine completeness of HBV notification forms within the CMJAH Infection Prevention and Control Unit

1.6.3 To determine factors associated with completeness of HBV notification forms within the CMJAH Infection Prevention and Control Unit

1.6.4 To establish the timeliness of reporting of positive HBV cases at CMJAH from 1 January 2017 to 31 December 2018.

1.6.5 To determine health care worker perceptions of the attributes of the HBV surveillance system at CMJAH

2. Chapter 2: Literature Review

2.1 Search Criteria

Search databases such as Google Scholar and Pub Med were used. The search terms used were Hepatitis B, evaluation of surveillance systems, South Africa, completeness, timeliness, simplicity, acceptability, flexibility and attributes of the surveillance systems. Similar articles to the study were extracted from citations in articles that were obtained from the search criteria.

2.2 Burden of Hepatitis B virus

Hepatitis is caused by infection with one of the hepatides (Hepatitis A virus, Hepatitis B virus, Hepatitis C, Hepatitis D or Hepatitis E). Acute infection with Hepatitis B virus is often-self-limiting. Chronic Hepatitis B is where the Hepatitis B surface antigen (HBsAg) remains positive post the infectious or symptomatic period. Some people may remain "healthy carriers" without further symptoms while others develop chronic persistent or chronic active hepatitis. It is the latter which is associated with dysplastic hepatocytes, focal, nodular hyperplasia, hepatocyte necrosis, and cirrhosis. Cirrhosis is the most common precursor to hepatocellular carcinoma (Popper et al., 1987).

Hepatitis B virus is a public health threat globally. The World Health Organization estimates that 3.5% of the worlds' population are chronically infected with HBV (World Health Organization, 2017a). It has been established that complications of cirrhosis and hepatocellular carcinoma caused by chronic HBV infection are the largest burdens of hepatitis infection. It is further estimated that 15-20% of adults with chronic HBV infection will die from HBV associated liver cirrhosis or liver cancer (World Health Organization, 2017b)

Infection with HBV is prevalent throughout Sub-Saharan Africa (Kew, 2008). Hepatitis B is estimated to have a prevalence of 6.1% and account for 87 890 deaths annually in sub-Saharan Africa (World Health Organization, 2017a). The prevalence of HBV varies in South Africa, ranging from 1-15% (Kew, 2008). There are differences in racial groups, with HBV infection most prevalent in the Black population. Furthermore, the prevalence of HBV

infection is higher in rural settings (Kew, 2008, Firhaber et al., 2008, Woodhall et al.). Accurate figures of prevalence of acute viral hepatitis are difficult to obtain in South Africa because, although the disease is notifiable, many cases are not notified (Kew, 2008).

In Gauteng province, the prevalence of HBV disease is 18%. This is the highest reported in South Africa (Nair, 2011).

2.3 Hepatitis B virus as a public health concern

Although a vaccine for HBV does exist, mortality from viral hepatitis has increased by 22% since 2000 (World Health Organization, 2017a). Acute infection is self-limiting. However, chronic infection may lead to chronic hepatitis, cirrhosis or carcinoma of the liver. With 257 million people living with chronic HBV globally, it is a growing public health concern (World Health Organization, 2017a). Furthermore, globally, viral hepatitis had deaths comparable with TB and HIV in 2015. Despite TB and HIV having declining mortality, deaths related to viral hepatitis are increasing (World Health Organization, 2017a).

In May 2016, the World Health Assembly adopted the Global Health Sector Strategy (GHSS) on viral hepatitis for 2016–2021. The 194 Member States of WHO committed to eliminating viral hepatitis as a public health threat by 2030 (World Health Organization, 2017a). To monitor the progress of the GHSS, reliable surveillance systems need to be in place to track incidence of HBV infection and its' complications (especially mortality associated with cirrhosis and/or hepatocellular carcinoma).

2.4 Disease Surveillance

Public health surveillance is the ongoing collection, analysis and interpretation, as well as dissemination of health-related data for use in public health to inform actions that reduce morbidity and mortality and to improve health (World Health Organization, 2006). The functions of a communicable disease surveillance system are to elicit early warning potential threats to public health and monitor disease-related programmes. For surveillance systems to work effectively, it requires information to be collected, analyzed and interpreted in a valid, timely manner. Thus, an evaluation of public health surveillance systems should be

conducted to ensure that public health issues are being monitored effectively and efficiently. Notification of disease is a passive form of surveillance which is used to respond to disease outbreaks and monitor effectiveness of eradication or elimination programmes.

2.5 South African Disease Surveillance System

In SA, national surveillance systems must comply with International Health Regulations (IHR). Positive HBV case notification is a statutory obligation in the South African health care system, according to regulations of the National Health Act (NHA) No 63 of 1977 (South African National Department of Health, 2017). In March 2017, the Department of Health introduced electronic based reporting of notifiable diseases into legislation (South African National Department of Health, 2017). However, paper-based reporting still exists in many institutions and a dual method of reporting is allowed for until electronic roll-out is completed in all provinces. Infection with HBV falls under the category 2 medical conditions, which requires health workers to notify the local authority via mail/fax within 7 days of first coming into contact with a patient. Diseases are reported on a Notifiable Medical Condition (NMC) case notification form (Appendix II) and on weekly line lists (Appendix III) from the health care facility to the district office and to the National Institute of Communicable Diseases. Notification forms are collated at the district health level and are reported on a weekly basis to the provincial level health focal person unit using the NMC case line listing forms. At the provincial level, reporting is further aggregated and reported at the national level focal person (South African National Department of Health, 2018).

Laboratory based reporting of notifiable diseases also occurs via the National Health Laboratory Services. Electronic real time reporting, upon resulting of an NMC cases within the Laboratory Information System (LIS), will automatically be notified to the NMC national system and an alert sent to all relevant focal people at Health Establishment, Sub-District, District, Province and National (South African National Department of Health, 2018).

2.6 Process of the surveillance system of Hepatitis B at CMJAH

Charlotte Maxeke Johannesburg Academic Hospital is one of four central hospitals in Gauteng. It services patients from within the province as well as patients from other provinces. Hepatitis B virus testing is ordered by doctors at the CMJAH NHLS laboratory

when infection with the virus is suspected. Positive HBV results (IgM positive) are sent to the Infection, Prevention and Control Unit. The reporting of HBV is conducted by both doctors and the IPC unit at CMJAH. A line list is compiled monthly and submitted to the City of Johannesburg (COJ) District Office. The positive Hepatitis B results are traced back to the ward which ordered the testing and a medical practitioner (intern, medical officer or registrar) completes the case notification form. A copy of the form is kept in the patient file, and one is submitted to the COJ District office and another to the NICD (Brown, 2019). Simultaneously, electronic reporting of the positive HBV result is sent to the NMC national system and is collected by the Notifiable Medical Conditions Unit at the NICD. The COJ district office also submits the line list to the Provincial Public Health Unit and the notification form to the NICD.

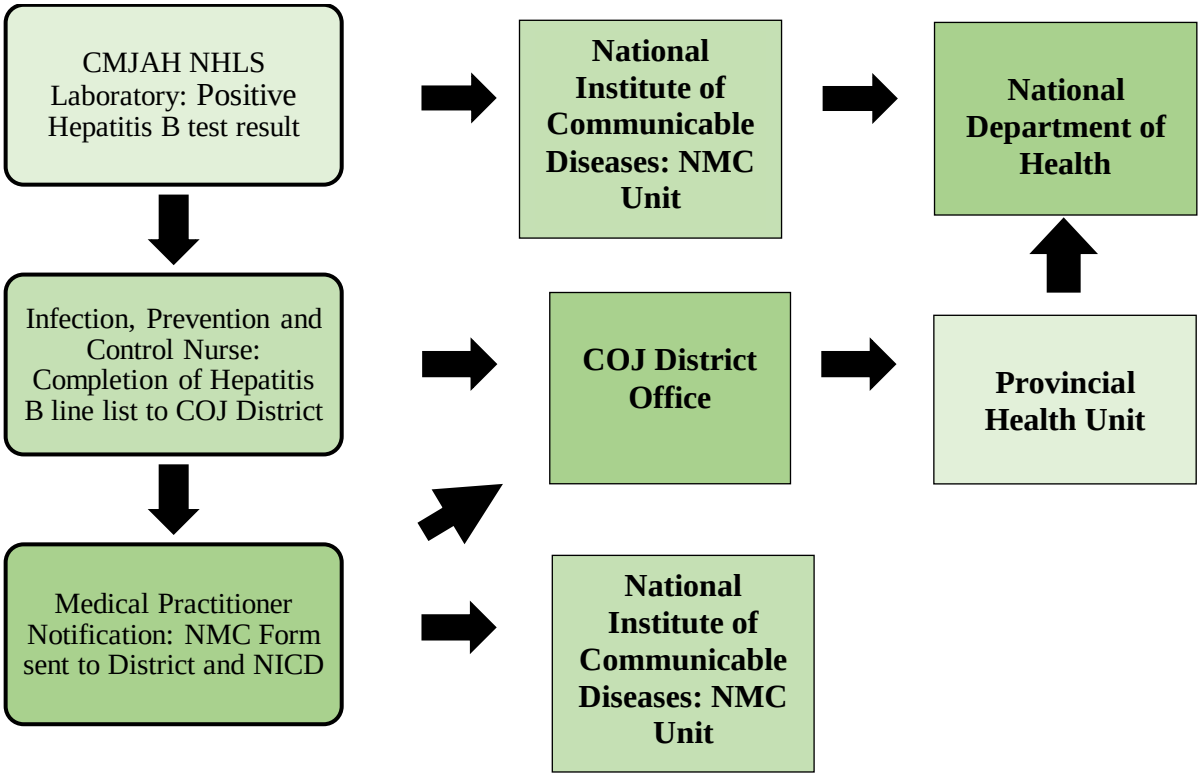


Figure 1: Process flow of reporting of positive Hepatitis B cases at Charlotte Maxeke Johannesburg Academic Hospital

2.7 Evaluation of a surveillance system

Surveillance systems must be assessed to ensure that problems of public health importance are being monitored efficiently and effectively. The precision and validity of evaluation of public health surveillance systems must include an assessment of system attributes. The Center for Disease Control and Prevention (CDC) has proposed a framework of attributes of the surveillance system (figure 2) including simplicity, flexibility, data quality (completeness and validity), acceptability, sensitivity, predictive value positive, representativeness, timeliness, and stability are essential in the evaluation (Centers for Disease Control and Prevention, 2001)

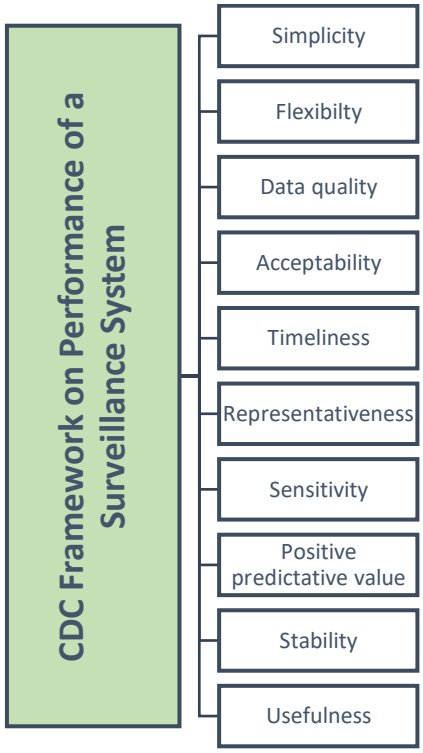


Figure 2: CDC Framework on Performance of the Surveillance System

Data quality reflects the completeness and validity of the data recorded in the public health surveillance system (World Health Organization, 2006).To ensure data quality, the surveillance system must be evaluated. Data quality evaluation is based on an assessment of completeness of reporting of notifiable diseases. Completeness encompasses completeness of reporting sites/surveillance forms, completeness of disease case reporting, and completeness of surveillance data (Centers for Disease Control and Prevention, 2001). Completeness of surveillance data refers to the completeness of the data fields collected.

Timeliness reflects the time taken between for notification to reach from one level of a health care authority to another in a public health surveillance system (World Health Organization, 2006) Timeliness enables immediate control efforts, prevention of continued exposure, or program planning. In studies done previously, timeliness varied among diseases notified and was found to be inadequately meeting reporting standards (Braz et al., 2016, Reijn et al., 2011). Completeness and timeliness of disease reporting have been jointly more reported on than other attributes of the surveillance system (Garcell H G, 2014, Overhage et al., 2008, Braz et al., 2016, Dixon et al., 2017).

The other attributes of the CDC framework are also useful in assessing the performance of surveillance systems. Simplicity denotes the structure and ease of operation of the surveillance system. Simplicity is often assessed subjectively rather than by quantitative means (World Health Organization, 2006). Communicable disease surveillance and response systems: guide to monitoring and evaluating). A useful surveillance system is one that produces early warnings so that public health threats can be responded to in a timely fashion. Acceptability of a system is a reflection of the willingness of the surveillance staff to implement the system, and of the end users to accept and use the data generated through the system.

Many studies have used aspects of the Disease Control Framework for evaluating the overall surveillance systems in countries or disease specific surveillance systems. However, there has been very few studies evaluating Hepatitis B surveillance systems both globally and locally. (Benson et al., 2018, Karim and Dilraj, 1996). Thus, it would be important to utilize the CDC framework to evaluate HBV surveillance systems.

2.8 Challenges with Surveillance

Completeness of reporting cases has varied in countries. In a systematic review conducted in the United States of America, completeness of infectious disease case reporting varied from 22-96% (Doyle et al., 2002). Completeness also differs on the disease which is notified. HIV and Tuberculosis (TB) cases have been found to have higher portions of notification than other mandatory notifiable conditions (Doyle et al., 2002, Keramarou and Evans, 2012). However, this is not consistent as other studies have shown that TB can also be underreported. It is therefore thought that completeness of notification may not be associated

with the type of disease being notified (Pillaye and Clarke, 2003). Studies have also shown that even when completeness of disease reporting may be good, other attributes such as timeliness may be found to be below international standards (Braz et al., 2016) Mostly, studies showed that diseases were found to be underreported (Doyle et al., 2002, Keramarou and Evans, 2012, Mellou et al., 2013).

In some studies, timeliness of reporting differed among diseases. In Netherlands, reporting of Hepatitis A timeliness was found to be at 90.3% compared to Shigellosis which was at 0.4% (Reijn et al., 2011).

Other factors that have been found to be associated with increased completeness of disease reporting. In a study conducted in Nairobi, Kenya, weekly reporting forms (i.e. zero reporting on a weekly basis) and having a designated surveillance focal person were associated with better reporting of cases (Mwatondo et al., 2016). Diseases with longer incubation times were also associated with better completeness of reporting (Jajosky and Groseclose, 2004).

2.9 Challenges with the South African Surveillance system

In South Africa, there has been limited evaluations of the notifiable disease surveillance system (Benson et al., 2016). A study conducted recently found 25 % of the stakeholders perceived the system to be acceptable, 51 % to be flexible, 45 % to be timely, 61 % to be useful, and 74 % to be simple (Benson et al., 2016). This study did not assess the completeness of reporting of NMCs. Furthermore, the key stakeholders were not end users to the system but role players from national and provincial surveillance divisions.

Moreover, there is no published data regarding attributes of the HBV surveillance system in South Africa since the rollout of the new reporting system in 2017. There is also no national system for ongoing, routine assessment of the burden of Hepatitis-B disease in South Africa (Woodhall et al.).

In summary, studies conducted in various countries have different findings on the performance of the attributes of the surveillance system (Keramarou and Evans, 2012, Dunbar et al., 2011, Mellou et al., 2013). The performance of the HBV surveillance system in South Africa is unknown.

Chapter 3: Methods

This section describes the methods that were undertaken to conduct the research study. The description of the methods is presented sequentially as per the objectives. The retrospective record reviews (Objective 1 – 4) is represented in 3.4 (Part A) and the HBV surveillance system survey that was carried out at CMJAH (Objective 5) is found in 3.5 (Part B).

3.1 Study design

This was a cross-sectional study. Part A was a retrospective record review of the completeness and timeliness of the HBV notification at CMJAH. Part B consisted of a survey of the perceptions of the attributes (simplicity, acceptability, timeliness, flexibility and usefulness) of the Hepatitis B surveillance system by doctors and IPC nurses at CMJAH (Figure 3).

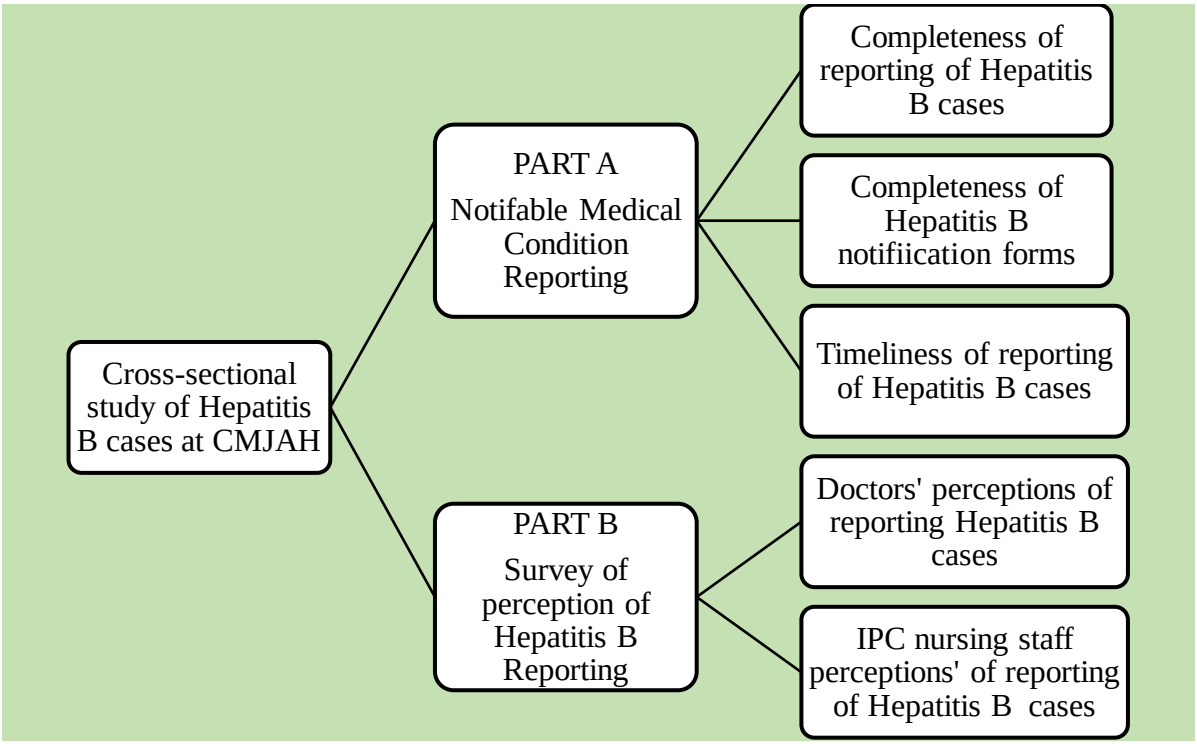


Figure 3. Schematic diagram depicting the study design

3.2 Study setting

The study was conducted at CMJAH. CMJAH is a 1228 bedded, central hospital located in Johannesburg district in the Gauteng province of South Africa (Gauteng Department of Health, 2017). It serves the 13-14 million population of Gauteng as well as acts as a referral central hospital for patients from Limpopo and Mpumalanga provinces.

3.3 Definitions

The methods used in evaluating the performance of the HBV surveillance system are based on Updated Guidelines for Evaluating Public Health Surveillance Systems published by the Centers for Disease Control and Prevention (Centers for Disease Control and Prevention, 2001) which define the surveillance system attributes as follows:

- Completeness of case reporting - refers to the mismatch between the number of cases reported and the actual number of cases tested positive.
- Completeness of notification form - refers to the mismatch between the number of fields filled on a notification form and the number of fields required to be filled.
- Timeliness - refers to the difference in time taken from the date of diagnosis of HBV from the CMJAH line list sent to COJ and the notification date received by the NICD from the CMJAH NHLS laboratory (Figure 1).
- Usefulness - a useful system is one which contributes to the prevention and control of adverse health-related events and includes an improved understanding of the public health. Usefulness was evaluated in this study by the end-users of the system.
- Acceptability - reflects the willingness of the surveillance staff to implement the surveillance system
- Simplicity - the structure and ease of operation of the surveillance system
- Flexibility – refers to the adaptability of a system to change information needs or operating conditions with little additional time, personnel, or allocated funds.

3.4 Part A: Retrospective record review of the attributes of the Hepatitis B surveillance system.

This section includes the study population and data analysis as well as data management plan related to the retrospective record review of the HBV surveillance system at CMJAH.

3.4.1 Study population

All cases of HBV that were notified via the CMJAH Infection Prevention and Control (IPC) Unit notification line list register from January 2017 to December 2018 were included in the study. All HBV positive laboratory results that were notified to the NICD were included in the analysis.

3.4.2 Sampling

There was no sampling performed. All cases of HBV notified at CMJAH to the COJ District Office via line lists from January 2017 to December 2018 and all cases of HBV from CMJAH received by the NICD from the NHLS were included in the analysis (Figure 1). All HBV case notification forms were assessed for completeness.

3.4.3 Data Analysis Plan

Objective 1: To determine completeness of reporting of Hepatitis B virus at CMJAH		
Variables	**Data Source**	**Data analysis**
Number of HBV cases per month at CMJAH reported to the COJ District Office from January 2017 to December 2018	NMC HBV line list at CMJAH	The completeness of reporting is described as a percentage of disease notifications reported on the NMC case line listing forms per month (numerator) divided by the cases tested and reported to be positive by NHLS (denominator).
Number of cases of HBV at CMJAH tested and reported by the National Health Laboratory Service (NHLS) reported to the NICD from	NMC Database at the NICD	

January 2017 to December 2018		
Objective 2: To determine completeness of notification forms of HBV at CMJAH		
Variables	**Data Source**	**Data Analysis**
Patient details	NMC case notification form	The completeness of 27 fields under the categories: patient details, medical condition details, travel history, vaccination history, specimen details and other on the NMC forms were described using percentages. The completeness of each field variable is the total number of fields filled on the NMC form (numerator) over total number of required fields expected to be filled (denominator).
First Name		
Surname		
Age		
Date of birth		
ID Number		
Passport number		
Citizenship		
Gender		
Contact number		
Pregnancy status		
Residential address		
Employer address		
Medical Condition details		
NMC diagnosed		
History of previous exposure (contact)		
Method of diagnosis		
Clinical Symptoms		
Treatment given		
Date of diagnosis		
Patient admission status		
Patient vital status		
Travel history		
History of patient travel outside residence		
Vaccination history		
Vaccination status		
Specimen details		
Was a specimen collected?		
Other		
Name of health facility		
Sub-district		
Date of notification		

<table>
<tr><td>Patient folder number</td><td></td><td></td></tr>
<tr><td colspan="3">Objective 3: To determine characteristics associated with completeness of HBV notification forms at CMJAH</td></tr>
<tr><td>Variables</td><td>Data Source</td><td rowspan="9">Data Analysis Plan
The exposure variables were fields on the NMC form that may be associated with variation of completeness of the NMC form. Patient details and medical condition details were tested for associations with completion of forms using linear regression. Variables were chosen a priori based our previous literature and logical reasoning (Keramarou and Evans, 2012) (Mellou et al., 2013). Assumptions of a linear regression model were checked. A p-value of 0.05 was considered significant.</td></tr>
<tr><td>Exposure variables</td><td rowspan="8">NMC case notification form</td></tr>
<tr><td>Age</td></tr>
<tr><td>Gender</td></tr>
<tr><td>Citizenship</td></tr>
<tr><td>Method of diagnosis</td></tr>
<tr><td>Patient admission status</td></tr>
<tr><td>Outcome variable</td></tr>
<tr><td>Completeness of NMC forms</td></tr>
<tr><td colspan="3">Objective 4: To establish the timeliness of reporting of Hepatitis B virus at CMJAH from January 2017 to December 2018.</td></tr>
<tr><td>Variables</td><td>Data Source</td><td rowspan="3">Data Analysis Plan
The time taken to report HBV cases was calculated as the difference between the date of diagnosis at CMJAH and the date of notification of HBV cases at NICD. Timeliness was measured as the percentage utilizing the time to report (numerator) divided by expected time of reporting (denominator). Timeliness was reported as a categorical variable with “No” (Untimely) if >7 days difference in dates and “Yes” (Timely) if ≤7 days difference in dates.</td></tr>
<tr><td>Date of notification.</td><td>NMC Database at the NICD</td></tr>
<tr><td>Date of diagnosis</td><td>NMC HBV line list</td></tr>
</table>

3.4.4 Data Management

Data was collected and entered in a Microsoft Excel® spreadsheet and stored using password protection (Microsoft Corporation, 2018). Data was cleaned for duplicate entries via searching for duplicate hospital numbers and patient initials. Data was also cleaned for

missing data and correctness of information. Thereafter, data was exported into STATA 13® for analysis (StataCorp, 2013). Identifiable data was stored separately from encoded data.

3.5 Part B: Survey of health worker perception of Hepatitis B surveillance system at CMJAH

This section includes the study population, sampling and data analysis and management related to the survey on health worker perceptions of the attributes of the HBV surveillance system at CMJAH.

3.5.1 Study Population

All nursing staff at the IPC unit and all doctors at CMJAH were asked to participate in the survey. At CMJAH, the NMC case notification forms are completed by doctors and NMC line lists are collated by IPC nurses only.

3.5.2 Sampling

No sampling was performed. All doctors and IPC nurses working at CMJAH were asked to completed the survey. A sample size was calculated to assess the minimum number of respondents required to achieve an 80% power. CMJAH employs approximately 750 doctors and 8 IPC nurses. The sample size was calculated based on the following assumptions. 1) Proportion (P) - Approximately 37% of health care workers notify diseases (Weber, 2007) 2) 5% margin of error (d). 3) A population of 758 participants (N). 4) Design Effect (DEFF) of 1.0 A sample size of 244 respondents was required to achieved a 95% confidence level with 5% level of significance. The formula for calculation from OpenEPI® for population based surveys is given by (JavaScript, 2009):

Sample size $\boldsymbol{n = [DEFF*Np(1-p)]/ [(d^2/Z^{21-\alpha/2}*(N-1) + p*(1-p)]}$

$= [1.0*758(0.37(1-0.37)]/ [0.05^2/1.96^{2\ 1-0.05/2}*(758-1) + 0.37(1-0.37)]$

$= 244$

3.5.3 Data Collection

A semi-structured self-administered questionnaire (Appendix IV) was adapted from a tool that was previously piloted and tested in South Africa which looked at key stakeholder perceptions of the South African Notifiable Disease System (Benson et al., 2016). The questionnaire was adapted to ask specifically about the HBV surveillance system and developed on RedCap® software programme to specifically assess the perceptions of the notification system for Hepatitis B (Paul A. Harris, 2009).

A dual method of handing out surveys to all staff were used to ensure as many respondents as possible. A list of all clinical departments (sampling frame) with the email addresses were collated. Surveys were sent out electronically via. Doctors were also approached during clinical departmental meetings and ward rounds in each clinical department to complete the survey if they had not done so electronically. Paper-based surveys were also left at each clinical department to ensure that all staff had access to the forms. Paper-based forms that were completed, were collected and imputed into the Research Electronic Data Capture (RedCap®) software programme (Paul A. Harris, 2009). A reminder to complete surveys was sent electronically to all clinical departments on a weekly basis. To ensure that there were no duplications of surveys, staff were asked to complete either an electronic form or a paper-based form. Nurses at the IPC unit were asked to complete the survey during unit meetings.

The survey was first sent out on 03 December 2019 and reminders were sent out weekly for 4 weeks. After 4 weeks, only 40 participants had responded to the survey and an effort was made to extend the survey for four more weeks until 31st January 2020 to achieve a better response rate.

3.5.3.1 Measures

Measures of simplicity, flexibility, timeliness, usefulness and acceptability of HBV case reporting was examined using a seven point Likert Scale ranging from one (strongly disagree) to 7 (strongly agree). The questionnaire consisted of one to three questions per attribute for system attributes. The Cronbach's alpha coefficients were calculated on the adapted tool used in our study to determine reliability and coherence between items. The

Cronbach alpha co-efficient ranged from 0.69 – 0.76 indicating acceptable reliability and coherence among items on the Likert scale.

3.5.3.2 Data Analysis

Data was exported from RedCap® into a Microsoft Excel® spreadsheet and analysed using STATA 13 (Microsoft Corporation, 2018, Paul A. Harris, 2009, StataCorp, 2013). Numerical variables were summarized using means and medians. Categorical variables were summarized used percentages. We described each attribute individually. The responses were aggregated into three categories: "agreed", "neither agree or disagree" and "disagree" from the 7 point Likert scale.

The attributes of the surveillance system were categorized under the following:

i) Simplicity (3 questions) – looking at simplicity of the notification process and simplicity and ease of the notification form used
ii) Acceptability (1 question) – considered whether clinicians were willing to notify HBV
iii) Timeliness (2 questions) – looked at whether HBV was notified in a timely or untimely manner based on clinical suspicion and on diagnosis
iv) Flexibility (1 question) – considered when the HBV notification system had been able to adapt to meet the changing circumstances and needs of the health system
v) Usefulness (2 question) – regarded whether the information from the HBV notification system was used and if clinicians believed the system was important

We performed an analysis looking at factors associated with each attribute. Type of staff, age, number of years of training of experience and training received on NMC (exposure variable) were tested for associations with the attributes of the surveillance system (outcome variable) using logistic regression. We used the most appropriate question for each attribute as the outcome variable in the logistic regression model in outcomes which had more than one question assigned to it. For simplicity, we used simplicity of the notification process as the outcome variable. For timeliness, timely notification of HBV on diagnosis rather than timeliness of notification based on clinical suspicion was used. Usefulness of the information being used for public health action was used as the outcome variable. The decision to use one

outcome variable from each attribute was that one of the questions more accurately reflected the attribute than the other questions.

For univariate analysis, variables which had a p-value of <0.10 were added into a multivariate analysis. A multinomial logistic regression was done. Confounders such as age and duration of experience were controlled for in the model. Goodness of Fit tests using the Likelihood ratio test were performed where observations between models were the same.

3.6 Ethical considerations

Ethics approval was obtained from the Witwatersrand Human Research Ethics Committee, Clearance Certificate Number: M190212 (Appendix V). Permission for data collection was be obtained from CMJAH (Appendix VI) and the NICD (Appendix VII) to obtain information. For the survey, participants were informed that participation was voluntary and that there would be no identifiers collected. Consent was given by completing the survey (Appendix IV).

3.7 Funding

As this is part of a scholarly process, funding for printing costs were deemed a personal cost. Funding from a postgraduate grant will be sought for publication cost for intended manuscripts developed from this study.

4. Chapter 4: Results

The results reported below are divided into 4.1 (Part A: record review) and 4.2 (Part B: survey) in alignment with the objectives and methods. The results shown further follow the framework for evaluating the performance of a surveillance system (Centers for Disease Control and Prevention, 2001).

4.1 Results: Part A

4.1.1 Completeness of reporting of HBV positive cases at CMJAH

Figure 4 depicts the completeness of reporting from the laboratory to the IPC staff at CMJAH. Out of all positive cases of HBV at CMAJH from 2017 - 2018, 45.2% of HBV positive cases were reported on line lists to the sub-district between January 2017 – December 2018. Of the 45.2% of HBV positive cases of HBV reported to the sub-district, 4.6% had NMC case notification forms completed.

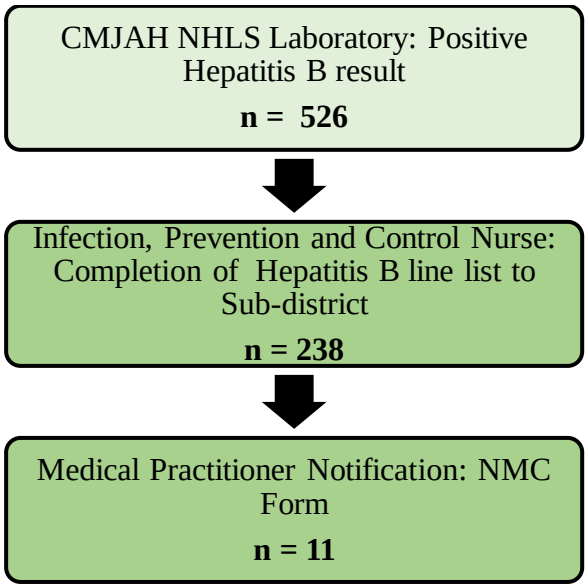


Figure 4: Number of Hepatitis B cases reported by Charlotte Maxeke Johannesburg Academic Hospital

Table 1 depicts the completeness of HBV reporting at CMJAH for the time-period January 2017 - December 2018. Overall, the completeness of HBV positive cases was 45.2% (n=238). In 2017, the reporting completeness of HBV positive cases at CMJAH was high (97.1%, n=238) as compared to 2018, where completeness of reporting of HBV positive cases was zero (0.0%).

Table 1: the completeness of Hepatitis B cases reported by Charlotte Maxeke Johannesburg Academic Hospital for 2017 - 2018

	CMJAH: Number of cases reported on line lists (n)	NICD: Number of cases reported by CMJAH NHLS laboratory (n)	Completeness of reporting (%)
Year			
Overall	238	526	45.2%
2017	238	245	97.1%
2018	0	281	0.0%

4.1.2 Completeness of reporting of HBV Notification Forms at CMJAH

Table 2 shows the reporting completeness of NMC forms for HBV that were completed and submitted to the sub-district. Of the 526 HBV cases that were reported by the laboratory to the NICD, 11 (2.1%) NMC forms were completed by doctors at CMJAH from January 2017 to December 2018. When assessing the fields that were filled in the NMC form, under the category of patient details, identity number (ID), passport number, citizenship, contacted number, pregnancy status, residential address and employer address were all inadequately completed (i.e. less than 90% complete). Under the category of medical details, clinical details, treatment given and date of diagnosis were inadequately completed (i.e. less than 90%). Field categories of travel history and vaccination history were both completed adequately (n=11; 100%).

Table 2: Completeness of NMC forms filled by CMJAH

NMC forms	n = 11	Completeness (%)
Overall field count completed adequately		
Completeness ≥ 90%	0	0%
Completeness < 90%	11	100%

Mean Completeness score for overall filed count (Range)	77.1% (70.4 – 88.9%)	
Per field completeness	N = 11	
Patient details		
First Name	11	100.0%
Surname	11	100.0%
Age	11	100.0%
Date of birth	11	100.0%
ID number	1	9.1%
Passport number	0	0.0%
Citizenship	7	63.6%
Gender	11	100.0%
Contact number	3	27.3%
Pregnancy status	11	100.0%
Residential address	1	9.1%
Employer address	0	0.0%
Medical Condition details		
NMC diagnosed	11	100.0%
History of previous exposure (contact)	10	90.9%
Method of diagnosis	11	100.0%
Clinical Symptoms	1	9.1%
Treatment given	1	9.1%
Date of diagnosis	9	81.8%
Patient admission status	11	100.0%
Patient vital status	10	90.9%
Travel history		
History of patient travel outside residence	11	100.0%
Vaccination history		
Vaccination status	11	100.0%
Specimen details		
Was a specimen collected?	10	90.9%
Other		
Name of health facility	11	100.0%
Sub-district	11	100.0%
Date of notification	11	100.0%
Patient folder number	11	100.0%

4.1.3 Characteristics associated with completeness of HBV notification forms within CMJAH

Field categories chosen a priori were tested for associations with completeness. None of the exposure field variables were found to be associated with outcome variable of completeness of HBV (Appendix VIII). Other fields of interest (vaccination history, travel history etc.) could not be tested as there were no differences in completeness i.e. all fields were 100% complete.

4.1.4 Timeliness of reporting of Hepatitis B virus at CMJAH

Timeliness referred to the difference in the reporting date from CMJAH line list to the sub-district to the notification date received by the NICD from the laboratory. Records were matched by hospital number to assess the differences in timeliness. Of the 236 cases reported by CMJAH and 526 cases received by NICD, only 83 hospital numbers were common to both sources. Of the 83 matched cases, 37/83 (44.6%) were found to be reported timely i.e. within 7 days (Figure 5). The median number of days taken to report HBV positive cases at CMJAH was 18 days which is 2.6 times higher than the required 7 days of reporting.

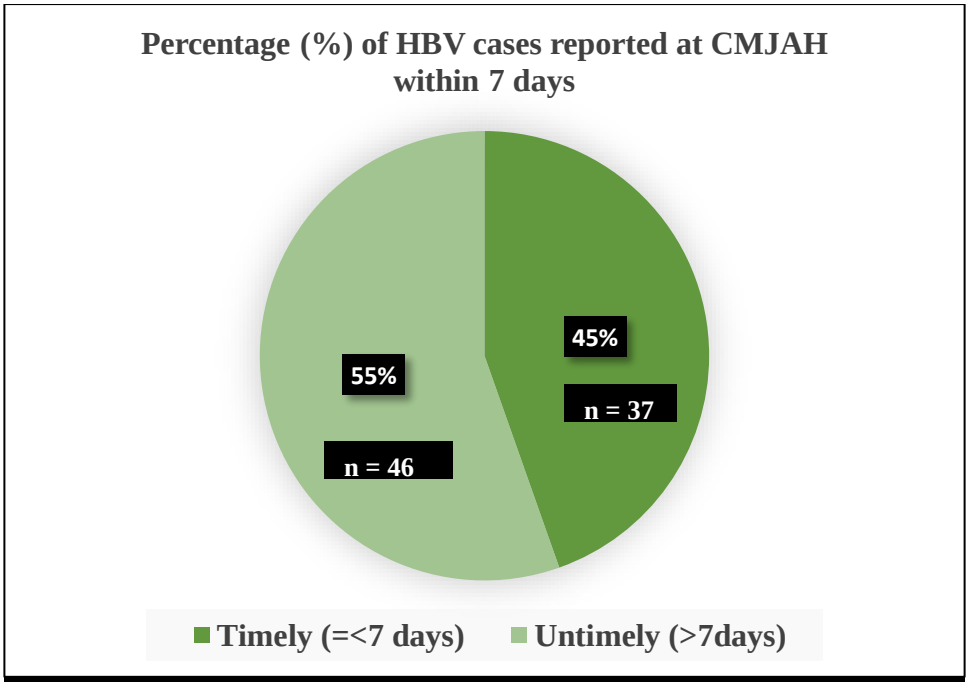


Figure 5 showing the timeliness of reporting of HBV cases at CMJAH

4.2 Results: Part B

In total, 82 health care workers responded to the HBV surveillance system survey (Table 3). A response rate of 10.8% was achieved. Majority of respondents were registrars (34.2%), had a mean age of 32.9 years old and were not trained in NMC (67.1%).

Table 3: Characteristics of health care worker survey respondents at CMJAH	
Type of health care worker	n = 82 (%)
IPC Nurse	8 (9.8 %)
Intern	22 (26.8%)
Medical Officer	12 (14.6%)
Registrar	28 (34.2%)
Consultant	12 (14.6%)
Age (in years)	n = 82
Mean (Range)	32.9 years old (19 – 58)
Median (IQR)	30 years old (27; 37)
Number of years of experience (in months)	n = 79
Mean (Range)	62.8 months (0 – 324)
Median (IQR)	48.0 months (24; 96)
Category of number of years of experience	
Category 1: < 60 months (< 5 years)	43 (54.4%)
Category 2: 61 - 120 months (5 – 10 years)	28 (35.5%)
Category 3: > 120 (>10 years)	8 (10.1%)
Training in NMC	n = 82
No	55 (67.1%)
Yes	27 (32.9%)

4.2.1 Simplicity of the HBV Surveillance System

Figure 6 shows the perception of simplicity of the HBV surveillance system at CMJAH. Overall, majority of the respondents neither agreed or disagreed with the simplicity of the HBV surveillance system [simplicity of understanding the NMC form: 59.3% (n=48); simplicity of completing the NMC form: 54.3% (n=44) and simplicity of the notification process: 39.5% (n=32)]. With regards to the simplicity of the form, more participants agreed

that the forms were simple to understand as compared to respondents who disagreed that the forms were simple to understand [28.4% (n=23) vs. 12.3% (n=10)]. However, a higher proportion of respondents disagreed that the notification process was simple as compared to agreeing that the process was simple [33.3% (n=27) vs. 27.2% (n=22)].

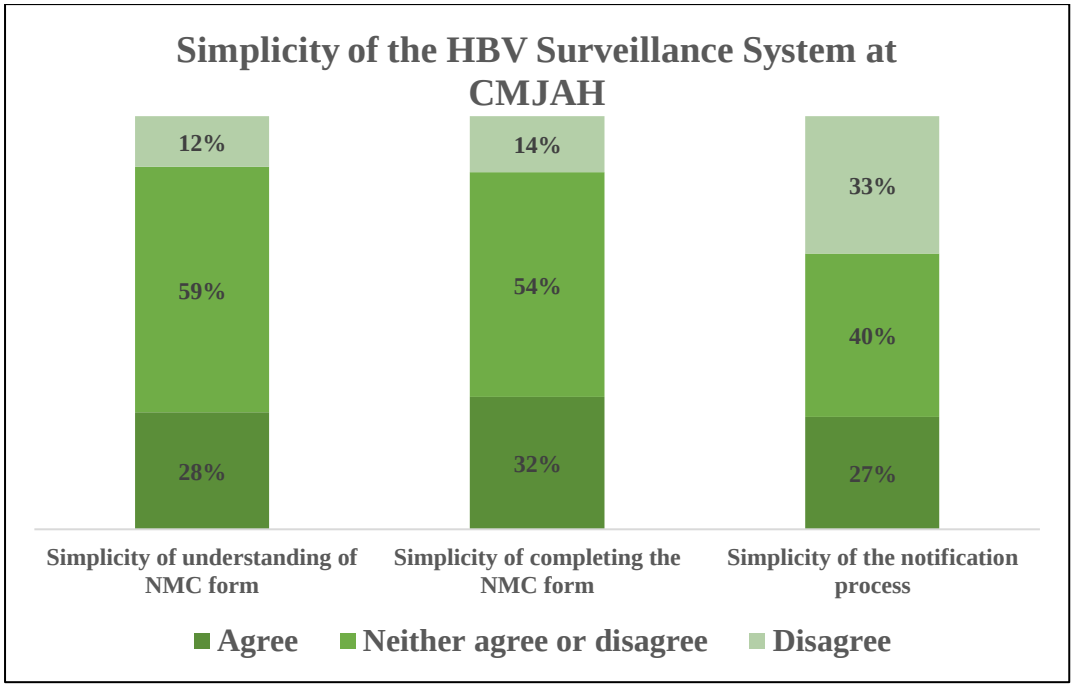


Figure 6 Perceptions of simplicity of the HBV surveillance system at CMJAH by respondents

4.1.2 Factors associated with Simplicity of the HBV notification process

In the univariate analysis looking at factors associated with simplicity of HBV notification process, we found that there were no factors associated with agreeing as compared to disagreeing that the HBV notification process at CMJAH is simple. However, the relative risk of interns choosing to neither agree or disagree with the simplicity of the HBV notification process was 14.67 times higher compared to disagreeing with simplicity of the HBV notification process (p=0.038). In the multivariate analysis, when controlled for confounders age and work experience, we found that this association was found to be marginally significant (p=0.083).

Table 4: Factors associated with Simplicity of the HBV Surveillance System						
Agree that the HBV system is Simple Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Intern	3.11	0.41; 23.39	0.270			
Medical officer	1.33	0.17; 10.25	0.782			
Registrar	1.90	0.32; 11.31	0.478			
Consultant	1.00	0.12; 8.31	1.000			
IPC Nurse	Base					
Age	0.96	0.89; 1.02	0.190			
NMC Training						
Yes	0.85	0.27; 2.70	0.782			
No	Base					
Work experience						
60 – 120 months	0.62	0.17; 2.21	0.456			
>120 months	0.92	0.17; 5.16	0.927			
< 60 months	Base					
Disagree with the HBV system is simple	Base					
Neither Agree or Disagree that the HBV system is Simple Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Intern	14.67	1.16; 185.23	0.038*	19.95	0.68; 585.86	0.083
Medical officer	4	0.30; 53.47	0.295	5.34	0.25; 116.05	0.286
Registrar	6.29	0.58; 68.42	0.131	7.45	0.43: 129.88	0.168
Consultant	5	0.39; 64.39	0.217	4.72	0.29; 77.61	0.278

IPC Nurse	base					
Age	0.96	0.90; 1.03	0.240	1.07	0.95; 1.20	0.299
NMC Training						
Yes	0.48	0.15; 1.55	0.220			
No	Base					
Work experience						
60 – 120 months	0.55	0.17; 1.79	0.321	0.69	0.16; 3.03	0.626
>120 months	0.15	0.01; 1.65	0.121	0.14	0.01; 2.71	0.191
< 60 months	Base					

*p < 0.10 for multivariate analysis

4.2.1 Acceptability of the HB Surveillance system

Majority of health care workers [45.0% (n=36)] agreed that clinicians were unwilling to participate in the HBV surveillance system (Figure 7).

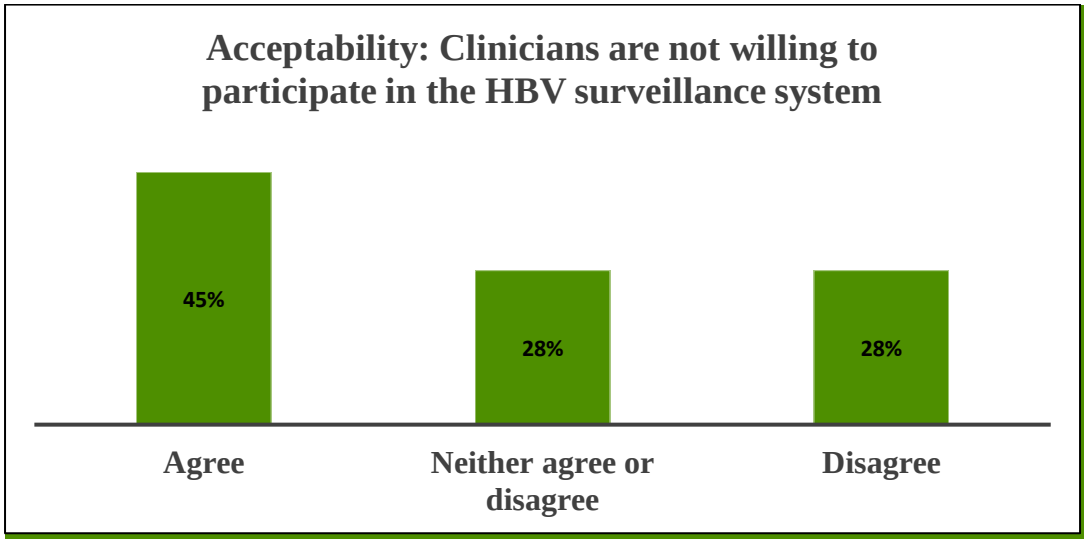


Figure 7 showing the results of the perceptions of acceptability of the HBV surveillance system at CMJAH by respondents.

4.2.2 Factors associated with Acceptability of the HBV Surveillance System

In the univariate analysis looking at factors associated with acceptability of the HBV surveillance system, we found that there were no factors associated with agreeing or neither agreeing /disagreeing that clinicians were not willing to participate in the HBV surveillance system when compared to respondents disagreeing that clinicians were not willing to participate in the HBV surveillance system. (Appendix IX).

4.3.1 Timeliness of the HBV case notification at CMJAH

Health care workers agreed that HBV was not notified either on *clinical suspicion* [51.2% (n=42)] and disagreed that clinicians notify within 7 days of diagnosis [37.8%]. Furthermore, a larger proportion of respondents disagreed as compared to agreed, that HBV was notified on *diagnosis* with the required time-period of 7 days [37.8% (n=31)] (Figure 8).

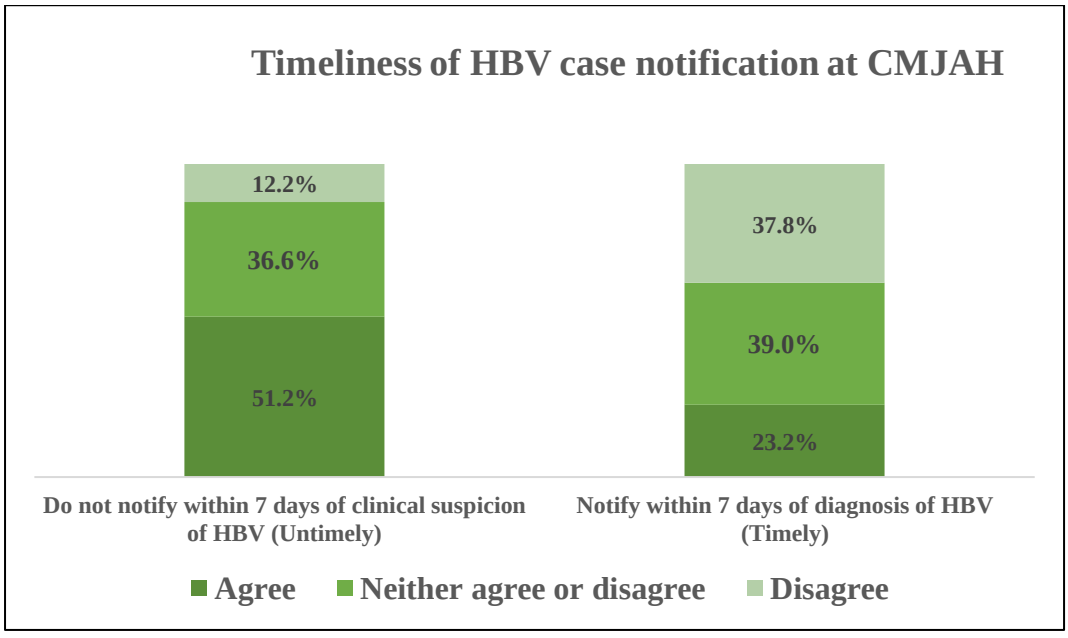


Figure 8 showing the results of the perceptions of timeliness of the HBV surveillance system at CMJAH by respondents.

4.3.2 Factors associated with Timeliness of reporting of HBV within 7 days of diagnosis

Registrars, consultants and IPC nurses compared to interns were significantly more likely to agree that clinicians notified HBV cases within 7 days of diagnosis than disagree (RRR = 336.55, 1544.17, 399.14; P-value = 0.001, 0.004, 0.016 respectively). As age increased, the respondents were 0.74 times more likely to agree that clinicians notified HBV cases within 7 days of diagnosis than disagree (p=0.011). Those respondents who had work experience of 60-120 months compared to <60 months were 0.06 times more likely to agree that clinicians notified HBV cases within 7 days of diagnosis than disagree that clinicians notified HBV cases within 7 days of diagnosis (p=0.027).

Table 5: Factors associated with Timeliness of the HBV Surveillance System

Agree that the clinicians do notify within 7 days of diagnosis Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Medical officer	0.90	0.13; 6.08	0.914	5.16	0.48; 55.93	0.177
Registrar	4.87	0.90; 26.42	0.067*	336.55	10.28; 11013.19	0.001*
Consultant	9.00	0.76; 105.96	0.081*	1544.17	10.82; 220367.9	0.004*
IPC Nurse	2.50	0.37; 16.89	0.347	399.14	3.12; 51005.07	0.016*
Intern	Base					
Age	1.00	0.93; 1.06	0.883	0.74	0.58; 0.93	0.011*
NMC Training						
Yes	0.45	0.14; 1.49	0.193			
No	Base					
Work experience						
60 - 120 months	0.72	0.20; 2.57	0.616	0.06	0.00; 0.72	0.027*
> 120 months	4.51	0.47; 43.06	0.191	536.37	0.68; 421778.6	0.065
< 60 months	Base					

Neither Agree or Disagree that the clinicians do not report within 7 days of diagnosis Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Medical officer	0.40	0.08; 2.06	0.273			
Registrar	1.37	0.30; 6.20	0.679			
Consultant	2.50	0.24; 26.47	0.447			
IPC Nurse	2.53e-07	0; -	0.985			
Intern	Base					
Age	0.97	0.91; 1.04	0.384			
NMC Training						
Yes	0.43	0.13; 1.42	0.168			
No	Base					
Work experience						
60 – 120 months	0.62	0.19; 2.06	0.434			
>120 months	4.90e-07	0; -	0.988			
< 60 months	Base					

*p < 0.10 for multivariate analysis

4.4.1 Flexibility of the HBV Surveillance System

Of the 82 health care worker respondents, 59.8% (n=49) neither agreed or disagreed that the HBV surveillance system at CMJAH was flexible i.e. the HBV surveillance system met the needs or adapted to the changing circumstances of the health care workers in the last decade (Figure 9)

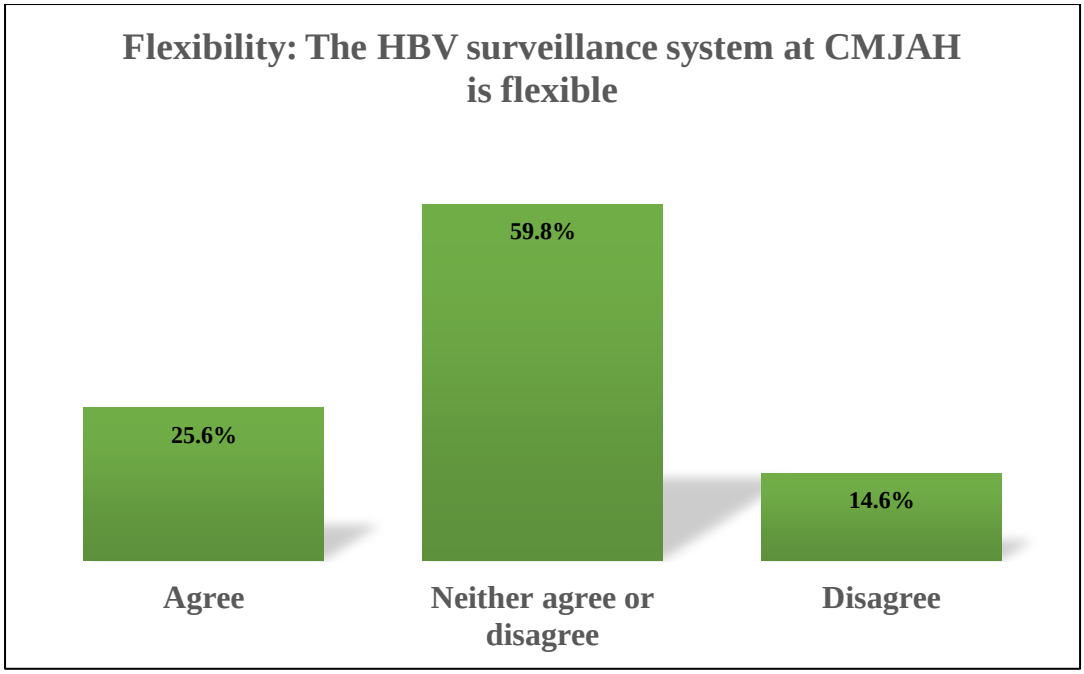


Figure 9 Perceptions of flexibility of the HBV surveillance system at CMJAH by respondents.

4.4.2 Factors associated with Flexibility of the HBV Surveillance System

Overall, there were no factors associated with agreeing that the HBV surveillance system is flexible as compared to disagreeing that the HBV surveillance system is flexible. In the univariate analysis looking at factors associated with neither agreeing or disagreeing that the HBV surveillance system is flexible as compared to disagreeing that the HBV surveillance system is flexible, age was found to be significantly associated with neither agreeing or disagreeing that the HBV surveillance system is flexible when compared to disagreeing that the system was flexible (RRR=0.90, p=0.020). Those respondents with work experience of 60 – 120 months were 0.55 times higher to neither agreeing or disagreeing that the HBV surveillance system is flexible than disagreeing that the system is flexible as compared to respondents with work experience <60 months (p=0.043).

Table 6: Factors associated with Flexibility of the HBV Surveillance System		
Agree that the HBV system is Flexible Vs. Disagree		
	Univariate	**Multivariate**

	Relative Risk Ratio (RRR)	Confidence Interval (95%)	P-value P =	Relative Risk Ratio (RRR)	Confidence Interval (95%)	P-value P =
Professional Category						
Intern	3328194**	0; -	0.993	634341	0; -	0.991
Registrar	0.11	0.01; 1.09	0.060*	0.23	0.02; 2.93	0.259
Consultant	0.50	0.05; 5.15	0.560	1.01	0.05; 19.27	0.996
IPC Nurse	0.07	0.00; 1.06	0.055*	0.31	0.01; 7.06	0.462
Medical officer	Base					
Age	0.93	0.85; 1.01	0.104	0.96	0.86; 1.09	0.543
NMC Training						
Yes	0.55	0.13; 2.40	0.427			
No	Base					
Work experience						
60 - 120 months	0.17	0.02; 1.14	0.068*	0.55	0.12; 2.47	0.437
> 120 months	0.63	0.09; 4.22	0.630	0.14	0.01; 2.38	0.175
< 60 months	Base					
Neither Agree or Disagree that the HBV system is Flexible Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Intern	2.22e+07	0; -	0.996			
Registrar	0.63	0.10; 3.78	0.613			
Consultant	0.67	0.08; 5.54	0.707			
IPC Nurse	3.41e-09	0; -	0.993			
Medical officer	Base					
Age	0.88	0.81; 0.94	0.000*	0.90	0.82; 0.98	0.020*
NMC Training						
Yes	0.38	0.14; 1.15	0.089*	0.35	0.09; 1.33	0.123
No	Base					

Work experience						
60 – 120 months	0.25	0.07; 0.86	0.027*	0.25	0.07; 0.96	0.043*
>120 months	0.04	0.00; 0.42	0.008*	0.18	0.01; 2.81	0.223
< 60 months	Base					

*p < 0.10 for multivariate analysis

**RRR is larger due to very small n

4.5.1 Usefulness

Figure 10 shows the health care worker perceptions of usefulness of the HBV surveillance system at CMJAH. Most of the health care worker respondents disagreed that the department provided regular feedback to them regarding the HBV surveillance system [74.1%, (n=60)]. Health care workers also felt that supervision was necessary to comply to the requirements of the surveillance system [54.9%, (n=45)].

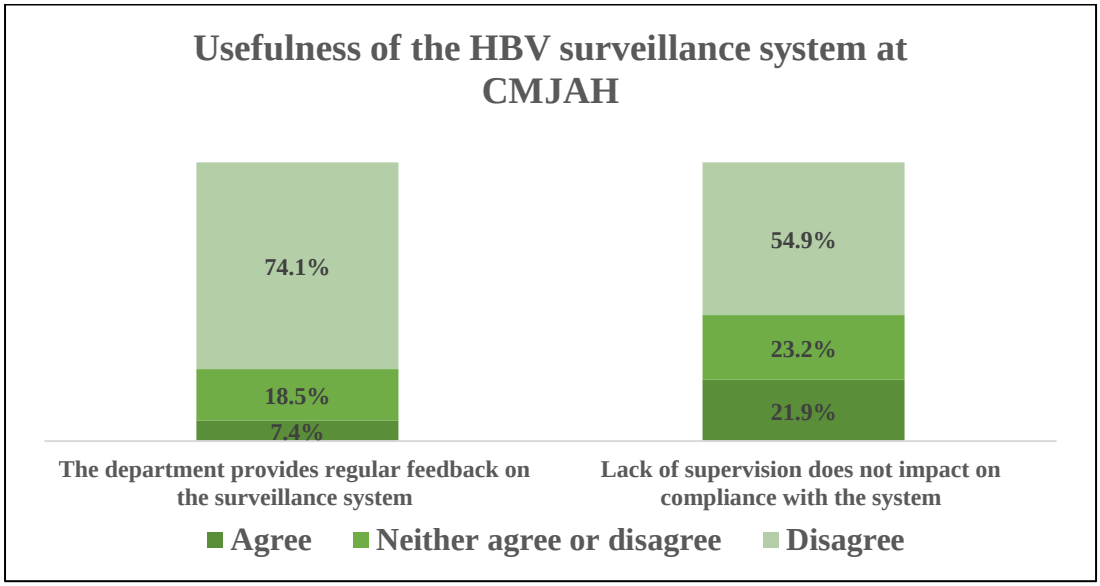


Figure 10 showing the results of the perceptions of usefulness of the HBV surveillance system at CMJAH by respondents.

4.5.2 Factors associated with Usefulness

With increasing age, respondents were 0.81 times likely to agree than disagree that the HBV surveillance system was useful i.e. that the department provided regular feedback to doctors or nurses on notifiable diseases to contribute to the understanding and management of the HBV surveillance system (p=0.004).

Table 7: Factors associated with Usefulness of the HBV Surveillance System

Agree that the HBV system is useful Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Intern	9789739**	0; -	0.990			
Medical officer	1.07	0.13; 8.79	0.952			
Registrar	8.80	0.66; 117.22	0.100			
Consultant	9676825	0; -	0.992			
IPC Nurse	Base					
Age	0.90	0.83; 0.98	0.020*	0.81	0.70; 0.93	0.004
NMC Training						
Yes	0.46	0.09; 2.51	0.372			
No	Base					
Work experience						
60 - 120 months	0.17	0.02; 1.60	0.121	0.24	0.02; 2.93	0.261
> 120 months	0.23	0.01; 4.20	0.324	8.17	0.14; 479.98	0.311
< 60 months						
Neither Agree or Disagree that the HBV system is Useful Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**

Professional Category						
Intern	1.53e+07	0: -	0.989			
Medical officer	0.67	0.02; 18.06	0.809			
Registrar	10.00	0.40; 250.45	0.161			
Consultant	1.61e+07	0: -	0.992			
IPC Nurse	Base					
Age	0.93	0.84; 1.02	0.137	0.93	0.81; 1.07	0.285
NMC Training						
Yes	0.50	0.07; 3.43	0.481			
No	Base					
Work experience						
60 – 120 months	0.91	0.01; 1.08	0.057*	0.09	0.01; 1.12	0.061
>120 months	3.21e-08	0; -	0.992	1.65e-07	0; -	0.991
< 60 months	Base					

*p < 0.10 for multivariate analysis

**RRR is larger due to very small n

5. Chapter 5: Discussion

This section critically discusses the findings on the evaluation of the performance of the HBV surveillance system at CMJAH and seeks to deliberate the relevance of the results, review the current literature and provides recommendations to improve the gaps found. The main purpose of a surveillance system is to provide timely, accurate information to improve health making decisions and inform action. A surveillance system which is unable to perform effectively will result in poor prevention of disease and its' associated morbidity and mortality. The findings of this study showed that the HBV surveillance system was underperforming. Completeness of HBV cases was variable and reporting of HBV cases was untimely. Furthermore, end users of the HBV surveillance system perceived the system to be unacceptable and not useful.

5.1 Completeness of the HBV surveillance system

5.1.1 Completeness of reporting of HBV positive cases

Completeness of reporting varied in the two-year study period at CMJAH. Under half (45.2%) of HBV positive cases at CMJAH were reported to the COJ district office via line lists. However, it was found that in 2017, the reporting of HBV was complete (97.1%) as compared to 2018 where notified cases were inadequately completed (0.0%). The dramatic decrease in the completeness of reporting is believed to be due to changes in staff at the IPC unit at CMJAH between 2017 - 2018 (Brown, 2019).

The gap in completeness of reporting to the COJ district office prevents the district office from fully appreciating the extent of HBV incidence in this geographical area. Under representation of HBV at the district level could affect health planning and distribution of funds to support HBV prevention and elimination.

Previous systematic reviews have shown that there is great variability in completeness of reporting of notifiable diseases (Keramarou and Evans, 2012, Doyle et al., 2002). In the United States, a systematic review revealed that completeness of reporting of notifiable diseases varied from 9 – 99% (Doyle et al., 2002). Although surveillance systems may be different in the developed country context, these studies are in keeping with the variability of

HBV notification in our setting and show that South Africa's challenges with completeness are mirrored in many other settings

Reporting may also vary due to the type of hospital reporting – some studies have shown that larger university hospitals (like CMJAH) had significantly higher underreporting rates than district level hospitals, possibly due to higher workloads (Mellou et al., 2013). It is important to understand why the reporting of HBV cases at CMJAH decreased dramatically in 2018. Possible reasons include; changes in staff at the IPC unit and/or inadequate communication between IPC unit and the CMJAH NHLS laboratory. It has been found that poor communication between two reporting units has also been linked to the underreporting of TB in a study conducted in Italy (Melosini et al., 2012). However, these factors were not sought after in this study.

5.1.2 Completeness of HBV case notification forms

Majority of the HBV cases that were reported via the IPC unit to the district office did not have HBV case notification forms completed by health care workers. Of the 238 HBV cases that were reported to the district by the IPC unit, 11 (4.67%) HBV case notification forms were filled. These forms provide important information for surveillance (e.g. travel history, vaccination history, treatment given) which are not available on laboratory forms which are used when testing for HBV. Important personal information such as identity number and residential numbers were poorly completed in this study (Completeness: 9.1% and 9.1% respectively). Clinical information such as clinical symptoms and treatment given were also poorly completed (9.1% and 9.1% respectively).

Epidemiologists also use geographic information system (GIS) mapping to track "hotspots" for infection. This enables targeting of interventions to specific groups or geographical areas. The knock-on effect of poorly filled personal information of patients means that surveillance teams may not be able to perform tracing of cases and their contacts, resulting in poor prevention control. This has population health consequences for the country.

Possible reasons for poor completion of residential address on the forms potentially relates to the high workload for health care workers in South Africa's public health system. It is also possible that health care workers do not understand how this information is used, or why it is

important, and therefore de-prioritise this task. The CDC recommended guidelines for surveillance monitoring states that acceptability might be associated with, and impact completeness of, reporting (Centers for Disease Control and Prevention, 2001). Health care worker perceptions of the HBV surveillance system may have impacted their willingness to complete HBV case notification forms. As seen in this study, 45% of respondents agree that clinicians were unwilling to participate in the HBV surveillance system at CMJAH. Another study further provided possible reasons for health care workers' failure to report notifiable diseases such as lack of knowledge of legal mandate to report, lack of knowledge of diseases that are notifiable as well as belief that someone else will report the case (Jones et al., 1992).

Patients factors may also prevent this information from being completed, for example; critically ill patients may not be able to communicate these details and/or many people residing in South Africa live in informal settlements without proper addresses. Other studies accord with this one, showing variability in completeness of field categories - one study showed residential addresses to be inadequately complete as compared to contact number (completeness: 68.1% vs. 84.7%) (Garcell H G, 2014).

In our study, there were no factors found to be associated with completion of NMC forms. This is in keeping with other studies which have shown similar findings. A study on reporting of salmonellosis and shigellosis in Greece showed that age and sex were not related to the probability of reporting (Mellou et al., 2013). It may be that in general, there were other systematic factors such as staff training, lack of knowledge and/or unacceptability of the surveillance system which may have influenced the severe underreporting by clinical staff. However, these factors were not tested in our study.

Studies have shown that automated reporting of electronic data was found to be associated with improved completeness and timeliness of reporting of diseases. (Overhage et al., 2008). Currently, CMJAH is reporting NMC on a paper-based system. The electronic system had not been rolled out at CMJAH at the time of the study period. Reporting via electronic applications from the laboratory on a positive result with alerts such as that all sources are notified simultaneously may improve completeness and timeliness of reporting. Currently, the only electronic notification of HBV via the CMJAH NHLS laboratory goes directly to the NICD. If the IPC unit was included as a recipient to this notification of positive HBV cases, improvements in reporting of HBV may occur to the district office.

5.2 Timeliness of reporting of HBV

The NHLS laboratory at CMJAH reports positive HBV cases to both the IPC unit and the NICD. Reporting of positive HBV cases should be reported within seven days of diagnosis as mandated by the Notifiable Medical Conditions regulations of South Africa (South African National Department of Health, 2017). However, we found that less than half (44.6%) of positive HBV cases were reported in a timeous manner.

Timely notification of diseases enables early warning system activation and effective prevention and control measures to take place. Infection with HBV is a blood borne disease which can be spread from person to person sexually, to health care workers via infected patients and needle sharing among drug users. For effective control measures to be put into place (such as large HBV vaccination campaigns), timely notification of HBV is critical.

Possible reasons for poor timeliness of reporting of positive HBV cases at CMJAH could be due to a lack of knowledge by health care workers of reporting on HBV within seven days. Furthermore, the use of a paper-based system for reporting at CMJAH as opposed to an electronic system of reporting could affect timeliness. Automated reporting of diseases has been shown to improve timeliness of reporting of diseases (Overhage et al., 2008). Timeliness of reporting of diseases has also shown to be improved post training of staff (Garcell H G, 2014). Our survey showed that 67.1% of the health care worker respondents were not trained in NMC. This may have been a critical factor in influencing timeliness of reporting of HBV at CMJAH.

Timeliness of reporting of notifiable diseases have varied in other studies – in Afghanistan, 80% of measles cases were reported within the time required (Mofleh and Ansari, 2014). In another study conducted in Netherlands, reporting of six notifiable diseases >3 days after diagnosis varied from 12.0 – 42.0% (Reijn et al., 2011). Timeliness of reporting of diseases also differs between diseases – in Qatar, acute hepatitis had a mean reporting time of 18.5 days vs. TB which had a mean reporting time of 61.7 days (Garcell H G, 2014).

In our survey, age was associated with a higher proportion of respondents agreeing that positive HBV diagnosis was reported timely as compared to disagreeing that positive HBV

diagnosis was reported timely. This was further in keeping with more senior health workers agreeing that positive HBV diagnosis reporting was timely i.e. registrars, consultants and IPC nurses as compared to interns agreed that HBV diagnosis was reported in a timely manner. However, that was not seen on the objective analysis of the timeliness of reporting of positive HBV cases at CMJAH. Interns are often tasked with filling notification forms and therefore their perception of timeliness may represent the true reflection of the timeliness of the HBV surveillance system at CMJAH. Another possibility for the difference between health care worker perception of timeliness and the objective analysis is due to a lack of feedback on the performance of the HBV surveillance system at CMJAH.

5.3 Simplicity of the HBV surveillance system

Most health care workers remained ambivalent regarding the simplicity of the HBV surveillance system process and the forms. Interns were marginally more likely to neither agree nor disagree regarding their perceptions of simplicity of the HBV surveillance system (RRR = 19.95, p=0.083). The impact of intern's perception of simplicity of HBV surveillance system at CMJAH may have an impact on the performance of the surveillance system.

The implications of a surveillance system that is not deemed to be simple by health care workers could have far reaching effects on the system. Simplicity is closely related to acceptability and timeliness (Centers for Disease Control and Prevention, 2001). If systems are deemed to be complicated, this may decrease acceptability of the system and increase the time to report rendering the system inefficient and ineffective.

In a study conducted on key stakeholder perceptions of simplicity of the national surveillance system in South Africa, 74% of stakeholders reported that the national surveillance system was sufficiently simple (Benson et al., 2016). However, the notable difference is that the respondents in the national surveillance system survey were not health care workers based at health care facilities but rather key stakeholders at higher levels of the surveillance system (i.e. provincial surveillance system, members of the national outbreak response team). The difference in perceptions of simplicity of the notification system is very likely related to the level of operation in the system, where the higher levels of staff are not the ones who would be required to fill out the forms. Participation in higher levels of disease surveillance systems

have been found to be associated with perceiving the surveillance system as useful when compared to health care workers in lower levels of participation (viz. participation in national outbreak response vs. participation in provincial outbreak response team) (Benson et al., 2016). Health care workers at CMJAH participate in the lowest level of disease surveillance (i.e. at a facility level) and may not see the follow-on impact of reporting HBV cases such as public health actions such as vaccination campaigns, health promotion initiatives and increase in supply of HBV antivirals. Therefore, the system may be deemed to be inept.

5.4 Acceptability of the HBV surveillance system

Majority of health workers (45.0%) agreed that clinicians are unwilling to participate in the HBV surveillance system i.e. the HBV surveillance system is unacceptable to them. We found that there were no factors associated with acceptability of the HBV surveillance system at CMJAH.

The impact of an unacceptable system can overflow into other attributes which affect the performance of a surveillance system. In particular, low acceptability of the HBV surveillance system may be associated with low completeness of reporting of cases (Centers for Disease Control and Prevention, 2001). This was seen in our study, where both completeness and acceptability of HBV case reporting was suboptimal.

Reasons for health workers being unwilling to participate in the HBV surveillance system include lack of simplicity of the notification process (as found in our study), lack of training on the surveillance system, lack of knowledge of the legal mandate to notify diseases as well as lack of insight into the impact of poor surveillance systems.

In another study looking at the national surveillance system in South Africa, years of experience was found to be significantly associated with acceptability of the surveillance system (Benson et al., 2016). However, this was dissimilar to findings in our study.

5.5 Flexibility of the HBV surveillance system

Most respondents (59.8%) were uncertain (nether agreed nor disagreed) of the flexibility of the HBV surveillance system and its ability to change in accordance with changing

circumstances and needs. Increasing age and work experience of 60-120 months were associated with remaining ambivalent of the flexibility of the HBV surveillance system as opposed to disagreeing that the HBV surveillance system was flexible. The implications of an inflexible system are that the system is unable to meet new demands of the surveillance which can impact on reporting of diseases. New demands include new diseases, new reporting technologies, new case definitions and new funding sources (Centers for Disease Control and Prevention, 2001).

Health workers at CMJAH may not be familiar with the changing requirements of the surveillance system as many (61.7% in our study) have not been trained in NMC. Furthermore, the regulations regarding electronic reporting of NMC has not yet been introduced to health care workers at CMJAH. Although the new regulations regarding NMC were introduced in 2018, CMJAH has not yet implemented them. The HBV surveillance system at CMJAH may therefore have reduced flexibility as they have not yet met the new demands that the system requires.

The findings of uncertainty of the flexibility of the HBV surveillance system in our study were different from another study in South Africa which showed that many health care workers felt that the TB surveillance system was inflexible (Heidebrecht et al., 2011). However, this study was based on an electronic system of reporting as compared to paper-based reporting system which is used for HBV positive case reporting at CMJAH and the inflexibility was largely attributed to the inflexibility of the software programme. This would be critical to be aware of when introducing electronic reporting to CMJAH.

5.6 Usefulness of the HBV surveillance system

An overwhelming proportion of health care worker respondents (74.1%) felt that the (clinical) department did not provide feedback on the surveillance system to them. Increasing age was associated with agreeing that that the system was useful as compared to those who disagreed that the system was useful (RRR=0.81; p=0.004). This is an important finding as reporting of NMC is often left to interns, who are generally younger in age and who may not prioritize reporting of HBV cases as they do not see the importance or usefulness of the system.

The direct impact of a system deemed not useful may result in poor completeness and poor timeliness of HBV case reporting. Likewise, a surveillance system which has poor data quality due to inadequate completeness of reporting of positive cases as well as poor timeliness of reporting, cannot use the information provide in a useful manner to prevent and promote public health action.

In summary, the performance of the attributes of the surveillance system are an indication of whether a surveillance system is functioning well or not. In our study, we found that all the attributes of the surveillance system were underperforming. We further found that the attributes of the surveillance system share a relationship with each other, with each attribute influencing other attributes of the system (Figure 6). The attributes of acceptability, usefulness, simplicity and flexibility influence the completeness of reporting. An unacceptable, useless, complicated system of HBV case notification was related to decreased completeness of HBV positive case reporting as well as decreased timeliness. Additionally, incomplete and untimely reporting of HBV cases resulted in the information not being perceived by health care workers to be used in a useful manner.

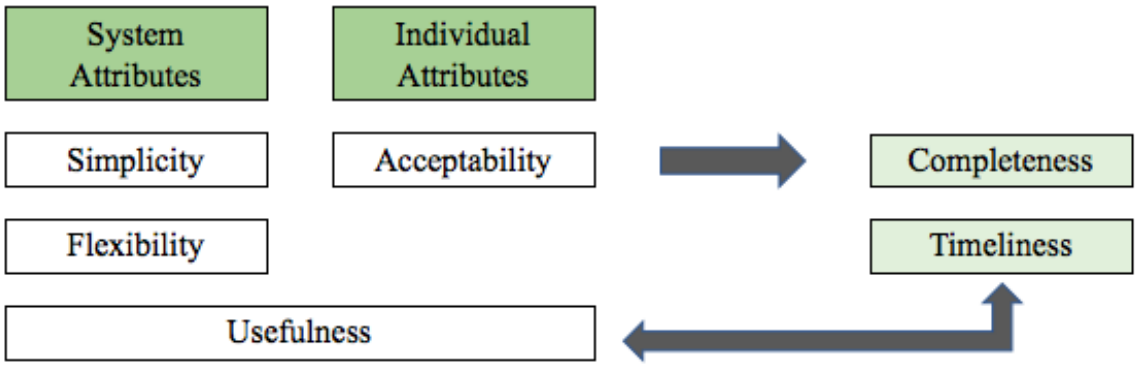


Figure 6. Relationship of the attributes of the HBV surveillance system at CMJAH

For a surveillance system to inform public health action to reduce morbidity and mortality, all the attributes of the surveillance system must function synergistically. Due to the underperformance of the attributes of the HBV surveillance system, CMJAH is unable to adequately impact on the prevention of HBV-related morbidity and mortality.

5.7 Limitations

We did not look at the other less commonly reported attributes of the surveillance system such as sensitivity, positive predict value, stability and representativeness as it would have required evaluation of other institutes such as NHLS and COJ district which was beyond the scope of this study.

5.7.1 Internal validity

The study could not utilize the approach of capture-recapture in assessing completeness of reporting which is a common methodology to determine completeness of reporting of diseases. This was due to the sources of data not being independent (i.e. both reliant on NHLS). Therefore, there may be an overestimation of the level of completeness of reporting of cases seen in our study.

Sample size

For the survey, we did not attain the required sample size to give power to our findings to achieve a statistically significant result. Therefore, caution must be given when reading the results.
For our analysis on timeliness of HBV reporting, only 83 matched cases were found. Reasons for this could include delays with data cleaning from NICD (therefore only release of some cases reported), mistakes with data entry of hospital numbers or incomplete case reporting from CMJAH and/or the laboratory. This would affect the precision of the analysis.

Information Bias

Information bias through manual data entries of the line lists and case notification forms could lead to measurement error. In the survey, no identifiers were collected - a limitation is that it is possible that one participant could have filled the survey more than once. However, all staff who completed paper-based forms were asked at the point of collection if they had completed an electronic version.

Recall bias

There could be recall bias encountered within the survey. Health care workers may further be biased in answering questions regarding notification of HBV. One possibility is that health care workers may be more likely to overestimate that they were reporting HBV in a timely manner. This may have been mitigated by the objective review of timeliness through record reviews.

Confounding

In the linear regression model looking at factors associated with completeness of the HBV case notification form, it was difficult to assess potential confounders with the given exposure and outcome variables.

In the logistic regression analysis conducted in the survey, confounders such as age and years of experience were controlled for in the analysis of the survey.

5.7.2 External Validity

The study is limited in its' generalizability to other provinces in South Africa as it only looked at one central hospital in Gauteng province. However, the study would add value to the central hospital in which it was conducted, as well as provide baseline information to further inform future studies.

5.8 Recommendations

Based on the findings of the record review and survey conducted, recommendations to improve the performance of the HBV surveillance system at CMJAH have been put forth below. The recommendations are cross-cutting for improvement of all attributes of the HBV surveillance system.

5.8.1 Staff training.

Staff awareness of the legal mandate of reporting of notifiable medical conditions should be highlighted. As part of staff training, facility based guidelines should be used to guide training and daily operations. The National Department of Health has a standard operation procedure on notifiable medical conditions. However, this has not been translated down to a facility level for use at CMJAH. Having a standard operating procedure or guideline which delineates functions of reporting by all role players at CMJAH will improve the performance of the HBV surveillance system.

A prominent finding of our study showed that many health care workers were not trained in notifying of medical conditions. Training of health care workers involved in reporting of notifiable diseases should be instituted. Filling of forms should be taught to improve the quality of the data filled.

5.8.2 Monitoring and feedback

All attributes of the surveillance system must be monitored on an ongoing basis. Within the IPC unit, feedback at their weekly meetings must include the completeness of cases of NMC (including HBV) reported as well as the timeliness. Currently, the IPC unit only reports on the incidence of HBV (i.e. the number of cases tested positive by the laboratory). However, it does not correlate the information to the number of NMC forms filled or the number of cases submitted to the district office by line-lists.

An integral part of the surveillance system is the dissemination of health-related data for use in public health to inform actions that reduce morbidity and mortality and to improve health.

Dissemination of information (including feedback on performance) must be conducted to health care workers involved in reporting of notifiable diseases. This may allow health care workers to value the surveillance system and find the system useful in preventing and improving poor health care outcomes. Health care workers may be more likely to report NMC if they were made aware of their performance and the subsequent implications of not reporting NMC.

5.8.3 Use of electronic reporting systems

The increasing use of electronic data collection from reporting sources (e.g. an electronic laboratory-based surveillance system) and/or via the Internet (a web-based system), as well as the increasing use of electronic data interchange by surveillance systems, could be used to improve the surveillance system at CMJAH (Centers for Disease Control and Prevention, 2001).

5.8.4 Communication

Communication between the different levels of reporting should also be improved. Delegation of duty to a designated member of the IPC unit to liaise with the laboratory at CMJAH to ensure that HBV results always are communicated timeously may also improve completeness and timeliness of reporting. Furthermore, communication between IPC staff and doctors completing NMC forms must exist. Positive HBV cases reported by IPC staff to the sub-district must be communicated to doctors in a standardized manner.

Additionally, this study will provide feedback to the IPC staff as well as the Departmental Heads of Unit to feedback to all health care workers. It is hoped that the findings as well as the recommendations will provide impetus to change the current performance of the surveillance system.

5.8.5 Research

Increasing staff participation in research at CMJAH could help improve knowledge of gaps in the surveillance system. Participatory tools (such as focused group discussions) to find out

more about reasons for the poor perceptions of health care workers can be used. This could improve decision making and improve surveillance systems overall (Schulz et al., 2016).

Further studies such as qualitative studies would further the knowledge regarding reasons behind underperformance of several of the attributes of the surveillance system such as inadequate completion of case notification forms and the higher proportion of unacceptability of the HBV surveillance system at CMJAH.

6. Chapter 6: Conclusion

Overall, the performance of the HBV surveillance system at CMJAH between January 2017 – December 2018 was poor. The completeness of reporting of HBV positive cases was inadequate, the completeness of NMC forms was insufficient and the timeliness of reporting of HBV positive cases was suboptimal. The HBV surveillance system at CMJAH was also perceived to be unacceptable, untimely and inept by healthcare workers.

The impact of a poor functioning surveillance system is the inability of the system to detect public health threats and to inform public health actions timeously. Dysfunction of the HBV surveillance system would directly impact on South Africa's ability to eliminate viral hepatitis by 2030. It would further compromise health initiatives targeted at decreasing HBV-related morbidities such as liver cancer and liver cirrhosis. Accordingly, effort must be put into improving the HBV surveillance system at CMAJH.

The performance of the HBV surveillance can be enriched by improving staff participation and training on notifiable medical conditions. Roll out of the electronic system of reporting of NMC at CMJAH could also improve timeliness of reporting and increase acceptability of the surveillance system. Feedback and monitoring of the HBV surveillance system are also critical components in system processes to enhance the performance of the HBV surveillance system and must be conducted on a routine basis.

7. References

BENSON, F., MUSEKIWA, A., BLUMBERG, L. & RISPEL, L. 2016. Survey of the perceptions of key stakeholders on the attributes of the South African Notifiable Diseases Surveillance System. *BMC public health,* 16**,** 1120.

BENSON, F. G., LEVIN, J. & RISPEL, L. C. 2018. Health care providers' compliance with the notifiable diseases surveillance system in South Africa. *PloS one,* 13**,** e0195194.

BRAZ, R. M., TAUIL, P. L., SANTELLI, A. C. F. & FONTES, C. J. F. 2016. Evaluation of the completeness and timeliness of malaria reporting in the Brazilian Amazon, 2003-2012. *Epidemiologia e Serviços de Saúde,* 25**,** 21-32.

BROWN, F. 2019. Process of notification at Charlotte Maxeke Johannesburg Academic Hospital. *In:* KISTAN, J. (ed.).

CENTERS FOR DISEASE CONTROL AND PREVENTION 2001. Updated guidelines for evaluating public health surveillance systems: Recommendations from the Guidelines Working Group. Morbidity and Mortality Weekly Report.

DIXON, B. E., ZHANG, Z., LAI, P. T., KIRBIYIK, U., WILLIAMS, J., HILLS, R., REVERE, D., GIBSON, P. J. & GRANNIS, S. J. 2017. Completeness and timeliness of notifiable disease reporting: a comparison of laboratory and provider reports submitted to a large county health department. *BMC medical informatics and decision making,* 17**,** 87.

DOYLE, T. J., GLYNN, M. K. & GROSECLOSE, S. L. 2002. Completeness of notifiable infectious disease reporting in the United States: an analytical literature review. *American journal of epidemiology,* 155**,** 866-874.

DUNBAR, R., VAN HEST, R., LAWRENCE, K., VERVER, S., ENARSON, D., LOMBARD, C., BEYERS, N. & BARNES, J. 2011. Capture-recapture to estimate completeness of tuberculosis surveillance in two communities in South Africa. *The International Journal of Tuberculosis and Lung Disease,* 15**,** 1038-1043.

FIRHABER, C., REYNEKE, A., SCHULZ, D., MALOPE, B., MACPHAIL, P., SANNE, E. & BISEGLIE, A. 2008. The prevalence of hepatitis B co infection in a South African (SA) urban government HIV clinic. *South African Medical Journal,* 98**,** 541-544.

GARCELL H G, T. M. F. H., ELMUSBASHER ABU BAKER ABDO, ARIADNA VILLANUEVA ARIAS 2014. Evaluation of timeliness and completeness of communicable disease reporting: Surevillance in The Cuban Hospital, Qatar. *Qatar Medical Journal*.

GAUTENG DEPARTMENT OF HEALTH 2017. Charlotte Maxeke Johannesburg Academic Hospital Operational Plan. *In:* HEALTH, D. O. (ed.).

HEIDEBRECHT, C., TUGWELL, P., WELLS, G. & ENGEL, M. 2011. Tuberculosis surveillance in Cape Town, South Africa: an evaluation. *The International journal of tuberculosis and lung disease,* 15**,** 912-918.

JAJOSKY, R. A. & GROSECLOSE, S. L. 2004. Evaluation of reporting timeliness of public health surveillance systems for infectious diseases. *BMC public health,* 4**,** 29.

JAVASCRIPT 2009. OpenEpi.

JONES, J. L., MEYER, P., GARRISON, C., KETTINGER, L. & HERMANN, P. 1992. Physician and infection control practitioner HIV/AIDS reporting characteristics. *American journal of public health,* 82**,** 889-891.

KARIM, S. S. A. & DILRAJ, A. 1996. Reasons for nderreporting of notifiable conditions. *Samj,* 86**,** 834-836.

KERAMAROU, M. & EVANS, M. R. 2012. Completeness of infectious disease notification in the United Kingdom: a systematic review. *Journal of Infection,* 64**,** 555-564.

KEW, M. C. 2008. Hepatitis B virus infection: the burden of disease in South Africa. *Southern African Journal of Epidemiology and Infection,* 23**,** 4-8.

MELLOU, K., SIDEROGLOU, T., KALLIMANI, A., POTAMITI-KOMI, M., PERVANIDOU, D., LILLAKOU, E., GEORGAKOPOULOU, T., MANDILARA, G., LAMBIRI, M. & VATOPOULOS, A. 2013. Evaluation of underreporting of salmonellosis and shigellosis hospitalised cases in Greece, 2011: results of a capture-recapture study and a hospital registry review. *BMC public health,* 13**,** 875.

MELOSINI, L., VETRANO, U., DENTE, F. L., CRISTOFANO, M., GIRALDI, M., GABBRIELLI, L., NOVELLI, F., AQUILINI, F., RINDI, L. & MENICHETTI, F. 2012. Evaluation of underreporting tuberculosis in Central Italy by means of record linkage. *BMC Public Health,* 12**,** 472.

MICROSOFT CORPORATION 2018. Microsoft Excel.

MOFLEH, J. & ANSARI, J. 2014. Evaluation of measles surveillance systems in Afghanistan-2010. *Journal of Public Health and Epidemiology,* 6**,** 407.

MWATONDO, A. J., MAINA, C., MAKAYOTTO, L., MWANGI, M., NJERU, I. & ARVELO, W. 2016. Factors associated with adequate weekly reporting for disease surveillance data among health facilities in Nairobi County, Kenya, 2013. *Pan African Medical Journal,* 23.

NAIR, G. Hepatitis B virus prevalence: Implications for a tenofovir-based HIV prevention strategy. . MTN Regional Meeting, 2011 Cape Town.

OVERHAGE, J. M., GRANNIS, S. & MCDONALD, C. J. 2008. A comparison of the completeness and timeliness of automated electronic laboratory reporting and spontaneous reporting of notifiable conditions. *American journal of public health,* 98**,** 344-350.

PAUL A. HARRIS, R. T., ROBERT THIELKE, JONATHON PAYNE, NATHANIEL GONZALEZ, JOSE G. CONDE 2009. Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. University of Witwatersrand.

PILLAYE, J. & CLARKE, A. 2003. An evaluation of completeness of tuberculosis notification in the United Kingdom. *BMC Public Health,* 3**,** 31.

POPPER, H., SHAFRITZ, D. A. & HOOFNAGLE, J. H. 1987. Relation of the hepatitis B virus carrier state to hepatocellular carcinoma. *Hepatology,* 7**,** 764-772.

REIJN, E., SWAAN, C. M., KRETZSCHMAR, M. E. & VAN STEENBERGEN, J. E. 2011. Analysis of timeliness of infectious disease reporting in the Netherlands. *BMC public health,* 11**,** 409.

SCHULZ, K., CALBA, C., PEYRE, M., STAUBACH, C. & CONRATHS, F. J. 2016. Hunters' acceptability of the surveillance system and alternative surveillance strategies for classical swine fever in wild boar-a participatory approach. *BMC veterinary research,* 12**,** 187.

SOUTH AFRICAN NATIONAL DEPARTMENT OF HEALTH 2003. National Health Care Act, 2003. *In:* HEALTH, D. O. (ed.).

SOUTH AFRICAN NATIONAL DEPARTMENT OF HEALTH 2017. Regulations relating to surveillance and the control of notifiable medical conditions. *In:* HEALTH, D. O. (ed.).

SOUTH AFRICAN NATIONAL DEPARTMENT OF HEALTH 2018. Standard Operating Procedures: Reporting of Notifiable Medical Conditions (NMC). Version 2.0. *In:* HEALTH, D. O. (ed.).

STATACORP 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP.
WEBER, I. B. 2007. *Evaluation of the Notifable Disease Surveillance System in Gauteng Province, South Africa.* Master of Medicine in Community Health, University of Pretoria.
WOODHALL, S., MANAMELA, J., PRABDIAL-SINGH, N., NCUBE, F., PUREN, A. & SUCHARD, M. THE LANDSCAPE FOR HBV-RELATED SURVEILLANCE IN SOUTH AFRICA: WHERE ARE WE NOW? *DEVELOPMENT OF BROAD NEUTRALIZING ANTIBODIES TO HIV–IMPLICATIONS FOR VACCINE DESIGN***,** 33.
WORLD HEALTH ORGANIZATION 2006. Communicable disease surveillance and response systems: a guide to planning. Lyon [France]: World Health Organization.
WORLD HEALTH ORGANIZATION 2017a. *Global hepatitis report 2017*, World Health Organization.
WORLD HEALTH ORGANIZATION. 2017b. Hepatitis B. World Health Organization Fact Sheet No 204. Available: http://www.who.int/mediacentre/factsheets/fs204/en/ [Accessed 06 November 2019].

Appendix I

SCHOOL OF PUBLIC HEALTH

STUDENT DECLARATION

PLAGIARISM

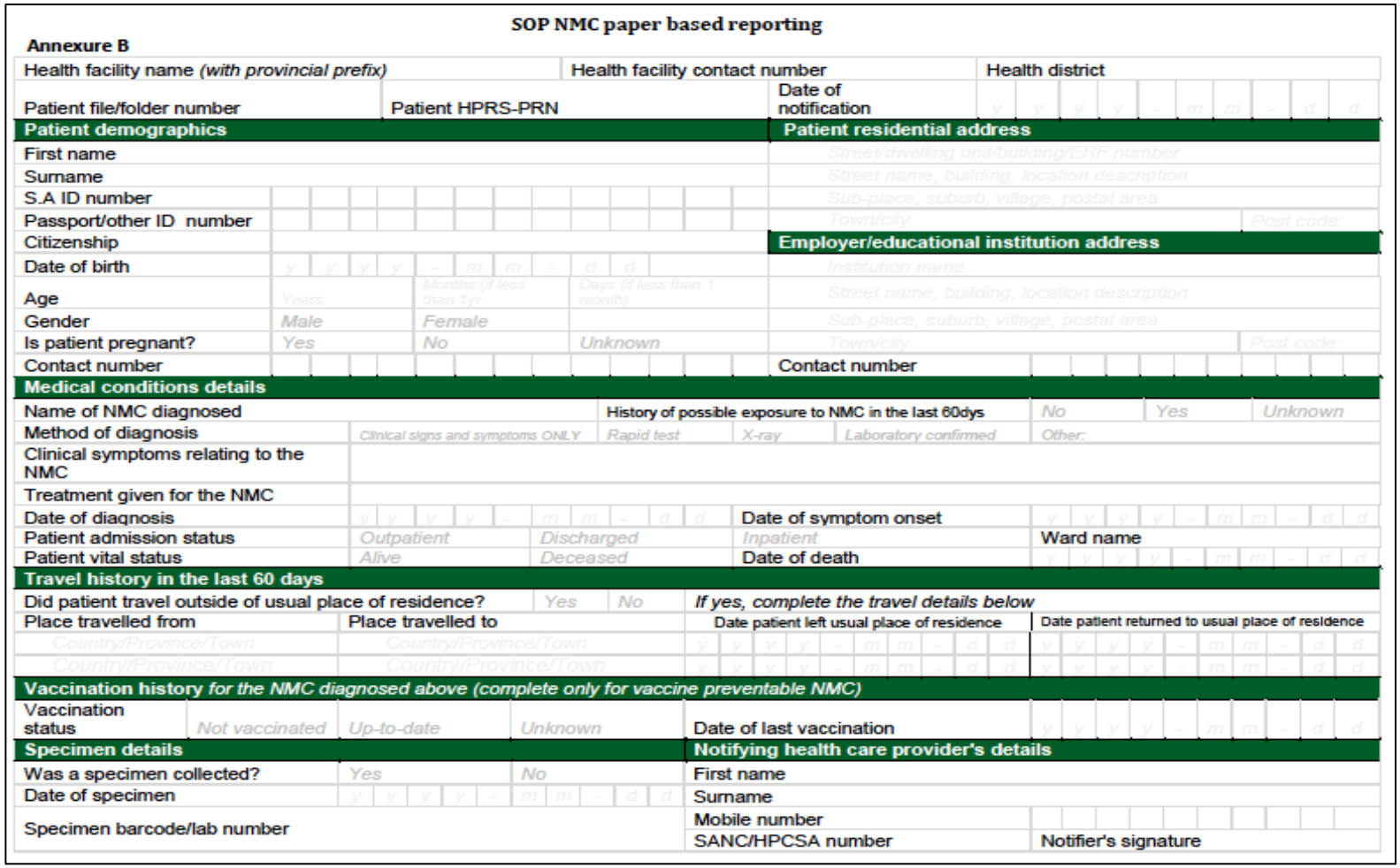
I _Jesne Kistan_ (student number: 1810179_) am a post-graduate student registered for the degree Master of Medicine in Public Health Medicine_ in the Wits School of Public Health.

I hereby declare the following:

- I am aware that plagiarism is the use of someone else's work without their permission and/or without acknowledging the original source.
- I am aware that plagiarism is wrong
- I confirm that the work submitted for the above course and module, is my own work, except where I have stated otherwise
- I have followed the required conventions in referencing the thoughts and ideas of others
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or if I have failed to acknowledge the ideas or writing.

Signature: Jesne Kistan (electronic signature) Date: 20 March 2020

Appendix II



SOP NMC paper based reporting

Annexure B

Health facility name *(with provincial prefix)*	Health facility contact number	Health district
Patient file/folder number	Patient HPRS-PRN	Date of notification y y y y - m m - d d

Patient demographics				**Patient residential address**
First name				Street/dwelling unit/building/ERF number
Surname				Street name, building, location description
S.A ID number				Sub-place, suburb, village, postal area
Passport/other ID number				Town/city Post code:
Citizenship				**Employer/educational institution address**
Date of birth	y y y y - m m - d d			Institution name
Age	Years	Months (if less than 1yr	Days (if less than 1 month)	Street name, building, location description
Gender	Male	Female		Sub-place, suburb, village, postal area
Is patient pregnant?	Yes	No	Unknown	Town/city Post code:
Contact number				Contact number

Medical conditions details						
Name of NMC diagnosed			History of possible exposure to NMC in the last 60dys		No Yes Unknown	
Method of diagnosis	Clinical signs and symptoms ONLY		Rapid test	X-ray	Laboratory confirmed	Other:
Clinical symptoms relating to the NMC						
Treatment given for the NMC						
Date of diagnosis	y y y y - m m - d d			Date of symptom onset		y y y y - m m - d d
Patient admission status	Outpatient	Discharged		Inpatient		Ward name
Patient vital status	Alive	Deceased		Date of death		y y y y - m m - d d

Travel history in the last 60 days			
Did patient travel outside of usual place of residence? Yes No		*If yes, complete the travel details below*	
Place travelled from	Place travelled to	Date patient left usual place of residence	Date patient returned to usual place of residence
Country/Province/Town	Country/Province/Town	y y y y - m m - d d	y y y y - m m - d d
Country/Province/Town	Country/Province/Town	y y y y - m m - d d	y y y y - m m - d d

Vaccination history *for the NMC diagnosed above (complete only for vaccine preventable NMC)*				
Vaccination status	Not vaccinated	Up-to-date	Unknown	Date of last vaccination y y y y - m m - d d

Specimen details			**Notifying health care provider's details**	
Was a specimen collected?	Yes	No	First name	
Date of specimen	y y y y - m m - d d		Surname	
Specimen barcode/lab number			Mobile number	
			SANC/HPCSA number	Notifier's signature

Appendix III

NMC case line list form (To be submitted weekly by each District)

Week starting Monday (yyyy-mm-dd):				**Week ending Sunday (yyyy-mm-dd):**			
Sub-district reporting during the reporting period:				**District:**			
Province:				**Submitted by (Name and surname):**			
Patient Name & Patient Surname	**Name of NMC notified**	**Age** • **Years** • **Months (if less than 1yr** • **Days (if less than 1 month)**	**Gender M = male F= Female**	**Health facility name**	**Date of Notification**	**Date of Death**	**Public Health Action Taken**

Appendix IV

My First Instrument

Record ID	_____
My name is Dr. Jesne Kistan. I am a registrar in the Department of Public Health Medicine at the University of the Witwatersrand in Johannesburg. I am doing research on the Hepatitis B notification system at Charlotte Maxeke Johannesburg Academic Hospital, which focuses on the attributes of the surveillance system (completeness, timeliness, acceptability, usefulness and simplicity) of Hepatitis B virus case reporting.	_____
How old are you (age in years)?	_____
For how long have you worked in Infection, Prevention and Control at Charlotte Maxeke Academic Hospital (number of years and months)?	_____
Did you ever receive training on the Notifiable medical condition reporting system?	○ Yes ○ No
On average, for how many years have you worked with communicable diseases or notifiable medical conditions (number of months and years)?	_____
The form used to notify Hepatitis B diseases is easy to understand	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
The form used to notify Hepatitis B diseases takes a long time to fill.	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
The notification process is easy to comply with.	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree

Clinicians are not willing to participate in the notifiable disease surveillance system.	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
Clinicians do not notify Hepatitis B within 7 days of clinical suspicion	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
Clinicians notify Hepatitis B within 7 days of diagnosis	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
The notifiable disease surveillance system has been changed to meet changing circumstances and needs in the last decade	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
The department provides regular feedback to doctors or nurses on notifiable diseases	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree
Lack of supervision does not impact on compliance with the system	○ Strongly disagree ○ Disagree ○ Disagree slightly ○ Neither agree or disagree ○ Agree slightly ○ Agree ○ Strongly agree

Appendix V

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr Jesne Barry Kistan

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190212

NAME: (Principal Investigator)	Dr Jesne Barry Kistan
DEPARTMENT:	Community Health Medicine Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	An evaluation of completeness and timelines of hepatitis B disease notification at Charlotte Maxeke Johannesburg Academic Hospital for 2017-2018
DATE CONSIDERED:	22/02/2019
DECISION:	Approved Unconditionally
CONDITIONS:	
SUPERVISOR:	
APPROVED BY:	Doctor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	27/06/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in February and will therefore be due in the month of February each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix VI

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. G. Ngwenya
Office of the Nursing Director
Tel: (011): 488-4558
Fax: (011): 488-3786
16 January 2019

Dr. Jesne Kistan
Department of Community Health in the School of Public Health
University of Witwatersrand
Faculty of Health Science
Provisional NHRD REF: NEWINPROGRESSRP 5322

Dear Jesne Kistan

RE: "An evaluation of completeness and timeliness of Hepatitis B disease notification at Charlotte Maxeke Johannesburg Academic Hospital for 2018"

Please note that permission to conduct the above-mentioned study is provisional approved. Your study can only commence once ethics approval and supporting letter from Head of Department is obtained. Please forward a copy of your ethics clearance icertificate as soon as the study is approved by the ethics committee for the CEO's office to give you the final approval to conduct the study.

Supported / not supported

Ms. M.M Pule
Nursing Director
DATE:

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 18.01.2019

Appendix VII

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES
Division of the National Health Laboratory Service
Practice Number: 5200296

Notifiable Medical Conditions (NMC) Surveillance Unit
Division for Public Health Surveillance and Response
1 Modderfontein Road, Sandringham, 2031
Tel: +27 (0)11 555 0532
E-mail: LazarusK@nicd.ac.za

Date: 13 September 2019

From: Dr Lazarus Kuonza,
Head, NMC Surveillance Unit, Division for Public Health Surveillance and Response,
National Institute for Communicable Diseases

To: Human Research Ethics Committee (Medical)
University of Witwatersrand

Re: Permission to conduct research project for degree purposes - Dr J Klstan - Ethics Clearance Certificate Number: M190212

This letter serves to confirm that the Notifiable Medical Conditions (NMC) surveillance programme has approved the request from Dr J Klstan, to use our data to complete a research project titled: "An evaluation of completeness and timeliness of Hepatitis B disease notification at Charlotte Maxeke Johannesburg Academic Hospital for 2017-2018".

The NMC programme has granted this approval on condition that:

- The dataset is utilized strictly for the purpose of this research project, as approved by the ethics committee
- The data is managed and analysed as defined in the research protocol that was presented with the request
- The results from the research project, and/or the final report from the research project will be shared with the NMC programme
- The project is for degree purposes. The investigator should seek additional permission/approval from the NMC programme for any potential abstract, conference presentation, or other scientific publication, that may result from the project.

Regards

Dr Lazarus Kuonza
Head: NMC Surveillance Unit, DPHSR, NICD

Appendix VIII

Table: Field Categories associated with completeness of HBV notification forms within CMJAH			
Variable	**Co-efficient**	**Confidence Interval**	**P-value**
Age	-0.001	-0.01; 0.01	0.615
Gender			0.973
Male	-0.002	-0.18; 0.18	
Female	Base		
Citizenship			0.234
South African	0.091	-0.08; 0.26	
Unknown	Base		
Diagnostic Method			0.428
Laboratory Confirmed	0.043	-0.01; 0.17	
Clinical Signs and Symptoms only	Base		
Patient Status			0.947
Alive	-0.004	-0.13; 0.13	
Unknown	Base		

Appendix IX

Table: Factors associated with Acceptability of the HBV Surveillance System						
Agree that the HBV system as acceptable Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Intern	2.08	0.28; 15.77	0.477			
Medical officer	1.67	0.21; 13.22	0.629			
Registrar	1.33	0.21; 8.48	0.761			
Consultant	1.87	0.20; 17.26	0.579			
IPC Nurse	Base					
Age	0.97	0.90; 1.04	0.357			
NMC Training						
Yes	1.14	0.38; 3.47	0.814			
No	Base					
Work experience						
60 - 120 months	1.21	0.38; 3.89	0.744			
> 120 months	1.42	.2585242 7.763081	0.688			
< 60 months						
Neither Agree or Disagree that the HBV system as acceptable Vs. Disagree						
	Univariate			**Multivariate**		
	Relative Risk Ratio (RRR)	**Confidence Interval (95%)**	**P-value P =**	**Relative Risk Ratio (RRR)**	**Confidence Interval (95%)**	**P-value P =**
Professional Category						
Intern	1.63	0; -	0.991			
Medical officer		0; -	0.991			
Registrar		0; -	0.991			
Consultant	1.22	0; -	0.991			

IPC Nurse	Base					
Age	0.99	0.93; 1.05	0.700			
NMC Training						
Yes	0.75	0.23; 2.41	0.629			
No	Base					
Work experience						
60 – 120 months	0.38	0.11; 1.30	0.122			
>120 months	0.27	0.03; 2.64	0.258			
< 60 months	Base					