Establishing External Ventricular Drain Best Practice Guidelines to Decrease Infection Rates

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Establishing External Ventricular Drain Best Practice Guidelines to Decrease Infection Rates.

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Declaration Form

I declare that this dissertation, which I submit to RCSI for examination in consideration of the award of a higher degree MSc Physician Associate Studies, is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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Date: 25/09/2020

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Abstract

An external ventricular drain or EVD is one of the most common neurosurgical procedures. Its application allows for excessive cerebrospinal fluid (CSF) drainage, continuous measurement and monitoring of intracranial pressure, investigation of CSF dynamics, direct treatment and prevention of CSF leaks after neurosurgical operations. Nonetheless, its application is also associated with various complications. Undoubtedly one of the most significant risks of EVD placement is the risk of infection, which can result in ventriculitis, meningitis and even death. The organisation in which the quality improvement project took place is one of the leading institutions performing neurosurgical procedures in Ireland, establishment of EVD related infection rate was a crucial step for the institution and to guide the quality improvement project (QIP). A total of 116 patients received EVDs in 2019, however 3 patients were excluded due to pre-existing cerebral infection. This resulted in 113 patients being included in the study, of which 15 patients were identified to have EVD-related infection, establishing the EVD-related infection rate for 2019 to be 13.27%. The results from this study is higher than the mean incidence rate of 9%. The DMAIC (define, measure, analyse, improve, control) framework for quality improvement (QI) was used to formulate a QI plan to reduce the reduce EVD-related infections. QI tools such as stakeholder analysis, SIPOC analysis, driver diagram and fishbone diagrams were utilised to identify the root causes and guide the hospital to make improvements to the current model with the hopes of reducing EVD-related infection rates.

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Abbreviations

C.diff – Clostridioides difficile

CDC/NHSN – Centres for Disease Control and Prevention/ National Healthcare Safety Network

CNS – Central Nervous System

CSF – Cerebrospinal Fluid

DMAIC – Define Measure Analyse Improve Control

EVD – External Ventricular Drain

HSE – Health Service Executive

ICP – Intracranial Pressure

ICU – Intensive Care Unit

IDSA – Infectious Disease Society of America

JAMA – Journal of the American Medical Association

MSSA – Methicillin-Sensitive Staphylococcus Aureus

NHS – National Health Service

PA – Physician Associate

PDSA – Plan Do Study Act

PIPE – Patient Information Profile Explorer

QI – Quality Improvement

QIP – Quality Improvement project

RBC – Red Blood Cell

SIPOC – Supplier Input Process Output Customer

VAP – Ventilator-Associated Pneumonia

VRE – Vancomycin-Resistant enterococcus

WBC – White Blood Cell

Chapter 1: Introduction

1.0 Introduction

Chapter one of this quality improvement project (QIP) begins introducing external ventricular drains (EVDs). Section 1.2 provides an explanation of the rationale for the QIP and its potential impact. The aims and objectives are outlined in section 1.3. and finally, Section 1.5 and 1.6 ends with a brief description of the organisation and the role of the student within the QIP and the organisation in question.

1.1 Introduction to External Ventricular Drains

Cerebrospinal fluid (CSF) is a modified form of plasma consisting of water, glucose, protein, minerals, hormones and lymphocytes which circulates around the central nervous system (CNS). CSF is continuously being secreted by the choroid plexus of the two lateral ventricles at an approximate rate of 500mL per day. Once produced it flows through the intraventricular foramen of Monro into the third ventricle and then through the single aqueduct of Sylvius into the fourth ventricle. Once in the fourth ventricle, the CSF flows into the subarachnoid space though the median aperture where it will flow around and over the brain onto the spinal canal and into the spinal cord (NHS, 2014). Eventually the CSF is reabsorbed by the arachnoid villi and leaves the subarachnoid space to enter the venous bloodstream (Waugh and Grant, 2014).

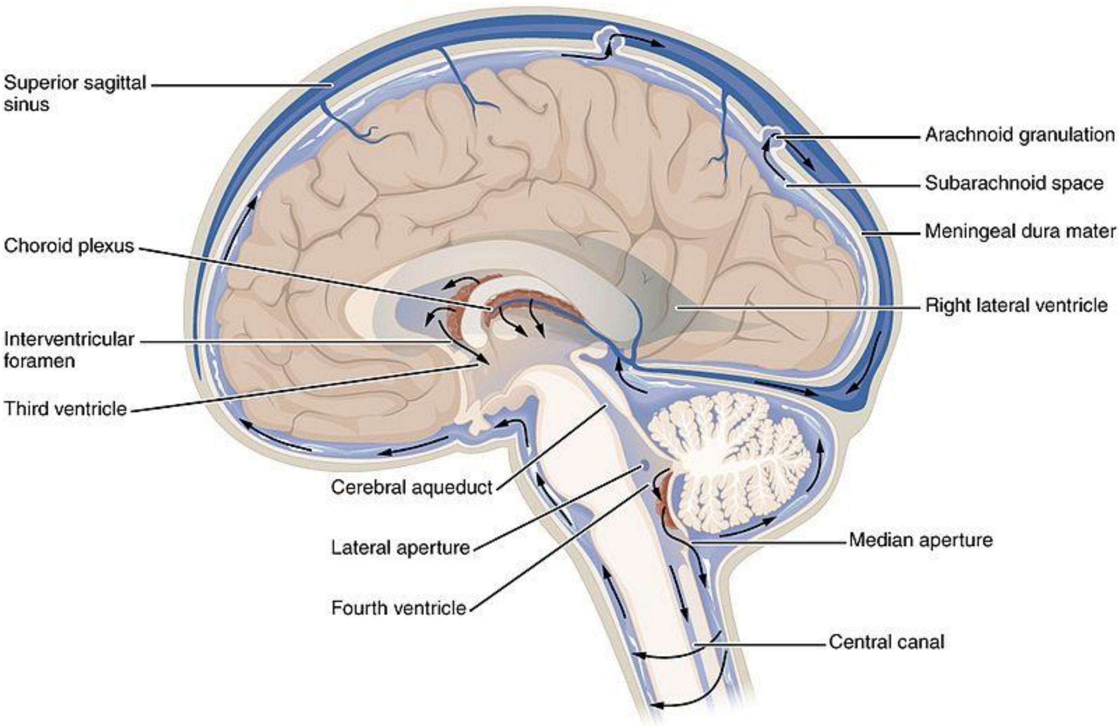

Figure 1: CSF Distribution, Version 8.25 from the Anatomy and Physiology Textbook (OpenStax, 2016)

The function of CSF is to provide buoyancy and support to the brain and spinal cord. It relies on a constant flow of CSF being produced and absorbed in the correct amount as described by the Monro-Kellie doctrine principle of homeostatic intracerebral volume regulation. The principle states that the central nervous system can be divided into three compartments composed mainly of incompressible liquids: intravascular blood, parenchyma and CSF (Kim *et al*., 2012). In adults all the components are contained within a rigid compartment known as the skull. The sum of all these components is constant and there is a fine balance in maintaining CSF volume and intracranial pressure (ICP). When there is a disturbance in this balance by formation, flow or absorption of CSF, there is an increase of CSF volume or hydrocephalus, thus causing intracranial hypertension. Conditions with an ICP above 20mmhg requires immediate intervention, as an elevated ICP can result in severe consequences and even death (NHS, 2014).

Hydrocephalus, the most common cause of increased ICP, is often associated with various causes such as subarachnoid haemorrhage, intraventricular haemorrhage, tumours, infection such as meningitis or ventriculitis and even genetic disorders. It is considered to be a disorder of CSF hydrodynamics caused by impaired absorption or occasionally due to excessive secretion resulting a build-up of CSF and increased ICP thus, reducing the blood flow to the brain, starving it of oxygen, glucose and other vital substances. If left untreated, hydrocephalus will lead to brain herniation, a condition where the brain shifts into any available space usually downwards descending into the foramen magnum, crushing the structures of the brain stem impeding the vital functions they control such as respiration and heart rate (Woodward and Mestecky, 2011) causing a person to go into cardiopulmonary arrest, hence it is considered a medical emergency. Treatment for hydrocephalus involves an attempt to drain excess CSF by the insertion of a cerebral drain such as EVDs.

EVDs is defined as a temporary method of treatment that allows for excessive CSF to drain from the lateral ventricles of the brain to relieve increased ICP (NHS, 2014). An EVD system involves the insertion of a radiopaque catheter into the lateral ventricles through a burr hole made in the skull, by a Neurosurgeon in an operating theatre under strict sterile conditions. The catheter is connected to an external drainage system, which comprises of a measuring chamber which is connected to a drainage bag with a sampling port and stopcock between them as shown on figure 2. The drainage chamber needs to be zeroed in reference to the patient. This pressure level corresponds to the amount of pressure that must be inside the ventricles before CSF drains into the catheter. The point of reference used to zero is the external auditory canal meatus, a landmark that approximately locates the catheter at the foramen of

Monro. In the external drainage system this corresponds to the height which the collection chamber hangs. The drip chamber can be moved up or down against zero reference level according to the Neurosurgeon's indication. It is crucial to monitor EVDs meticulously and ensure the zero point in the scale is horizontally level with the patient's tragus and the prescribed pressure level is correct to avoid over-and under-drainage (Humphrey., 2018).

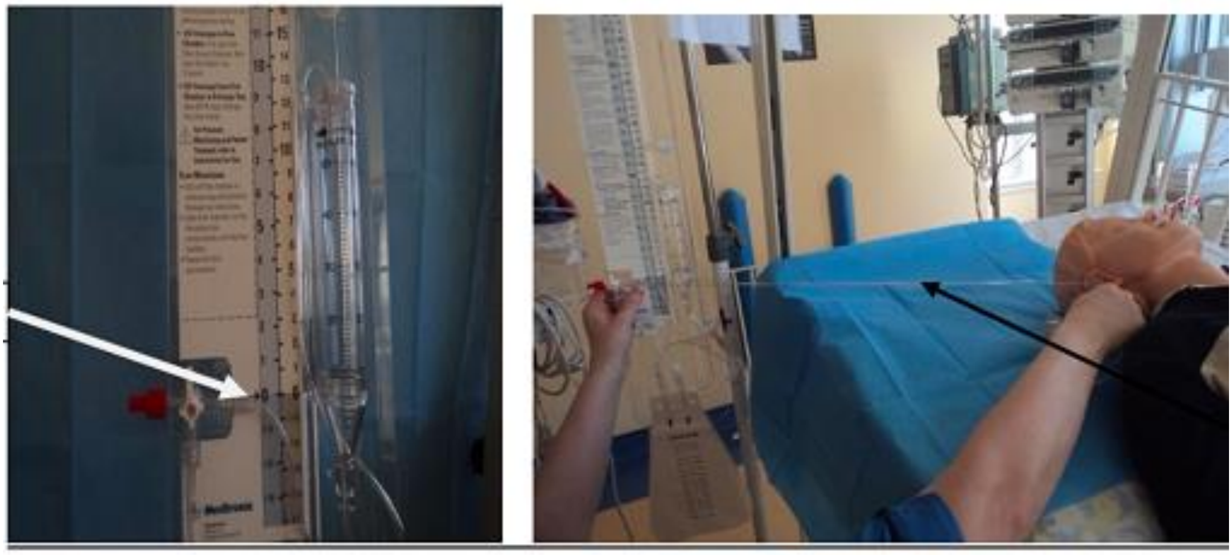

Figure 2: Zeroing of EVD (National Health Service Greater Glasgow & Clyde 2014).

1.2 Rational for Quality Improvement Plan

The placement of EVDs is one of the most elementary and most common neurosurgical procedures worldwide. Unfortunately its application is frequently accompanied by several complications such as haemorrhage, misplacement, dislodgement, blockage and an increased risk of a device-related infection. Undoubtedly the most important and common complications of EVD placement is the risk of infection (Cinibulak *et al*., 2016) resulting in patients suffering from altered mental status, fever, headaches, seizures and even more life-threatening consequences such as meningitis and ventriculitis, which carries a sever toll in terms of morbidity and mortality. Patient's with EVD-related infections require intensive therapeutic interventions and lengthy intensive care unit stays, thus increasing the cost, length of hospital stay and exposure to systemic antibiotics (Champey *et al*., 2019) as well as having major societal and familial effects beyond the patient's prognosis.

Reported incidence of EVD-related infections within the literature ranges from 2%-24% (Shang *et al*., 2018), with a mean cumulative incidence rate of 9% (Sieg *et al*., 2018). Major efforts have been directed towards reducing EVD-related infection rates as a whole, attracting attention from experts world-wide and generating multiple studies. Jajoom and colleagues carried out the most recent study investigating EVD-related infections in Ireland and the UK. The study evaluated a total of 495 EVD catheters that were inserted into 452 patients. The EVD-related infection rate during the period of this study was established to be 9.3% (Jajoom *et al*., 2018). This is in comparison to the study in Germany by Hagel *et al*., (2014) which found the incidence of EVD related infections to be 8.3% or the study carried out by Lwin *et al*., (2012) which stated the baseline infection rate in Singapore to be 6.1%.

The pathophysiology of EVD colonisation still remains unclear. There is compelling evidence implicating EVD insertion as the potential access point for organisms to enter the intracranial compartment. It is thought that EVD-related infections results from either the inoculation of pathogens during EVD placement and/ or contamination and colonisation of the EVD system during the post-operative period. It is speculated that post-operative colonisation can either arise from endogenous organisms present in the skin tract or by exogenous organisms introduced into the EVD system during wrongful manipulation (Hagel *et al*., 2014).

Significant increase in morbidity and mortality is associated with patients with EVD-related infections. Early diagnosis is crucial to allow for therapeutic intervention as soon as possible. Diagnosis in this cohort of patients is an ongoing challenge and can often be delayed due to the non-specificity of clinical signs and symptoms/or CSF laboratory parameters. The change in mental status that occurs in patients in whom meningitis or ventriculitis develops may be difficult to distinguish in our cohort of patients who are often unresponsive. Therefore, the diagnosis of CSF infections is highly dependent on laboratory findings, specially CSF culture and analysis. Infection definition for EVD-related infections can be quite varied within the literature. The Centres for Disease Control and Prevention/ National Healthcare Safety Network (CDC/NHSN) surveillance definition is the most widely used, it defines EVD-related infections as; (1) A positive CSF culture result plus clinical symptoms or CSF pleocytosis/ cell count increase or (2) In case of negative CSF cultures clinical symptoms and CNS pleocytosis/cell count increase. Any positive CSF culture or inflammatory markers and white cell count without the clinical symptoms were considered colonisation. Lack of a standardised definition for EVD-related infection is only contributing to this already challenging task. Having a clear definition would aid in the reduction of potential pitfalls in diagnosis which subsequently results in delayed initiation of appropriate antimicrobial therapy thus preventing any further devastating sequalae.

Early occurrence of EVD-related infections highlights the need for complete diligence in all steps of EVD management from operating theatre to the ward. Integrated services and the delivery of best practice is essential for patients with EVDs. The combined efforts of surgeons, ward doctors, nursing staff and all other healthcare professionals is a necessity in the management of EVDs in order to provide optimal care of these patients. Recent research of EVDs has focused on improving the overall safety of the system. Evidence-Based guidelines are highly recommended throughout the literature and are associated in reducing EVD-related infection rates (Flint *et al*., 2013). Flint and his colleagues demonstrated a reduction in the risk of EVD-related infections from 9.8% at baseline to an astonishing 0.8% by the introduction of evidence-based infection control guidelines (Flint *et al*.,2013). The incorporation of evidence-based guidelines promotes healthcare that is up to date, effective and consistent; key aspects of healthcare embodied in the National Clinical Programme for Neurology, Model of Care (HSE 2016). The purpose of this QIP was to establish 2019 EVD related infection rates and baseline infections in the hospital involved and carry out an investigation into the current EVD care plan. Areas that could be modified and improved were identified to introduce new guidelines as a means to reduce infection rates.

1.3 Aim and Objectives

1.3.1 Aim

The aim of this QIP is to reduce External Ventricular Drain related infections.

1.3.2 Objectives

The objectives for this QIP are to:

1. Investigate the number of EVD-related infections documented in patients' charts, over a 12-month period.
2. Assess the risk factors that are contributing to EVD-related infections rates by March 2020.
3. Evaluate the current EVD care plan and identify areas for improvements.

1.4 Organisational Context

This QIP was conducted in one of Ireland's leading acute healthcare institutions. The hospital first opened its doors to the public in November 1987 and since then has substantially expanded its services. It comprises of 820 beds, providing 24-hour emergency service and acute care across 54 medical specialties to approximately 290,000 people in the surrounding community. It employs over 3000 staff and it is one of the largest hospitals in Ireland (Beaumont.ie, 2019).

The Neurosurgical department within the organisation in question is the National Centre for Neurosurgery in the Republic of Ireland and it is the department in which this QIP will be executed. The department is a provider of neurosurgical care to one of the largest catchment populations amongst the UK and Ireland a population of 3.5 million people. The neurosurgery unit is made up of three neurosurgical wards Richmond ICU, Richmond and Adams McConnel. It avails of three neurosurgery theatre five days a week making it one of the busiest departments in the hospital. The department is led by ten consultant neurosurgeons alongside a dynamic and responsive group of healthcare professionals dedicated to providing best available care and the highest degree of services to patients facing neurological conditions. It offers specialised expertise in a wide range of neurosurgical subspecialties including neuro-trauma, neuro-oncology, epilepsy, anterior and lateral skull base, pituitary, neurovascular, hydrocephalus and CSF disorders, trigeminal neuralgia, stereotactic radiosurgery, complex spinal surgery and paediatric neurosurgery in conjunction with Temple Street Children's University Hospital (Beaumont Hospital, 2017).

1.5 Role of the Student in the Organisation and Project

Second year Physician Associate (PA) students at Royal College of Surgeons Ireland (RCSI) are required to complete a QIP in order to fulfil the requirements of the Masters programme. The purpose of a QIP is to outline an area within the organisation that requires improvement. Following a discussion with a member of the neurosurgery team and having read the literature around the topic it became evident that the potential risk of infection in patients that receive EVDs was significantly high. This prompted the student to analyse the current EVD care plan to identify areas that could be improved. The project was very much welcomed within the neurosurgery team and the staff were all very keen to participate. A quality improvement (QI) team was assembled with the help of the lead sponsor. The student became a key component of the team, her roles included collecting and analysing the data, establishing the organisations EVD-related infection rate and evaluating the current EVD care plan in place for the purpose to identify areas of improvement. The student will also have the responsibility of presenting the data that was collected to the stakeholders along with the rest of the neurosurgery department at one of their mortality and morbidity monthly meetings in order to raise awareness of the project and garner support before implementation of the new guidelines.

1.6 Summary

This chapter introduced the proposed project and outlined an overview of the organisation in which the QIP took place. The aim and objectives of the project were listed and the role of the student in the project was discussed. Chapter 2 discusses a review of the literature relating to EVD-related infections with regards to their associated risk factors and the lack of evidence-based guidelines for their insertion, management and care. Chapter 3 will review the methodology including the QI tools used to execute the project. Chapter 4 reviews how the proposed plan would be evaluated. Finally, chapter 5 critiques the completed QI plan and outlines any conclusions that emerged from the completion of the project.

Chapter 2: Literature Review

2.1 Introduction

This chapter presents a comprehensive review of the published literature describing EVD-related infections. Section 2.2 outlines the search strategy carried out by the student in order to gather information relevant to the QIP. Section 2.3 explores the themes which emerged from the existing literature. Section 2.4 discusses the implications of the literature on the QIP, and section 2.5 ends with a brief summary.

2.2 Search Strategy

A broad search of the literature was carried out on databases such as PubMed and Google Scholar, as well as key websites such as the NSH and HSE to find of relevant studies relating to EVD-related infections and protocols or guidelines that focused on infection reduction techniques. The application of MeSH terms increased the precision of the search, these search terms included ‘External ventricular drain related infection’, ‘risk factors for EVD-related infections’, ‘EVD infection reduction’, ‘EVD insertion, care and management’, ‘EVD guidelines’, ‘EVD management ‘EVD protocol’ ‘EVD nursing’, ‘EVD bundle’. The parameters on the search engine were set to include relevant papers from the last ten years, which yielded hundreds of results. A thorough review of the abstracts was carried out in order to gather relevant information for the QIP. Additionally, information was also extracted from international guidelines such as; EVD Guideline-Neuroinstitute Glasgow (NSH, 2011), External ventricular Drain

Management in Adults Institute of Neurosciences, Southern General Hospital (NHS, 2014), External Ventricular Device Guidelines Royal Hospital for Sick Children, PICU – Neurosurgery (NHS, 2014) and 2017 Infectious Disease Society of America (IDSA) Clinical Practice Guidelines for Healthcare-Associated Ventriculitis and Meningitis (Tunkel *et al*., 2017).

2.3 **Review of the Themes**

After reviewing the literature, two major themes associated with EVD-related infections emerged. One of the themes that emerged was: risk factors associated with EVD-related infections. This theme is further broken down into frequency of CSF sampling, duration of catherisation and multiple catherisation. The second theme which surfaced from the literature was lack of evidence based guidelines.

2.3.1 Risk Factors Associated with EVD-related Infections

Even though EVDs are considered to be a common therapeutic tool, its application is associated with purported infective complications. Identification of risk factors associated with EVD-related infections can play a vital role in the prevention of infective complications by encouraging staff to take all the precautionary measures against them, thus reducing their rate of occurrence. A variety of risk factors have been identified throughout the literature, a meta-analysis study carried out by Sorinola *et. al.,* (2019), generated a total of 15 risk factors which included; age, gender, co-infections, CSF leaks, aetiology, frequency of CSF sampling, insertion technique, CSF glucose, catheter type and duration of catherisation (Sorinola *et al*., 2019). Some of these risk factors are non-modifiable as there is no precautionary actions available for them. However, there are some modifiable risk factors such as frequency of CSF sampling, duration of catherisation and multiple catherisation where precautionary actions are available. These will be discussed in more detail in this section.

2.3.1.1 Frequency of CSF Sampling

As previously mentioned diagnosis of EVD-related infections can be a challenging task as the patients are often unresponsive in the intensive care unit and unable to report new symptoms. The change in mental status that occurs in patients in whom meningitis or ventriculitis develops may be difficult to distinguish from the impaired level of consciousness that may manifest due to the patient’s underlying disease. Patients with CSF drain–related ventriculitis, signs and symptoms are often not very useful (Tunkle *et al*., 2017), therefore the diagnosis of CSF infection is highly dependent on laboratory findings, specifically CSF culture and analysis. The standard workup of suspected CSF infection includes CSF cell count, differential, protein, glucose, gram stain and culture and should ideally be obtained prior to commencing antibiotic treatment. CSF sampling is generally obtained through the port that is most distal to the patient and should be performed by a trained clinician using a strict sterile technique due to risk of infection. Samples should not be collected from sample bags due to rapid degeneration of cellular component (Woodward *et al*., 2002).

Frequency of CSF sampling varies from scheduled collection daily to three times per week within the literature (Hepburn-Smith *et al*,. 2016). It poses the issue of whether

CSF sampling should be collected regularly. The rationale for this practice was that CSF values are a useful tool to predict and diagnose EVD-related infections and could be used to tailor treatment. However, most of the recent literature is actually diverging from this practice. According to the most recent evidence-based guidelines published, sampling should only be performed on a needed basis and avoid frequent CSF sampling as it is closely correlated with EVD-related infections (Fried *et al*.,2017). Maintenance of a closed EVD circuit and minimal inappropriate CSF sampling are common features seen in EVD protocols and are associated with reduced EVD-related infections (Thien *et al*. 2020). Although the exact pathogenesis of EVD colonisation is unknown, there is a consensus that infections are likely introduced into the ventricles by retrograde movement of microbes due to wrongful manipulation of the catheter system. This was demonstrated in the study carried out in Germany in 2014, which reported Staphylococcus, Enterococcus spp. and Enterobacter to be the most commonly identified pathogens; a pattern of microbes which is commonly seen in skin flora and hospital environments (Hagel *et al.,* 2014). Studies have also shown how the risk of infection increases the more frequently an EVD is accessed by health professionals for CSF sampling. Patients with confirmed EVD-related infections, have been found to be sampled more frequently than those with no infection (Jamjoom *et al*., 2018).

2.3.1.2 Duration of Catherisation

Multiple studies have shown that the duration of catherisation significantly corelates to the risk of developing EVD-related infections. Within the literature the duration of catherisation ranges from 1 to 44 days. (Camacho *et al*.,2011,Omar *et al*., 2010, and

Pople at al., 2012). No strict criteria for catheter placement currently exists, even though studies have shown that there is a direct proportional relationship between drainage time and infection. The longer an EVD remains in situ the higher the risk of infection. Seven days is considered to be a crucial time for the indwelling of EVDs within the literature. The incidence of EVD-related infection rates has been reported as high as 30.6% in patients with EVD in situ for greater than seven days, compared to 12.9% in those with EVD in situ for less than seven days. In light of this some neurocritical intensive care units have adapted the use of prophylactic EVD exchange, with the hopes of preventing CSF infections (Beer *et al*., 2008), other authors do not see the necessity and actually consider replacement procedures a risk factor as it's once again accessing the cranial vault, thus increasing the risk of infection (Cinibulak *et al*., 2016).

2.3.1.3 Multiple Catherisation

Multiple catheters has also been identified as a risk factor for EVD-related infection, with each additional catheter further increasing the risk of infection. Incidence of infection in patients who received multiple catheters range from 42% to 85.5%, versus a 3% to 18.3% in patients who only received one catheter (Sorinola *et al.,* 2019). It is also worth noting that each re-insertion not only does it increase the risk of infection, it also has been shown to increase the duration of catherisation, thus increasing length of hospitalisation. This particular observation was seen in a study conducted by Kazier and colleagues (2019) who examined the risk factors for CNS infection among patients with CSF drain in situ. Up until this study was carried out, the practice was to routinely replace EVDs every 5 days. The study since has introduced a new protocol which states that EVDs should remain in place in the absence of device malfunction and clinical manifestations. A four-fold decrease in EVD-related infections was observed in the group which did not have their EVDs prophylactically removed as well as a 20 day decrease in length of hospitalisation. The results of this study were so significant that the new protocol was implemented immediately into practice (Kazier *et al*., 2019).

2.3.2 Lack of Evidence-based Guidelines

The literature has shown that potential for infection in this vulnerable patient population can be as high as 45%, imposing tremendously on the healthcare system. Despite EVDs widespread use and high infection rates, many hospital do not adhere to strict protocols for EVD placement and maintenance nor do they tract these infections with the same diligence as central-lines or catheter infections (Hepburn-Smith *et al*., 2016). A recent survey of American Academy of Neurological surgeons found that fewer than one-half practiced in settings with such protocols and even in institutions in which such protocols had been adopted, barely one-third adhered to those protocols strictly (Sieg *et al*., 2018). It is postulated that the vast assortment of EVD management practices and recommendations available within the literature is a contributing factor to the lack of adherence. In pursuit of lower infection rates many institutions have implemented and published EVD protocols. However, a consensus on best evidence-based guidelines for insertion and management of EVDs still remains uncertain, resulting in a wide practice variation. Several measures have been proposed by the IDSA to reduce the incidence of EVD-related infections. Nonetheless, many of these recommendations are based on expert opinion and lack of rigorous clinical data (Tunkle *et al*.2017), most of the studies reflect practices at individual institutions.

Randomised controlled studies in EVD insertion and maintenance are rarely conducted, thereby limiting the reporting of scientific evidence (Hepburn-Smith *et al*., 2016). A review of the available protocols for EVD insertion, care and maintenance was carried out by Hepburn-Smith *et al*., 2016. Upon review of the protocols, the variability in technique and practice for insertion and handling EVDs became quite evident. Many points of divergence and controversy including catheter selection, insertion venue, skin and hair prepping pre-surgery, dressing type and maintenance, drainage duration and replacement and CSF sampling frequency were identified. Summary of pertinent results can be found in appendix 1. One consistent factor that persisted throughout the various studies was the benefits associated with the development and implementation of a meticulous evidence-based protocol for reduction in the frequency of infection. Studies have reported a 40%-70% reduction in infection rates post protocol implementation (Sieg *et al*.,2018). This observation was echoed in numerous studies for example; the study from The Netherlands where implementation of a bundle approach resulted in the reduction of drain-related meningitis within a period of 5 years from 37% to 9% (Cinibulak et at., 2016) ; or the study carried out by Flint *et al*.,2013 which demonstrated how the introduction of evidence-based infection control protocol was associated with a dramatic reduction in the risk of EVD related infections. Rates of CSF positive culture decreased from 9.8% at baseline to an astonishing 0.8% in the EVD infection control period (Flint *et al*., 2013). These results were even duplicated in Singapore in a study by Lwin *et al*.,2012 who demonstrated a reduction in EVD-related infections from 6.1% to 3.8% by the introduction of an EVD protocol for neurosurgery doctors which included proper surgical techniques to minimise intra-operative infections by educating junior doctors on proper CSF sampling from the EVD and minimising the number of days the EVD is maintained in situ. (Lwin *et al*., 2012). Because physician and nursing teamwork is essential to successfully reduce the rates of infection, the protocol also included instructions for neurosurgery nurse clinicians providing a homogeneous management approach. Additionally, EVD care workshops and competency skill checks on the management of EVDs for nurses working in the neurosurgical wards were also carried out (Lwin *et al*., 2012). Frequent education sessions for nurses, physicians and trainees about EVD maintenance and infection prevention promotes understanding of risk factors for infection and compliance with protocols (Camacho *et al*., 2013; Chatzi *et al*., 2014).

Lack of guidelines or protocols may also contribute to the variation in the definition of infection that is seen amongst authors. Some identified infection as a positive CSF culture, whilst others identified infection by the CDC/ NSH definition criteria for meningitis or ventriculitis, or even both. It is well known that EVD-related infections may be difficult to diagnose as changes in CSF parameters are often subtle, and clinical signs and symptoms may be a challenge to pick up due to postsurgical changes, invasive devices, prior antimicrobial exposure, and underlying CNS disease. The lack of standardised definition or diagnostic pathways is only adding to this challenge (Martin *et al*., 2018). Furthermore, each EVD-related infection definition is open to criticism and could be resulting in over or under reporting of EVD-related infections. Evaluating CSF samples using standardised definitions of infection would aid measurement and optimise the analytical performance for clinical diagnosis. Additionally, standardisation across all centres would enable accurate epidemiology and refinement of diagnosis and treatment guidelines (Martin *et al*. 2018).

2.4 Implications of the Literature Review on the QIP

The literature suggests that patients with EVDs are a particularly vulnerable population with high risk for infections. These infections can dramatically impact the patient's hospital course, increase morbidity and ultimately the risk of death. Even with such high stakes and devastating consequences, incidence of EVD-related infections within the literature has been reported as high as 45% (Sorinola *et al*., 2019). Patients require intensive therapeutic interventions and lengthy intensive care unit stays, thus significantly increasing cost, hospital stay, exposure to systemic antibiotics, morbidity and mortality (Champey *et al*., 2019). All efforts should be directed towards reducing infection rates as a whole. As such all healthcare professionals responsible for the care of patients with EVDs should be aware of the risk factors associated with insertion of EVD devices and take all the measures to avoid them by intensifying aseptic techniques, reducing system manipulation, avoiding frequent CSF sampling, managing devices by trained personnel and trying to avoid catheter exchange and their maintenance for more than 7 days. Early occurrence of EVD-related infections highlights the need for a complete diligence in all steps of EVD management, from the operation theatre to the wards. Evidence-based guidelines or protocols are highly recommended throughout the literature and are associated in reducing the incidence of EVD-related infections. Nonetheless, areas of divergence exist within current available protocols highlighting the need for quality improvement projects and audits must continue their effort in identifying areas of improvement and continue the quest for comprehensive standardised EVD care guidelines.

2.5 Summary

This chapter presented a summary of the published literature describing EVD-relating infections. The development of the two main themes; risk factors associated with EVD-related infections and lack of evidence-based guidelines provides a strong foundation for the development of the QIP in the coming chapters.

Chapter 3: Methodology

3.1 Introduction

This chapter reviews key QI methodologies that are frequently utilised in healthcare. Section 3.3 explains the rationale behind the selected model chosen for the development of this QIP, while Section 3.4 presents multiple QI tools chosen to illustrate and summarise the data collected.

3.2 Approach to QI

The landscape of healthcare is ever-changing in order to ensure quality care and services to patients. QIP are at the forefront of this evolution through the implementations of research evidence into practice. Although QI practices were originally developed for the manufacturing industry, QI methodologies have been adopted by other industries outside manufacturing such as healthcare to accomplish their improvement goals. In the past healthcare mainly focused on quality assurance and quality control, however these methods weren't sufficient enough to enhance outcomes. Checking for defects and recommending changes without recognising the effects of these changes on other parts of the organisation may improve one process but harm others. Consequently, the best organisations are now combining quality assurance with proactive quality improvement (Varkey *et al*., 2007).

The term quality improvement in the healthcare sector corresponds to providing and maintaining healthcare that is safe, effective, timely, equitable and person-centred.

Many approaches and models are to be considered when planning QIP in healthcare. No one approach is better than another and several are often employed simultaneously. With regards to this QIP the three models that were considered were the Plan-Do-Study-Act Cycle (PDSA), the HSE framework for improving and the Lean Six Sigma Model.

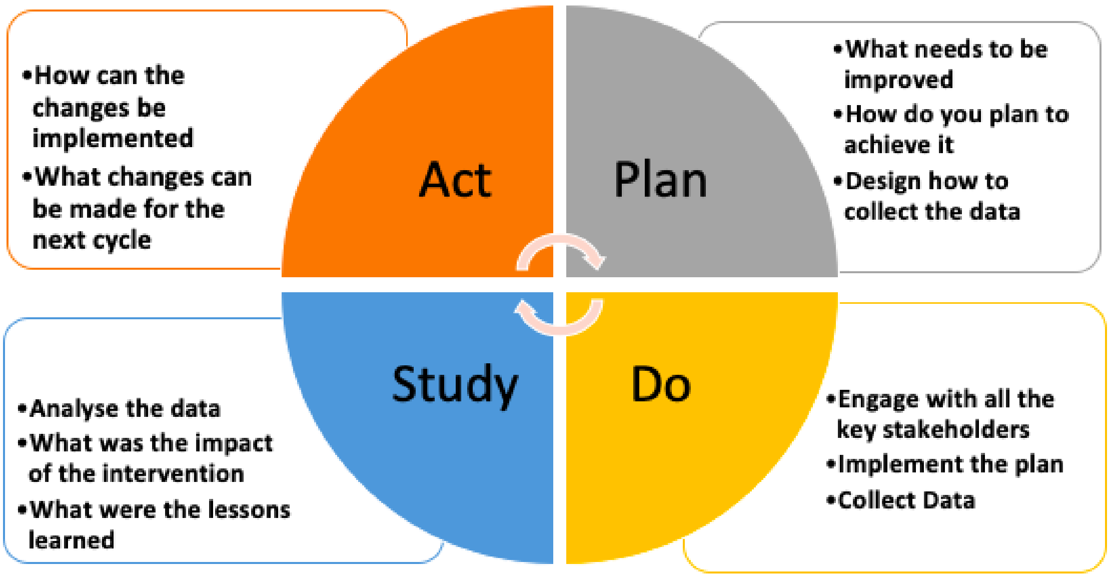

Figure 3: Plan-Do-Study-Act.

The Plan-Do -Study- Act or PDSA is the most commonly used approach for rapid cycle improvement in healthcare, It involves a four step system to monitor the effect of change over time. These cycles are linked with key questions; 'what are we trying to accomplish', 'how will we know that change is improved?' and 'what changes can be made that will result in improvement?' (The Health Foundation, 2013). Each phase of the cycle answers the core questions of the Institute for Healthcare Improvement model. The initial 'Plan' phase includes establishing the objectives and processes to deliver the desired output. The 'Do' phase involves small scale implementations of the new process where any deviations are documented. The 'Study' phase requires observing differences between the desired and observed outcome, and finally the 'Act' phase involves analysing the lessons learnt from the study phase and incorporating them into the test. This process is then repeated, serving as a structural model for continuous development (Taylor *et al*.,2014).

Figure 4: HSE Driver and Framework for Improving Quality (HSE, 2016b)

The second model to be discussed is the HSE Framework for Improving Quality, it was devised to orientate the planning and delivery of health care away from crisis management to proactive service, a much-needed improvement during these times of strained healthcare resources. It provides a strategic approach to improving quality, productivity and efficiency. It is comprised of six drivers (Figure 4), which were designed to be used in combination with each other with the purpose to provide the best environment for improvement to thrive. The Framework was developed with a vision to provide ‘A healthier Ireland with high quality service valued by all’. It was adapted from international models as well as local improvement experience and learning (HSE,2015). The Framework is firmly orientated to create a culture within healthcare that is continuously seeking to provide safe, effective, and person-centered care across all services, driven by the combined efforts of everyone, from healthcare professionals, patients, their families, commissioners, providers and educators to make the changes that will lead to better patient outcome and experience along with continued development and support of staff on the delivery of quality care (HSE, 2016).

3.3 Rationale for Model selected

After a thoughtful consideration of the QI methodologies available, the Lean Six Sigma model was selected for the development of this project. Whilst the PDSA cycle amongst other QI models are useful in quality improvement, they had limiting capabilities for the magnitude of this project. The structure provided by the application of the DMAIC framework rendered the tools required to identify the problems that has led to high rates of EVD-related infections. It particularly suited this project as it permits the user to define a problem, measure it, analyse it and implement changes based on the data that was collected and analysed, guiding the project towards providing a quality service system with high patient satisfaction.

3.3.1 Lean Six Sigma Model

Lean Six Sigma is a combination of two QI models the Lean and Six Sigma. Lean Methodology originated from the Toyota production system in 1990, it aims to eliminate waste in a system by reducing unnecessary steps in a process pathway while preserving steps to maximise the value to the consumer. Other lean principles include reducing time and resources required to generate results for the consumer and improving the system's ability to respond to the changing needs of the consumer (Fong, 2017). Using Lean methods allows administrators to work closely with their staff, encouraging both individual and organisational improvement (Cantiello *et al*., 2016). Six Sigma was also developed in a corporate setting in 1986 by Motorola and aims to eliminate deficits in processes with the purpose to create a low-cost, high quality product. The objective of Six Sigma is first to identify the problem, then to measure it, and finally to analyse this process and determine the cause of the issue (Cantiello *et al*., 2016). It involves both qualitative and quantitative measures to determine the root cause (Ashok *et al*.,2013). Even though the two models are different, they are complimentary to each other as both seek to improve the process by reducing waste, variation and work imbalance within an organisation. Given the clearly defined benefits, it’s no surprise that this amalgamated model has gradually been adopted into healthcare in order to reduce medical errors and improve patient care and safety levels (Taner *et al*., 2007). The Lean Six Sigma uses the DMAIC (Define, Measure, Analyse, Improve, Control) framework, a five-phase improvement cycle used for typical problem-solving: (1) Define the problems and issues that need to be addressed; (2) Measure and quantify the problem by obtaining baseline data; (3) Analyse the cause of the problem; (4)Iimprove the process and remove barriers; and (5) Control the process solution by routine monitoring (Loftus *et al*., 2015).

Figure 5 gives a briefly outline of the various QI tools used in this QIP within each phase of the DMAIC framework, how they are applied with regards to this QIP, which will be discussed in section 3.4.

Define	Measure	Analyse	Improve	Control
Stakeholder Analysis SIPOC Analysis Driver Diagram	Online theatre system data Patient Information Profile Explorer (PIPE) data	Fishbone Diagram Histogram Run chart Pie charts	Brainstorming Refinement	Control Plan Update Documents

Figure 5: Lean Six Sigma DMAIC outline

3.4 Model Overview

This section will discuss in detail four out of the five phases of the DMAIC framework, each phase will be outlined under different headings.

3.4.1 Define

The first phase of the DMAIC is the Define phase. It requires the project lead (the student) to define an area for improvement, order for the problem statement to be devised. As mentioned in the literature review, EVD insertion is one of the most common neurological procedures, however despite their ubiquity there is a high risk of infection associated with their placement, with reported incidence of EVD-related infections as high as 45% (Hepburn-Smith *et al*.,2016). It has been postulated within the literature that these high infection rates may be due to the lack of standardised EVD guidelines available for insertion, management and care of EVDs. Furthermore, EVD infections are typically not tracked with the same diligence as central-line catheter infections, because there are no widely accepted standards for routine management of EVDs (Hepburn-Smith *et al.,* 2016). Following a discussion with a member of the neurosurgical team and having read the literature around this topic, it prompted the student to evaluate and establish 2019 EVD related infection rate in the organisation and carry out an investigation into the current EVD care plan, identifying areas that could be improved in order to reduce infection rates.

To begin, a project charter was devised (appendix 2). Formulation of the project charter assisted in defining the problem, the scope of the project and its goals. It also served as a reference point in identifying possible stakeholders. A stakeholder is anyone considered internal or external to the organisation, who has a particular interest in the project and who can also have an impact on its success or failure (Silver *et al*., 2016). Identification of stakeholders at an early stage is essential for the development, success and longevity of the QIP. Recognition of all participating parties was achieved through the process of a stakeholder analysis. Once all the stakeholders were identified, they were mapped out on a power versus interest grid (Figure. 6). Next a project sponsor needed to be chosen. The project sponsor should have huge interest, influence and a strong connection to the area of improvement in order to drive the project to success. The neurosurgical consultant with whom the student had been liaising agreed to sponsor this QIP. Other key members of the team were also identified and helped gain better understanding of the group dynamic. Devising a stakeholder analysis ensures that all relevant parties are informed and involved effectively by maintaining continuous engagement during the course of the project **(**Concannon *et al*., 2014).

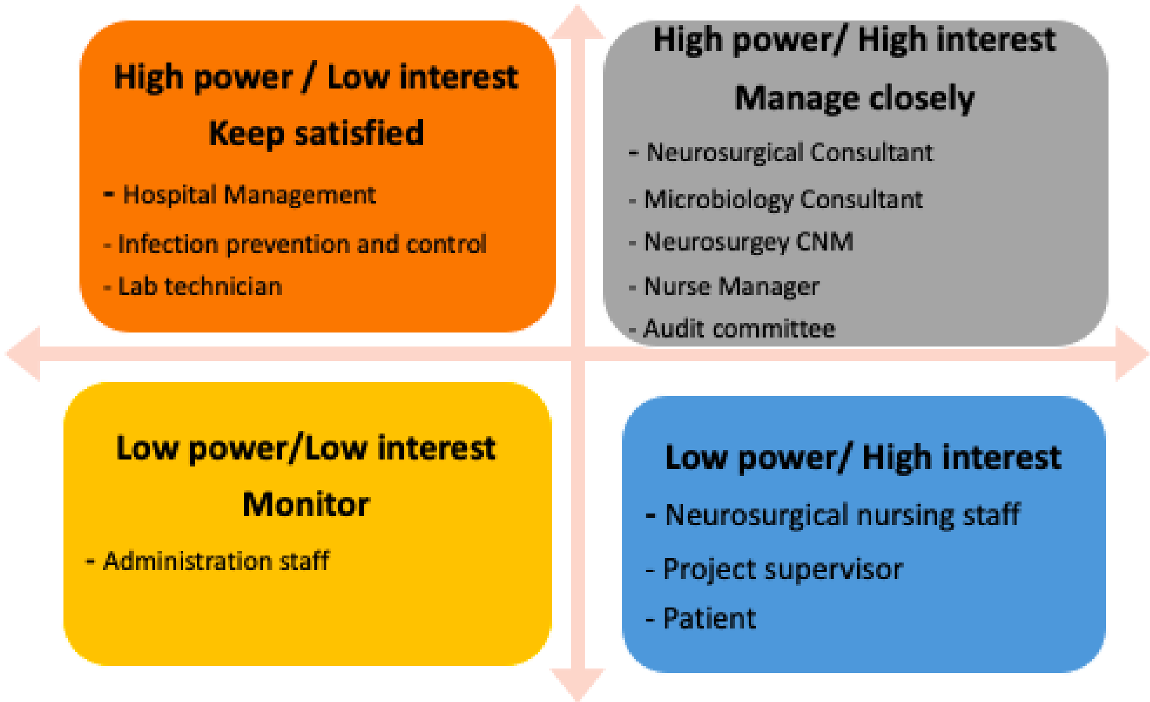

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Figure 6: Stakeholder Analysis

The stakeholder analysis allowed for easy identification of those in areas of low interest. Steps were taken in order to try persuade these stakeholders from areas of low interest into areas of high interest. This was achieved by building a relationship with all involved and understanding their perspectives and motivations in order to overcome their resistance to change. Agreement and co-operation of stakeholders is vital to move the project forward and implementing the proposed change (Varvasovszky and Brugha, 2000**)**.

3.4.1.2 SIPOC Analysis

In order for any process to be improved upon it must first be understood. Insight into the current process helps understand where the problems are and identifies areas for improvement. Normally a Process Flow Diagram is developed to help establish the scope of the process and identify significant issues. However when applying this QI tool to the project it was noted that it perhaps wasn't the most suitable tool. It was observed by the student that EVD related infection could occur at any stage of the process from the moment of insertion up to removal of the device. Depicting all these various processes in a single Process Flow Diagram was going to be very challenging. Therefore, the student decided to look at other QI tools that were better suited for the QIP. SIPOC analysis was chosen as it looks at a very simplified version of the process and all its impacting factors. Supplier, Input, Process, Output and Customer (SIPOC) analysis is a tool used by teams to identify all relevant elements of a process involvement before it begins (SIPOC Diagram, 2020) This QIP tool was specially designed to identify the potential gaps between output and customer expectations of the process. The development SIPOC helped the team gain a better understanding of the process components and its boundaries.

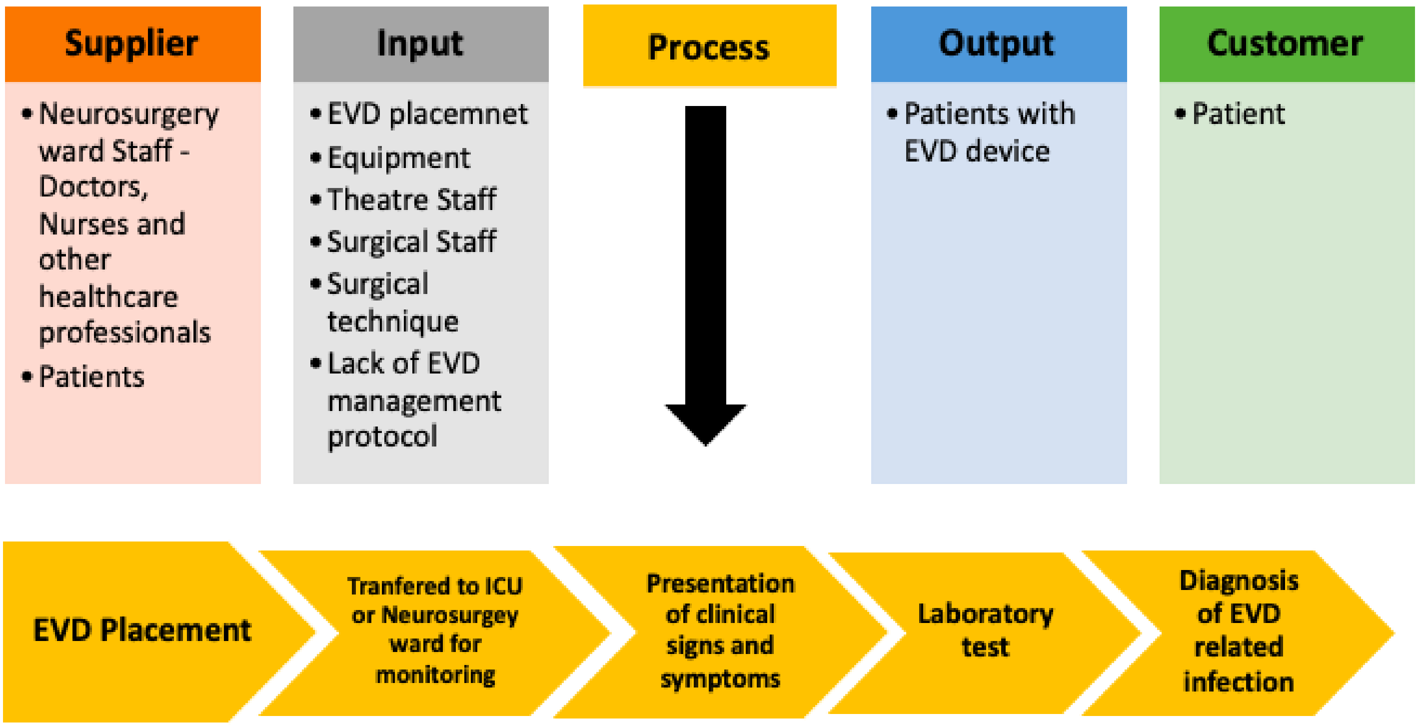

Figure 7: SIPOC Analysis

Figure 7 was developed by the student to understand and demonstrate the process flow of patients that receive EVD devices which become infected and identify its inputs, outputs, suppliers and customers. The process begins with the placement of an EVD and follows the patients until its diagnosis of EVD-related infection. Placement of an EVD device occurs in an operation theatre under strict sterile conditions. The patient is then transferred to either ICU or a Neurosurgery ward for recovery and observation. Management of EVDs is very hands on and requires critical judgment and close co-ordination of the whole medical team. A holistic understanding of EVDs and their management is required for safe care of patients with EVD in situ. Suspicion of infection begins with the presentations of new clinical signs or symptoms which include; new or worsening headache, persistent or recurrent fever, new or worsening leukocytosis, nausea, lethargy, or neurological deterioration. CSF is only tested when infection is suspected clinically on the basis of new or worsening signs and symptoms. Once an infection is suspected, a panel of CSF and blood test should be performed and sent out to microbiology to evaluate the patients and device's CSF for infection and to identify the causative organism. It is important to repeat CSF culture to confirm any positive results in order to confirm diagnosis as a positive result can be due to a contamination, colonisation or infection.

3.4.1.3 Driver Diagram

A fundamental concept in quality improvement is that we can control the outcomes by controlling inputs and how they are used. The identification of the QIP's inputs and outputs from the SIPOC analysis led to the usage of a Driver Diagram. A Driver Diagram is a visual structural tool used by teams for problem solving in complex environments. It is a tool which aims to demonstrate the relationship between the overall aim of the project and the primary drivers that directly contribute to it (IHI,2020). It achieves this by transforming high level improvement goals into a logical set of supporting goals and activities, as demonstrated below (Figure 8). The application of this QI tool allowed the entire change program to be captured and conveyed in a single diagram, which helped gain support and engagement of team members and stakeholders, as they were now able to visualise their role in the whole project. Full team involvement was essential in order to gain advice, insight and ideas from all team members and get a broader understanding of the QIP increasing its likelihood of success.

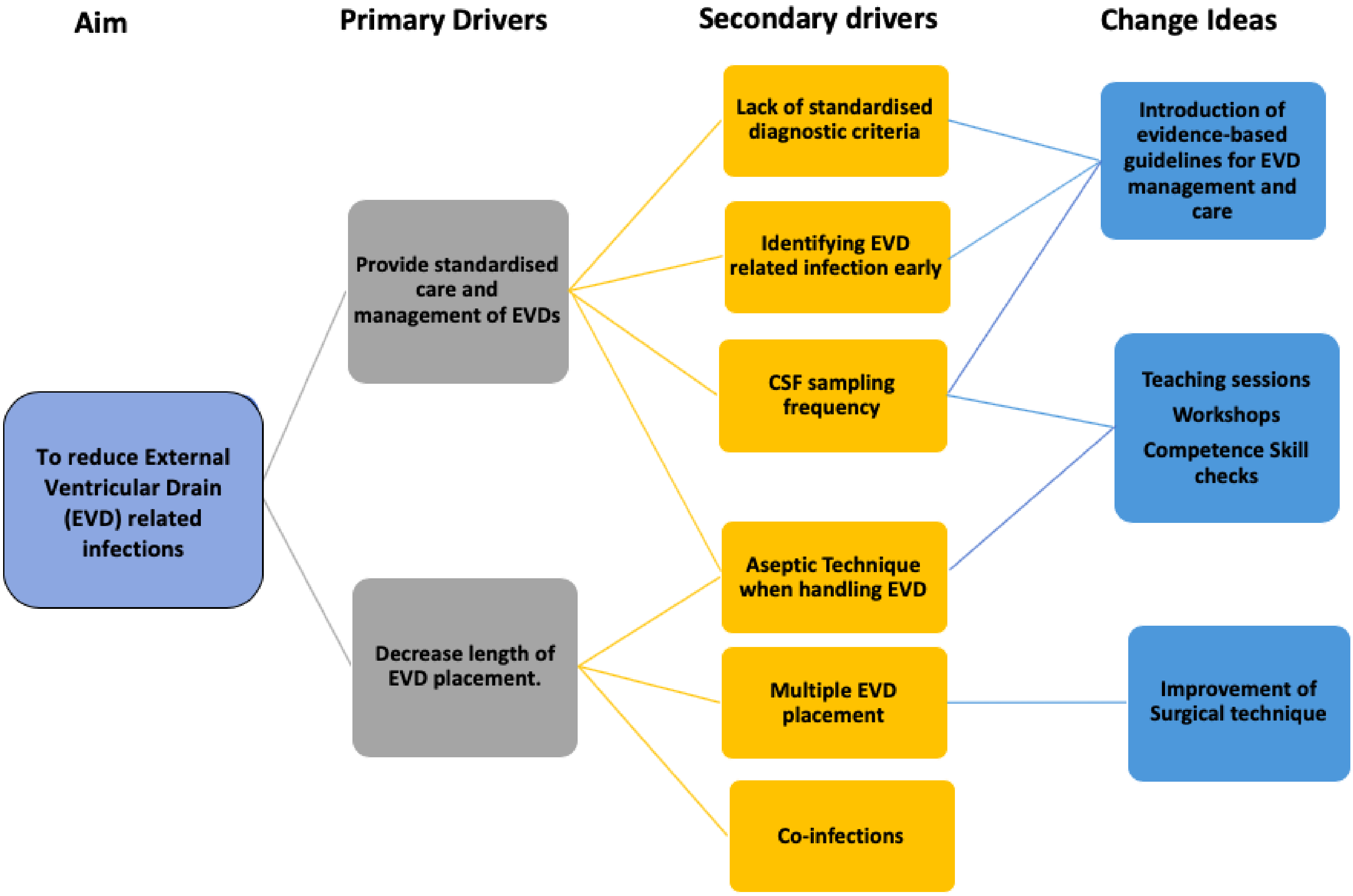

Figure 8: Driver Diagram

The development of a Driver Diagram was a pivotal point in identifying the various factors that would aid in the reduction of EVD-related infections. It highlighted the needed for standardised EVD care and management. By addressing this issue, it could consequently have a positive impact on four out of the six secondary drivers; lack of standardised diagnostic criteria, early identification, CSF sampling frequency and aseptic techniques as shown on Figure 8.

3.4.2 Measure

The second phase of DMAIC, the Measure phase, is a fundamental component of QIP. The aim of this phase is to quantify the defined problem by measuring the current performance level of the process and establish a baseline. It focuses on monitoring the outcomes of a system overtime and learning how potential interventions have affected processes and outcomes, so that subsequent improvement steps can be taken (Silver *et al.,* 2016).The establishment of a baseline is a vital step as it can be used for comparison following implementation of the project to determine whether changes have improved the process.

The student liaised with the project sponsor and other members of the team and developed a data collection plan. It was decided to conduct a retrospective analysis to investigate EVD-related infections in 2019, the data was extracted from the hospitals database from January 2019 to December 2019. The online theatre system was used to create a list of all of the EVD inserted in 2019, which included a patient's episode number and name.

The next step was identifying the number of EVDs that were infected. For the purpose of this study the CDC/NHSN surveillance definition was used to identify such patients. Access was gained by the student to discharge letters and microbiology laboratory test results from Patient Information Profile Explorer (PIPE) or patient charts, to identify patients with EVD related infections. The following data was collected and inputted to a Microsoft Excel sheet (appendix 3):

- Indication for insertion
- Duration of EVD placement (insertion date and removal date)
- Pre, intra and post neurosurgical operations
- Concurrent infections
- Re-insertions (dates)
- Number of CSF sampling
- Type of infection
- Organism causing the infection
- Course of treatment of infection
- Clinical outcome

A total of 154 EVDs were placed in 2019, of which 38 were re-insertions giving a total of 116 patients that received EVDs in 2019. 3 of those were excluded from the study as they had a pre-existing cerebral infection. Therefore 113 patients were included and of those patients, 15 met the CDC/NHSN surveillance definition for EVD related infection. The data was combined and quantified to give a total of 13.27% rate of EVD-related infection in 2019 (Table 1).

Numbers of EVDs inserted in 2019	154
Time Frame	January 2019 - December 2019
Number of patients that received EVDs	116 (38 re-insertion)
Patients diagnosed with EVD related infection	15 patients (13.27%)
Criteria for diagnosis of EVD related infection	CDC/NHSN surveillance definition: - Positive CSF culture plus clinical symptoms or CNS pleocytosis/ cell count increase OR - In the case of a negative CSF culture, clinical symptoms and CNS pleocytosis/ cell count increase
Excluded	3
Exclusion criteria	Pre-existing cerebral infection

Table 1: Data demonstrating 2019 EVD related infection rate

3.4.3 Analyse

The third phase of DMAIC framework is the 'Analyse phase'. The aim of this section is to identify the cause of the problem by applying relevant analysing tools to present the data collected during the measure phase. Information was arranged and categorised to be depicted visually using tables, diagrams and various types of charts.

The main objective of this phase was to determine the root causes that increases the risk of EVD-related infections, so that they can be eliminated, thus improving the process. To initiate our investigation a statistical analysis was carried out, which generated a list of potential root causes. Ideally, to validate these root causes a questionnaire would have been devised and distributed to all staff members that are involved in the care of patients with EVDs. The questionnaire would have allowed the staff to have their expertise input on the causative effect and indicate any necessary corrective measures which could improve the process. However due to unforeseen circumstances of COVID-19 the questionnaire was not feasible. Instead, expert advice from the project sponsor was procured. Five major groups contributing to the process were identified and are as follow:

- Equipment: Type of catheter, sterile equipment, dressings
- Nursing staff: Aseptic technique, knowledge of EVD management
- Physicians: Aseptic technique, surgical technique, Knowledge of EVD management
- Patient: Gender, age, co-infections, CSF leaks, aetiology
- Process: Lack of protocol, frequency of CSF sampling, multiple EVDs

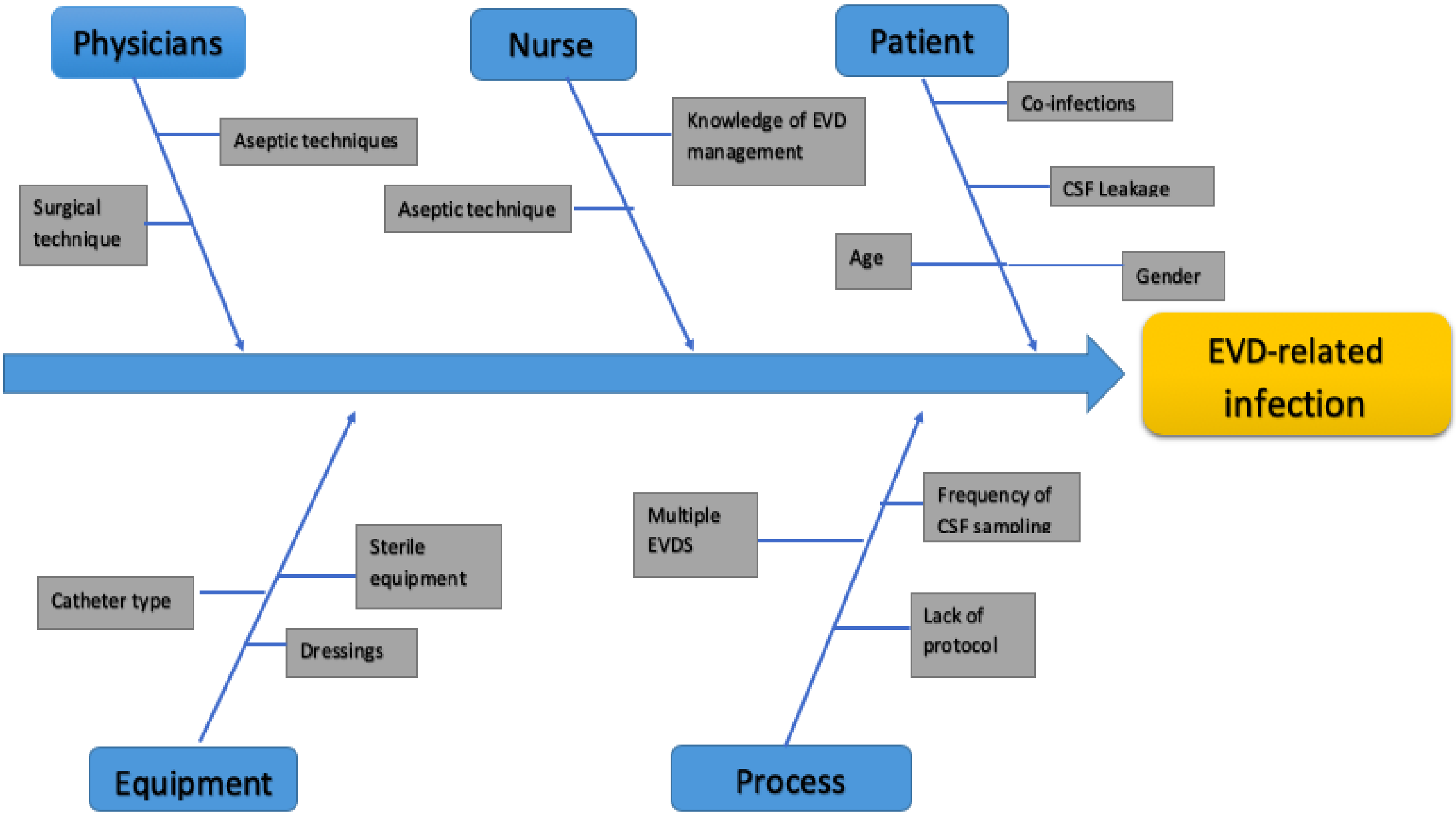

Figure 9: Fishbone diagram

In order to illustrate this information, the student decided to construct a Fishbone Diagram, a visual tool that was invented in the 1960's by Ishikawa (Improta *et al*, 2017). It allows the user to identify the different root causes and potential effect of the problem (Figure 9). The focused problem is in a box at the head of the diagram and the spine of the 'fish' has a number of branches or 'backbones' which represent issues that may be contributing to the problem (Nathanand Kaplan, 2017). There are numbers of factors contributing to EVD-related infections, all of which are divided into the categories under the headings of physicians, nurses, patients, equipment and process. Further analysis of the data collected during the measure phase divulged the effects each of these categories has on EVD-related infection rates.

A total of 116 patients received EVDs in 2019, with 3 excluded due to pre-existing cerebral infections. Thus 113 patients were included in the study, of which 15 were identified to have an EVD-related infection, establishing the EVD-related infection rate for 2019 to be a 13.27% (Figure 10).

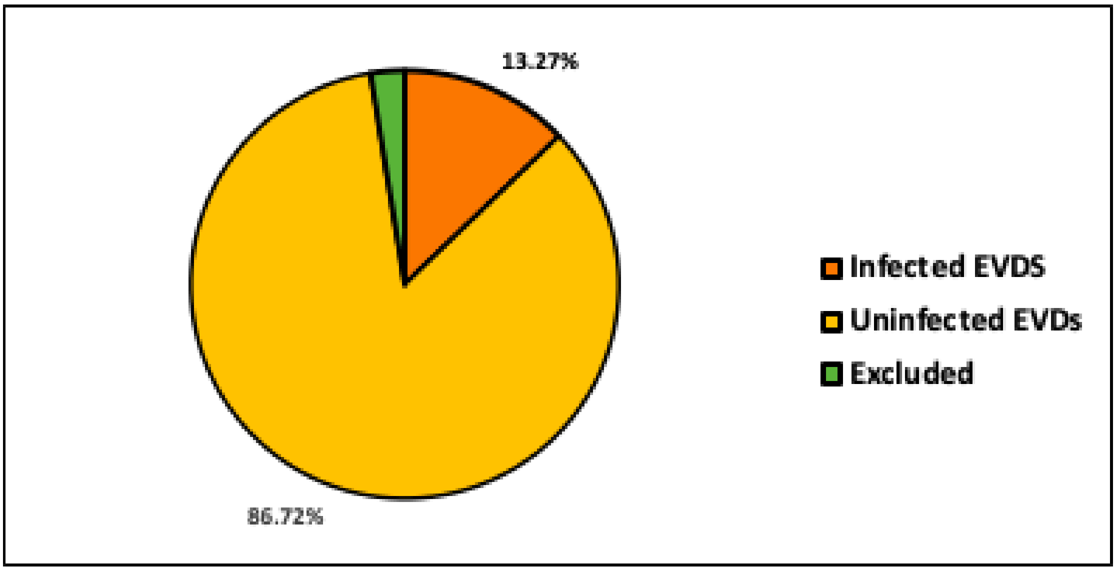

Figure 10: Percentage of infected and non-infected EVDs.

The data was categorised into patient demographic which included gender, age and risk factors such as; neurological procedures (n=9), intra-neurological procedure (n=6), post neurological procedure within 30 days (n=4), concurrent infections (n=10) which include vancomycin-resistant enterococcus (VRE), methicillin-sensitive Staphylococcus aureus (MSSA), ventilator-associated pneumonia (VAP) and Clostridium difficile (C.diff). Tables 2 and 3 provide a summary of these results. It is important to note that due to the time constraints of the QIP, analysation of all 98 non-infected cases was not feasible. Instead 15 patients were randomly selected to be compared against the infected cases. Although it is a small sample size decreasing its statistical significance, it is the same sample size as the infected cases thus allowing for easy comparison between the two groups.

Variable	Non-infected	Infected	Non-infected %	Infected %
Patient	n=98	n=15	86.27%	13.27%
Age Mean Media Range	μ= 46 47 10-71	μ =54 60 16-70	-	-
Gender Male Female	n=9 n=6	n=4 n=11	60% 40%	26.66% 73.33%
Pathology Trauma Tumour VP shunt malfunction Haemorrhage Other	n=0 n=3 n=0 n=6 n=5	n=1 n=3 n=1 n=7 n=3	0% 20% 0% 40% 33.33%	6.66% 20% 6.66% 46.66% 20%

Table 2: Patient Demographic

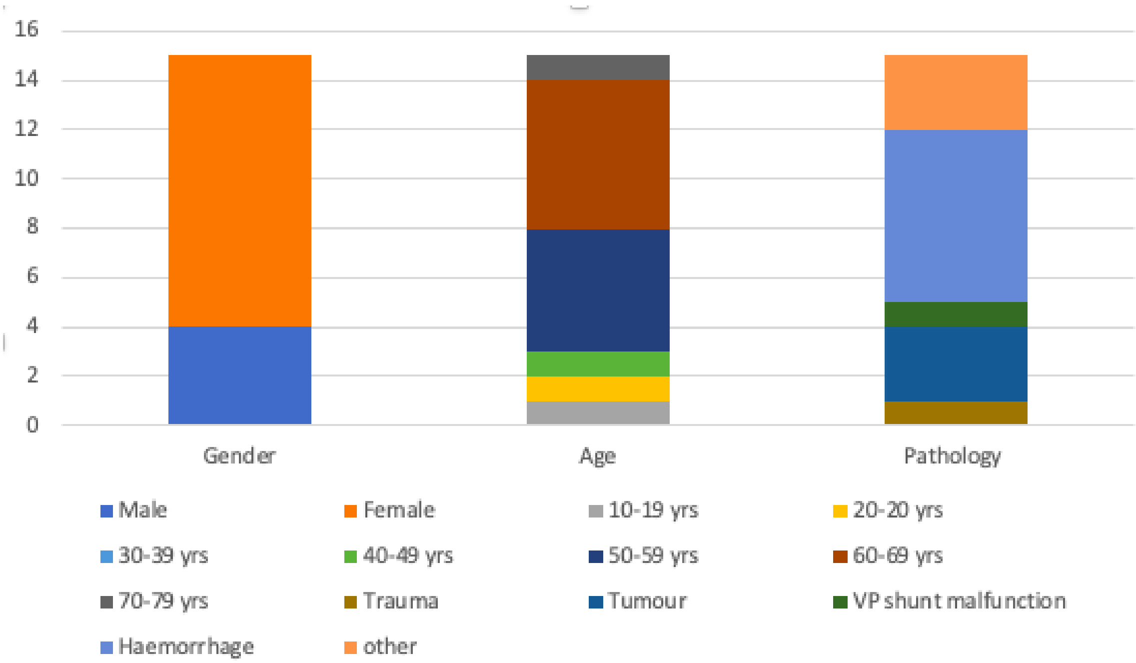

Figure: 11: Patient demographic of infected patients

Procedure characteristics	Number	Percentage
Pre-neurosurgical procedure	9	60%
Intra-neurosurgical procedure	6	40%
Post-neurosurgical procedure	4	26.66%
Concurrent infection		
VRE	4	26.66%
MSSA	2	13.33%
VAP	2	13.33%
C.diff	1	6.66%
Tracheostomy	6	40%
Frequent organisms		
Klebsiella oxytoca	4	26.66%
Pseudomona aeruginosa	2	13.33%
Staphylococcus aureus	2	13.33%
Staph haemolyticus	2	13.33%
E.coli	1	6.66%
Staph epidermis	1	6.66%
Staph capititis	1	6.66%
Enterococcus	1	6.66%
No culture	4	26.66%

Table 3: Infected cases Risk factors

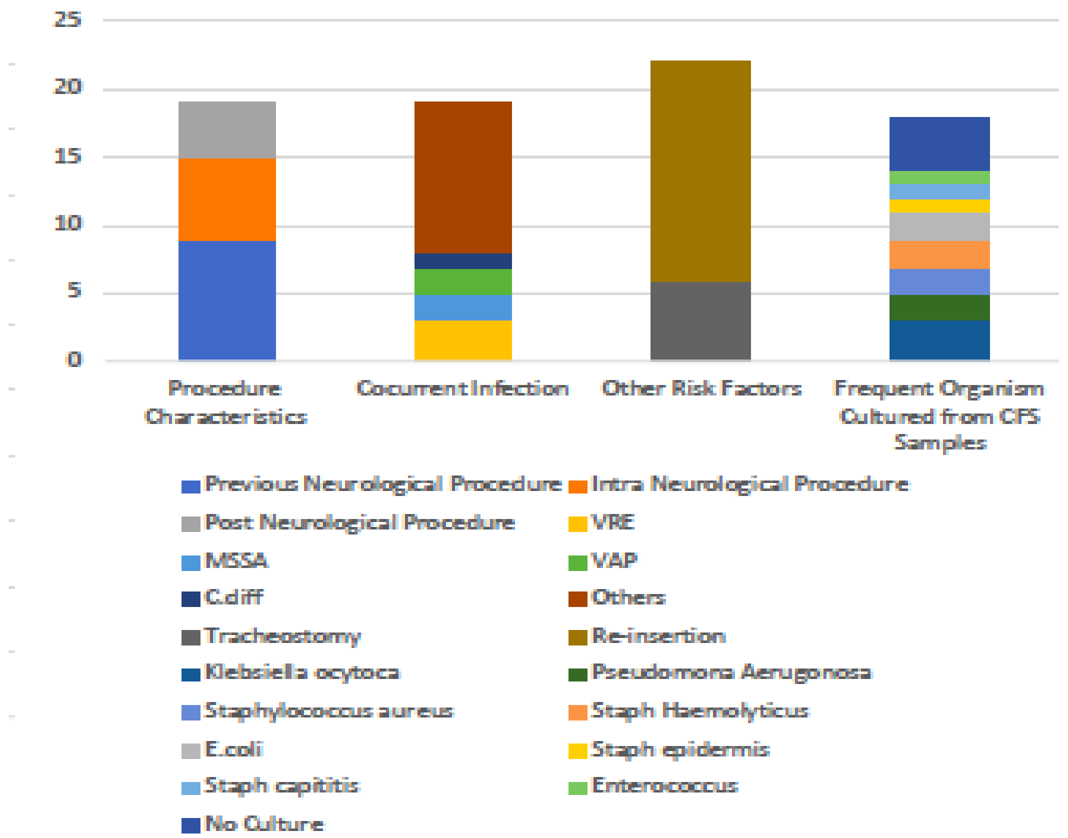

Figure 12: Infected cases associated risk factors.

As the literature review established, there are numerous of prevailing risk factors that contribute to an increased risk of EVD-related infections. An evaluation of these risk factors and their impact on non-infected and infected cases was carried out. Special emphasis was placed to investigate the relationship between infected patients and the modifiable risk factors; number of EVD insertions, duration of EVD placement and frequency of CSF sampling.

Modifiable risk factors	Non-infected	Infected	Non-infected %	Infected %
Duration of EVD catherization Median Range	μ= 11.2 2-36 days	μ= 19.58 5-91 days	-	-
CSF sampling	1-5 samples	1-22 samples	-	-
EVD re-insertion		n= 9	10.2%	60%

Table 4: Modifiable risk factors associated with EVD-related infections

Figures 13 and 14 show a positive correlation between infected patients and the number of EVD insertions. Evaluation of the data showed a 36.6%-100% rate of EVD-related infection in patients who received multiple catherisation, with each additional catheter increasing the risk of infection. This is compared to a 7.07% rate of infection in patients who only received one EVD (Figure 13). This implicates multiple catherisation as a risk factor for the development of EVD-related infections. Figure 14 further supports this, by demonstrating the percentage of non-infected devices according to the number of EVDs placed.

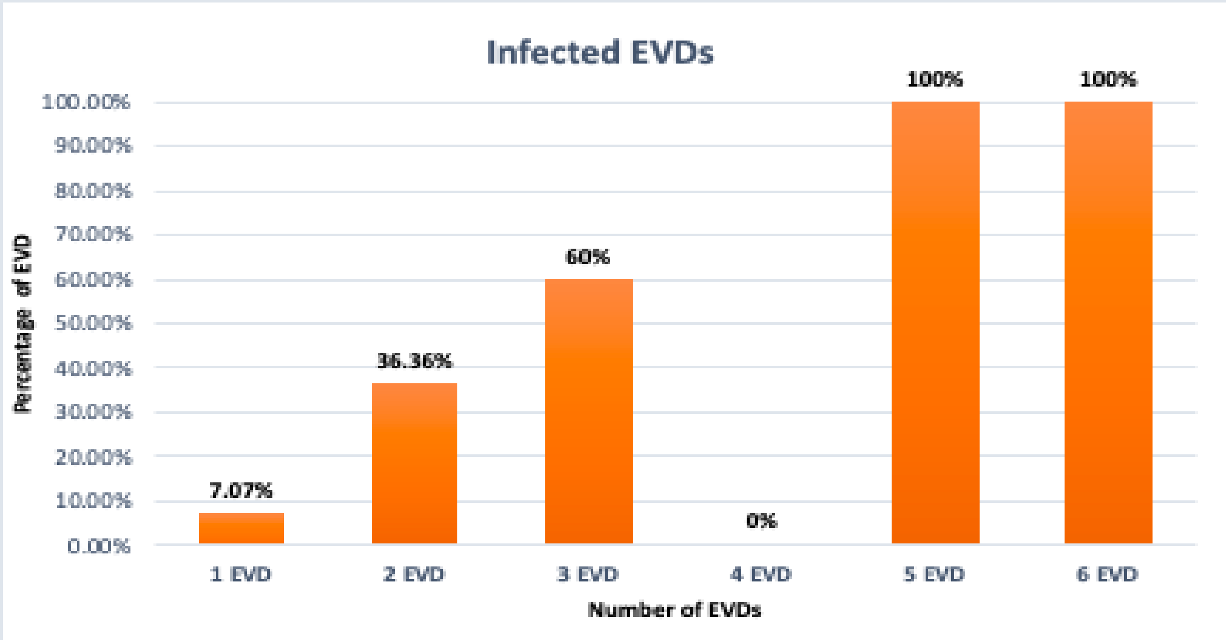

Figure 13 Percentage of Infected EVDs stratified by the numbers of EVDs placed.

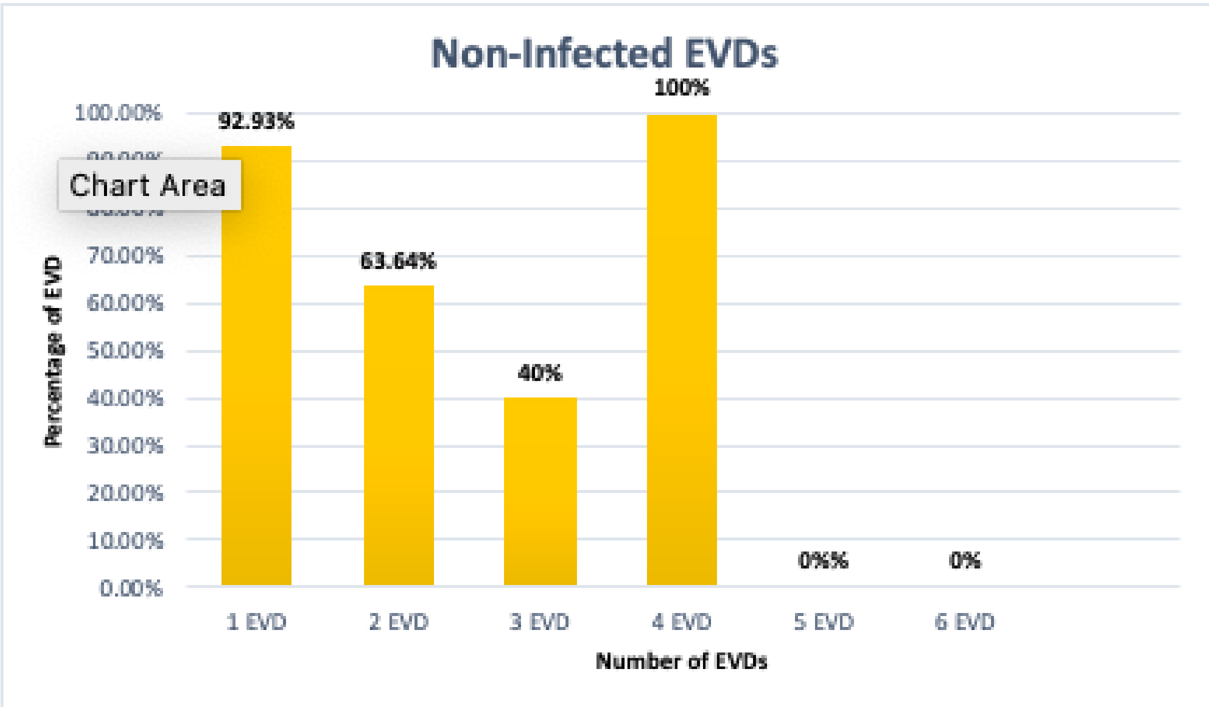

Figure 14 Percentage of Non-Infected EVDs stratified by the numbers of EVDs placed.

Long duration of catherisation has also been implicated in increasing the risk of EVD-related infections. The average length of catherisation in infected cases was 19.85 days compared to 11.2 days in non-infected cases as shown on Table 4. It was also noted that a higher percentage of infected cases (76.9%) had the EVD in situ for longer than 7 days compared to non-infected cases (53.3%).

Recent evidence-based guidelines suggests avoiding frequent CSF sampling as it has been linked to increase EVD-related infection rates. Patients who have confirmed EVD-related infections have been found to be sampled more frequently. Frequency of CSF sampling in the infected cases ranges from 1 sample to 22 samples compared to non-infected cases which ranges from 1 to 5 samples. Maintenance of a closed EVD circuit and minimal inappropriate CSF sampling is associated with a reduced risk of EVD related infections. Infections are thought to be introduced into the ventricle through an intracutaneous tract or by the introduction of exogenous organisms to the drain system by wrongful manipulation. This led to the investigation of a correlation between extracranial pathogens and intracranial pathogens. The first step was identifying the causative intracranial pathogens.

Out of 15 infected patients, 10 pathogens were identified as seen on Table 5, which demonstrates the frequency of all isolated intracranial organisms. Next was selecting patients with co-infections and identifying their extracranial pathogens. Once all pathogens were established, it made it much simpler to recognise any correlation between extracranial and intracranial infections. 40% of pathogens found in CSF infections was identical to those in other infections such as respiratory tract infections.

Organism cultured	Number	Percentage
Klebsiella oxytoca	4	26.66%
Pseudomona aeruginosa	2	13.33%
Staphylococcus aureus	2	13.33%
Staph haemolyticus	2	13.33%
E.coli	1	6.66%
Staph epidermis	1	6.66%
Staph capititis	1	6.66%
Enterococcus	1	6.66%
No culture	4	26.66%

Table 5: Organisms cultured from CSF sample

This observation is of great interest in the light of the current pandemic. COVID-19 is one of the major viruses that primarily targets the human respiratory system, but it also been seen to have neuroinvasive capabilities and can spread from the respiratory tract to the central nervous system. COVID-19 infections have been associated with neurological manifestations such as confusion, headaches, seizures, encephalopathy, cerebrovascular problems, anosmia and ageusia. This association has prompted the question are these symptoms a manifestation of general inflammation or is the virus entering the central nervous system? While these neurological manifestations of COVID-19 have yet be studied appropriately, it is highly likely that there is some CNS involvement with a growing body of evidence showing that neuroinvasion and neurotropism is a common feature of COVID-19 (Asadi-Pooya *et al*., 2020) The most recent publication in JAMA Neurology journal, has speculated several routes of neuroinvasion, including transsynaptic transfer across infected neurons, entry via the olfactory nerve, infection of vascular endothelium or leukocyte migration across the blood brain barrier. Recognition and understanding of the range of neurological disorders associated with COVID-19 may lead to improved clinical outcomes and better treatment algorithms. Neuropathogenesis studies will also l be crucial to understand the pathogenesis of the disease in the central nervous system and any long-term neurologic sequelae (Zubair *et al*., 2020).

3.4.4 Improve

The fourth phase of DMAIC framework is the Improve phase. The purpose of this phase is to identify and implement solutions to remedy the problems previously outlined. It began with a brainstorming session with the purpose to generate as many possible solutions for the identified problems. Careful consideration went into choosing feasible corrective measures that would reduce EVD-related infections, whilst keeping closely aligned to the objectives set out in chapter one. Major emphasis had been placed on lack of standardised guidelines for EVD care and was identified as one of the primary drivers contributing to infection rates. The potential for EVD-related infection in 2019 in our organisation was at 13.27%, yet no accepted standards for routine management for EVDs are available to provide consistency in the care and delivery of patients with EVDs, thus preventing and reducing infection. The proposed solution by the team was to amalgamate available protocols and guidelines to devise a holistic set of best-practice guidelines that offer a practical and useful approach to all healthcare providers in the insertion, management and care of EVD systems in order to reduce infection rates and bridge any gaps that might exist within EVD care. These guidelines will address the issues previously highlighted, while providing healthcare providers with a deeper understanding of the key element and functioning of EVDs, rendering the tools necessary to assist healthcare providers in providing homogeneous care.

3.4.4.2 Development of new best-practice guidelines

The team reviewed articles and internationals protocols and guidelines to use them as a template for the proposed solution. Two protocols from the U.K. National Health Service that are of particular significance to this QIP are the External Ventricular Device Guide, from the Royal Hospital for Sick Children and the EVD management in Adult patients from the Institute of Neurosciences Southern General Hospital. These are the two protocols the team have chosen as a benchmark. Following a review and careful amalgamation of the protocols and guidelines by the team, it was decided that the new proposed guidelines will include the following subheadings:

- Introduction: CSF circulation, function of CSF, causes of hydrocephalus
- Signs and symptoms
- Scope
- Roles and responsibilities
- Insertion of EVDs
- Drainage system and Equipment: Positioning, zeroing and securing
- Nursing and medical care: Observations, complications, red flags, transfer and Golden rules.
- CSF sampling from an EVD
- Measuring intracranial pressure from EVD
- Changing collecting bag
- Accidental disconnection
- Removal of EVD
- Competency checklist for EVD drainage.
- Infection diagnostic tools

The guidelines will also contain visual aids such as images demonstrating a proper insertion site and dressing, equipment set up and zeroing of EVD.

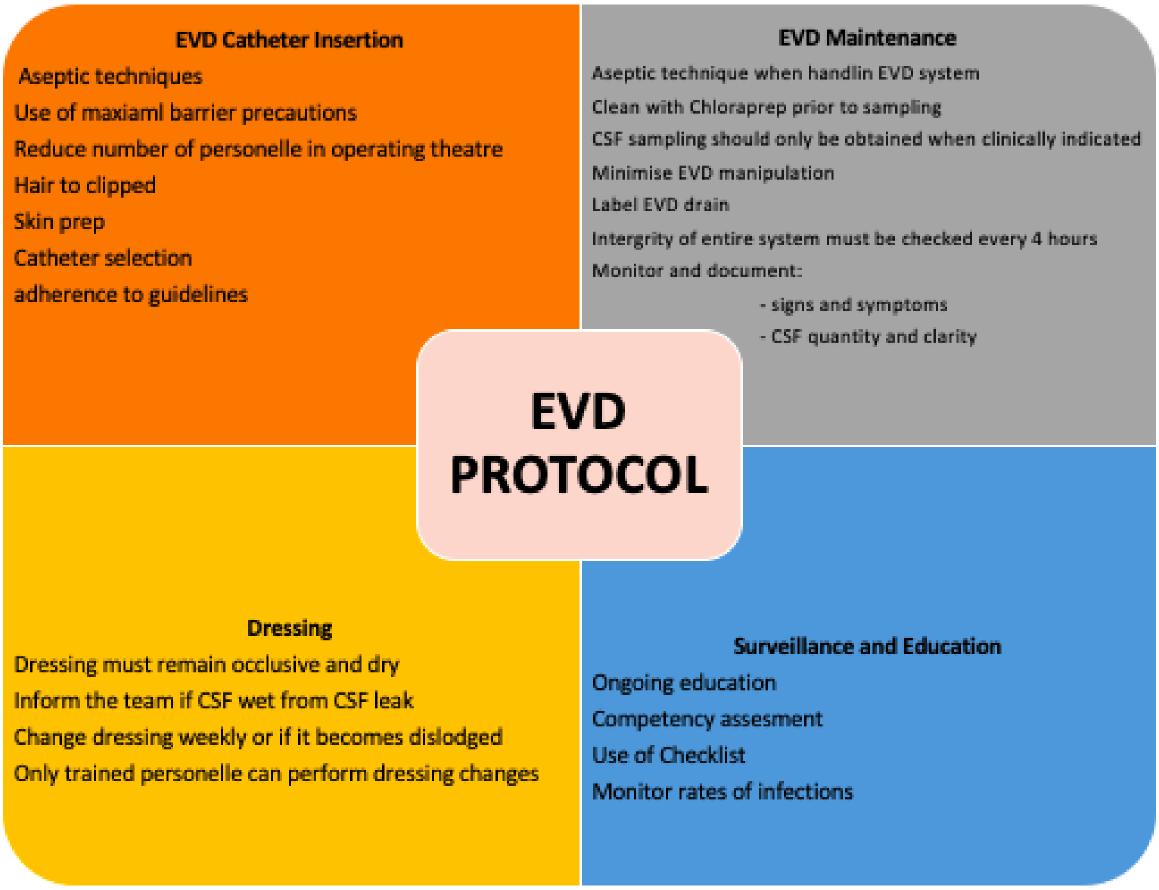

Figure 15: Outline of EVD management protocol

Recommendation for EVD management as a result of the review of articles, protocols and guidelines as well as own practice experiences and learnings are depicted in Figure 15. This diagram was developed by the student in the hopes for it to be displayed around the neurosurgical wards in order to educate staff and highlight key aspects of EVD management.

3.4.4.3 Inclusion of Clinical Algorithms

Early recognition and diagnosis of EVD-related infections is crucial for the management and treatment of patients with EVD-devices. Lack of standardised definition of infection or a diagnostic pathway is a major obstacle for early diagnosis. In practice, diagnosing EVD-related infection requires a thoughtful approach that considers the patients clinical signs and symptoms, and overall condition, the proximity in time to the device placement and trends in laboratory values (Martin *et al*., 2018). Inclusion of clinical algorithms for the evaluation of patients with clinically suspected EVD-associated CNS infection (Figure 16), CSF testing algorithm and diagnostic classification (Figure 17) and routine CSF laboratory test and parameters for the diagnosis of EVD-associated CNS infection (Table 6) was proposed to be included in the guidelines booklet as a diagnostic tool and also be included in patient's charts who received an EVD device.

As shown in Figure 16, any new headaches, persistent or recurrent fever, new or worsening leukocytosis, lethargy, nausea or deterioration in mental status should prompt the consideration of EVD-related infections. CSF should only be tested when infection is suspected clinically on the basis of new or worsening signs and symptoms. When infection is suspected a panel of CSF and blood tests are required to evaluate the patient's CSF for infection and to identify the causative organisms for treatment (Martin *et al*.,2018).

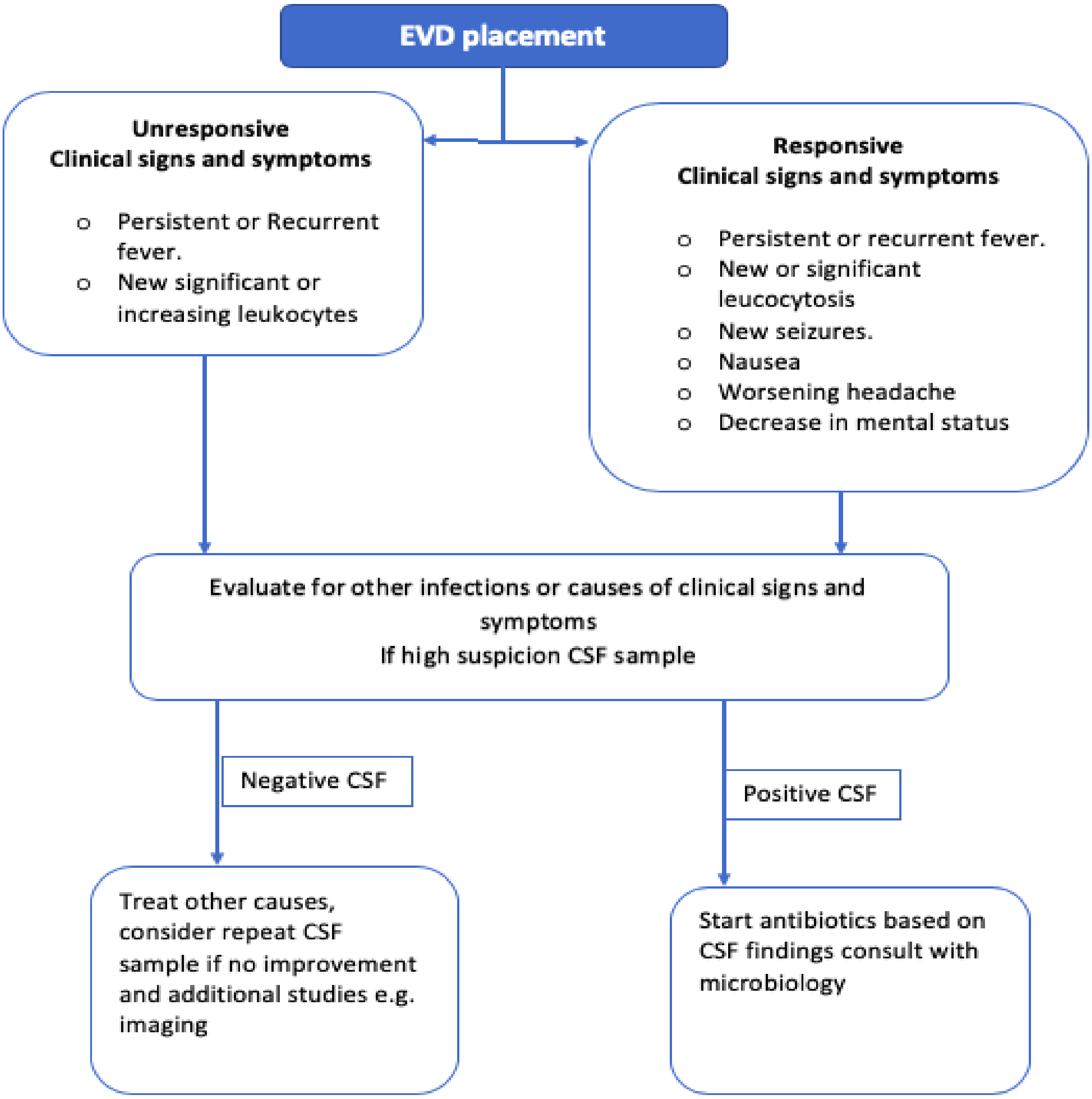

Figure 16: Clinical algorithms for the evaluation of patients with clinically suspected EVD-related infection adapted from Martin *et al*., (2018).

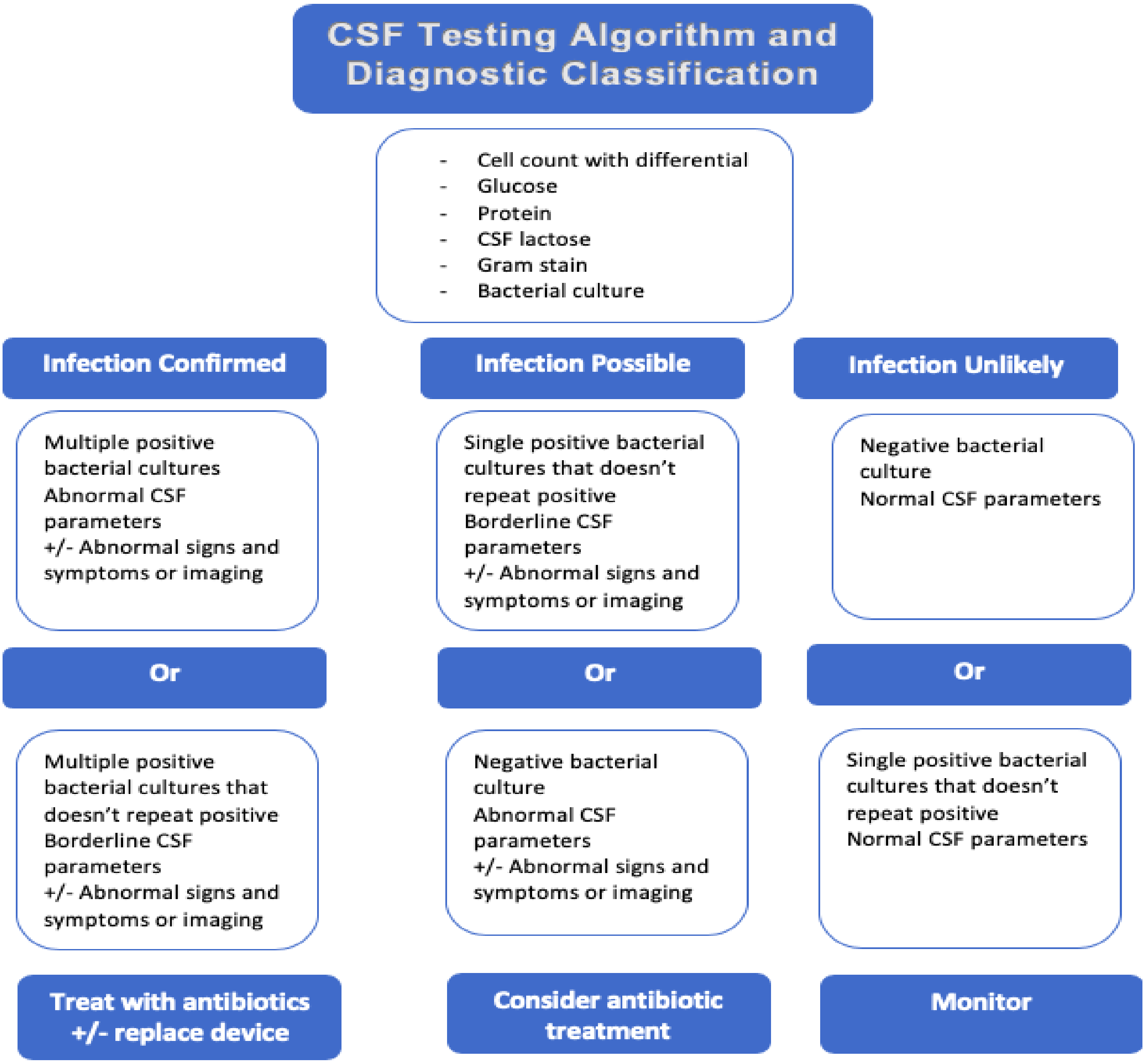

Figure 17: CSF testing algorithm and diagnostic classification (Martin *et al*., 2018)

It is important to note that a negative CSF gram stain does not rule out infections. A study revealed that CSF gram stain was only positive in 71% of cases (Kim *et al.,* 2012). Routine 48 hours microbiology study, sometimes won't suffice and a special request for longer incubation period of up to 10 days must be requested in order to identify the slow growing organisms such as *P.acnes* (Martin *et al.,* 2018).

Test	Results suggesting CNS infection
CSF Cell index	CSF WBC/RBC ratio >5
CSF glucose/serum glucose	CSF/ serum glucose ratio < 0.5
CSF Lactase	>3.5 mmol/litre
CSF Gram stain	Positive Gram stain
CSF bacterial culture	Positive bacterial culture

Table 6: Routine CSF laboratory test and parameters (Martin *et al*., 2018).

3.4.4.4 Education

The creation of written policies will not improve rates of infection if clinical practices are not amended to reflect those policies (Hepburn-Smith *et al*., 2016). Frequent education sessions about EVD maintenance and infection prevention along with competency skill checks have been shown to reduce infection rates while raising awareness and promoting understanding and compliance of the new guidelines.

A presentation to members of the neurosurgical ward on the new best-practice guidelines and education around the topic will be delivered prior to the implementation of the new guidelines to raise awareness and understanding of the new best-practice guidelines. Further education sessions will be required to educate rotating members of the teams on the new guidelines. Additionally, any healthcare professional managing patients with EVDs should complete competency skill check on:

- Infection control policies about handling, monitoring and cleaning medical devices,
- How to asses patients for infections
- Aseptic technique principles.
- Understand how EVDs function and the importance of alignment with tragus.
- The on and off position of the stopcock

- Identifying EVD related complications and how to manage them.
- Proper CSF sampling from EVD.

These checks should ideally be carried out by a competent and permanent team members. It was suggested for the PA to be designated to carrying out the competency skill checks, CSF sampling and train the rotating junior doctors on proper CSF sampling technique. Having one trained person offering their expertise should help minimise practise variation thus alleviating EVD-related infection.

3.5 Control Phase

The Control phase is the final component of the DMAIC framework, the purpose of this phase is ensuring the improved performance is maintained. The sustainability of these changes closely correlated longevity and prosperity of the QIP and will be discussed with greater detail in the following evaluation chapter.

3.6 Summary

This chapter began with a reviewing the QI models commonly used in healthcare. The chosen methodology, Lean-Six Sigma model was described in great detail along with the various QI tools that were utilised in order to guide this project forward. This was then followed by an outline of the methods used to collect and analyse the data. The chapter ends with the proposed improvements.

Chapter 4: Evaluation

4.1 Introduction

This chapter provides an overview to the proposed QIP while determining the ideal methods of evaluating this project. Section 4.2 reviews the expected outcomes and goals for the project following implementation of the guidelines. Section 4.3 discusses the proposed method of evaluating and monitoring the project with reference to the Control phase of the DMAIC framework. Section 4.4 concludes with an outline of the dissemination plan.

4.2 Overview of the QIP and Expected Outcomes

The primary aim of this QIP is to reduce EVD-related infection, an evaluation was carried out to identify areas of improvement in the current EVD care plan and the introduction of best-practice guidelines for the insertion, management and care of EVDs. The overall goal of the project is to develop a holistic set of guidelines that offer a practical and useful approach to all healthcare providers for the insertion, management and care of EVD systems in order to reduce infection rates and bridge any gaps that might exist and to provide homogeneous care to all patients with EVD devices.

It was quite evident from the literature that EVD-related infections are a major complication associated with the placement of the EVD device. To gain better understanding of this complex issue a literature review was conducted and themes were identified. Major emphasis within the literature had been placed on the need for complete diligence in all steps of EVD management from the operating theatre to the wards, yet no standardised evidence-based guidelines for the insertion, management and care of EVDs exist even though they are highly recommended throughout the literature and are associated with a reduction of EVD-related infection rates (Flint *et al*., 2013). The Establishment of EVD-related infection rate for 2019 in the organisation in question, validated the need for infection prevention measures to be taken. Out of 116 patients that received EVDs in 2019, 13.27% had an EVD-related infection. The infection rate in this study was higher compared to 9.3% seen in related studies previously conducted in the UK and Ireland (Jamjoom *et al*.,2018) or the study carried out by Lwin *et al*., (2012) which established the baseline infection rate in Singapore to be 6.1%.

In accordance with the literature review and the keeping in mind the overall goal of the project, a QIP plan was devised using the Lean-Six Sigma model and DMAIC framework. Application of various QI tools assisted in identifying the major contributing factors affecting the process. Two primary drivers were identified as seen in chapter three, however for the purpose of this QIP the focus was placed on a lack of evidence-based guidelines. Various recommendations were made concerning potential factors that affect this driver and led to the proposed solution of amalgamating available protocols and guidelines to devise a holistic set of best-practice guidelines that offer a practical and useful approach to all healthcare providers for the insertion, management and care of EVD systems in order to reduce infection rates and bridge any gaps that might exist within EVD care. Additionally there will also be competency skill checks carried out to ensure clinical practices to reflect the written policies.

It is postulated that in the short term, implementation of the best-practice EVD guidelines and the introduction of competency skill checks will result in staff having a better understanding about EVD maintenance and infection prevention, ensuring all healthcare providers are sufficiently equipped for the management of patients with EVD devices. In the long-term this improvement could reduce EVD-related infection rates lessening the prolonged hospital stay, increased cost and the negative effect it has on the overall health of the patient.

4.3 Evaluation

Feedback, monitoring and learning are essential for continuous quality improvement. Evaluation plays a vital role in this process as it demonstrates whether the intervention is a success or not. A well designed evaluation plan must address the wider questions, in order for it to help solve problems, make decisions and gain better knowledge of one's project, which will help to demonstrate its success, explain failure and convert sceptics.

4.3.1 Aim of Control Phase in DMAIC

The final phase of the DMAIC framework is the Control phase. The main aim of this phase is to ensure that the achieved improvement is effectively implemented and maintained. A monitoring plan must be put in place in order to sustain the achieved improvement. Vigilant and consistent monitoring is integral for the success of the project. It necessitates early discovery of impending causes or problems as well as early interference. This ensures the process continues to work well, produces the desired results and maintain high quality levels (Arafeh *et al*., 2018).

4.3.2 Monitoring and Review

In order to monitor the success of an improvement, re-evaluation and collection of new baseline data is required to ensure the QIP meets its intended aim, initially implied in chapter one. All data that was measured is to be repeated one year later to allow for comparison between pre-guidelines implementation data and post-guidelines implementation data. In doing so the team can confirm if the changes implemented have the desired outcome of reducing EVD-related infection rates or highlight the need for additional efforts to be made in order to achieve set goals. If the project does not have the desired outcome, the team must reflect on why this is the case and make appropriate modifications.

Due to the physiological process of EVD-related infections, the efficiency improvement measures implemented can be measured in terms of the reduction of the numbers of patients with EVD-related infections. New data can be collected and quantified to obtain the new baseline of EVD-related infection rate post EVD guidelines implementation. This new data can be compared and contrasted with previously collected data. The new data should once again be collected for the full 12 month period January to December, and carried out in a similar manner to that described in the measure phase of the methodology chapter to avoid any discrepancies. As before, patient data should be inserted in an Excel spreadsheet to allow for statistical analysis of the data.

An alternative method which could be utilised to test the expected outcome would be devising satisfaction surveys for all healthcare professionals managing EVD patients, the stakeholders and QI team members, in order to ascertain their level of satisfaction with the new guidelines. The survey would include a section that allows the personnel to address their concerns and opinions and overall effectiveness and efficiency of the improvement. Gathering people's views and experiences is very important in revealing the acceptability of the QIP. The feedback obtained could potentially identify further areas of improvement and refinement, thus enabling further PDSA cycles to be developed. Lastly the student suggests that the QI team continue to meet once monthly to monitor the compliance and acceptability of the new guidelines and to make sure any adjustments required are implemented.

4.3.3 Expected Results

It is expected that the integration of best evidence practice, through the implementation of EVD guidelines, promoting insertion, care and management of EVDs that is up to date, effective and consistent will reduce the potential risk of infection. It is important to note that overall infection rates are expected to decrease in light of the current Pandemic. Compliance with handwashing and infection prevention has been ingrained in everybody's day-to-day activities especially within the healthcare sector in the hopes to prevent the spread of COVID-19. This does not take away from the enduring benefits implementation of EVD guidelines would have on reducing infection rates, as well as having the added benefits of:

- Improving and optimising patient outcomes
- Providing evidence-based practice
- Standardisation of approach to avoid errors and duplications
- Reduce variation in clinical practice

Furthermore these guidelines will provide healthcare providers with a deeper understanding of the key element and functioning of EVDs, ensuring all healthcare providers are sufficiently equipped for the management of patients with EVD devices. It is through consistency, reduction in variation and sharing of best practice approach and expertise that better patient outcomes and satisfaction is achieved.

4.4 Dissemination of Plan

In order for this plan to be successfully implemented it must be appropriately disseminated. The student will commence by presenting the project findings and proposed improvement plan to the project sponsor. Key findings and results should be discussed and all queries should be addressed at this point. Next all relevant data, findings and recommendations should be presented via a Power - Point presentation to the stakeholders and staff members of the neurosurgical ward at one of their Morbidity and Mortality monthly meetings. A hard or digital copy of the plan should be made available to all interested parties and should be made accessible to any routinely changing members of the teams. A poster presentation would also be effective in displaying the findings of the QIP to a broader hospital audience; the wider the dissemination plan the greater amount of feedback which would aid the project going forward. Following implementation and the gathering of new data and the quantification of a new baseline, it would be beneficial to present the new findings and update attendees of the progress. It would also be extremely useful to present at conferences, in order to gain advice from other healthcare professionals and share our findings and experiences, as the quest for a comprehensive, gold standard for EVD care continues.

4.5 Summary

This chapter outlined how further evaluation of the QIP will be carried out once EVD guidelines have been adopted. It provided an overview of the QIP and how it is expected to reduce EVD-related infections. The chapter continues to discuss how the success of the QIP will be measured and how its success will be sustained. Finally, methods to disseminate this QIP to all relevant parties was highlighted.

Chapter 5: Discussion and Conclusion

5.1 Introduction

This final chapter discusses the likely impact the QIP will have on the stakeholders and practice. Section 5.3 and 5.4 critiques the perceived strengths and limitations that may have emerged. Section 5.5 outlines the recommendations for the project while section 5.6 explores the learning and experiences the student gained on quality improvement.

5.2 Project Impact

5.2.1 Stakeholders

It is expected that QIP will have a positive impact on stakeholders as well as any member of the neurosurgical teams. Revision of the current EVD care practice was well overdue and required various modifications in order for it to be consistent with the latest evidence. The development of the new best-practice guidelines renders the tools for any healthcare provider to treat and manage patients with EVD devices in an appropriate consistent manner, consequently contributing to improved quality of care and reduction in infection rates. Furthermore, the data from this study could also provide further evidence-based support for the development of an integrated new gold standard for EVD insertion and care for the prevention of EVD-related infections.

One particular stakeholder on whom a reduction will have a significant impact is the patient. EVD-related infections dramatically impact the patients hospital course and can cause death. Common EVD-related infection complications seen amongst patients are: ventriculitis, subdural empyema, intracranial abscesses, haemorrhages, abdominal abscesses , skin infections, endocarditis, sepsis and osteomyelitis. Patient's with EVD-related infections require intensive therapeutic interventions and lengthy intensive care unit stays, thus increasing the cost, length of hospital stay and exposure to systemic antibiotics (Champey *et al*., 2019). Besides having immense impacts on the patients well-being, EVD-related infections have also been shown to have major societal and familial effects beyond the patient's prognosis. On account of these devastating consequences, EVD infection prevention should always be a priority for healthcare professionals and why they should strive for a 0% EVD-related infection rate.

5.2.1 Practice

This project shows the use of QI methodologies will help healthcare professionals to increase efficiency, reduce cost and improve quality of service. It is hoped that with the implementation of the new best-practice guidelines, competency, skill checks and continuous monitoring that each patient will receive efficient, effective and consistent care. Subsequently, a reduction in infection will result in increased patient satisfaction as well as potentially have a positive impact on the hospital expenses. It is estimated that the material cost of EVD replacement is in the range of approximately $1,3000-3,200 per replacement (Aten *et al*.,2017) which is illustrated in appendix 4. Additionally, patients who acquire EVD-related infections increase expenditure as previously stated. Reducing EVD infections will eradicate long hospital stays and improve patient well-being.

5.3 Strengths of the project

A key strength of this project was establishing the aims and objectives early on thus enabling the student devise the project plan and setting the QIP in motion from the get go. As a result, the collection of data was carried out within the initial stages of the QIP which was a huge advantage for the student as she had collected the majority of her data before March 13th, when students were pulled off placement due to the COVID-19 pandemic. The application of DMAIC framework and the various QI tools really helped with the development of the project in a structural and functional manner. The stakeholder analysis was a particularly vital tool for the development of the QIP. Determining those who were best equipped to advise and guide this project was a fundamental step for the advancement of the project. The support and investment of the project sponsor was tremendous during these unprecedented times, his guidance and advice helped the student overcome any barriers or unforeseen problems that arose throughout the project. Without his insight and expertise completion of the QIP may not have been achieved.

With respect to the strength of the data, given the time constraints of the QIP and COVID-19 pandemic, the sample size and data collection was substantial and demonstrated a variety of problems, highlighting the need for the current EVD care plan to be revised and thus supporting a need for this QIP. Furthermore, the project was carried out with a non-biased approach. The student, who is not a member of the neurosurgical team carried out the data collection, meaning the project could not be influenced by an existing bias.

5.4 Limitations of the project

There were a few obstacles encountered while performing this QIP which are important areas to reflect upon for future studies. First, and the most significant was the time constraint on the project. The available time in which to complete the project on top of the limited time the student had out on clinical placement has a huge impact on the project especially on data collection. Ideally all non-infected patients would have been evaluated instead of randomly selecting 15 patients for the project to have more statistical significance. Additional information like patients' risk factors, length of hospitalisation, use of antibiotics and morbidity and mortality of infected patients would have also been collected and examined to form a more holistic understanding of EVD-related infections.

Secondly, engagement between stakeholders was limited. Continuous communication with all the stakeholders should have been maintained throughout the course of project. However due to the student not being on clinical placement, this proved to be rather difficult and communication had to be condensed to the most prominent stakeholders. Early identification of who were likely to benefit from this improvement from the stakeholder analysis, helped the student maintain communication with the prominent stakeholders about the progression of the project while remotely working from home.

Thirdly, our choice of EVD-related infection definition could be open to criticism, as previously discussed there are several definitions available and although the chosen definition is the most comprehensive and most widely used, it could be argued that the use of this definition has led to over or underestimation of EVD-related infections.

A major limitation especially for the data collection phase of the QIP, was the vast variation that the student came across in the documented information on the discharge letters and theatre notes on PIPE. Clinical notes were not standardised, valuable information such as date of removal of EVDs was not easy to access. Lastly, with any study of this nature human error is a limitation that must also be acknowledged.

5.5 Recommendations

There are number of recommendations that would help for the future. Firstly and foremost it is recommended that those caring for patients with EVD devices familiarise themselves with the new best-practice guidelines and infection control policies. A hard copy should be kept in the neurosurgery ward for easy access and used as a guide. It is worthy nothing that recommendations don't always account for individual variation among patients and should not supplement physician judgement. It would also be beneficial for all neurosurgical staff to get re-trained on appropriate aseptic EVD manipulation techniques and CSF sampling. As mentioned during the improve phase, CSF sampling would be designated to the PA to minimise variability in CSF sampling technique and alleviate EVD-related infection rates. The student advises that this task be delegated to various competent staff members to compensate for the times the PA isn't available, such as weekends.

A correlation between extra-cranial organisms and EVD-related infections were noted during the analysis phase. To address this issue the student suggests bathing the patients with antibacterial agents to eradicate any skin flora organism as well as clearly marking the head pillows so that they're maintained as sterile as possible and do not get confused with other supportive pillows when making the beds.

Additional information like patients risk factors, length of hospitalisation, use of antibiotics and morbidity and mortality of patients is recommended to be collected and examined to form a more holistic understanding of EVD-related infections. Finally it is recommended that the process is continuously audited and frequently amended as outlined in chapter four.

5.6 Learning about Quality Improvement

This dissertation was the students first experience in the field of QI which meant there was a steep learning curve. Further reading and independent learning was needed to gain better understanding around the topic of QI. Having no previous experience with QIPs meant that the topic was quite daunting. However, it soon became apparent that that the skills required to execute a research project are similar to those required to execute a QIP. Undertaking this QIP helped the student develop her communication, organisational, research and analytical skills simultaneously. The completion of a comprehensive literature review helped the student have an extensive understanding about EVDs devices and their workings, whilst the methodology chapter really helped gain an appreciation and understanding for the various QI models and tools available. It wasn't till the student was fully emerged in the project and had to orchestrate and manage the QIP that all this learning came together. The project was a perfect example in demonstrating how it is possible to adapt the tools and methods of business such as the Lean-Six Sigma approach to the healthcare sector to increase efficiency, reduce waste, cost and improve the quality of service. The application of QI will improve the student's knowledge and skills which she can put into practice as a PA to make a real difference to the quality of clinical practice, team work and most importantly patient care.

Although the QIP proved to extremely challenging at times, there was so much to gain from its completion. The importance of teamwork was highlighted early on demonstrating how much more effectively and efficiently a goal can be achieved when a group of people are working together to achieve a set goal. Self-motivation and organisation proved to be a necessity for the competition of this project, breaking down the project into lesser milestones and approaching it one step at a time helped allowed the student to stay organised and on track. Which was particularly challenging at times, as the majority of the project had to be carried out remotely from home.

5.7 Summary and Conclusion

The placement of EVDs is one of the most common neurosurgical procedures worldwide. It allows for continuous measurement and monitoring of ICP, investigation of CSF dynamics, controlled CSF treatment and prevention of CSF leaks in post neurosurgical operations. Despite its widespread use, no commonly accepted EVD guidelines have been developed for the for insertion and management of these devices to prevent any of the issues that are associated with its usage. Undoubtedly one of the most important aspects of EVD placement is the risk of infection occurring in 13.27% of patients. The aim of this QIP was to identify areas within the current EVD care plan of improvement with the hopes of reducing infection rates. The application of the DMAIC framework allowed the student to identify the various areas within the process that could potentially be improved and subsequently, the proposed solution. This included development of new best-practice guidelines, inclusion of clinical algorithms for the evaluation and management of patients EVD devices, educating and raising awareness to promote compliance of the new guidelines. Implementation of evidence-based guidelines are highly recommended throughout the literature for the reduction of EVD-related infection. It is to be hoped that this study will go some way to prevent infection rates and improve patients' experiences.

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Appendices

Appendix 1: Reduction of Ventriculostomy-Related Infection After Implementation of a Protocol (Hepburn-Smith et al., 2016)

Study, Year; Country	Interventions	Infection Rate Preintervention	Infection Rate Postintervention
Camacho et al., 2013; Brazil	The protocol defined appropriate EVD care (hand hygiene before/after handling the EVD, use of clippers for whole scalp hair removal before insertion) and implemented educational interventions for neurosurgery residents, neurosurgeons, and nursing staff in the intensive care unit (training sessions, handouts, posters).	9.5%	4.8%
Chatzi et al., 2014; Greece	This institution created a bundle of EVD-associated ventriculitis reduction measures, which included reeducation of personnel on issues of infection control related to EVDs, meticulous EVD handling, CSF sampling only when clinically necessary, and routine replacement of the drainage catheter on the seventh drainage day if the catheter was still necessary.	28%	10.5%
Dasic, Hanna, Bojanic, & Kerr, 2006; United Kingdom	This institution introduced an evidence-based protocol for EVD insertion and management, which included insertion taking place in operating room only, the use of prophylactic antibiotics, tunneling of the catheter at least 10 cm, avoidance of daily sampling unless clinically indicated, and avoidance of routine catheter changes at 5 days, unless clinically indicated.	27%	12%
Flint et al., 2013; United States	These authors generated formal EVD infection control policies and procedures that established strict standards for placement and manipulation of EVDs (use of an antibiotic-impregnated catheter, broad clipping of hair, chlorhexidine skin preparation before draping, tunneled catheter that is secured in a question-mark pattern using surgical staples, chlorhexidine-eluting patch applied over catheter exit site) and education on the protocol through face-to-face meetings and web-based multimedia.	9.8%	0.8%
Hill et al., 2012; United States	As part of a multidisciplinary review, guidelines were generated regarding the insertion and maintenance of EVDs (sterile EVD dressing change as needed by RNs, dressing caddies with laminated cards outlining the dressing change process, check-off list, accurate documentation of procedures, and weekly infection control rounds by the educator and infection prevention practitioner to ensure that EVD dressings are sterile and occlusive).	16 per 1000 catheter days[a]	0 in 25 months
Honda et al., 2010; France	This hospital introduced three interventions: (a) a requirement for all personnel in the procedure room to wear a mask and a cap, (b) a standardized dressing protocol (use of sterile gauze dressing with adhesive tape to cover the catheter site, changing of the intraventricular catheter site dressing every 48 hours by nurses who received standard training, and documentation of the date and time of gauze-dressing change), and (c) use of an antibiotic-impregnated EVD.	3.56 per 1000 catheter days[a]	0.87 per 1000 catheter days

(continues)

TABLE 2. Reduction of Ventriculostomy-Related Infections After Implementation of a Protocol, Continued

Study, Year; Country	Interventions	Infection Rate Preintervention	Infection Rate Postintervention
Korinek et al., 2005; United States	These authors created a written protocol for EVD insertion (hair clipping, tunneled catheter), nursing (sterile dressing covering the entire head, routine CSF cultures not performed), and surveillance (file documenting dates of dressing changes, forbidden manipulations, CSF samplings, EVD bag emptying, daily maximal temperature, cause of EVD removal, result of catheter culture, and presence of a CSF leak).	9.9%	4.6%
Kubilay et al., 2013; United States	This institution developed an insertion bundle that included training of staff, strict hygienic measures, full surgical draping, use of prophylactic antibiotics, feedback of infection rates to the care team, and use of an antimicrobial-impregnated catheter.	9.2%	0.46%
Leverstein-van Hall et al., 2010; Netherlands	These authors introduced an intervention strategy based on five pillars: increased awareness (surveillance and educational programs), focused standard operating procedures (insertion and handling of the EVDs), a diagnostic and therapeutic algorithm for patients with clinical suspicion of drain-related meningitis, timely administration of prophylaxis, and improvement of the drainage system (compared with the previous system, the number of sampling sites was reduced from five to four, and a Luer Lock injection site was provided with the system).	37%	9%
Lwin, Low, Choy, Yeo, & Chou, 2012; Singapore	The following measures to reduce EVD infection rate were introduced: proper surgical techniques, minimization of the number of catheterization days, CSF sampling only in the setting of clinical suspicion of an infection, development of standard operating procedures on nursing management of EVDs, conduction of EVD care workshops and competency skill checks for nurses, and use of silver-coated EVDs.	6.1%	0%

Note. EVD = external ventricular drain; CSF = cerebrospinal fluid.
[a]Percentages of patients with infection were not documented; rates of infection were recorded per 1000 catheter days.

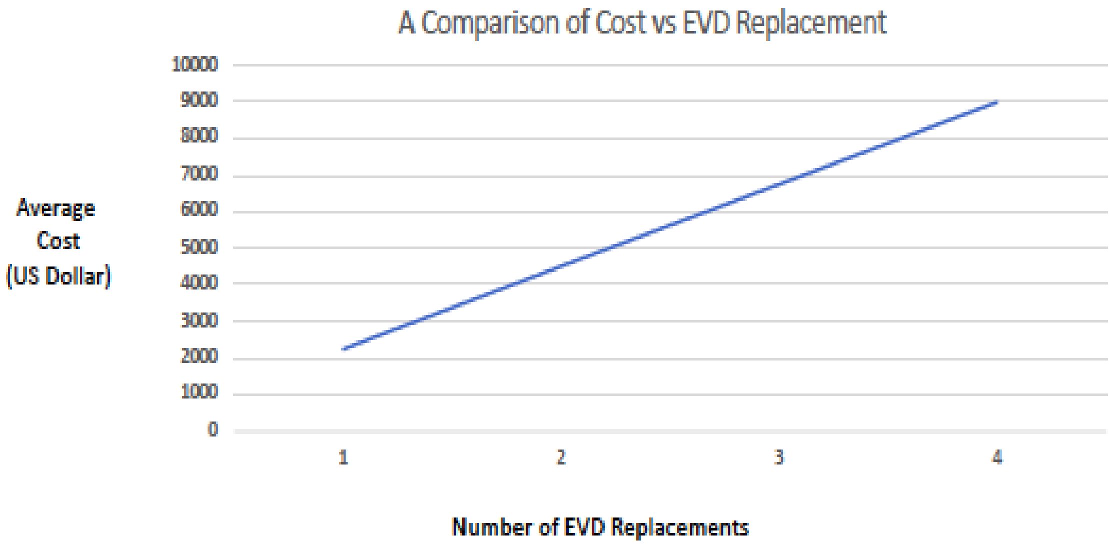
Appendix 2: Project Charter

Problem Statement	2019 EVD related infection rate is high compared to international studies. Revision of current EVD care is overdue and requires various modifications in order for it to be consistent with the latest evidence
Aim	To reduce EVD-related infection rates by the introduction of new best practice guidelines.
Objectives	Collect data to highlight the problem and support the solution Analyse the problem using QI tools Propose solutions to identified problems by: - Devise new best-practice guidelines - Implementing competency skill checks - Educate staff Devise dissemination plan Evaluate project's success
Possible benefits	Decrease EVD related infection rate Improving and optimising patient outcomes Providing evidence-based practice Standardisation of approach to avoid errors and duplications Reduce variation in clinical practice Develop specialised staff with relevant skills and experiences,
Possible Barriers	Resistance to change from staff Compliance to new guidelines Variation in practice
Scope	Establishing EVD-related infection rates and assessing current EVD care to identify areas of improvement to introduce new best-practice guidelines.
Time lines	January 2020- August 2020

Appendix 3: : Microsoft Excel Sheet of Infected Patients.

A	B	C	D	E	F	G	H	I	J	K	L	M
Date of Birtl	**Age**	**Indication for insertion**		**Duration of EVD**		**pre**	**intra**	**post**	**no. CSF sam**	**Re-insertion**	**status**	**infection**
21/02/1964	54 yr old	Hydrocephalus secondary		**9 days (31/01/2019)**		X	X	X	**(4)** 1. 22/01	(1) reinsertic	Recovered	CITOBACTER KO
24/06/2002	16 year old	VP shunt malfunction insit		**6 days 17/02/2019**		X	X		**(4)** 1) 10/02	NO	RIP	Gram possitive
25/08/1958	60 year old	pneumocephalus causing		**23 days left Evd remove c**		X			**(9)** 1) 21/01	(1) new EVD	Recovered	GRam possitive
18/11/1972	46 yr old	fungal meningitis, enceph		**91 days Multiple EVDS (08/06/2019)**				X	**(22)** 1) 09/0:	(3)11/03/20:	RIP	Fungal meningit
10/11/1997	21 yr old	Shunted Hydrocephalus		**5 days (25/03/2019)**		X	X			(1) right post	Recovered	meningicoccal r
14/04/1968	51 year old	hydrocephalus 2ndary to S		**17 days (28/05/2019)**			X		**(3)** 1) 15/05	NO	Recovered	ventriculitis/ me
17/05/1951	68 year old	Hydrocephalus 2ndary to S		**7 days (11/07/2019)- 29/(**		X	X		**(3)** 1) 04/07	(1) stereotat	RIP	bacterial mening
09/05/1960	59 year old	Hydrocephalus 2ndary to S		**31 total = 16 days (14/07/2019)+ 15 days reinsertion till (29/07)**					**(4)** 1)14/07	(1) left front	Recovered- I	klebsiella oxytoc
											Recovered	
13/10/1956	62 year old	SAH		**12 days**					**(1)** (13/09/2	NO	RECOVERED	
23/04/1958	60 year old	Trauma		**16 days (12)(4)**		X			**(2)** 1) 11/10/	(1) yes 15/1(	Recovered	PSEUDOMONAS
09/04/1949	70 year old	Tumour		**8 days**		X			**(6)** 1)10/10/	(1) yes 10/1(	Recovered	KLEBSIELLA OCY
27/02/1963	56 year old	tumour		**16 days ?**		X	X	X		(1) yes 15/0!	Recovered- Home	
30/06/1966	53 year old	SAH		**17 days**				X	**(2)** 1st 14/1C	NO	Recovered	
10/01/1950	68 year old	SAH								NO	Recovered - HOME	
05/09/1952	68 year old	Haemorrhage				X				NO	RIP	
	812/15 = 54.13			**258 / 13 = 19.85 DAYS**		9	6	4	**60 samples/**	**9 /15 = 60%**	**RIP = 4**	**10 organisms**
											RECOVERED= 11	

Appendix 4: A comparison of cost vs EVD replacement



Appendix 5: Gantt chart