Understanding sepsis recognition and management in a Ghanaian emergency department: a convergent mixed methods study

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Abstract

Background: Sepsis is a severe response to an overwhelming infection, resulting in inflammation, coagulation, multi-organ failure and potentially death when not recognised and treated promptly. Sepsis is recognised as a significant cause of hospital admission and preventable deaths globally, hence it is considered a medical emergency. Many high-income countries have prioritised sepsis; however, it has received less attention in adult populations in low-income healthcare contexts, including Ghana, except in children and pregnant women. This study, therefore, explored existing practices associated with the recognition and management of sepsis in a Ghanaian secondary level hospital emergency department (ED) in order to develop a context-sensitive evidence-based sepsis bundle and pathway for future implementation and testing.

Methods: A convergent multiphase mixed methods design was employed. This included a: (1) systematic literature review; (2) a retrospective case record review (n=75); and (3) process mapping of ED sepsis practices, including interviews with healthcare professionals (n=14). Quantitative data were analysed using SPSS version 28.0.0 and interviews and field notes after transcription were analysed using thematic analysis supported by NVIVO© version 14. Data were integrated and findings were (4) presented at a series of co-production workshops with stakeholders to develop a sepsis intervention and plan for future implementation.

Findings: Twenty-two papers met the inclusion criteria for the literature review. Most of the papers used the Surviving Sepsis Campaign (SSC) bundle (21/22): one adopted the integrated management of adolescent and adult illness (IMAI) tool. Prior to introducing the bundle, various engagement strategies were employed with local teams and bespoke training was developed for staff. Reduction in mortality was associated with timely interventions, however, one reported increased mortality as a consequence of oversimplification of the implemented bundle.

The retrospective case record review identified delays and inaccurate sepsis recognition at presentation, time to medical assessment, omission or delayed vital sign/deteriorating patient re-assessment, access to lactate estimation and speed of reporting of routine blood tests and blood cultures. Elements of the SSC bundle

were embedded in practice but others were unavailable due to resource and financial constraints. Similar findings were uncovered in the process mapping interviews and workshops, including, not thinking of sepsis as a probable diagnosis until later whereas it was found that other conditions, such as malaria, contribute to targeted management delays and poorer outcomes. Integration using the capability, opportunity, motivation - behaviour (COM-B) model was used to illuminate findings which were discussed in the co- production workshops to improve the recognition of sepsis and implementation of appropriate interventions. In this case, a sepsis algorithm and educational package were designed.

Discussion: The literature review suggested the SSC bundle could be successfully implemented in LMICs if contextual needs were accommodated and engagement with local multidisciplinary teams occurred. With this background, the retrospective review of case notes and process mapping aided in identifying the current practices regarding sepsis recognition and care. With this, possible pathway components and processes were identified through the lens of COM-B and Kotter's eight step change models and debated through integration and co-production workshops. These were contextualised, and a sepsis algorithm with a standard operating procedure was adapted to enhance sepsis identification and management (nurse led approach to identification), including regular monitoring of vital signs/deterioration, reorganisation of sample collection and reporting services and a policy approach for antimicrobial stewardship. These were developed to support implementation together with an education programme.

Conclusion: This study demonstrates that engagement with key stakeholders in the target site is complex and necessary to develop a culturally specific evidence-based sepsis pathway. Early phases identified potential barriers and facilitators to successful implementation, and these have been considered, and where appropriate, integrated into the proposed implementation model. Recommendations for the designed intervention and implementation plan are outlined for future testing in the target clinical setting.

Dedication

To Mr. Obed Asante who has been immensely supportive throughout this PhD study.

And

To my beloved late mum, Elizabeth Bentil, dad, Kwame Prah, and sister Dorothy Binney, who always prayed for me but did not live to see this dream fulfilled.

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List of abbreviations

AACP…… American Association of Chest Physicians

ATS……Australian Triage System

AT……First Supervisor

AP……. Main researcher

BCTs……. Behaviour Change Techniques

CASP……Critical Appraisal Skills Program

CDC……. Center for Disease Control

CEI……Community Engagement and Involvement

CHAG……Christian Health Association of Ghana

COM-B……. Capability, Opportunity, Motivation - Behaviour

CTAS……. Canadian Triage Scoring System

ED……. Emergency Department

HER……Electronic Health Record

ESICM……European Society of Intensive Care Medicine

EWS……Early Warning Scores

GCP……. Good clinical practice

GHS……. Ghana Health Service

HCP……. Healthcare Professionals

HFH……Holy Family Hospital

HICS……. High Income Countries

ICU……Intensive care unit

JSST……. Just Say Sepsis Tool

LMICs……Low- and Middle-Income Countries

LLD……Second Supervisor

MDT……. Multidisciplinary Team

MOH……. Ministry of Health

MRC……. Medical Research Council

MTS……. Manchester Triage System

NCQAT……Newcastle Ottawa Quality Assessment Tool

NEWS……. National Early Warning Scores

OPD……. Outpatient Department

PHC……. Population Health Census

PMW……Process Mapping Workshop

PPI……Patient Public Involvement

PRISMA……Preferred reporting of systematic reviews and meta-analysis

QSOFA…. ……. Quick Sequential Organ Failure Assessment

RCT……. Randomised Controlled Trials

SATS……South African Triage Scale

SCCM……. Society of Critical Care Medicine

SIRS……Systemic Inflammatory Responses

SOFA……. Sequential Organ Failure Assessment

SSC……. Surviving Sepsis Campaign

SSVs……. ……. Surviving sepsis Volunteers

WHA……World Health Assembly

WHO……World Health Organisation

CHAPTER ONE

THE NEED TO EXPLORE SEPSIS CARE IN A GHANAIAN EMERGENCY DEPARTMENT

1.1 Introduction

This study was conducted in response to the identification of increase in Emergency Department (ED) deaths due to sepsis among patients presenting to Holy Family Hospital, Techiman in Ghana. Despite sepsis being one of the top ten causes of mortality according to local ED data, it had never been identified as one of the top ten diagnoses on admission (HFH Annual Report, 2020). As an emergency nurse with over ten years professional experience, I developed an interest in sepsis detection and possible strategies that could be used to improve healthcare in the ED where I work.

This introductory chapter describes the challenge sepsis presents, encompassing its definitions, historical context, worldwide burden, specific focus on low- and middle-income countries (LMICs) including Ghana, and the rationale behind this study. The aims and structure of this thesis have also been presented.

1.2.0 Background

1.2.1 Definitions and history of sepsis

Infection occurs when microorganisms such as viruses, bacteria or other germs infiltrate the human body and initiate a process of replication (Krismer, 2012). This replication activates the coagulation system (Antoniak and Mackman, 2014; Antoniak et al., 2016), which serves as a host defence mechanism to stop the infection from spreading. Blood coagulation, immune cells (leucocyte recruitment), and platelets interact to limit the spread of pathogens throughout the body (Gaertner and Massberg, 2016). More significantly, neutrophil extracellular traps (NETs) consisting

of nuclear Deoxyribonucleic acid (DNA), histones, and a number of neutrophil enzymes, including elastase are released (Gotts and Matthay, 2016). These NETs exhibit significant antibacterial and possible antiviral properties, as well as a coagulation- enhancing effect because of their negative charge (Agraz-Cibrian et al., 2017; Gotts and Matthay, 2016; Reges et al., 2010). Leukocytes are therefore believed to have a significant role in the immunological response during an infection.

Sepsis develops when there is a continuing immune and coagulation system activity as a result of an existing infection (Antoniak, 2018). Unfortunately, in cases of acute bacteraemia and viremia, the coagulation system can become overactive, which can cause disseminated intravascular coagulation (DIC), microvascular thrombosis-induced hypoxia contributing to multiorgan failure, septic shock, and ultimately death without early detection and treatment (Antoniak, 2018).

Recorded accounts of sepsis date back to the fourth century, between 460 and 370 BC. The word “sepsis” comes from the Greek word “σήψις”, meaning decomposition (Vincent and Abraham, 2006). It was also represented by “sepidon”, meaning distortion or dissolution of a web structure, and was used in poems as “sepo”, which meant “rotted” (Vincent and Abraham, 2006).

In 1991, the American Association of Chest Physicians (AACP) and the Society of Critical Care Medicine (SCCM) met in Chicago to develop a consensus definition for sepsis. The agreed definition that emerged from their deliberation was the ‘’presentation with a minimum of two of four parameters observed in the Systemic Inflammatory Responses Syndrome (SIRS)’’ (Bone et al., 1992). Namely: temperature (≥ 38 or ≤36°C), heart rate (>90 beats/minute), respiratory rate (> 20 breaths/minute); partial pressure of CO2 (<32 mmHg); and leucocyte count - >

12,000 or < 4,000/microlitres or > 10% immature forms or bands) (Balk, 2014; Kaukonen et al., 2015).

Subsequently, in 2001, it was recognised that patients who met the SIRS criteria of two or more parameters were not necessarily septic but had an infection that in many cases did not result in organ failure or death (Kumar, 2017). As a result, the Association of Critical Care Medicine (ACCM), SCCM, European Society of Critical Care Medicine (ESCCM), American Thoracic Society (ATS) and Surgical Infection Society (SIS) collectively proposed a new definition for sepsis as ‘’a clinical syndrome with organ injuries, including findings such as oliguria, coagulopathy, haemodynamic instability and an altered liver function test ‘’ (Levy et al., 2003 Pg 533). Nonetheless, the criteria for recognising sepsis remained unchanged. These early definitions became recognised as inadequate over time (Kumar, 2017; Singer et al., 2016) largely due to advances in epidemiology, pathophysiology and sepsis management.

A revised definition for sepsis was introduced in 2016, describing sepsis as “a dysregulated host immune system leading to severe organ dysfunction due to infection” (Singer et al., 2016, Pg 3). This was accompanied by the development of a Sequential Organ Failure scoring system (SOFA) which is used to assess the performance of organ systems such as the liver and kidney functions and a rapid sequential organ failure assessment, assessing three parameters: respiratory rate, blood pressure and level of consciousness (Jozwiak et al., 2016).

In 2022, the World Sepsis Committee recognised the challenges associated with the implementation of universal recommendations, hence, the need for a definition and

associated assessment for sepsis that considers contextual limitations experienced in many resources limited settings (ASA, 2022).

1.2.2 The Burden of Sepsis Globally, Including Low and Middle-Income Countries (LMICs)

Globally, the prevalence of sepsis is estimated to be 49 million annually, with a mortality rate of 11 million (Rudd et al., 2020). In the United States (US), sepsis is estimated to affect around 1.5 million individuals annually (CDC, 2017), with mortality of 250,000 individuals. It is responsible for one out of every three hospital deaths (CDC, 2017). In the United Kingdom (UK), sepsis affects 250,000 people annually, with 52,000 deaths (Daniels et al., 2019) and accounts for 57,000 deaths in France annually (ESR, 2021). Out of the global prevalence, 41.5 million incident cases were recorded in low, low middle and middle countries with a corresponding 8.2 million deaths (Rudd et al., 2020; WHO, 2018). This number is more than 70% of the global incidence. Most LMICs, including those in sub–Saharan Africa, lack an appropriate registry for sepsis except for children and maternal (WHO, 2018).

These global rates and corresponding mortality led the World Health Organization (WHO) and the World Health Assembly (WHA) to declare sepsis a global health priority in 2017 (WHO, 2018). All member states were urged to improve sepsis prevention, diagnosis and management in health facilities, especially beyond the confines of Intensive Care units (ICU) (Reinhart et al., 2013). The awareness drive sought to improve knowledge across populations in enabling speed in identifying the signs of sepsis, reporting to hospitals quickly and increasing expectations regarding healthcare delivery. In addition, enabling Health Care Professionals (HCPs) to identify sepsis correctly from the patient’s presentation to improve their care and

outcomes (WSD 2019; Evans et al., 2021). Many developed and developing countries have responded to the WHO call and are designing and implementing systems and processes to tackle this challenge (Evans et al., 2021).

1.2.3 The situation in Africa and Ghana: Why this Study is Needed

The incidence of sepsis from Africa was estimated in 2017 to be 17 million (35% of global cases), with 3.5 million deaths (32% of global death) (Keeley and Nsutebu, 2021; Rudd et al., 2020). Sepsis was declared a significant healthcare burden and required African nations to step up by improving its prevention, recognition and the provision of timely interventions after the WHO declaration. This led to the formation of the Africa Sepsis Alliance (ASA) who produced a declaration and commitment to address these aims (Keeley and Nsutebu, 2021). Challenges such policy makers in African countries not prioritising sepsis, non-existence of national action plans and a lack of commitment and the absence of data especially for adults has made it impossible for action to be taken (Rudd et al., 2020; Keeley and Nsutebu, 2021). In view of this, there is a need for improvement, concerning sepsis in adults, which is mostly overlooked (Keeley and Nsutebu, 2021).

In Ghana, data related to paediatric, maternal and neonatal sepsis cases are collected (Adatara et al., 2019; Adatara et al., 2018; Ganyaglo and Hill, 2012; Labi et al., 2016; Owusu et al., 2021). There is no publicly available data on the incidence or interventions regarding sepsis in adults. However, the study site records high mortality from sepsis even though it has not been listed as one of the causes of admissions (HFH Annual report, 2020), meaning it is frequently missed.

Considering these, global strategies (see 1.2.4) have been put in place to help manage sepsis, however, these are limited in LMICs, including Ghana.

1.2.4 Strategies used in managing sepsis

The most radical and far-reaching campaign, named the Surviving Sepsis Campaign (SSC), was initiated jointly by the European Society of Intensive Care medicine (ESICM) and the Society of Critical Care Medicine (SCCM) in 2002. The primary aim of the campaign was to reduce sepsis-related mortality in ICU patients. However, much of the learning and approach has subsequently been adopted and used across all emergency settings (Gatewood et al., 2015; Hayden et al., 2016; Hirschy et al., 2018). Even though the sepsis bundle advocated by the SSC was developed in high income settings, as a consequence, LMICs who have already introduced interventions to manage sepsis more effectively have often adapted the SSC bundle to meet local contexts. Also, the original bundle published in 2002 has been revised in response to emerging evidence and several improvements have been made (Evans et al., 2021). The SSC campaign includes guidelines for identification and management of sepsis with a bundle of interventions (Dellinger et al., 2008; Evans et al, 2021; Rhodes et al, 2017). This bundle of interventions creates a framework for directing the care of patients with sepsis, with the aim of improving outcomes and reducing mortality. The “sepsis bundle” is a collection of evidence-based practices which serves as a framework for directing the care of patients with sepsis to improve outcomes (Evans et al., 2021; Lavallée et al., 2017). Although the campaign initially targeted reducing sepsis-related mortality in ICU patients, it subsequently, spread and cascaded across most emergency care settings, as mentioned earlier (Baig et al., 2017; Dellinger et al., 2004; Dellinger et al., 2007; Dellinger et al., 2008; Dellinger et al., 2013). The sepsis bundle includes measuring serum lactate, drawing blood samples for culture before administering broad-spectrum antibiotics, rapid

administration of crystalloids, use of vasopressors and oxygen administration when necessary (Evans et al., 2021). All these interventions must be completed sequentially within an hour of recognising suspected sepsis, often called the “Golden Hour” (Evans et al., 2021; Kodan et al., 2018).

Global evidence has shown that delays in initiating antibiotics and administering intravenous fluids increase mortality (Bone et al., 1992) in suspected or confirmed sepsis patients. These delays have been estimated to equate to a 7.6% increase in mortality for every four hours of delay (Kumar et al., 2006). When the sepsis bundle was introduced in developed health economies such as the UK, the United States of America (USA) and some European countries, significant improvements were observed in standards of care, leading to reductions in mortality rates (WHO, 2018). A recent study in the USA identified that sepsis patients who received the components of the sepsis bundle in the optimum period had improved outcome (Townsend et al., 2022). That is a reduced 30-day mortality (22.22% versus 26.28%) (Townsend et al., 2022). In 2016, the effectiveness of using the sepsis bundle in adult patients in the UK also found that compliance with the bundle reduced mortality, ICU admissions, and hospital length of stay (Lin, 2021).

Countries in LMICs, such as Brazil, have had good outcomes from implementing the bundle, however, in Zambia, adverse effects due to oversimplification of the bundle has been reported. Given this, the context in which guidelines are implemented is imperative because there is a risk of adverse effects such as increased mortality (Andrews et al., 2014), hence, a careful, gradual and context specific intervention will be much more beneficial (Evans et al., 2021; Keeley and Nsutebu, 2021).

In Ghana, there is no publicly available contextual adult sepsis recognition and management guideline; even though there are elements in use such as the South African Triage Scoring System (described in chapter two) for triaging all patients and antibiotic policy (Jimah, 2020). Some of these guidelines have not been adopted in individual hospitals (Jimah, 2020; Koduah et al., 2021; Yevutsey et al., 2017). For example, studies conducted to examine if Ghanaian national antimicrobial stewardship policy had been implemented in individual hospitals, which is important when it comes to sepsis, identified non-localisation (adoption) of the policy which is one of the challenges of implementing the Ghana healthcare policies (Amponsah et al., 2022; Jimah, 2020; Yevutsey et al., 2017). Without this policy, clinicians tend to overlook the place of blood cultures, combination of antibiotics, misuse and de-escalation.

With the ED as the first point of contact for most adults and the WHO call to improve sepsis recognition and care (WHO, 2018), outside the intensive care, coupled with the absence of national data regarding sepsis incidence and mortality in Ghana, this study was relevant to identifying current healthcare practices in a Ghanaian ED. In doing so, stakeholder discussions aiming at improving care for patients reporting to the ED with sepsis can be achieved.

This study examined sepsis care in a hospital ED in Ghana with the following specific objectives:

1. To undertake a systematic review of identification and implementation of sepsis interventions in emergency departments in low- and middle-income countries (LMICs), described in chapter 3.

2. To examine the current practices concerning the identification and management of sepsis in Holy Family Hospital, Techiman, Ghana through retrospective analysis of case notes and process mapping, discussed in chapters 4, 5, 6,7 and 8.

3. To co-design a context specific sepsis algorithm and educational package with stakeholders as presented in chapter 9.

1.3.0 Summary

This chapter reviewed the history and definitions of sepsis, the burden of sepsis globally and in LMICs, the situation in Africa and why this work is needed. The current definition for sepsis is the dysregulation of a host immune system leading to organ failure due to infection. Evidence suggests that being able to recognise and implement interventions for sepsis has higher chances of improving care and reducing mortality. These interventions for sepsis have progressed well in HICs, however, they are limited in LMICs, including Ghana, as discussed in this chapter, hence the need for this study. The next chapter will explore the context of this study, including the overview of the healthcare system and emergency services in Ghana.

CHAPTER TWO

CONTEXT OF THE STUDY

2.1 Introduction

The previous chapter introduced sepsis and the need for this doctoral study. This chapter describes the Ghanaian healthcare context, with particular attention paid to the delivery of emergency services, where the impact of the health policy on healthcare in Ghana will be contextualised. A description of the study site, processes of care and the justification of hospital of focus have also been discussed.

2.2 Profile of Ghana

Ghana is one of West Africa's most stable and democratic nations with a multi-ethnicity and abundant natural resources. Following the slave trade in the 12th century, Ghana became the first Sub-Saharan nation in colonial Africa to achieve independence in 1957 under the leadership of Dr. Kwame Nkrumah, which was much earlier than Nigeria (Gocking, 2008). The population of Ghana is 32,337,370 as of 2021 (GSS, 2021). This is half of the UK population and one-sixth of the population of Nigeria (World Bank, 2022; Population for England, Ireland and Wales, 2021). Ghana occupies 227,533 square kilometres and 11,000 square kilometres of land and water, respectively (GSS, 2021). Ghana is divided into sixteen regions as a first level of subnational government due to decentralisation of activities in the country (Figure 1).

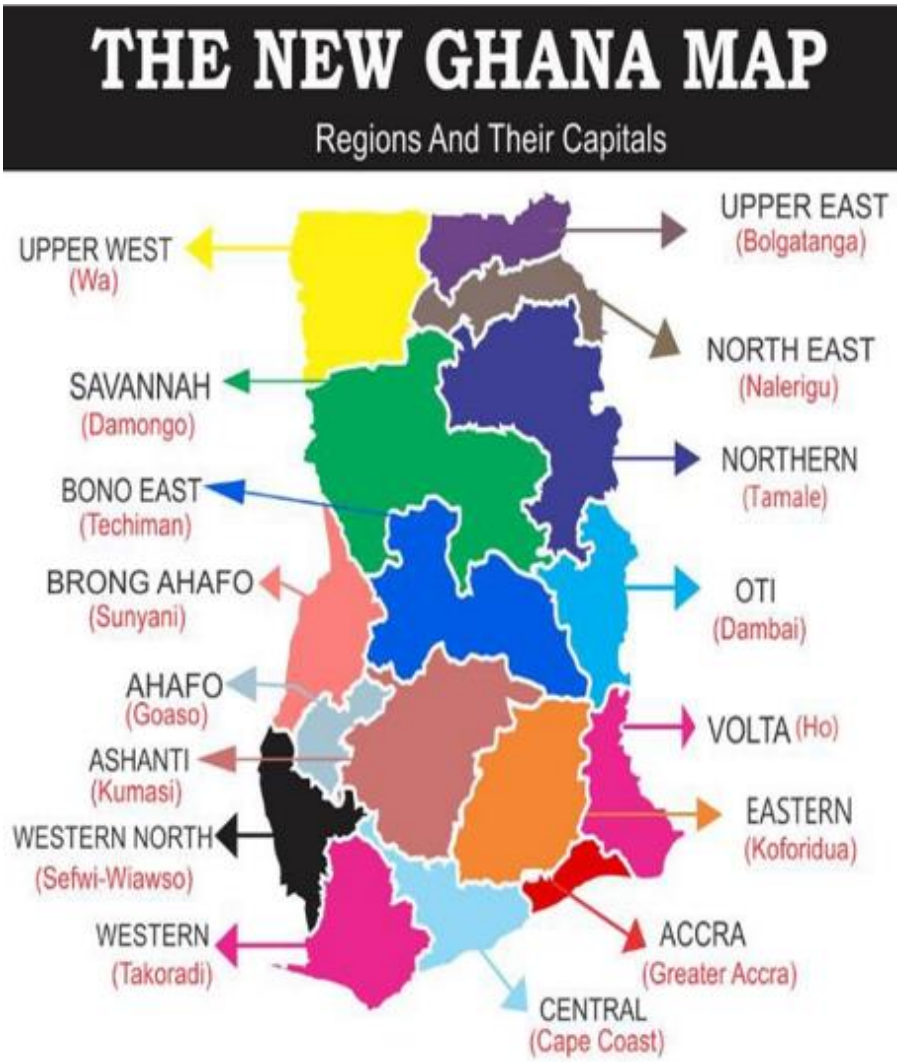

Figure 1. The New Ghana map (Source: accessed online 20.06.2023: https://www.graphic.com.gh/news/general-news/new-ghana-map-with-16-regional-capitals.html)

Techiman is the capital of the Bono East Region where this study was conducted (see the blue colour close to Savanna in the middle), Brong Ahafo and Ahafo region (fig 1). Almost half of the inhabitants living and working in this region are engaged in agriculture (GSS, 2021). Even though more than half of Ghanaians identify as Christians, approximately a fifth identify as other religion such as Muslims, and a small percentage practise traditional indigenous religion: as illustrated in Figure 2.

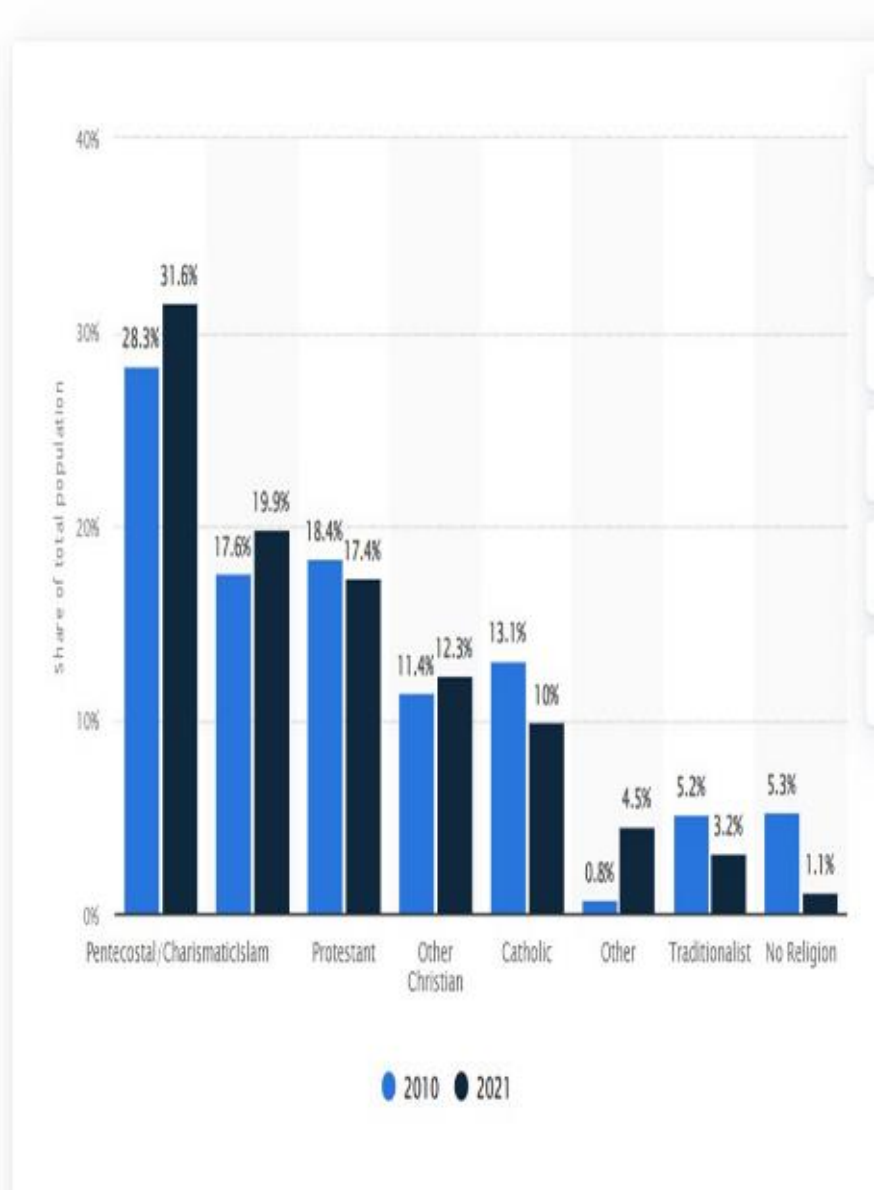

Figure 2. Religious affiliations and age breakdown of Ghanaians (Source: Population Health Census report, 2021)

Ghana's population is significantly younger (under 59) than some LMICs and HICs.

The proportion of people aged 60 and older in these populations is increasing faster

than those under age 64.

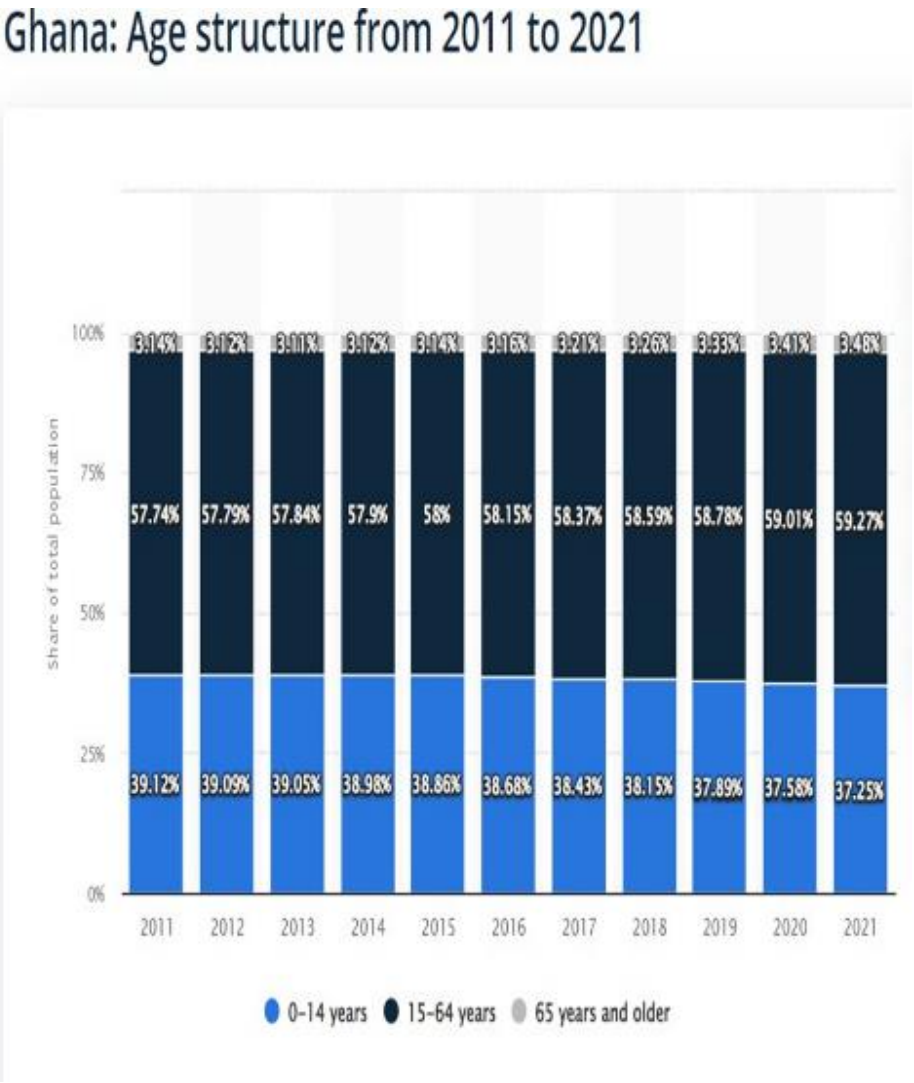

Figure 3. Age breakdown of Ghanaians (Source: Population Health Census Report, 2021)

According to the 2022 health profile of the country, males in Ghana have a life expectancy of 62 years and females 64 years (WHO, 2022). Both figures are higher than the average life expectancy elsewhere in the African continent, which is 58 years for males and 62 years for females (WHO, 2022). Hence, Ghana is seen as a relatively healthier country based on the primary health indicators used by the WHO (Home Office Report, 2019).

2.3 Description of the Ghana Health System

Compared to many countries in Sub-Saharan Africa, the West African nation of Ghana has a developed healthcare system (Home Office Report, 2019). Teaching hospitals and private hospitals (e.g., Christian Health Association of Ghana (CHAG) - that is hospitals led by faith-based organisations such as Catholics) make up the Ministry of Health (MOH) (Fig 4). Others, such as traditional and other sectors (e.g. food and agriculture) collaborate with MOH on health matters. In the public and CHAG hospitals, the Ghanaian government pays most of the staff salaries, including those of doctors and nurses, while the private facilities are managed by individually owned people (Home Office report, 2019). These facilities are classified into primary, secondary and tertiary (Ashiagbor et al., 2020; Korah et al., 2023).

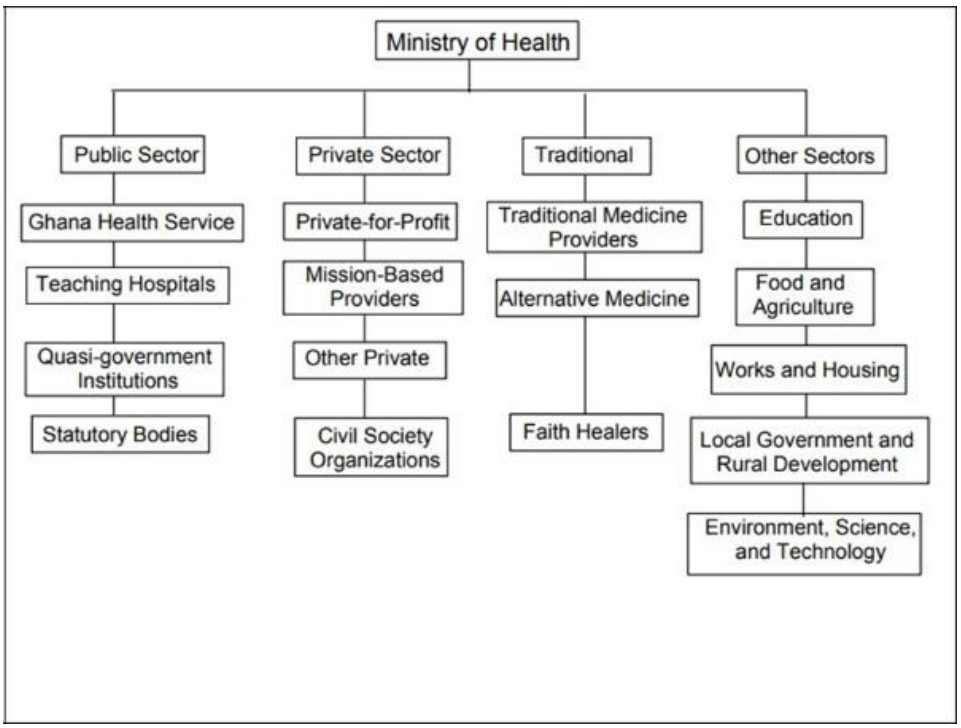

Figure 4. Organisation of the Ministry of Health (Source: Overview of Ghana Health System Report, 2020)

The first point of contact for primary health care (basic curative and preventive care) is at the community level due to the decentralised administrative structure (regions) of the healthcare system in Ghana (Drislane et al., 2014). This means that instead of a patient from a town or village travelling to regional capitals to seek health care, there are community services, which is the first contact services for healthcare concerns, problems and issues before further referral if required. Services provided at the community level include basic curative services such as treatment of malaria, health promotion and preventive services. These services in the districts and communities are run by physician assistants and midwives and staffed by nurses (Drislane et al., 2014). To achieve a universal health coverage, Ghana also adopted a community-based services planning (CHPS) concept (CHPS operational policy, 2005). This concept is to ensure that communities in subdistricts who are deprived of healthcare are able to access healthcare. Community health officers and volunteers are used to deliver a basic package of care, such as health promotion and prevention, management of minor ailments and referral to a primary, secondary or tertiary facility.

At secondary level facilities, all services needed for healthcare such as outpatient services, emergency and theatres could be found (Korah et al., 2023). These hospitals are also classified as regional hospitals and have the capacity to offer some specialist care such as obstetrics and gynaecology, however, specialist services such as neurology are limited and most specialist cases tend to be referred to tertiary level hospitals. Although the hospital of focus for this study was classified as a secondary-level hospital at the time of data collection, it was upgraded to a tertiary level facility as of November 2023.

Tertiary hospitals are classified as teaching hospitals providing higher levels of specialist care such as neurosurgery and plastics (Korah et al., 2023). These hospitals also offer tertiary education in Ghana, such as in the Northern, Ashanti, Greater Accra, and central regions. This system is similar to the Nigerian healthcare system and that of Oman in Saudi Arabia, where services are rendered based on primary, secondary or tertiary classifications.

Ghana's physician, nurse and midwifery workforce fall short of the WHO's African recommended average threshold of 134 doctors, nurses, and midwives per 10,000 (Ahmat et al., 2022; Home Office report, 2019), that is; 7.77 doctors, 58.64 nurses and midwives, 14.72 chemists and pharmacy technicians/assistants, 14.0 medical and pathology laboratory scientists/technicians, 25.34 community health workers, and 13.88 other health cadres per 10,000 individuals (Ahmat et al., 2022). Even though Ghana falls short of these numbers, it performs exceptionally well, compared to the vast majority of African countries such as Nigeria (Home Office Report, 2019). However, because there are only one and one- tenth of medical doctors and nine and a half-registered nurses and midwives for every 10,000 people (MOH, 2018), this hinders the quality of medical care provided.

In 2016, there were 1003 clinics, 404 hospitals, 855 health centres, and three psychiatric hospitals (Ahmat et al., 2022) comprising the Ghanaian health system. In the same year, 13,231 registered general nurses, 14,791 community health nurses, 7,662 midwives, and 3,365 doctors were employed (Home Office Report, 2019). The doctor-to-population ratio in 2016 was 1:9,301 and the nurse-to-patient ratio was 1:18, illustrating the shortages in the health workforce (Asamani et al., 2021) across the country including the study site. Even though Ghana recorded a nurse-to-patient ratio of 1:18, in 2016, due to emigration reasons, this changed constantly over time

leading to shortage of nursing staff. The general practice of medicine is comparable in principle to that practised in countries with higher levels of wealth, including range of illnesses (Asamani et al., 2021). However, certain illnesses such as malaria, infections and trauma are seen in a significantly higher proportion than in HICs.

Approximately two out of five Ghanaians live more than 15 kilometres from a health care facility, so access can be limited (Pacific Prime Report, 2019). Poor transportation and infrastructure results in individuals being delayed in seeking treatment, and report late following deterioration to hospitals, contributing to an increased mortality rate.

Ghana has a health insurance system called the National Health Insurance Scheme (NHIS) where Ghanaians only need to contribute a very small amount annually and renew their subscription each year (Kumi-Kyereme et al., 2017; Pacific Prime report, 2019; Vellekoop). In 2003, when the policy was introduced, it contributed to a significant improvement in healthcare provision evidenced by health outcomes, comparable to those of other African countries (Home Office Report, 2019). Despite the health insurance system, obstacles and challenges can prevent people from accessing quality healthcare (Blanchet et al., 2012; Kumi-Kyereme et al., 2017). For example, the NHIS has limitations to medications included and some types of surgeries (Aboagye et al., 2021; Blanchet et al., 2012; Christmals and Aidam, 2020). For example, if a patient is prescribed any medication outside the health insurance scheme such as Meropenem (an antibiotic), which is on the WHO's list of essential medicines, the patient has to either pay if it is available at the facility or buy it from an outside pharmacy. This adds financial burden to patients, especially those who are poor. This implies that even though the NHIS makes some form of payment, patients still have to pay out of their own pocket to compliment that of the NHIS (Aboagye et

al., 2021). Another qualitive study conducted to assess the quality of healthcare services found that patients paid for some laboratory investigations and medications even though they were under the NHIS policy (Kodom et al., 2019). In 2021, a study assessing whether patients under the NHIS policy made any payments in three regions of Ghana reported 46.9% out of 49.7% of patients were paying for care consultation and medication despite being on the NHIS policy (Akweongo et al., 2021). The reason for this is unclear (Kodom et al., 2019), however, this causes people to access healthcare using a cash-and-carry system (pay before service is rendered). The study site, however, operates a pay-later policy (24-48 hours) in addition to its services, where in emergencies, patients are taken care of before they pay later if need be (detailed in chapter 7). The Nursing and Midwifery Council of Ghana coordinates all activities pertaining to nurses and midwives while the Ghana medical association coordinates activities of doctors.

2.4 Emergency Care Services in Ghana

Historically, emergency care in Ghana was inadequate with few staff and limited equipment. In 2001, a stadium disaster during a football match resulted in the death of thousands of Ghanaians (Osei et al., 2013). Even though there had been ongoing discussions to formalise emergency care before the incident, this situation expedited improvements in emergency care. Currently, the scope of service for the emergency system is formalised with national emergency guidelines (Bam and Bell, 2015) that are implemented across all regions. These are comparable to those provided in other African countries such as South Africa.

Until 2010, practitioners working in the ED were general medical and nursing staff without formal training in emergency medicine. Fortunately, in 2010, Ghana gained certification as a nation for its programme to train emergency physicians and nurses (Bam and Bell, 2015; Drislane et al., 2014), which I benefitted from as the second cohort of emergency nurses to be trained in 2011. Their contributions to emergency care have significantly impacted patient outcomes in EDs, even though there are insufficient trained ED staff to cover all shifts (Drislane et al., 2014). The type of hospital, either primary, secondary or tertiary, determines the ED's capacity and organisation as discussed earlier, unlike in HICs where there is similar capacity across EDs. Government institutions, charitable organisations and individual donors contribute to funding equipment for emergency medical care (Home Office report, 2019). The ratio of nurses to doctors in EDs depends on the type of facility. For example, in a secondary level hospital, such as the study site, the nurse-to-patient ratio of 1:10 can be found in the ED based on local hospital data, unlike the UK with a ratio of 1:4 or 1:5 depending on patient acuity (NICE, 2014). Major trauma, pneumonia, diabetic ketoacidosis, and acute abdomen are examples of common conditions seen in EDs in Ghana, including the study site (Drislane et al., 2014).

A national ambulance system is in place (Tansley et al. 2016) as part of the provision of emergency services in Ghana. However, people prefer using their own means of transport to the hospital even when severely compromised due to the lack of sensitisation and misinformation regarding the use of the national ambulance as well as inadequate number of ambulances (Tansley et al 2016). This is not the case in HICs like Germany (Roessler and Zuzan, 2006) and the UK (Wankhade, 2011), where the ambulance system is well established. Though efforts have been made so far to make emergency care services available and accessible to all, factors such as

patients' decisions to seek care, ED overcrowding, having to pay for some interventions and long waiting times, still make people reluctant to seek care unless their condition deteriorates (Kodom et al 2019).

2.5 Study Setting

Holy Family Hospital (HFH), located in Techiman, in the Bono East Region of Ghana, was the study site. It is the largest hospital in the region and is also one of three hospitals in the surrounding area affiliated with the Christian Health Association of Ghana (CHAG). Bono East Region has a population of 1,203,306. Techiman also serves as the capital of the Bono East Region and it is situated at a historical intersection of trade routes and the Tano River. According to the 2021 census, the total number of people living in Techiman's settlements was 243,335 (GSS, 2021). The Bono East Region is home to about twenty or more medical establishments, including hospitals and clinics (HFH Report, 2020).

In addition to providing services to ED patients needing care, specialties such as surgery, obstetrics and gynaecology, public health, and paediatrics are also served. HFH is the primary referral point for all nearby hospitals and clinics. The hospital has 330 beds and 841 medical and allied health professionals. Annually, approximately 25,000 patients are admitted, and the ED sees approximately 10,000 patients annually (HFH Report, 2020). The ED has a bed capacity of 34 and a total nursing staff strength of 75, in addition to doctors (1 doctor per shift during the weekday) and other allied health professionals working in the ED in a team as described in table 1. Even though the bed capacity of the ED is 34, most of the time, there are stretchers, wheelchairs and chairs with patients being cared for.

Table 1: Description of staffing and role function in the study site ED

Category of staff	Number	Role
ED Nurse manager	1	Takes the nursing leadership role
Emergency physician	1	Takes the overall leadership role in the ED. Supervises medical officers and junior doctors in case management as well as providing governance of the ED
Registered ED nurses (These are RGNs who have undergone two years of top-up post-registration in a university to acquire a bachelor's degree in emergency nursing)	3	Provides nursing leadership in the ED by maintaining standards and providing quality emergency nursing care to all patients. Also, oversee patient safety and governance of the ED
Medical officers	5	Attend to all patients who report to the ED
Registered general nurses (RGN) who have undergone three years (diploma in nursing (DN) and/or four years (BSc Nursing)	44	They work in the various zones in the ED ensuring holistic nursing care is provided to all patients. They have assigned roles in the ED based on the coded colour system. There is an infection prevention focal person per day who ensures that the safety of patients and staff is worked on appropriately.
Nurse assistant clinical (NAC)- these nurses have undergone two years of training	11	They work directly with the RGNs, undertaking vital signs monitoring, administration of medication and assisting in minor procedures
Ward assistant	1	Ensures the cleanliness of the unit and assists in minor procedures
Porters	5	Ensures patients are received into the ED and transported to other departments, e.g. radiological investigations and sometimes blood samples to the lab.

Other personnel contribute to the smooth running of the ED. These include:

- A cleaning company providing cleaning services at the ED twenty-four hours a day, seven days a week.
- Laboratory and pharmacy staff who provide a scheduled timetable (rostered cover) from their respective base in the hospital twenty-four hours a day, seven days a week.
- On each shift, morning (7:30 am-1:30 pm), afternoon (1:30 pm-7:30 pm) or night (7:30 pm-7:30 am), there are on average nine nurses (seven RGNs, two NAC), two porters, two cleaners and one pharmacist.
- A lab technician collects samples during the morning shift, Mondays to Fridays, up to 4 pm and takes them to the central lab. Out of hours, samples are transported to the central laboratory, which is a two-minute walk from the emergency by one of the nurses (any of the categories of nurses on duty).
- House officers (doctors on internship) from various specialties provide rostered shift cover in the ED during the weekends. They attend to any patients, including those with suspected sepsis.
- Per shift, one doctor (MO) takes care of over 30-40 incoming patients from Monday to Friday.
- Apart from ED doctors attending to incoming patients, all specialties such as medicine, surgery, paediatrics, obstetrics and gynaecology conduct morning reviews at the ED to see patients who have been admitted to the ED based on their specialty to either discharge or transfer them to their respective wards.

- There are services for records, where patient identification numbers are activated using the Electronic Health Records (EHR) when they arrive to enable clinicians to document every process of care.
- A pharmacy, a sample collection area, finance and a two-bedded isolation unit, and a two-bed High Dependency Unit (HDU) are also included in the ED's facilities.

2.6 Process of care

As part of the national guidelines for emergency care, triaging of patients in EDs in Ghana utilise the South African triage scoring system (SATS) (Hammersley et al., 2017; Rominski, 2014), which is comparable to the NEWS2 in the UK (Smith et al., 2019), however, it lacks guidance on the frequency of monitoring after the initial triage (detailed in chapter 7). Even though there are a variety of triage systems, such as Australian Triage Scale (ATS) available, no single system is universal. Hence, many LMICs have developed variations and unique triage scores (Nannan et al., 2017; O'Reilly et al., 2012), such as the South African Triage Score (SATS), to fit healthcare needs, including local disease burdens and resource availability. This tool is used as the standardised triage tool in Ghana, including the study site. It incorporates a colour-coded system to stratify patients reporting to ED into red, orange, yellow, green or blue (see Appendix 1). A patient classified in the red category signifies immediate attention; this is comparable to a patient scoring 7 or more in the NEWS score, orange needs attention in 10 minutes, 5 or more in the NEWS2 (Smith et al., 2019), 60 minutes for yellow, and 240 minutes (4 hours) for green. A blue or black category signifies death and needs a doctor assessment and confirmation of death before performing last offices and preparing them for the morgue. Considering these timelines, EDs in Ghana usually care for red, orange and yellow patients (see Appendix 1). Normally, all

patients triaged as green are referred to outpatient departments (OPD), unless there is a discriminator (Appendix 1), such as bleeding or vomiting, which can indicate close observation is warranted, hence reviewed at the ED.

The ED in Ghana takes care of adults and children with medico surgical emergencies as well as assault and trauma cases, which is common in most LMICs (Khan et al., 2018), as compared to HICs. When patients present themselves to the ED, they are first evaluated in the triage area, where their vital signs are recorded by the nurse, and a preliminary assessment of their presenting condition is made by the ED doctor. Following this evaluation, the patient is assigned a priority level according to the SATS (SATS Manual, 2012). Life-saving interventions are initiated in the two bedded resuscitation area for red or orange patients such as oxygenation, intravenous cannulation, sample taking, initial doses of medication, and radiology investigations. Patients are assigned to red or orange where they will remain for ongoing observation and, if necessary, will be transferred to the inpatient wards or ICU afterwards or discharged. However, all yellow cases are sent directly to the yellow zone after triage for care. Regardless of whether or not they have an initial diagnosis of sepsis, patients who present to the ED follow a general pathway (as described) without flagging sepsis from the beginning.

2.7 Justification of hospital of focus (study site)

The study location was chosen for this doctoral endeavour for a number of reasons; first, sepsis is clinically listed as one of the top ten causes of death in the ED and the entire hospital. It is expected that this study will help identify barriers and facilitators to sepsis recognition and management to reduce the mortality rate and improve the standard of care.

Second, because of its location near major crossroads and as the regional capital, HFH frequently treats patients from both the northern and southern parts of Ghana who have complex medical needs and are transported from all nearby districts.

Finally, HFH is the largest hospital in the Bono East Region, providing specialist services and advanced diagnostics compared with the neighbouring districts.

2.8 Summary

This chapter has explained Ghana's healthcare and emergency care systems, including the country’s profile. Triage and the process of care in general was also explored. Even though the Ghana health system is decentralised, emergency systems in place, including an ambulance system and a national health insurance policy, patients have to make some form of payment before some investigations and treatments are initiated. The next chapter will present a systematic literature review undertaken to ascertain the identification and implementation of sepsis interventions in LMICs.

CHAPTER THREE SYSTEMATIC LITERATURE REVIEW

IDENTIFICATION AND IMPLEMENTATION OF SEPSIS INTERVENTIONS IN EMERGENCY DEPARTMENTS IN LOW AND MIDDLE-INCOME COUNTRIES

3.0 Introduction

The previous chapters presented an introduction, background, rationale and aim for this doctoral research, including how this thesis has been structured. Chapter one presented an introduction to sepsis as being a global priority and the need for measures to improve its identification and care. The surviving sepsis campaign guidelines (SSC) (Evans et al., 2021) were instated to improve recognition and management of patients presenting with sepsis. The bundle has been adopted in HICs, however, LMICs still face challenges in implementation. With this background, the focus of this chapter is to critically review the evidence associated with implementing the SSC bundle in LMICs, thereby providing evidence to guide adoption in a Ghanaian context. The aim and objectives of this review, methods used in identifying the included papers, results, discussion of findings and recommendations for future research and practice will be discussed in this chapter.

Systemised reporting adhering to the preferred reporting items for systematic reviews and meta-analysis (PRISMA) is used along with eight review questions.

3.1.0 Aim and objectives of the review

The aim of this review was to conduct a systematic review, identifying how sepsis identification and interventions in adults have been conducted in EDs in LMICs to identify what might work best in Ghana.

The review questions include:

1. What processes are used to recognise sepsis in emergency departments in low- and middle-income countries (LMICs)?

2. What screening tools for sepsis detection are in use in emergency departments in LMICS?

3. What are the component parts of any interventions or bundles for sepsis in use in emergency departments in LMICs?

4. What are the optimum timelines for implementation of sepsis interventions?

5. How effective are measures to recognise and manage sepsis in emergency departments?

6. What is the impact of sepsis interventions used in emergency departments on patient mortality in LMICs?

7. What are the enablers or barriers to sepsis pathway/bundle management in emergency departments in LMICs?

8. What are the roles and responsibilities of different health care workers in the operationalisation of any sepsis bundle or interventions in use in emergency departments in LMICs?

3.2.0 Methods

To avoid duplication, promote transparency, and reduce the potential for bias of this review, a protocol was registered with the International Register for Systematic Reviews: registration No: CRD42020184208 (Prah et al., 2020). The Participant, Intervention, Comparator, Outcome Setting and Study Design (PICOS) framework

(Schardt et al., 2007) was used to build the inclusion and exclusion criteria and assist in formulating the search strategy. The PICO was selected over other frameworks such as PEO as the interest of the review was to identify interventions in sepsis care. Table 2 below describes the inclusion and exclusion criteria based on the PICOS framework.

Only studies conducted solely in EDs and where ED episode data could be retrieved were included.

The purpose of the review was to inform the development of an intervention or bundle for implementation in an emergency department. Therefore, any study design that described sepsis identification, management/intervention or how to implement a sepsis identification or management intervention were included. For example, if an intervention described an assessment tool used to recognise sepsis, and/or was used in ongoing monitoring of patients with suspected sepsis, it was included. This was because an objective of the review was to determine what parameters should be measured, and with what level of precision, to reach a differential diagnosis or adequately monitor sepsis or suspected sepsis. Timing of interventions and frequency of monitoring and length of assessment and intervals between assessments were also extracted as the timeline of intervention often referred to as “the golden hour” was an objective for the study (Evans et al., 2021). Similarly, information about outcomes used to measure the effect of any interventions adopted (e.g. mortality or use of antibiotics, etc.,), and/or the roles played by the different healthcare professionals such as nurses, doctors, pharmacists and laboratory personnel in managing patient presenting with suspected sepsis were also extracted.

Table 2: PICOS framework

	Inclusion Criteria	Exclusion Criteria
Participants	Adults 18 years and above diagnosed with potential or confirmed sepsis	Patients below 18 years
Intervention	Interventions, bundles, or locally adapted tools to identify sepsis and appropriate interventions	Conditions other than sepsis
Comparator	No interventions, bundles, or locally adapted tools to identify sepsis and appropriate interventions	Interventions not related to sepsis
Outcome	The impact on mortality of sepsis	Mortality not related to sepsis
Setting	Emergency department in LMIC	Not emergency department in high-income country
Study Design	Any study design describing the design or implementation of a sepsis intervention	Study designs that did not describe interventions or tools or processes or outcomes used in the identification and management of sepsis in an emergency department.

3.3.0 Search Strategy

The following databases were searched: Medline, PubMed, Embase, Web of Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Google Scholar (Bramer et al., 2017). These databases were chosen, as they include literature from nursing, allied health, biomedical research, and psychology. The databases were searched for studies published between 2002 (the date SSC was launched) and 2023. This search was re-run and updated in 2024.

To ensure all papers met the inclusion criteria, several search strategies were used systematically: firstly, Boolean operators (a set of simple words such as “and”, “not”, “or”, to combine keywords in library databases) and secondly, Medical Subject Headings (MeSH) terms.

The following search terms were included in the database searches recognition or identification or detection) AND (sepsis OR septic OR severe sepsis or septic shock OR systemic inflammatory response syndrome) AND (sepsis bundle or sepsis protocol OR sepsis six or sepsis three or sepsis one) AND (early goal-directed therapy in the treatment of severe sepsis and septic shock) AND surviving sepsis campaign guidelines AND deterioration in sepsis AND (emergency department or emergency room or accident and emergency or accident & emergency or a&e or a & e) AND (low and middle income countries or developing countries) AND (Adult OR 18 years and above). (See Appendix 2 for detailed search strategy).

3.4.0 Study selection and data extraction

After completing all database searches, all articles were transferred to Endnote© (reference management system) and later to the Rayyan web application (Ouzzani et al., 2016). Rayyan supports the removal of duplicates and facilitates the screening process, allowing multiple reviewers to independently assess papers by title and abstract and full text against the inclusion/exclusion criteria. It also allows note making and remarks and for these to be shared. Two reviewers (AP and AT) first completed screening titles and abstracts independently and, after discussion of any differences, reached a consensus regarding which studies to retain. The searches identified 6,930 papers; 230 duplicates were removed, leaving 6,700 papers screened by title and abstract. After applying the exclusion criteria, 6,628 articles were excluded based on

context, participants of interest and design. The remaining 72 full text articles were assessed by two reviewers (AP & AT), where 22 papers met the inclusion criteria and were included in the narrative synthesis. Meta-analysis was not performed. Figure 5 presents the Transparent Reporting of Systematic Reviews and Meta-Analyses (PRISMA) diagram showing the decision process flow:

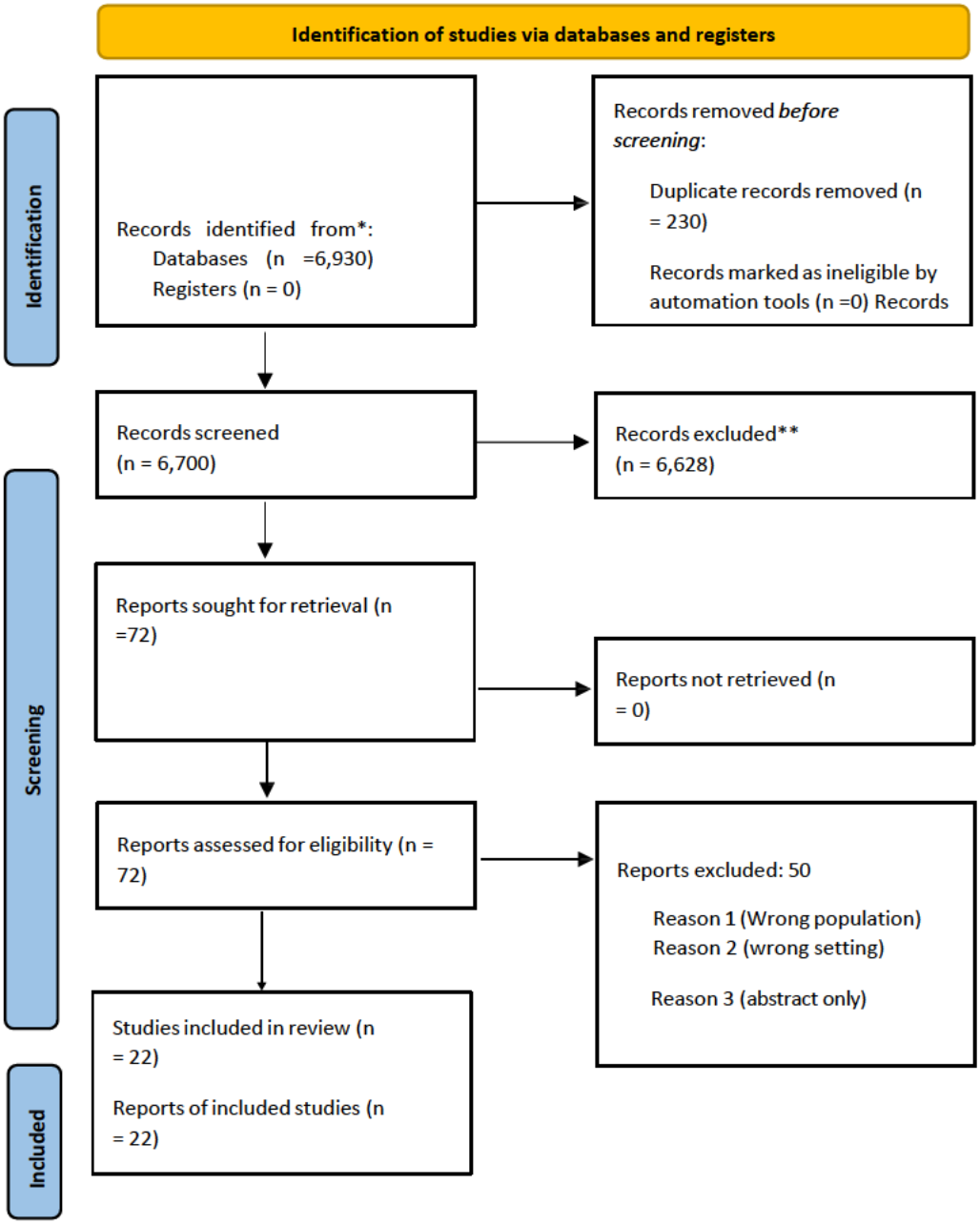

Figure 5: Prisma flow diagram (Source: The PRISMA 2020 statement an updated guideline for reporting systematic review)

3.5.0 Risk of bias in individual studies

To assess the validity of studies, the Newcastle Ottawa Quality Assessment Tool (NCQAT) (Lo et al., 2014) was used to critically appraise non-randomised studies. including case-control, cohort, and cross-sectional studies. The tool has three parts: selection (4 questions), comparator (1 question) and outcome (3 questions). Each question is awarded a star; the higher the number of stars in each study, the higher the quality of the evidence (AP) – (see Appendix 3). The selection factor evaluates the adequacy of the exposed group's representativeness, the approach employed to choose the non-exposed cohort, the determination of exposure, and the verification that the desired result was not present at the start of the trial. The comparability component aims to ensure that cohorts are comparable by employing a design or analysis that effectively accounts for confounding variables. The result component evaluates the frequency of outcomes by considering aspects such as the sufficiency and length of the follow-up period, as well as whether the description of outcomes is included or not. A good quality study is given a rating of 3 or 4 stars in the selection category, 1 or 2 stars in the comparison category, and 2 or 3 stars in the outcome/exposure category. The domain of fair quality is given a rating of 2 stars in the selection category, while the comparability category is assessed with either 1 or 2 stars, and the outcome/exposure category is rated with either 2 or 3 stars. Poor quality is rated with a score of 0 or 1 star in the selection domain, or 0 stars in the comparability domain, or 0 or 1 stars in the outcome/exposure domain.

The Critical Appraisal Programme (CASP) tool was also used for randomised studies (RCTs) which contains eleven items essential in identifying the relevance and credibility of studies. Two studies were assessed using CASP for RCTs. Appendix 4

contains sample of the tools. Tables 3 and 4 below demonstrate the quality assessment of the included studies.

Table 3: Quality assessment of non-randomised studies using the NCQAT

Author (year of publication)	Study design	Selection	Comparability	Outcome
		1 2 3 4	1	1 2 3
Westphal *et al.*, (2011)	Prospective cohort study	* * * *	*	***
Na S *et al.*, (2012)	Prospective cohort study	* * *	*	***
Gilbert *et al.*, (2015)	Report on a series of patients with sepsis. Retrospective study	* * *	*	***
Machado *et al.*, (2017)	Prospective study cohort	* * *	*	***
Machado *et al.*, (2017)	Retrospective analysis cohort	* * * *	*	****
Papali *et al.*, (2017)	Retrospective chart review cohort	* * *	*	***
Akba Baig *et al.*, (2017)	Prospective study cohort	* * *	*	***
Nqobile *et al.*, (2018)	Retrospective chart review	* * * *	*	***
Rudd *et al.*, (2018)	Retrospective secondary analysis	* * * *	*	***
Adam *et al.*, (2018)	Retrospective cohort study	* * *	*	***
Kassyap *et al.*, (2018)	Prospective observational study cohort	* * *	*	***
El Khuri *et al.*, (2019)	Retrospective study cohort	* * * *	*	***
Arie *et al.*, (2019)	Cross-sectional design	* * * *	*	***
Rudd *et al.*, (2019)	Prospective cohort study	* * *	*	* * *
Noritomi *et al.*, (2014)	Prospective pre and post	* * *	*	* * *
Sinto *et al.*, (2019)	Prospective cohort study	* * *	*	* * *
Castano *et al.*, (2019)	Prospective cohort study	* * *	*	* * *
Nates *et al.*, (2020)	Longitudinal prospective study cohort	* * *	*	* * *
Machado *et al.*, 2020	Prospective cohort study	* * * *	*	* * *
Malhotra *et al.*, (2021)	Prospective study	* * *	*	* * *

Table 4: An example of the use of CASP for Randomised Studies

CASP questions – Source: Critical Appraisal Skills Program (2020). CASP (RCT)	Urayeneza et. al., (2018)	Andrews et. al., (2015)
1. Did the study address a clearly focused research question?	Examined the rate of early evidence-based interventions from introducing an infection treatment bundle. It looked at implementing an educational intervention and an infection treatment bundle.	The study's focus was on sepsis patients using a simplified severe sepsis treatment protocol in an African context
2. Was the assignment of patients to interventions randomised?	Randomization of the treatment was not indicated. However, this before and after feasibility study using a step-wedged approach compared phases one and two of the study.	A non-blinded RCT approach was used for patients with severe sepsis. A 1:1 ratio to either protocol or usual care was applied.
3. Were all the participants who entered the study accounted for at its conclusion?	Yes, none of the participants was lost to follow-up	The study was stopped early due to increased mortality as a result of respiratory compromise. Participants data were analysed based on the intention to treat.
4. Were the participants 'blind' to the intervention they were given? Were the investigators 'blind' to the intervention they gave participants? Were the people assessing/analysing outcome/s 'blinded'?	None of these was recorded to have been done	Investigators and people assessing and analysing outcomes were not blind to the intervention. Even though study staff were not blinded to the patient assignment, doctors were not informed of the patient assignment. Notwithstanding, the protocol was visible in the patient's notes
5. Were the study groups similar at the start of the randomised controlled trial?	Yes, baseline characteristics such as age were considered. Both adults and paediatrics were also considered	Yes, baseline characteristics such as age eighteen years and above were spelt out. Patients with respiratory problems were affected.
6. Apart from the experimental intervention, did each group receive the same level of care?	Yes, an acute infection treatment protocol was used.	Yes, a clearly defined, simple severe sepsis protocol was in place. All study groups received interventions within six hours of their enrolment

CASP questions – Source: Critical Appraisal Skills Program (2020). CASP (RCT)	Urayeneza et. al., (2018)	Andrews et. al., (2015)
7. Were the effects of the intervention reported comprehensively?	Yes, the intervention effect was reported. T-tests and chi-square tests were performed	Yes, a power calculation was undertaken, t-test and chi-square tests were done, and no dropout was recorded.
8. Was the precision of the estimate of the treatment or intervention effect reported?	Yes, confidence intervals were used to report the incidence of hospital survival.	Yes, confidence intervals were used
9. Do the benefits of the experimental intervention outweigh the harms and costs?	Yes, the benefit outweighs the harm, as there was an increased the rate of early evidence-based interventions	No, as the study was stopped on the way due to increased mortality due to a respiratory compromise.
10. Can the results be applied to your local population/in your context?	Yes, the outcomes from this study are significant to my context as the intervention improved the rate of evidence-based interventions	The outcome of this study can affect my local population the same way it happened in the study. Hence, context and feasibility must be considered before rolling out a larger implementation.
11. Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?	Yes, as contextual factors and resource availability are essential, this intervention will have a greater value. However, with additional resources, existing interventions could also be applicable	This experimental intervention would not provide value to the people in my care when context and differential diagnosis is not taken into consideration.

3.6.0 Results

Twenty-two studies (22) were included in this review (Aluisio et al., 2018; Andrews et al., 2014; Arie et al., 2019; Baig et al., 2017; Castaño et al., 2019; Dagher et al., 2015; El Khuri et al., 2019; Kassyap et al., 2018; Machado et al., 2020; Machado et al., 2017a; Machado et al., 2017b; Malhotra et al., 2021; Na et al., 2012; Nates et al., 2020; Ndadane and Maharaj, 2019; Noritomi et al., 2014; Papali et al., 2015a; Rudd et al., 2019a; Rudd et al., 2018; Sinto et al., 2020; Urayeneza et al., 2018, Westphal et al., 2011), published between 2011 and 2021.

3.6.1 Study characteristics: countries

The studies were undertaken in seventeen LMICs and one continent, Brazil (Machado et al., 2020; Machado et al., 2017a; Machado et al., 2017b; Nates et al., 2020; Noritomi et al., 2014; Westphal et al., 2011), Lebanon (Dagher et al., 2015; El Khuri et al., 2019), South Africa (Nqobile, 2019), Indonesia (Arie et al., 2019; Sinto et al., 2020), India (Kassyap et al., 2018; Malhotra et al., 2021), Rwanda (Aluisio et al., 2018; Rudd et al., 2018; Urayeneza et al., 2018), Thailand (Rudd et al., 2019a), Haiti (Papali et al., 2015), Asia (Na et al., 2012), Colombia (Arie et al., 2019), Pakistan (Baig et al., 2017), Zambia (Andrews et al., 2014), Bangladesh, Myanmar, Sierra Leone, Sri Lanka and Vietnam (Rudd et al., 2018) (Table 5).

Types of studies: The review included two RCTs (Andrews et al., 2014; Urayeneza et al., 2018) as mentioned earlier, one cross-sectional study (Arie et al., 2019) and the remaining 19 were cohort and secondary analysis studies. No studies describing qualitative or mixed methods designs were identified.

Study Participants: Across the studies there were 54,028 participants. Papers reporting the recruitment of participants from more than one hospital facility (multicentre) were 9/22 (Castaño et al., 2019; Machado et al., 2020; Machado et al., 2017a; Machado et al., 2017b; Na et al., 2012; Noritomi et al., 2014; Rudd et al., 2019a; Rudd et al., 2018; Westphal et al., 2011). While 9 out of the 22 papers involved a combination of EDs and other inpatient settings, ED episode data were identifiable and extracted using the EXCEL data extraction tool (Andrews et al., 2014; Machado et al., 2020; Machado et al., 2017a; Machado et al., 2017b; Nates et al., 2020; Noritomi et al., 2014; Rudd et al., 2019a; Rudd et al., 2018; Westphal et al., 2011). 13/22 papers were undertaken solely in an ED (Aluisio et al., 2018; Arie et al., 2019; Baig et al., 2017; Castaño et al., 2019; Dagher et al., 2015; El Khuri et al., 2019; Kassyap et al., 2018; Malhotra et al., 2021; Na et al., 2012; Nqobile, 2019; Papali et al., 2015; Sinto et al., 2020; Urayeneza et al., 2018).

Study description: Twelve - 12/22 included studies assessed patient outcomes based on the sepsis bundle of care (Arie et al., 2019; El Khuri et al., 2019; Machado et al., 2017a; Machado et al., 2017b; Malhotra et al., 2021; Na et al., 2012; Nates et al., 2020; Noritomi et al., 2014; Papali et al., Rudd et al, 2019; Urayeneza et al., 2018; Westphal et al., 2011). The mortality outcomes from QSOFA and SOFA scores were reported in 4/22 studies (Aluisio et al., 2018; Machado et al., 2020; Rudd et al., 2018; Sinto et al., 2020). Qsofa+lactate criteria were assessed in 1/22 (Sinto, 2020). The initial management of sepsis was examined in 2/22 (Dagher et al., 2015; Nqobile, 2019), 1/22 examined the utility of a point-of-care lactate meter in emergency rooms (Baig et al, 2017), and 1/22 also examined the obstacles to sepsis treatment goals in emergency rooms (Kassyap et al., 2018). The primary and secondary outcomes reported across the papers were similar namely: compliance to

the sepsis bundle, 28 day and in-hospital mortality, time taken to recognise sepsis, and length of ED stay. A summary of the key findings are illustrated in Table 5.

Table 5: Study Characteristics

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
1.Westphal et al., (2011)	Brazil	Prospective cohort study	217	The impact of instituting an in-hospital protocol for the prompt detection of sepsis and its influence on mortality.	Early detection of sepsis, 28 & total in hospital mortality	Mortality rate - There was a significant reduction in mortality. The 28-day mortality for sepsis was (47% vs 24.3%), and the total in-hospital mortality (61.7% vs 36.5%), respectively. There was a reduction in the time taken to identify sepsis. (34 hours and 11 hours, respectively) Compliance with the bundle did not significantly affect the mortality.
2. Na et al., (2012)	Asia	Prospective cohort study	556	The impact of a sepsis bundle implementation(check)	Compliance with the bundle, impact of a team and non-team model on hospital mortality	Mortality rate - In-hospital mortality of 24.5% and 32.7% was recorded with those who received the complete bundle and those who received components of the bundle, respectively Quarterly bundle completion increased throughout the six quartiles (13.3, 26.9, 37.5, 45.9, 48.8 and 54.5%)
3.El Khuri et al., (2015)	Lebanon	Retrospecti ve cohort study	97	Reported the series of patients with sepsis.	SIR's criteria utility,28day and in hospital mortality Hospital length of stay	Mortality rate - There was a reduction in mortality for the protocol-based group In-hospital mortality was 30 (30.9 %) septic patients. 28-day mortality was 20.6 %. ED length of stay was higher in the protocol than in the control group.

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
4. Rudd et al., (2019)	Thailand	Prospective cohort study	3716	The assessment of the early management of sepsis in medical patients in Thailand	Overall hospital mortality, admission to ICU and general ward and length of stay	Mortality rate - There was a reduction in mortality.28 days mortality was 21% (765/3716), more for the patients who were admitted to the ICUs (42%; 263 /627) than those admitted to the general medical wards within the first day of admission (16%; 502/3089) 8% (292/3716) was recorded as the overall hospital mortality. ED length of stay was less than an hour for all patients Most of the patients were managed in the general wards due to a shortage of ICU beds.
5.Machado et al., (2017a)	Brazil	Retrospective cohort study	21103	To evaluate a quality improvement programme on sepsis.	Hospital mortality. Compliance, length of stay, Time to sepsis diagnosis	Mortality rate – There was a significant reduction in the mortality rate. Compliance with the bundle improved. The mortality rate diminished from 53.9% in the first period to 38.5% in the last period. There was reduced ICU and hospital stay. There was a reduction in time to sepsis diagnosis and an improved sepsis awareness among staff
6. Andrews et al., (2014)	Zambia	Randomised controlled trial	112	Assessed the efficacy of how a goal-directed sepsis treatment protocol which is simple can reduce mortality in	Hospital mortality rate and all causes	Mortality rate - There was no difference in mortality rate in the protocol and control groups. Twenty-eight days of mortality in the protocol group was higher than in the control group.

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
				patients with severe sepsis		71.4% and 66.7% in the intervention and control groups, respectively, were mortalities recorded during 28 days. The study was ended early by the investigators before the scheduled period due to recognising that patients presenting with hypoxemic respiratory distress from the outset might be affected by the intervention negatively
7.Urayeneza et al., (2018)	Rwanda	Randomised control trial	1594	They assessed how a focused education programme and subsequent implementation of a treatment bundle would increase early interventions in patients with acute infections.	Differences in intervention rate for each patient within the first six hours	Mortality rate - Hospital survival improved in the course of the phases (635)/ (385). There was a reduction in hospital length of stay (5+-5) / (4+-4).
8. Noritomi et al., (2014)	Brazil	Cross-sectional	2120	The effectiveness of a quality improvement programme for sepsis in a network of hospitals to identify the compliance of its clinical implications	Compliance with the bundle Hospital mortality and cost effectiveness	Mortality rate - There was a significant reduction in overall hospital mortality. There was a significant reduction in overall mortality from 55% to 26% at the end of the programme. Compliance with the bundle improved over time. Full compliance with the bundle was associated with a reduction in the mortality rate.

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
						There was a reduction in cost during the programme
9. Nates et al., (2020)	Brazil	Prospective cohort study	416	To quantify 3 parameters (case fatality, compliance and satisfaction	Quantify sepsis and septic shock case fatality	Mortality rate - Hospital mortality was low (14.0%). Fatality rates were highly variable in the first six months and, after that, tended towards stabilisation at a lower level (below approximately (15.9%), the pre-specified goal of 25%. Compliance with the bundle was less than 50%
10. Machado et al., (2017b)	Brazil	Prospective cohort study	3435	Evaluated the results of a quality improvement measure in public hospitals.	Hospital mortality and quality indicators associated with mortality. Compliance	Mortality rate – There was a reduction in mortality in two out of nine institutions. All institution hospital mortality at baseline was 226(58.9); at the end of the eighth quarter, it was 166(46.5). ED hospital mortality at baseline was 94/184(51.1) and at the eighth quarter 113/248(45.6) Compliance with the bundle was increased in all institutions; however, not associated with mortality.
11. Papali et al., (2015)	Haiti	Retrospecti ve cohort study	99	Described the outcome of patients before and after the study after implementing an adapted sepsis protocol from the WHO.	Sepsis recognition Time to interventions Triage to second vital signs	Mortality rate - In-hospital mortality was 24.5% pre and 25.8% post. Protocol utilisation significantly improved actual outcomes associated with early recognition, patient monitoring and source identification. Increased physician documentation of sepsis Time to interventions reduced significantly.

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
						The median time to second vital signs was 240 minutes
12. Arie et al., (2019)	Indonesia	Cross-sectional	32	To record the implementation and outcome of SSC 2016, such as the 3 and 6-hour sepsis bundle as a baseline and the SOFA scores after 48 hours	Compliance with 3- and 6-hour bundles and 48-hour mortality	Mortality rate - There was a 15.6% mortality within 48 hours. There was increasing compliance with the bundle Compliance with the bundle correlated with clinical improvement. A higher SOFA score was related to mortality.
13. Aluisio et al., (2018)	Rwanda	Retrospective cohort study	760	To assess how the qSOFA score can predict risks for patients in the ED and hospital mortality.	All-cause emergency department and overall hospital mortality	Mortality rate - The mortality rate was 25.4%. ED mortality increased with a higher qSOFA score. The findings support the use of qSOFA in resource-limited settings.
14. Rudd et al., (2018)	10LMICS Bangladesh, Haiti, India, Indonesia, Myanmar Rwanda, Sierra Leone, Sri Lanka, Thailand,	Retrospective cohort study	6569	Assessed the relation of qSOFA with excess hospital mortality compared with the systemic inflammatory response syndrome (SIRS) criteria in patients with suspected sepsis.	Association between qSOFA and SIRS with excess mortality	Mortality rate - The percentage of patients who died increased consistently with a higher qSOFA score than the SIRS criteria. The mortality for 0, 1, 2, or 3 qSOFA were (3%,8%,16%, and 30%, respectively, and for 0,1,2,3, or 4 SIRS criteria in the combined cohort, mortality was 5%, 11%, 13%, 13%, and 12%) respectively The findings from the study support the use of qSOFA, which is easier to use in sepsis identification without laboratory testing.

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
	and Vietnam					Therefore, the study's findings supported the use of qSOFA rather than SIRS. This was because qSOFA was easier to use without laboratory testing.
15. Machado et al., (2020)		Prospective cohort	5460	Assessed the predictive accuracy of qSOFA for mortality in Brazil, focusing on sensitivity.	Hospital mortality Length of stay	Mortality rate - There was increased mortality in patients with qSOFA <= 1. The mortality rate of patients with a qSOFA score less than or equal to 1 was 8.3%. As a severity score, qSOFA performed well, with adequate mortality prediction. However, all other scores had a better performance than qSOFA in predicting mortality: that is, a number of organ dysfunctions, SIRS plus at least one organ dysfunction, and SOFA. qSOFA alone as a screening tool has a limited role as many cases might be missed. Using lactate criteria increases sensitivity. Hospital length of stay was longer for non-survivors than survivors.
16. Sinto et al., (2020)		Prospective cohort	1213	The principal aim of the study was to identify how simplified prognosis criteria in the emergency department perform compared to SOFA and SIRS.	The in-hospital mortality rate within 28 days	Mortality rate – In-hospital mortality rate was 34.7%. Qsofa with lactate was more specific.

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
17. Akbar et al., (2017)	Pakistan	Prospective cohort	43	The study assessed the effect of a timesaving point of care lactate checker in ED	Comparing POC fingertip and whole blood lactate to standard laboratory testing	POC was identified as a fast method of identifying severely sick patients to enable the institution of interventions. 86% of patients survived within 24 hours with a mortality rate of 23%
18. Kassyap et al., (2018)	India	Prospective cohort	75	The study identified factors that cause a delay in sepsis management	Time is taken to achieve 3- and 6-hour bundle	There was increasing (more than 70%) compliance with the three and 6-hour bundle
19. Nqobile (2019)	South Africa	Retrospecti ve cohort	52	This study aimed to describe the clinical profile as well as the initial management of patients with sepsis syndrome in an ED	In-hospital mortality rate Admissions to general wards, discharges and transfers to tertiary institutions	Mortality rate - In hospitals, mortality was 15% Two patients were transferred, and five were discharged.
20. Castano et al., (2019)	Colombia	Prospective cohort	705	Assessed the true association between appropriate prescriptions of antibiotics and prognosis in patients with sepsis.	Inpatient mortality and hospital length of stay	Mortality rate - Hospital mortality was 21% There was prolonged ED length of stay as there were late admissions to the ICU
21. Gilbert et al., (2015)	Lebanon	Prospective cohort	97	Aimed at reporting the series of patients with sepsis.	SIRS criteria utility, 28 days and in hospital mortality and length of stay	Mortality rate - n hospital mortality was 30(30.9%)28 days mortality was 20.6% ED length of stay was 13 and 17

Author Year of Publication	Location	Study type	Participants	Aim	Primary and secondary outcomes	Key Findings
22. Malhotra et al., (2021)	India	Prospective	293	To reduce door to antibiotic time	To increase blood culture collection by 30% and reduce arrival to antibiotic time	Mortality rate - Crude mortality reduced from 23% to 4% in the pre and post intervention respectively. Improved antibiotic administration within60 minutes from 85 to 36.6% Increased blood culture collection rate from 0% to 17%

3.6.2 – RQ1&2: What processes and screening tools are used to detect sepsis in emergency departments in LMICs?

The processes used in identifying sepsis were similar across all the papers reviewed, however, the components of the screening tools were diverse.

The SSC guideline was used in 21 of 22 of the reviewed studies, except one which adopted the WHO Integrated Management of Adolescent and Adult Illness (IMAI) clinician's guide in managing sepsis. The use of the WHO (IMAI) guidelines was based on the feasibility of using physiological parameters and feasibility in resource-limited settings with infrequent laboratory testing.

Regarding the screening tools, 9/22 used the Systemic Inflammatory Responses Framework (SIRS) plus or minus lactate or organ failure (Papali et al., 2015, El Khuri et al., 2015, Rudd et al., 2018, Sinto et al., 2020, Nqobile 2019, Dagher, 2015, Na S et al., 2012, Machado 2017a, Andrews 2014). 8/22 used Sequential Organ Failure Assessment (SOFA) (Arie et al., 2019; Castaño et al., 2019; El Khuri et al., 2019; Machado et al., 2017b; Noritomi et al., 2014b; Westphal et al., 2011, Rudd 2018, Rudd 2019). 7/22 used the quick Sequential Organ Failure Assessment (qSOFA) plus or minus lactate (Aluisio et al., 2018; Machado et al., 2017a; Machado et al., 2017b; Rudd et al., 2018; Urayeneza et al., 2018, Sinto et al., 2020, Nates et al., 2020). 1/22 used vital signs/physiological parameters or Early Warning Scoring (EWS) (Westphal et al., 2011). This was classified as clinical and expanded signs of infection – see Table 6.

Table 6: Screening tools used for sepsis identification

Tools	Description	Study Number
Systemic inflammatory Response Syndrome (SIRS)	Systemic inflammatory response syndrome (SIRS) is an excessive defence reaction of the body to a noxious stressor (infection, trauma, surgery, acute inflammation, ischemia or reperfusion, or cancer) to pinpoint and eradicate the endogenous or external insult. It is assessed in four components • Temperature ≥38 ≤36 degrees Celsius. • Heart rate - 90 beats/per minute • Respiratory rate - >20 bpm or partial pressure of CO2 - < 32 mmHg • Leukocyte count - >12000, <4000 /microliters, >10% immature forms or bands.	3,11,14,16,19,21
SIRS + lactate results	Lactate reflects a cellular dysfunction in sepsis patients. The SIRS criteria were enhanced by lactate results in order to recognise sepsis	2
SIRS + organ failure	One or more signs of organ dysfunction were used in addition to the SIRS criteria in recognising sepsis	5,6
Quick sequential organ failure assessment (qSOFA)	A bedside prompt called QSOFA may help identify patients with suspected infections who are more likely to have a worse outcome outside an intensive care unit (ICU). It assesses three components. • respiratory rate ≥ 22 breaths/min, • altered mental status, or • systolic blood pressure (SBP) ≤ 100 mm Hg. A qSOFA score ≥ 2 is suggestive of sepsis.	7,9,12,13,14,15
qSOFA + lactate	Combination of qSOFA and lactate to identify sepsis	16
Sequential Organ Failure Assessment (SOFA)	The Sequential Organ Failure Assessment (SOFA) score is a grading system that evaluates the function of numerous organ systems in the body (neurologic, blood, liver, kidney, and blood pressure/hemodynamic) and gives each system a grade based on the information gathered in that category.	4,8,10,12,14,16,17,20

Tools	Description	Study Number
Clinical signs of infection+ Organ Failure assessment	Clinical signs of infection (CSI): • temperature >38.5°C or <36°C • chills • heart rate >90 beats per minute • respiratory rate >20 breaths/min • systolic blood pressure <90 mm Hg • or mean arterial pressure (MAP) b65 mm Hg; • headache with neck stiffness - Expanded CSI (ECSI): the initial CSI, including clinically detectable signs of organ dysfunction: acute encephalopathy (drowsiness, disorientation, confusion, or coma); systolic blood pressure <90 mm Hg or MAP <65mm Hg; oliguria; or the need for oxygen supplementation. - Signs of organ dysfunction (SOD): acute encephalopathy, systolic blood pressure <90 mm Hg or MAP <65 mm Hg; peripheral oxygen saturation <90%; creatinine >2.0 mg/dL or hourly urine output <0.5 mL/kg for >2 hours; bilirubin >2 mg/dL; platelet count <100 000 mm3; or serum lactate >2 mmol/L.	1
Early warning scoring System (EWS)	Use of physiological parameters that is more practical in LMICs	11,22

3.6.3 RQ3: The components of interventions in the sepsis bundle used in emergency departments in LMICs

In all papers the sepsis interventions included some or all of the following components: blood culture sampling before administration of broad-spectrum antibiotics, broad-spectrum antibiotics and intravenous fluids administration, oxygen and vasopressors and vital signs monitoring with or without lactate check. Some of the contextual adaptations to the original SSC guidelines made, included adding malaria, tuberculosis (TB) and HIV tests (Papali et al., 2015; Westphal et al., 2011) as the prevalence of these in LMICs is high and without differential diagnosis, might impact the accuracy of diagnosis and subsequent patient management. For example, because the presentation of malaria is similar to that of sepsis with a raised temperature and body weakness, it is imperative to check for these. This allows delivery of malaria specific medications. However, because malaria is more common, this might obscure clinicians in thinking sepsis. Sepsis may be overlooked as a potential diagnosis due to malaria being more likely. These interventions are illustrated in Table 7.

Table 7: Components of sepsis bundle interventions

	Lactate checked	Blood culture	Antibiotic	Intravenous fluids	Vasopressor inotrope	Oxygen	Additional(supportive) components
Westphal et al. (2011)	√	√	√	√	√	√	Low-dose corticosteroids, c reactive protein and glucose maintenance
Na S et al., (2012)	√	√	√	√	√	√	Blood transfusion
Noritomi et al., (2014)	√	√	√	√	√	√	
El Khuri et al., (2015)	√	√	√	√	√	√	Steroids
Rudd et al., (2019)		√	√	√	√	√	
Machado et al., (2017)	√	√	√	√	√	√	
Andrews et al., (2014)		√	√	√	√	√	Blood transfusion, HIV tests, malaria, TB
Urayeneza et al., (2018)			√	√	√	√	Surgical source control in needed cases, glucose check
Nates et al., (2020)	√	√	√	√	√	√	
Machado et al., (2017)	√	√	√	√	√	√	
Papali et al., (2015)	√		√	√	√	√	Chest X-ray, HIV tests, malaria

	Lactate checked	Blood culture	Antibiotic	Intravenous fluids	Vasopressor inotrope	Oxygen	Additional(supportive) components
Arie et al., (2019)	√	√	√	√	√	√	Blood glucose control, steroid
Castano et al., (2019)	√	√	√				
Aluisio et al., (2018)			√	√	√	√	HIV tests
Sinto et al., (2020)	√	√					
Akbar et al., (2017)	√		√		√		Steroid administration
Nqobile & Maharaj (2019)		√	√	√			
Dagher et al., (2015)	√	√	√	√	√	√	Steroid
Malhotra et al., (2021)		√	√				

3.6.4 RQ 4,5,6: Timelines, impact and effectiveness of sepsis interventions used in LMICs

The range of timelines used in the studies was 1-24 hours. Identifying sepsis after six hours did not achieve any significant effect on patient's outcomes, however, the studies using the 1-6 hours had improvements in the care and outcomes of patients. The earlier sepsis was identified (within an hour), the better for interventions to be initiated to improve outcomes. The sepsis bundle intervention used by 5/22 papers (Arie et al., 2019; Kassyap et al, 2018; Na et al., (2012); Rudd et al., 2019; Urayeneza et al., 2018) was SSC three (3) hours; all elements to be completed within three (3) hours of recognition. The 6 hour bundle where interventions were carried out within 6 hours was reported in 12/22 (Andrews et al., 2014; Arie et al., 2019; Castaño et al., 2019; El Khuri et al., 2019; Kassyap et al., 2018; Machado et al., 2017a, Machado et al., 2017b ; Na et al., 2012; Nates et al., 2020; Noritomi et al., 2014; Urayeneza et al., 2018; Westphal et al., 2011). Only 1/22 of the studies reported using the 1-hour bundle in their interventions (Malhotra et al., 2021).

There was a statistically significant reduction in mortality rate in half of the papers even though different timelines were utilised in the implementation (Arie et al., 2019; El Khuri et al., 2019b; Machado et al., 2017b; Na et al., 2012a; Nates et al., 2020; Urayeneza et al., 2018; Westphal et al., 2011b) (see Table 8).

Table 8: Timelines, impact and effectiveness of sepsis interventions

Author/ Publication year	One hour	Three hours	Six hours	Twelve hours	Twenty-four hours	length of stay in the hospital	Compliance with the bundle	Reduced mortality	Increase mortality	EGDT	IMAI	Time taken to identify sepsis
Westphal et al., (2011)			√		√	↓	↑	√				↓
Na et al., (2012)		√	√			↓	↑	√				
El Khuri et al., (2015)			√			↑		√		√		
Rudd et al., (2019)		√				↓		√				
Machado et al., (2017)			√			↓	↑	√				
Andrews et al., (2014)			√						√			
Urayeneza et al., (2018)		√	√			↓		√				
Noritomi et al., (2014)			√				↑	√				
Nates et al., (2020)		√	√				↓	√				
Machado et al., (2017)			√				↑	√				↓
Papali et al., (2015)											√	
Arie et al., (2019)		√	√				↑	↔				
Machado et al., (2020)								↔				

Author/ Publication year	One hour	Three hours	Six hours	Twelve hours	Twenty-four hours	length of stay in the hospital	Compliance with the bundle	Reduced mortality	Increase mortality	EGDT	IMAI	Time taken to identify sepsis
Sinto et al., (2020)				√				↔				
Akbar et al., (2017)			√									
Kassyap et al., (2018)		√	√									
Castano et al., (2019)			√			↑		√				
Gilbert et al., (2015)								√				
Malhotra et al., (2021)	√						↑	√				↓

Symbol definition - √ (was used) ↑ (increased), ↓ (decreased), ↔ (same or not reported)

Compliance with the sepsis bundle and the time taken to complete the components of the intervention improved as staff gained adequate knowledge and awareness (Arie et al., 2019; Castaño et al., 2019; Machado et al., 2017a; Machado et al., 2017b; Na et al., 2012; Noritomi et al., 2014). ED length of stay was reported as extended in one of the studies, which was attributed to the non-availability of ICU beds, even though patients needed ICU care (El Khuri et al., 2019). However, one study (Rudd et al., 2019a) reported a thirty (30) minutes ED length of stay, which aided in improving the flow and decision-making to either discharge, admission or ward transfer. Even though the ED stay was less than an hour to transfer to the ward or discharge, 63% patients had blood cultures (n=2,032) taken and 67% had antibiotics prescribed (n=2,160) prior to ward transfer in the same study (Rudd et al., 2019a). In this case, the final decision to transfer the patient to the general wards, ICU, or be discharged home was made as re-evaluation was expedited.

3.6.5 RQ7&8 The facilitators, barriers and roles to sepsis pathway/bundle management in emergency departments in LMICs

Barriers and facilitators that contributed to the successful implementation of sepsis interventions were reported in 21/22 of the papers, classified into structural, contextual or knowledge (Thompson, 2018) (see Table 9). To create processes to facilitate ownership of the intervention, institutions were tasked with creating local teams who designed the sepsis protocol and assigned clinical champions to oversee and ensure that healthcare professionals comply with the intervention (Andrews et al., 2014; El Khuri et al., 2019; Machado et al., 2020; Na et al, 2012; Papali et al., 2015 Sinto et al., 2020; Westphal et al., 2011). This helped increase familiarity with and use of protocols, leading to increased compliance with implementation of the sepsis bundle and ultimately improved quality of care for patients. Similar

approaches such as training nursing technicians who are not registered nurses, to identify sepsis was adopted (Na et al., 2012). Several barriers were encountered including resistance to organisational change, overcrowding of EDs and shortage of staff, as described in Table 9.

Table 9: Enablers, barriers and roles of individual healthcare professionals in Sepsis Management

	Barriers	Facilitators
Structural	Availability of resources (10), lack/shortage of staff (2,10,5), overcrowding of EDs, inadequate process of care (10) shortage of ICU beds (8), unfavourable nurse to bed ratio (8,10), delay in triage (11,12) poor sampling techniques 10, physician diagnosis 9, organisational resistance to change 1,	Establishing of case managers and local clinical champions, and sepsis teams (2,5), bundle completion checklists2,10, audit and feedback 8,10, availability of resources 2, 3, 5, antibiotic stewardship (3). full involvement of local staff 17, bedside cards and reminders (2).
Contextual	Delay in arriving in ED, having to pay before blood workout (1) and low compliance to the sepsis bundle (1,5). Also, staff resistance to following guidelines, negative perceptions of the process, organisational resistance to change and the inability to prioritise patients in hospitals with sepsis (1.8).	Time taken to complete interventions (1), compliance with the bundle (5,12), short duration between symptoms and presentation to the hospital (7),
Knowledge	Inadequate knowledge of staff (1), Negative perception of the process (1), Inadequate training (1,9), Socio-economic conditions (2), delayed sepsis recognition 5, discharge against medical advice (4), oversimplification of inclusion criteria (5), low sepsis awareness among lay people (10), lack of good workflow 6, delayed arrival to the ED (6,10)	Training of medical and nursing staff (1,7,8), increased disease awareness (5,10), early recognition/screening tools for triage (5, 10,11,18).
Role of healthcare professionals		Nursing technicians trained to identify sepsis (1), participating centres going through educational sessions (2, 8,9,10, 11,15,16). Research nurses and assistants screening all patients (4,6,7,13,22).

Note: Numbered from the study characteristics

3.7.0 Discussion

3.7.1 RQ1&2 Processes and screening tools used for sepsis

Accurate and timely sepsis patient identification is essential to improve outcomes through more focused clinical treatment (Salameh and Aboamash, 2022). The SSC bundle was used in 21 studies, with or without lactate estimation and blood culture. This approach is consistent with sepsis studies conducted in both developing and developed countries (Cardoso et al., 2010; De Miguel-Yanes et al., 2009; Grek et al., 2017; Liu et al., 2016; Milano et al., 2018), where the SSC bundle is frequently used for sepsis identification while considering the context.

Screening tools that can identify sepsis and used easily by health care professionals are core to successfully recognising and implementing any sepsis intervention (Kestler et al., 2013, Evans et al., 2021). While similar processes were used across all the papers reviewed to identify sepsis, different screening tools were used, such as EWS, the SIRS criteria, SOFA, and qSOFA, sometimes alone or in combination. This aided prompt identification and implementation of appropriate interventions in a timely manner.

Tools that do not require laboratory testing from onset, such as the qSOFA or EWS were used possibly to drive interventions prior to laboratory testing due to limited resources and in some areas costs (Kassyap et al., 2018, Urayaneza et al., 2018). These limitations prevent the use of inappropriate complex tools in identifying sepsis from a patient's initial presentation, especially where urgent interventions are needed in LMICs. Hence, the need to consider physiological parameters and easily accessible tools in situations where laboratory tests could delay identification and

subsequently implementing interventions (Abdu et al., 2018; Bataar et al., 2010; Taniguchi et al., 2019).

In using the qSOFA tool for sepsis recognition, a score of two or greater has been used as the baseline however, it is argued that a qSOFA score of one is an indication of further deterioration, if monitoring and interventions are not initiated (Rudd et al., 2018). Consequently, further assessment and immediate interventions are needed, even if one qSOFA parameter is present. Sinto et al. (2020) recommend a combination of qSOFA and lactate estimations (preferably point of care testing if available, as it takes seconds to generate a result). This could serve as an effective and possibly more affordable combination approach for identifying sepsis for initiating interventions in LMICs (Rodriguez et al., 2018; Sinto et al., 2020; Ueno et al., 2021). Moreover, this supports the SSC guidance, which recommends the use of 'one or more tools in recognising sepsis' and the usage of simple physiological assessments in contexts where laboratory testing is unavailable or less consistently available (Evans et al., 2021). In standardising sepsis screening in LMICs, Keeley and Nsutebu (2021) assert the need to educate HCPs to bridge knowledge gaps of all staff regarding sepsis recognition and care, especially when there is no single accepted standard for diagnosing or identifying sepsis.

3.7.2 RQ3&4 Component and Timelines of interventions

The components of the SSC bundle include: drawing samples for lactate and blood culture; administering antibiotics after collection of blood samples; administering fluids when hypotensive; giving vasopressors or inotropes when there is fluid refractive shock while aiming for 92% or above oxygen saturation with close

monitoring (Evans et al., 2021). Even though this is the recommendation from SSC (Evans et al., 2021), this review identified contextual adaptations made, due to the limited availability of resources. Adaptations to the bundle such as including tests for malaria, tuberculosis and HIV, occur commonly in LMICs (Andrews et al., 2014; Urayeneza et al., 2018; Papali et al., 2015; Westphal et al., 2011). Moreover, due to resource constraints, lactate estimation or blood culture was not included in some of the papers (Malhoutra et al., 2021, Andrews et al., 2014, Urayeneza et al., 2018). This indicates the importance of contextualising the bundle to local populations.

Only one paper (Papali, 2015) used the WHO IMAI for identification and initiation of sepsis interventions. While the WHO's IMAI has been recommended for use in African countries (Keeley and Nsutebu, 2021), this does not specify timelines for interventions other than antibiotic administration; hence healthcare professionals may use professional discretion. This is not the case for the SSC bundle, where all interventions are time specific (Evans et al., 2021). Hence, regardless of the type of intervention, utilising a time sensitive parameter for all SSC components is imperative to expedite recognition and management of patients with sepsis. This is crucial for avoiding delayed intervention and resultant mortality (Evans et al., 2021)

3.7.2.0 Timelines for Sepsis Interventions

This review also found that performance timelines are essential to any successful sepsis bundled intervention. The SSC updated guidelines (Evans et al., 2021) recommend that all initial interventions be carried out within an hour, and ongoing patient monitoring undertaken. Adopting the one-hour bundle however could produce timely initiation of interventions (Malhoutra et al., 2021, Hu et al., 2020), thereby

detecting deterioration more speedily to enhance resuscitation measures to be instituted (Coba, 2010; Bruce et al., 2015; Gatewood et al., 2015). Conversely, some emergency doctors (Kalantari and Rezaie, 2019) have argued that the one-hour bundle should start at time zero, when a doctor assesses the patient in the ED making the diagnosis, not when the patient arrives in ED.

However, in the absence of a timeline for the touchpoints in the care of a patient with sepsis in LMICs, prior to the doctor's assessment, it would probably take longer to recognise and initiate interventions as few doctors take care of a high number of ED patients, which could be detrimental to the patient's health. Hence, adopting the one-hour bundle could produce timely initiation of interventions, speedy detection of deterioration and initiation of resuscitation measures. Timelines for interventions such as antibiotic administration, fluid resuscitation, blood culture and lactate estimation are discussed below:

Antibiotics

Timelines related to initiating some of the components of the sepsis bundle, such as the administration of antibiotics and fluids exceeded twelve hours, in some cases.

This was attributed to nursing staff shortages and a low nurse-to-patient ratio. Similar findings have been reported in LMICs in general (Carlbom and Rubenfeld, 2007; Mattison et al., 2016). This would suggest the necessity to utilise the one-hour bundle as a component of any interventions. Despite this Castano et al. (2019) argue that the delay of antibiotics does not affect the mortality rate in sepsis, however, other studies report every hour of delay (odds ratio of 0.04) decreasing the chances of survival (Cullen et al., 2013; Seymour et al., 2017; Vilella and Seifert, 2014). In most of the papers, antibiotics were administered within an hour, which may explain

reduced mortality rates in the absence of lactate estimation and pre-antibiotic administration before blood cultures.

Fluid resuscitation

Fluid resuscitation is one of the components of sepsis intervention (Brown and Semler, 2019), which most papers in this review reported managing successfully. However, one paper from Zambia (Andrews et al., 2014) was more cautious, arguing that careful assessment of patients must be in place before aggressive fluid resuscitation commences. These authors argued that assuming tissue hypoperfusion in all cases of organ dysfunction may not be suitable. For example, in unventilated patients, especially those with moderate to severe respiratory problems, administering IV fluid boluses needs to be done with caution to prevent compounding any respiratory problems. This indicates the importance of differential diagnosis and indications for administering IV fluids (Andrews et al., 2014). The updated SSC guideline recommends the administration of IV fluid boluses to those patients with a systolic blood pressure of less than 90mmhg (hypotension). Moreover, in instances where excessive fluid administration could compound the patient's condition, correction by other means, such as administering vasopressors/inotropes should be considered (Westphal 2011; Na et al., 2012; Brown and Semler, 2019; Hariyanto et al., 2017).

Blood culture and lactate estimation

The availability, sustainability and consistency of laboratory tests such as lactate may be poor in LMICs (Vukoja et al., 2014) or, even if accessible, the results might take time before they can be reported to clinicians. This review identified papers where blood cultures and lactate were available to assist in diagnosis (see Table 8).

In those studies where lactate estimations were available, interventions were put in place to reverse deterioration more speedily once abnormalities were reported (see Table 8). Lactate estimations also facilitated patient reassessment and determined their final disposition (e.g. ICU or general wards). Point-of-care lactate checks have the benefits of speed and accuracy to drive prompt interventions in sepsis (Baig et al., 2017; Gaieski et al., 2013; Singer et al., 2014). However, these tests might not be available in most cases in LMICs. Financial constraints and lack of resources in LMICs are undoubtedly significant barriers to sepsis bundle, including investigations such as point of care testing (Baelani et al., 2011). Even though some LMICs have access to health insurance schemes, these may not include costs for every investigation.

Patients may have to make payments before investigations such as blood cultures or lactates are taken. In other situations, they may not be available on-site, so patients must access these through private laboratories where pre-payment is required before the investigation is conducted, further delaying diagnosis. Similar findings have been reported in many LMICs (Abdu et al., 2018; Baker et al., 2013). Prioritising adult sepsis as a health service priority by governments in LMICs could help channel finances and resources, making engagement with policy makers key to successful SSC implementation.

3.7.3 RQ 5,6 Effectiveness and impact of sepsis interventions

This review identified that the effectiveness of any sepsis intervention could be measured in various ways such as compliance, ED length of stay, time to implement the component parts of the bundle and mortality rate. Most of the papers reviewed

reported a decline in mortality, only one otherwise (Andrews et al., 2014). Increased mortality in the paper was associated with administering IV fluids to all patients,

without considering comorbidities or any differential diagnosis. This highlights the importance of assessing contextual considerations carefully before implementing evidence-based interventions in different contexts.

ED length of stay was reported as unnecessarily prolonged in most papers in this review. Even though this depends on several issues, this was attributed to the lack of availability of beds in the ICU. Consequently, problems with the transfer of patients caused an increased length of stay in ED. However, being able to identify sepsis as early as possible and initiating interventions within an hour could aid re-triaging to the wards instead of the ICU to ease ED congestion (Rudd, 2018). Adverse patient outcomes and reduced quality of care have been associated with ED overcrowding (Hoot and Aronsky, 2008), hence the need for further investigation. One paper which reported ED length of stay as 30 minutes, where all sepsis interventions were carried out before transfer from ED, enhanced patient flows in and out of ED. Effective management of the flow of ED patients may help reduce sepsis-related deaths and should be considered when introducing and evaluating improvements such as sepsis bundles (Benjamin and Wolf, 2022). Easing congestion in the ED is a priority globally as it enhances prompt identification and implementation of sepsis interventions; likewise, ongoing surveillance of patients to monitor deterioration.

3.7.4 RQ 7&8 Barriers, facilitators and roles to identifying and managing sepsis

Facilitators to identifying and managing sepsis

The education and training of clinicians (irrespective of profession) regarding the sepsis bundle, assigning individual roles and delegation of responsibility are

essential (Na et al., 2012). Educating and training clinicians increases knowledge acquisition which may contribute to clinician behaviour or attitudinal change in doing things differently, including regular refresher training (Machado et al., 2017a). Considering the education of HCPs before implementing an intervention is paramount (Arie et al., 2019; Machado et al., 2017a, b). Even though sustainable change is unlikely to occur based on education alone, involving clinicians in implementing change such as the SSC bundle, allows barriers to implementation to be identified and strategies to avoid them surfacing. Ultimately this will ensure any changes are owned by those responsible for delivery (Grill, 2021; Machado et al., 2017a).

Local teams' involvement in developing any bundle implementation plan, such as developing a checklist, institutional protocols, algorithms, or screening tools, appears to facilitate the adoption of sepsis interventions (Kassyap et al., 2018; Machado et al., 2017b; Na et al., 2012; Nates et al., 2020; Noritomi et al., 2014; Urayeneza et al., 2018). Introducing any new model of care into a clinical setting should involve those responsible for facilitating its adoption, such as establishing committees, teams or 'sepsis champions' in the local context (Machado et al., 2017a). This enables the smooth roll out and sustainability of sepsis interventions, as they can spearhead the intervention (Machado et al., 2017a; Malhotra et al., 2021).

Barriers to sepsis identification and care

A barrier in some LMICs is the patient's ability to pay in advance for specific elements of the bundle such as payment for specific tests (Kassyap et al., 2018) and antibiotics (Kassyap et al., 2018). If a patient cannot pay for specific bundle parts, care may cease, which will delay clinical decision making and care. Another was the

shortage of health care staff, such as nurses or medical staff, coupled with inadequate sepsis knowledge, which consequently needs to be addressed before any bundle of care is introduced (Machado et al., 2017b). Consequently, HCPs require training in identifying sepsis, including interpreting clinical parameters. However, introducing change and adopting new systems can also bring challenges where individuals are expected to increase their knowledge and essentially change patterns of behaviours. Likewise, ensuring all clinicians have the most updated approach for inducting new staff can also motivate and encourage them to comply with interventions that have been instituted.

Nurse-led interventions have much potential to improve the quality of care (Çolak and Vural, 2022; Tonapa et al., 2022; New et al., 2003, Bruce et al., 2015). Even though it is usual practice in some LMICs for attending physicians to make a working diagnosis of sepsis before initiating interventions, this could be expedited by a triage recognition, and doctors prompted for interventions. This is because a nurse-led approach to sepsis identification could accelerate the implementation of interventions as early as possible to improve care.

3.8 Summary

The evidence examined in this review identified that with local adaptation, the SSC campaign guidelines could be successfully adopted in LMICs, either with or without lactate estimation. In addition, when following this protocol, comorbidities and differential diagnosis need to be considered. Working with the local team and constant training and education also facilitated the success of these interventions while eliminating barriers, such as delay in triage and staff resistance to following guidelines. Recognition of sepsis can be achieved using any of the tools used in this

review. As some tools, such as qSOFA and EWS, do not involve laboratory testing to calculate a warning score, they should be considered in any low-resource bundle.

With this in mind, understanding the current practices regarding sepsis identification and care is important to identifying any barriers and facilitators. This would then give scope to adopt the SSC bundle used in these studies, which are closely linked to the Ghanaian context.

This review is limited by the number of ED studies (n=13) and the rest from a combination of ED and other departments; therefore, findings should be generalised cautiously. The review has also raised many questions which need further investigation. Among them is the differences in screening tools, their use, reliability, and validity in detecting sepsis in LMICs, while engaging with the local team. Also, this review has made a pointer for me to understand resources in EDs which help in a context specific bundle adaptation, however, this needs to be explored further.

The next chapter will discuss the methodology and methods, used in this doctoral endeavour, including the philosophical and methodological underpinnings.

CHAPTER FOUR

METHODOLOGY

4.0 Introduction

This chapter will discuss how theories relating to behaviour and organisational change inform the epistemological and methodological approaches employed in this doctoral endeavour. This doctoral endeavour's philosophy, pragmatism, which is the underpinning epistemological backing has been discussed. Theoretical frameworks (capability, opportunity motivation of behaviour (COM-B) and Kotter's eight step organisational change theory) have also been explored including the methodological approach used in this study (convergent mixed methods design and the medical research council (MRC) framework) – Figure 6.

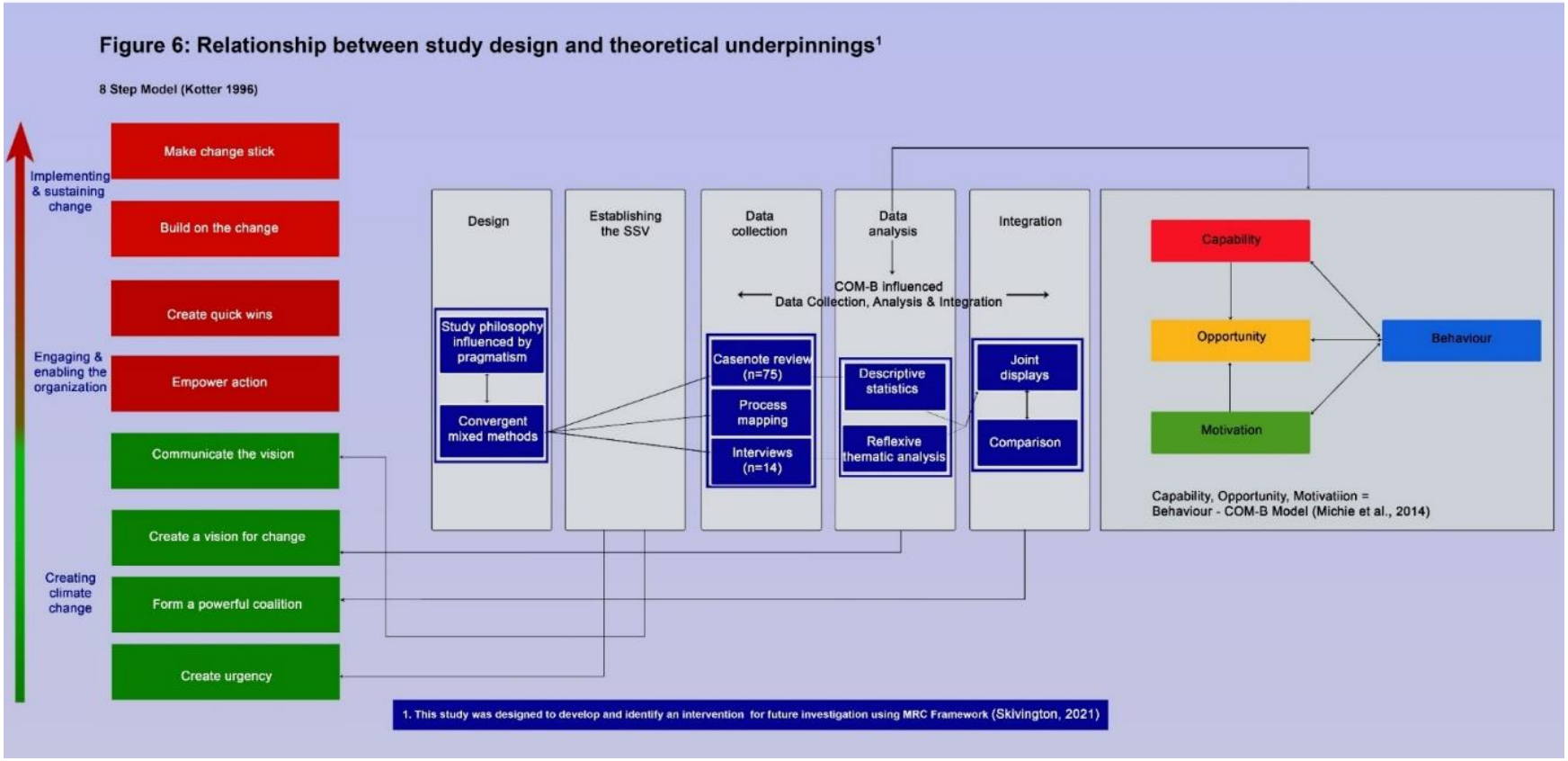

Figure 6: Relationship between study design and theoretical underpinnings

4.1.0 Research Philosophy

Undertaking credible research is contingent upon a cohesive set of assumptions. Consequently, when formulating a research philosophy, it is essential to carefully consider individual perspectives and assumptions in relation to prominent philosophies and research design. This approach facilitates a productive research endeavour (Saunders et al., 2023). While ontological assumptions refer to the underlying beliefs about the nature of reality that researchers encounter, epistemology pertains to the assumptions made by individuals regarding what can be understood and how knowledge can be acquired (LeBlanc, 2010). Epistemology and ontology significantly impact upon how researchers articulate their view of the world and their influence on their research inquiry, the methodologies and the manner in which findings are interpreted (Crotty, 1998). Several paradigms can be used to structure and organise research (Feilzer, 2010), however, the ontological underpinning for this research is pragmatism.

From an epistemological standpoint, pragmatism is founded on the notion that research has the capacity to direct its attention to developing practical understandings of tangible, real-world matters (Patton, 2002), rather than engaging in abstract discussions concerning the essence of truth and reality. Pragmatic inquiry acknowledges that individuals within social contexts, such as organisations, may perceive and respond to action and change in diverse ways. Consequently, this perspective encourages researchers to adopt flexible (malleable) research approaches (Onwuegbuzie and Leech, 2005). Patton (2002) argues that this aligns with interpretivist perspectives that prioritise qualitative research and the recognition of socially constructed realities. Whereas Morgan (2014) sees the primary focus of

research as the critical examination of the significance and implications of the findings to produce practical outcomes. This is particularly advantageous in organisational contexts where practice is intricately interconnected with processes, structures and in the case of healthcare, different members of the multidisciplinary team (MDT) working individually and collectively (Kelly and Cordeiro, 2020).

4.2.0 Pragmatism

The philosophical underpinnings of pragmatism can be traced back to the contributions of notable figures such as William James (1842-1910) and John Dewey (1859-1952) (Tashakkori et al., 2005). The term 'pragmatic' is commonly associated with the pursuit of practical and viable resolutions to intricate human issues (Long et al., 2018). The inception of this philosophical movement can be attributed to the researchers' shared rejection of conventional assumptions pertaining to the essence of reality, knowledge, and the process of inquiry (Kelly and Cordeiro, 2020). That is refuting the concept of social science inquiry and accessing reality through the use of a singular scientific technique. The pragmatist approach does not align itself with any single methodology, rather, it accommodates the use of the appropriate methods that allows a comprehensive understanding of the phenomena under investigation (Shaw et al., 2010). This facilitates the acquisition of unique insights and perspectives that would otherwise remain inaccessible, if a single method is used. Kelly and Cordeiro (2020) further classify pragmatism in three principles, namely prioritisation of actionable knowledge, acknowledgement of the interdependence of experience, knowing, acting, and the understanding of inquiry as an experienced process. These three principles guided this doctoral endeavour, especially in the choice of theories as explained below.

A fundamental principle in pragmatic inquiry posits that all research should originate from a motivation to generate knowledge that is practical and can be put into action (Kelly and Cordeiro, 2020). This includes addressing real-life problems and resolving situations, based on an analysis of effective patterns of behaviour (Feilzer, 2010). By ensuring that real life problems are acted upon in this doctoral study, the capability, opportunity, and motivation of behaviour (COM-B) model developed by Michie et al. (2014) was used to ascertain current behaviours pertaining to sepsis identification and management, including barriers and facilitators to effective care. This facilitated the design of strategies aimed at enhancing the provision of care. By placing a strong emphasis on the notion of actionable knowledge as a foundational element for this research, it was ensured that this research maintains practical relevance to the specific context. The COM-B framework has been employed throughout data collection, analysis and reported in chapters 8 and 9 to ascertain significant behaviours and delineate the obstacles and facilitators to the recognition and management of sepsis. By doing so, it may be possible to prompt individuals to engage in alternative behaviours.

One additional element that enhances the efficacy of a pragmatic inquiry process is the opportunity to investigate the interrelatedness of experience, knowledge acquisition, and action within the context of the research, such as within the organisation under study (Kelly and Cordeiro, 2020). Through the pursuit of enhanced understanding pertaining to the organisational procedures being examined, pragmatic researchers are capable of unveiling intricate patterns and concerns that may have been concealed (Long et al., 2018). Given this, Kotter's theory of organisational change was selected as the framework for examining the organisational processes, challenges and the imperative for change in the entire

study and detailed in Chapter 9 (Appelbaum et al., 2012). Triangulation was further employed in Chapter 8, which involves comparing and contrasting the information provided by respondents with what can be observed or evaluated. Pragmatism is thus deemed more appropriate than alternative philosophical frameworks for investigating the "inner world" of organisational processes due to its emphasis on experiential knowledge and its encouragement of researchers to analyse organisational practises through both experience and action (Kelly and Cordeiro, 2020). Despite occasional criticism for placing excessive emphasis on practicality, pragmatist researchers are able to transcend the gap between theory and practice (McKenna et al., 2011). By placing a strong emphasis on the concept of actionable knowledge throughout this research process, I was able to comprehensively explore the interplay between information acquisition, practical application, and experiential outcomes within an organisational context.

The third philosophical perspective of pragmatism according to Kelly and Coidero, (2020) is influenced by the concept of inquiry proposed by John Dewey, wherein beliefs and actions are connected through a deliberative process of decision-making (Morgan, 2014). Dewey (2021) posits that all conscious human actions necessitate a degree of inquiry or assessment as a response to a difficulty or hindrance. This inquiry or assessment is then accompanied by adaptation and modified behaviour in reaction to the situation. Even though Dewey's idea blurs the distinction between everyday life and research (Morgan, 2014), Dewey perceives research as a mode of investigation that is executed with greater precision and heightened self-awareness compared to other human reactions to challenging circumstances in the external world (Dewey, 2021). The incorporation of research into practical, everyday contexts renders classical pragmatism pertinent to practitioners. Furthermore, it tackles a

significant obstacle encountered in the field of organisational research: namely the need for researchers to cultivate a comprehensive understanding of intricate organisational processes (Lorino et al., 2011). In light of this, the Medical Research Council (MRC) framework for designing and evaluating complex interventions was used to develop and assess intricate procedures, placing significant emphasis on intervention design and core elements such as contextual factors and stakeholder engagement (Skivington et al., 2021a).

The MRC framework, Kotter's organisational change and the COM-B, drawing on the study design have facilitated an enhanced comprehension of macro- and micro-level viewpoints within the organisation under study, fostering a more comprehensive research approach that incorporates diverse stakeholders and enables them to contextualise their actions within a broader framework. The selection of pragmatism as the primary philosophical framework for this doctoral study was motivated by a strong inclination to generate valuable and applicable insights derived from the perspectives of respondents and analysis of case notes. This choice was made with the intention of providing practical significance to the identification and implementation of sepsis interventions.

4.3.0 Theoretical framework underpinning this research

There is substantial evidence suggesting that interventions that are grounded in comprehensive psychological theories are more likely to be successful in changing behaviour compared to interventions that lack theoretical underpinning (Hobbs et al., 2013, Michie et al., 2014). The aforementioned incites discussions over the efficacy of previous psychological models, theories, and frameworks in treatments targeting health behaviour. Michie et al., (2014) assert that commonly utilised psychological

models such as the health behaviour model (Jones et al., 2015) and the transtheoretical model (Prochasker and Velicer, 1997), may not encompass the full range of potential influences. Consequently, these models may inadvertently overlook crucial behaviours and fail to adequately address important factors such as impulsivity, disposition, emotional processing, willpower, and associative learning (Michie, 2014). Hence, it may be advantageous to employ contemporary integrative comprehensive models such as the COM-B framework that do not possess these restrictions. Considering these pros and cons, the COM-B model was chosen for a more comprehensive assessment of behaviours regarding sepsis recognition and care.

4.3.1 The capability, opportunity, motivation of behaviour (COM-B) model

The COM-B model of behaviour change proposes there are three components to any behaviour (Michie, 2014). That is capability, opportunity and motivation.

Capability refers to whether an individual has the knowledge and the requisite skills, required to perform a set behaviour. Capability can be classified into two distinct categories: physical capability, which refers to the possession of physical strength, skills, or energy needed to engage in a form of action; and psychological capability, which pertains to the possession of qualities such as awareness and skills necessary to engage in the same behaviour (Michie, 2014).

Opportunity encompasses both social and physical dimensions. The social aspect pertains to the influence of social cues, cultural norms, and interpersonal factors. On the other hand, the physical aspect refers to the environmental conditions that allow

or facilitate certain actions, including triggers, resources, time availability, physical barriers, and specific places.

Motivation which is the internal processes influencing our decision making may be categorised into two distinct types: automatic and reflexive. Automatic motivation encompasses processes that are driven by desires, impulses, reflex responses, wants, and needs. On the other hand, reflexive motivation involves self-conscious planning and assessments, which are influenced by one's opinions of what is considered good or bad (Michie, 2014). Several layers of the human motivational systems such as the PRIME (plans, responses, impulses, motives and evaluations) Theory of Motivation are generated by the interplay between automatic and reflective motivation components (West, 2013).

These components interact through interconnecting, which indicates that enhancing skill or opportunity has the potential to bolster motivation. Heightened motivation can serve as a catalyst for individuals to engage in activities that can improve their skills or increase their chances of success by bringing about a change in their behaviour. For example, having a standard sepsis recognition tool (representing an opportunity) or the possession of the skill to identifying sepsis (representing a capability) may potentially enhance an individual's motivation to engage in tracking patients with sepsis. Nevertheless, the presence of motivation alone does not suffice to aid people in identifying sepsis, unless the individual takes action by either taking a closer look at a sepsis protocol and engaging in constant refresher training on the tool to enable them become familiar (Michie, 2014).The COM-B model has been commonly used in healthcare to assess and determine behaviours and its application can lead to strategies which could potentially assist in change (Michie, 2014). These three components of COM-B interact with one another over time, making it possible to

view behaviour as a component of a dynamic system that contains both positive and negative feedback loops.

To perform a specific behaviour, there should be a psychological and physical capability (C), have the social and physical opportunity (O), and want or need to do so more than other competing behaviours (M) (Michie, 2014). Rather than the behaviour itself, capability and opportunity are demonstrated to have an impact on the link between motivation and behaviour. This illustrates the notion that, on a personal and moment-by-moment basis, they function as "logic gates," with both the "gates" (capacity and opportunity) having to be open in order for motivation to generate the behaviour (Michie, 2014). When considering capability and opportunity collectively over time and individuals, they can be conceived in terms of numbers: the more frequently the 'gates' open when the motivation is present, the more likely it is that a behaviour will occur.

A person's motivation to engage in a behaviour is frequently influenced by both capability and opportunity. An environment needs to be made conducive to execute a behaviour (Chauhan et al., 2017), as a less motivated one could be challenging.

Studies using the COM-B to develop interventions have seen much success with implementation (Costello et al., 2018; Irwin et al., 2022; Lohiniva et al., 2021). Given this, identifying the capability and available opportunities in place, that could be a motivation is paramount to developing a context specific solution (Michie et al., 2011b; Rothrock et al., 2020; Steinmo et al., 2016), as employed in this study. The COM-B model is part of a larger behaviour change wheel (BCW) (Michie, 2014) designed to assist intervention designers in moving from a behavioural analysis of a problem to an intervention (Michie et al., 2013). In so doing, identifying potential

intervention functions that could result in a systematic and transparent change. This was adopted in chapters 6,7, 8 and 9 of this study, where possible intervention functions were identified. Hence, specific behaviour change techniques that are most likely to be effective were adopted. Table 27 in Chapter 9 illustrates the overall COM-B application in this study. The thorough comprehension of the target behaviour through the allocation of time and effort is an essential yet often overlooked phase in the design of interventions. According to Michie et al., (2014), the more the precision in examining the targeted conduct, the higher the probability that the intervention would successfully modify the behaviour as intended. This stage holds significant importance since behaviour change strategies may be ineffectual due to erroneous assumptions made regarding the elements that necessitate modification (Michie, 2014). The COM-B model was therefore complemented with Kotter's organisational change model and the MRC framework, as discussed earlier, to inform a thorough assessment of sepsis recognition and care. These are explored further below:

4.3.2 Kotter's eight step organisational change theory

In his seminal work "Leading Change," published in 1996, John Kotter, a distinguished professor at Harvard Business School and an esteemed authority on organisational transformation, presented the 8-Step Change Model. This model was established after an extensive study of 100 organisations undergoing transformative processes and consists of eight distinct steps (Pollack and Pollack, 2015, Newcomb, 2008). These steps encompass the following actions: generating a sense of urgency; establishing influential guiding coalitions; formulating a vision and strategy; effectively communicating the vision; eliminating barriers and empowering

employees to take action; achieving short-term successes; solidifying progress; and fortifying change by embedding it within the organisational culture.

Kotter’s change model is predicated on the notion that the majority of significant change projects, regardless of their purpose to enhance quality or transform culture, provide only mediocre outcomes and sometimes lead to resounding failures (Harrison et al., 2021). Kotter (2007) argues that a significant number of leaders overlook the fact that transformation should be viewed as a gradual process rather than a singular occurrence. This oversight is often driven by the desire to accelerate the pace of change, resulting in leaders bypassing essential milestones in the transformation process. Kotter's 8-Step Change Model (initial 4 steps) was therefore predominantly employed in this PhD while considering change within the organisation’s practices, to prevent overlooking any processes of care.

This model was selected over other models, such as Lewin's 3-Stage Model of Change, or Kornacki's model (Harrison et al., 2021), based on its effectiveness in facilitating change (Harrison et al., 2021). For example, nurse-led improvement initiatives conducted in emergency departments, utilising Kotter's 8-Step Change Model (Alonso, 2013, Bowers, 2011), have demonstrated positive outcomes. These projects reported successful implementation of change, as evidenced by a notable rise in fall assessments after the intervention (Bowers, 2011), as well as the integration of an enhanced triage system into regular practise (Alonso, 2013).

By establishing the existence of a problem (urgency) and the need for a change, Chapter 6 reviews case notes of 75 patients to ascertain how existing sepsis interventions have been implemented. Process mapping interviews and workshops are presented in Chapter 7, while Chapter 8 uses COM-B to integrate the two

datasets, ascertaining the capability, opportunity and motivation of sepsis care. In Chapter 9, the stakeholder team (SSVs) formed at the beginning of the project engaged in a critical analysis of the findings derived from the retrospective review of case notes and the process mapping exercise. This analysis aimed to establish a comprehensive vision that would facilitate the enhancement of sepsis recognition and care in the target ED.

4.4.0 Methodological Approach

When conducting research to comprehend a target behaviour(s), it is crucial to collect data from a wide range of suitable sources. This is because a comprehensive understanding of the phenomenon is typically derived from the integration of many perspectives (Michie et al., 2011a). It is widely recognised that researchers often lack a comprehensive grasp of the underlying motivations behind human action due to the use of single methods (Nisbett and Wilson, 1977). However, employing many sources of data to triangulate findings can enhance the overall comprehension of the behaviour under investigation. It is advisable for researchers, if possible, to collect data using a variety of methods, including direct observations, interviews, questionnaires, and the evaluation of relevant local materials, such as case notes, expert opinions and service protocols (Michie et al., 2011). On the other hand, it is important to consider that the characteristics of behaviours to be understood can limit the methodology used for data collection. For instance, to understand sepsis practices in a Ghanaian context, the use of observation techniques alone may not be practical (Michie et al., 2011b), as it may not illuminate the actual factors influencing decisions. Hence, to determine the necessary modifications for the identification and implementation of sepsis interventions, a convergent mixed methods approach was

used. A combination of a retrospective review of case notes and process mapping was employed to gain insight into the perspectives and attitudes regarding the factors influencing sepsis identification and management.

4.4.1 Research Design

4.4.1.0 Convergent mixed methods design

The primary objective of research is to enhance comprehension and interpretation of events by moving beyond mere descriptive examination. To achieve this, it may be necessary in order to expand what is currently known or understood through the collection, analysis and interpretation of various data. Mixed methods research refers to study designs that incorporate both qualitative and quantitative data collection and appropriate analysis methodologies, operating in either parallel or sequential phases (Teddie and Tashakkori 2010). Although multiple definitions are available in the literature, mixed methods research is often used where the research seeks to understand complexity inherent in contexts such as healthcare, or where multi-level perspectives are needed and the influences that shape them (Cresswell et al., 2010). Indeed, the choice of mixed methods might be a consequence of the way the philosophical or theoretical position of the research is framed, whereas multimethod research refers to the use of different methods or styles of research resulting in the collection of several types of qualitative data or various types of quantitative data in a single study (Creswell, 2015; Morse 2015). In multi-methods research the intentional integration or combining to make inferences is absent (Plano Clark and Ivankova, 2016).

This study was originally designed with a focus on the pragmatic notion of ‘what works’ or could ‘work’ in this case in an LMIC emergency department. Through the

use of data extracted from a retrospective review of case notes, process mapping through observation and interviews, data were collected intentionally, by connecting data sets, and through integration it was possible to build understanding (Fetters et al., 2013). The study was framed by Kotter's (1996) model of change evident through engagement with stakeholders at various points throughout the study and through the use of integration ultimately enabled by the application of Michie et al.'s (2014) COM-B model theory of behaviour change. This generated an understanding of the current ways of identifying and managing sepsis in a Ghanaian emergency department. Further, through working with and sharing the inferences drawn from the mixed methods analysis with stakeholders ultimately produced a design for an approach for improving care of adults presenting with sepsis. This approach to design was also informed by the MRC Framework (Skivington et al., 2021) for developing complex interventions in this case for future testing.

Even though limitations such as time, cost and resources can impede the use of mixed methods in a study, one key advantage is that it aids in addressing multifaceted and complex research questions, which cannot be understood by either quantitative or qualitative designs alone (Creswell and Plano, 2018). Creswell and Plano (2011) present six primary mixed methods designs, including convergent and sequential (exploratory, and explanatory) research designs (primary options in a mixed methods design) (Creswell and Plano, 2018) (see Table 10).

Table 10: Mixed Methods Taxonomy

Mixed method design	Explanations
Convergent design	The quantitative and qualitative research strands are carried out concurrently and separately. Their findings are then incorporated into the overall interpretation.
Explanatory sequential design	Quantitative data is gathered and analysed, followed by qualitative data collection, which is utilised to explain the initial quantitative results.
Exploratory sequential design	Qualitative data is initially collected and analysed is followed by the collection of quantitative data to test or generalise the initial qualitative results.
Embedded design	In the context of a conventional qualitative or quantitative research design, an additional component from the alternative approach is incorporated to augment the overall design.
Transformative design	The interplay, priority, timing, and integration of the qualitative and quantitative strands are influenced by a transformational theoretical framework, such as feminism.
Multiphase design	Within a programme of study, more than two stages or both sequential and concurrent strands are merged over time to address an overall program objective.

An important consideration in the design of a mixed methods study is the time arrangement of its two (or more) components, hence, it is advisable to incorporate the terms "concurrent" or "sequential" in the title of the study design (Guest, 2013).

In a sequential design, either the quantitative component comes before the qualitative component, or the qualitative component comes before the quantitative component. In a concurrent design, both components are executed in close temporal proximity (see Table 10). Concurrence is denoted by the symbol "+" when combining components, for example, QUAL + quan.

Sequential designs are denoted by an arrow symbol (→), as exemplified by the

notation QUAL → quan (Morse, 1991). The utilisation of uppercase letters for one element and lowercase letters for another element within the same design implies that one element holds a key role, while the other element serves as secondary or supplementary.

Concurrent designs offer several benefits, including time and resource efficiency, a holistic and unbiased perspective of the phenomenon, and the ability to validate and corroborate data through integration (Creswell and Plano, 2018). Drawbacks include the complexity of integrating and interpreting many types of data at the same time and the required expertise and knowledge required of the researcher. Sequential designs offer several benefits, including increased flexibility and adaptability, a well-defined reasoning and study aim, and the ability to explore and confirm results (Creswell and Plano, 2018). Drawbacks from sequential designs include the potential for spending significant time and financial resources, establishing a hierarchical or dependent relationship between the methodologies, and introducing inconsistencies and biases in data collection and analysis.

Considering these factors, this study employed a convergent mixed method design. Convergent designs occur when the researcher uses concurrent timing to implement the quantitative and qualitative strands during the same phase of the research process, prioritises the methods equally, and keeps the strands independent during analysis and then mixes the results during the overall interpretation. This aligns with this study, where the retrospective review of case notes and process mapping interview data was gathered, both analysed independently using SPSS and reflexive thematic analysis and a further integration, enabling understanding of the practices regarding sepsis identification and management, and how the two datasets converge

and diverge. The different methods used do converge, and as a consequence the integration results is the preferred design of a sepsis pathway.

This choice was made based on my epistemological stance, that is pragmatism (what works and is applicable in the Ghanaian context, interest in changing behaviours if needed (COM-B) and the use of the MRC framework, to identify what works best when it comes to sepsis in a Ghanaian ED. A thorough understanding of the current procedures for detecting and managing sepsis was provided when case notes review data and process mapping were merged, which informed stakeholder workshops, facilitating discussions around improving the current process contextually. This includes the use of organisational and behaviour change strategies (Kotter's model and COM B).

As the aim of this doctoral endeavour was to design an intervention, the MRC framework's initial phase of intervention design (Figure 6) was also utilised in this study by considering the core elements needed to be able to study the context appropriately whilst engaging with stakeholders (explored below).

4.4.2 Medical Research Council (MRC) Framework

The MRC framework for designing and evaluating complex interventions highlights the importance of contextualising and culturally adapting interventions when presenting them to patients or professionals within a specific community, considering factors such as the political, social, and geographical aspects (Skivington et al., 2018; Skivington et al., 2021) – Figure 7.

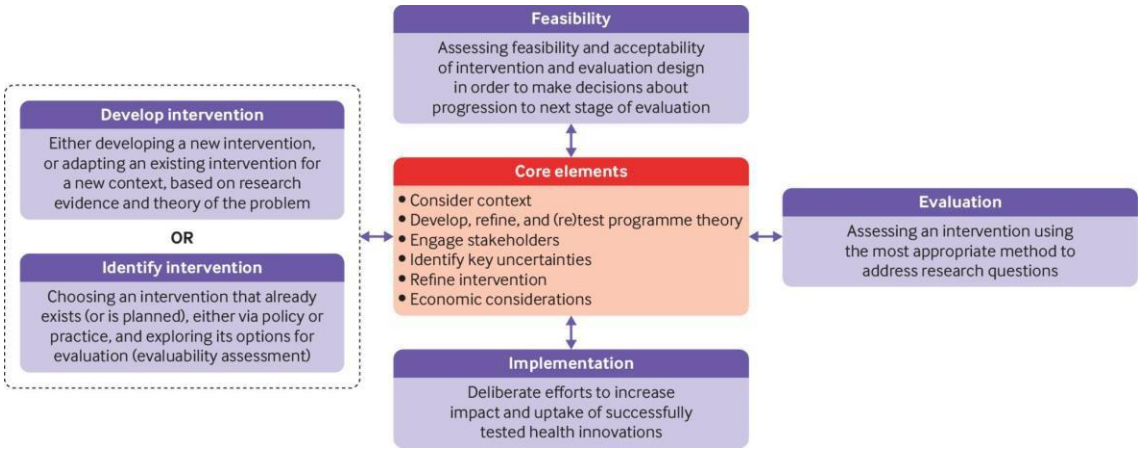

Figure 7. MRC framework: (Source: Skivington, 2021)

While it is true that an intervention may be implemented in several cultures, it is crucial to acknowledge that the societal context cannot be disregarded when considering the impact of the intervention (Craig et al., 2008). This is because the impact of certain interventions can vary across different societies. This framework, therefore, has been employed in this study to effectively incorporate mechanisms that are pertinent to the Ghanaian context, with the aim of bringing about desired transformations. The complexity of this study arises from the current variations in the care processes used to identify and manage patients with sepsis, the MDT delivering care and to effect any change proposed. Therefore, the intervention designed as the output of this study is classified as complex as it involves a series of interlinked processes (Skivington et al., 2021).

As mentioned earlier, the MRC framework attaches importance to either developing or identifying an already existing intervention, considering the core elements such as context and stakeholder engagement before testing feasibility, evaluation or implementation. With this background, this study focused on understanding, how

sepsis recognition and interventions have been carried out in a Ghanaian ED, using the SSC guidance as the gold standard.

Careful consideration of the Ghanaian context and engagement with stakeholders was required. In doing this, existing evidence regarding the identification and implementation of sepsis interventions in LMICs were reviewed (Chapter 3), which facilitated adoption of good practices to replicate in a Ghanaian context, considering the SSC guidelines and usual care components contextually (Evans et al., 2021). This enabled a thorough understanding of care, including the barriers and facilitators, which ultimately informed the design of a sepsis algorithm and an educational package.

4.5.0 Summary

In summary, this chapter has explored the research philosophy and theoretical frameworks underpinning this thesis and how it shaped the design and conduct of the study. Chapter 5 describes the methods used in this thesis. This includes various data collection strategies for the process mapping and retrospective case notes analysis. Discussion of the ways that reliability, validity, and bias were handled are also explored. Ethical considerations, rigour in mixed methods research and reflexivity have also been explained. As none of the studies explored in the literature review utilised a mixed methods approach, my PhD might be one of the few to understand sepsis practices in an LMIC using such approach.

CHAPTER FIVE

METHODS

5.1 Introduction

Having explored my philosophical stance, the choice of theories and the design for this study in the previous chapter, this chapter will discuss the methods used for the convergent mixed methods design, through gathering retrospective case notes data and a process mapping exercise. Engagement with stakeholders will also be discussed.

5.2.0 Stakeholder engagement

Prior to recruiting and involving stakeholders in this research, I conducted a stakeholder mapping to identify those who might wish to contribute, be able to bring rich insights to the project and ultimately support the change process.

5.2.1 Stakeholder mapping

The stakeholder mapping considered the following key areas: the influencers; implementers; and decision-makers, as illustrated in Figure 8 below.

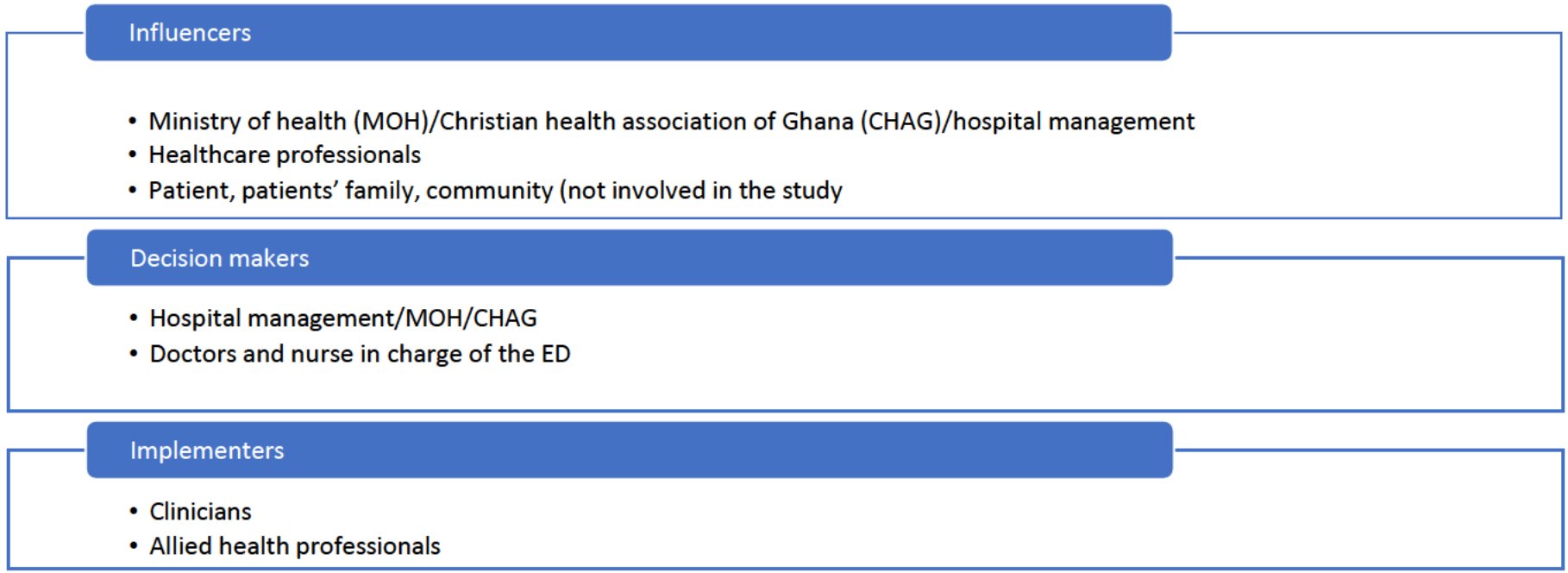

Figure 8. Stakeholder mapping

The hospital management team, medical, nursing and Allied Healthcare Professionals (AHP) staff working in the ED, patients and their families who would benefit from the intervention, and the community, were the stakeholders in this study. Hospital stakeholders were involved throughout the study. Their responsibilities included supporting inter-rater reliability of the case notes, awareness creation, participating in the process mapping exercise and engaging in co-designing a sepsis algorithm and an educational package.

5.2.2 Healthcare Professional Stakeholders

HCPs often bring great perspectives when involved in research, that considers not only their views but also those of the healthcare system and the patient population (Crocker et al., 2020). This can help ensure that the research addresses the crucial difficulties encountered in the real world by including their viewpoints from the beginning of the research and continuing to do so throughout its entirety (Crocker et al., 2020). Clinicians are, therefore, uniquely positioned to provide valuable insights into how new interventions may or may not integrate into established clinical workflows.

In this PhD study, healthcare professionals were involved as participants and researchers at specific points from the beginning of the design of an intervention. Throughout this study, the HCPs involved are called Sepsis Staff Volunteers (SSVs). These SSVs also served as part of the stakeholders as the most successful interventions are co-created with stakeholders and actively include those stakeholders throughout the project (Bero et al., 1998; Grill, 2021). Table 11 below provides the detailed roles and responsibilities of the healthcare professionals involved in this study.

Through early engagement with key clinical stakeholders, the likelihood that they would be open to the research findings is enhanced and may further serve as advocates to facilitate adoption of the intervention (Hewison and Rowan, 2016). There can be resistance to change and having clinical advocates involved in the design of any intervention and support implementation in the future can help bring about change in practice and importantly sustain implementation.

Table 11: SSVs responsibilities, including co-production responsibilities

Activity	Role
Sepsis awareness creation	Being the study stakeholders (local champions) supporting the creation of awareness about the study.
Retrospective case notes review	Assisted in interrater analysis for retrospective case note review.
Process mapping	Participated in process mapping workshops and interviews.
Co-design of intervention	Advised on context-specific intervention. Advised on education content, delivery, and context.

5.2.3 Staff Sepsis Volunteers (SSVs)

Evidence suggests that the successful implementation of sepsis bundles requires the support of local champions (Rhodes et al., 2017). An SSV group were recruited to support some aspects of data collection and involvement in co production workshops in this doctoral study. SSVs were both study participants and co-researchers. When acting as research participants, they were provided with a participant information sheet to read (PIS) and contact details of the researcher (AP) in order to discuss what would be expected of them before being invited to consent to participate (see Appendix 5 consent form: final version). They were asked to complete a signed consent form countersigned by the researcher (AP) after they willingly agreed to participate, and this was stored in a locked cupboard at the study site until scanned, and a copy was returned to each participant to keep. Afterwards, they were stored in an electronic study file on a password protected One Drive© on the University of Birmingham server in line with the university's data management plan, and the originals were destroyed.

SSVs also acted as co-researchers and were involved in various activities, including membership of the study steering committee and data extraction, undertaking inter-rater reliability tasks to support the retrospective review of case notes and the design of the intervention. When involved in any of these activities, they received training 24-72 hours before the activity, and these activities were recorded on a study delegation log (Appendix 6). Training included 'good clinical practice' (GCP) and covered good research governance, including confidentiality, informed consent and data protection. The selection of SSVs was based on their willingness to participate,

provide consent and whether they were actively involved in the care and management of patients attending ED with suspected sepsis.

5.2.4 Patient and Public Involvement (PPI)

A significant factor in raising the possibility that research will be pertinent to and beneficial to the population it will affect is patient and public involvement (PPI), also known as community engagement and involvement (CEI) (Brett et al., 2014; Farooqi et al., 2022). Hence, engaging people benefitting from an intervention is paramount to its success (Kroese et al., 2021). Even though in this PhD study, patients and the public were not engaged from the beginning of the design of the intervention, the outcome from engaging with the HCPs is driven towards improving their care; hence dissemination will involve engaging with them for any further recommendations and actions and as part of implementation evaluation.

5.3 Retrospective review of sepsis coded case notes

The assessment of the quality of care in written case notes is one of the standard means of assessing patients who have been exposed to any form of care either individually or in groups (Hutchinson et al., 2010a). This approach is often undertaken to assess any variations in care, which helps in learning from the previous experiences, thereby aiding in improving the quality of care and minimising or preventing adverse incidents. Various healthcare settings have adopted this method as part of a series of measures for assessing the quality of care, including that provided in emergency departments (O'Hara et al., 2012; Sari et al., 2007; Wolff and Bourke, 2002). Two principal methods are used as the basis for extracting data

from case records: implicit (holistic), which uses the reviewer's professional clinical knowledge of patient care in the contextual setting and explicit (criterion-based) review, whereby an already established standard of care is used (Hutchinson et al., 2010; Mason et al., 2013); the latter approach was adopted in this study. The 'Just Say Sepsis' tool commonly used for sepsis audit in the UK (NCEPOD, 2015) (Appendix 7) incorporating the SSC guidance, was the 'gold-standard' guideline adopted to formulate the data extraction tool. Existing gaps in care could be identified, including the level of consistency, when this approach is used. The information gleaned from the retrospective review of case notes, coupled with the process, mapping informed the development of a best-fit intervention to adopt in the ED at the study site to identify and manage sepsis. There is a scarcity of published sepsis audits from developing countries, however, there are quite a few related to obstetrics as maternal death has captured considerable WHO interest (ISA SE, 2013); hence, the case note review conducted as part of this study can add to the existing literature.

The research question guiding the review of case notes was ''what are the current practices in managing adult patients diagnosed with sepsis in a Ghanaian ED''?

5.3.1 Eligibility criteria

To be included in the review of case notes, records must relate to patients attending ED, 18 years and above, coded and identified as sepsis or septic shock. The Systematised Medical Nomenclature for Medicine – Clinical Terminology (SNOMED – CT) is the taxonomic system used to support the recording of clinical content in EHRs. Case notes relating to patients presenting to ED less than 18 years, with no -

sepsis coding and/or case notes relating to women presenting to ED with maternal sepsis (pregnancy related sepsis) were excluded.

5.3.2 Sampling of case notes

Determination of how many EHRs to include in a case note review is not straightforward as traditional sample size calculations have limited applicability (Gearing et al., 2006). In view of this, no formal sample size calculation was used, however, a convenience and purposive sampling approach was utlised. All case notes meeting the inclusion criteria relating to patients attending ED for sepsis from November 2019 to November 2020 were included in this retrospective review of case notes.

The hospital's electronic health records (EHR) system uses AksoftR. This system was searched to recover any case notes associated with patients diagnosed with sepsis by a doctor and coded with the relevant SNOMED-CT taxonomy between November 2019 and November 2020.

Within the period under study, 9,581 patients underwent triage assessment in the ED, with 5,059 categorised as the red (505), orange (1205), or yellow (3349) acuity with various diagnoses including sepsis. In total, 952 case notes with a sepsis code/diagnosis were retrieved. Out of the 952 case notes, 824 case notes related to patients with infection, who were not necessarily septic, were treated and discharged home the same day with or without antibiotics and were not included in the evaluation.

The inclusion and exclusion criteria were applied to the remaining one hundred and twenty-eight (n=128) case notes. Thirty-eight (n=38) case notes were excluded as they related to patients less than eighteen years of age. Fifteen (n=15) case notes had missing data and were excluded. Finally, seventy-five (n=75) case notes were selected for inclusion that fulfilled the requirements. Of this total, twenty-seven (n=27) case notes were categorised as red zone, and forty-eight (n=48) case notes yellow zone (Figure 9). These categorisations (red, orange, yellow, green) were explored in Chapter two. Data were extracted from the included notes, analysed and reported in Chapter 6.

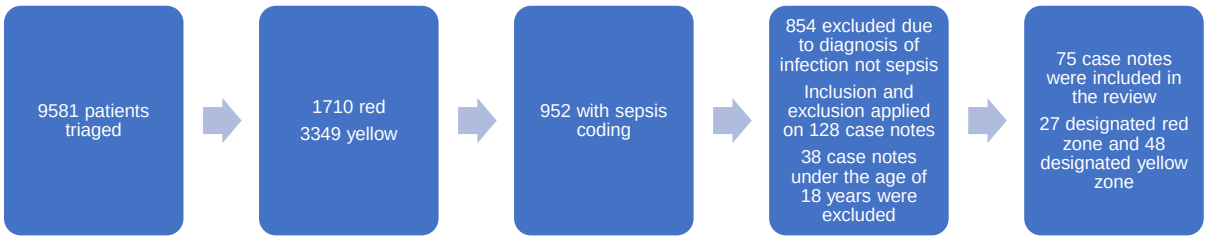

Figure 9. Electronic health records case notes sampling

A sample of 10% sepsis coded electronic patient records (EPRs) from the period, approximated to eight, were selected to assess inter-rater reliability. One clinician recruited from the ED, one of the nurse SSVs and a nursing officer agreed to participate in this aspect of the study. Before involvement they completed good

clinical practice (GCP) training. To ensure inter-rater reliability, they received instructions on how to use the data collection tool and undertake the extraction of data from case notes. The researcher (AP) collected data from the eight case notes. One clinician (registered nurse/SSV) also independently extracted data from the same case notes and inputted it into the data extraction tool. The two extraction sheets were compared for agreement. Further to this, interrater reliability using the scale and kappa interrater reliability test was tested (Mackridge, 2018). Both produced a result of 1.0, indicating strong inter-rater reliability. There were no discrepancies and clarifications /interpretations; hence an arbitrator (third clinician) was not involved.

Subsequently, the remaining 67 EHRs (90%) were reviewed and data extracted and inputted into extraction tool based on an adapted JSST (Appendix 6). Each record was allocated a unique identifier and no identifiable patient information (name, date of birth) was retained in order to maintain anonymity. Data regarding demography such as age, components of intervention and outcomes were extracted.

5.3.3 Data Analysis

After data collection it was imported into the Statistical Package for the Social Sciences (SPSS) (version 28) for analysis after data cleaning (Coakes, 2010; Nie, 1976). Data was then cleaned to identify duplicates or incomplete data. In addition, structural errors, such as the use of upper and lower cases, were amended to facilitate statistical analysis.

Coding and analysis of data in SPSS

Data were coded in SPSS variable view and each case note record extracted was assigned a unique identifier to facilitate easy analysis. Baseline patient demography and clinical data were presented using descriptive statistics, and frequencies and percentages were used to present categorical data. Association analyses using the Chi-square test and correlation were also conducted to establish any relationships between variables such as age, gender, type of admission and source of infection and the final outcome (discharge, transfer, death).

5.4.0 Process mapping

Process mapping is a managerial instrument employed to visually represent the progression of work and the sequential actions and individuals engaged in a corporate procedure. These maps are frequently presented as flowcharts or workflow diagrams (Cannavacciuolo et al., 2017). This tool is employed by organisations with the aim of enhancing their comprehension of a given process and ultimately to enhance or optimise its efficiency. Through the development of easily comprehensible diagrams, stakeholders are able to discern elements within a given process that possess potential for enhancement. This includes the identification of bottlenecks or pinch points within workflows and other inefficiencies.

Antonacci et al., (2018) describe a number of benefits of process mapping, including the ability to breakdown complexity and gather a shared understanding of reality, identification of gaps and improvement opportunities by adopting a system

perspective, engaging stakeholders in the project, identifying and aligning the project's objectives and appropriate intervention to the context and identifying responsibilities and monitoring project progress.

In this study, process mapping was undertaken to map the sepsis patient journey from arrival to the ED until their final outcome (discharge, transfer to an inpatient ward or unit, tertiary facility or death). Studies have revealed that careful understanding of the context where change is being proposed is important (Gaba et al., 2003; Klein, 2005; Mark and Elise, 2002) as most potential for improvement of healthcare quality is related to operations and systems at work, redesigning them and testing operationalisation can help improve the efficiency of care and outcomes (Doyle et al., 2013; Kim et al., 2010)

Process mapping is therefore enhanced when it involves capturing collective intuition through the involvement of stakeholders using techniques such as brainstorming sessions or interviews (Heher and Chen, 2017), due to the complexity of clinical pathways (Brill et al., 2011; Skipp, 2016). This approach has been used in this study to understand the current process and any requirement for potentially considerable organisational change. Given this, understanding the current situation and existing ED staff roles, responsibilities and competencies in sepsis detection and management is important. This helps in identifying the reality and any duplications or unnecessary steps. This, together with the case notes analysis and the evidence obtained from the literature review, including the process mapping assisted in locating any gaps and duplications in the patients' care (Skipp, 2016). Key activities carried out in the process mapping stage included interviews and workshops, with an initial pre-study period of observation (explained in Chapter 7).

5.4.1 Process mapping interviews

The primary aim of the mapping interviews was to explore healthcare professionals' (doctors, nurses, laboratory personnel and pharmacists) experiences of the current processes that patients with (suspected) sepsis undergo. The pathway from their arrival at the ED to their outcome-discharge, transfer or death was discussed. Sepsis identification, the various interventions employed, patient outcomes, and issues arising from the retrospective case note analysis were examined. Chapter 7 outlines the various themes and categories that were generated from the analysis of these interviews. In-depth conversational interviews were undertaken and analysed using the reflexive thematic approach described by Braun and Clarke (Braun and Clarke, 2022) and supported using the software platform NVIVO version 14. Furthermore,

the aim for involving the stakeholders was for them to own the project and ultimately the implementation of the sepsis bundle.

Even though several interview approaches exist, such as semi-structured interviews, an in-depth conversational interview approach was chosen (discovery-oriented method in obtaining detailed information) to understand the detailed care processes and the rationale behind each (Boyce, 2006). With this strategy, I was able to explore the gaps in care, including recommendations to improve the standard of care. All the interviews took place in the hospital's meeting room, which is a private setting.

Fourteen key stakeholders involved in the organisation and care delivery through the ED (who were all SSVs) participated in the individual interviews. This included four clinical managers (nursing, medical, laboratory and pharmacy) and ten other nursing, medical, pharmacy and laboratory staff working in the ED.

All interviews were audio-recorded on a password-protected audio recorder and subsequently transcribed. Interviews were conducted in English and lasted between thirty to forty-five (30-45) minutes. The aim of the interviews was to explore the processes of care of patients presenting with sepsis and focus on existing barriers and facilitators to effective sepsis identification and management, anticipatory factors that might impact the successful implementation of the sepsis bundle from their perspective and role in the patient pathway.

5.4.2 Transcription of data

AP transcribed all the encrypted interview sound files by going over the recording at least six times to ensure that every word from the interview had been captured.

Afterwards, the recordings were deleted and the word document password protected and saved on OneDrive for data protection.

5.5 Reflexive Thematic Analysis (RTA)

A thematic analysis approach was used to analyse the transcribed interviews (Braun and Clarke, 2016). NVIVO version 20, a qualitative research software, was used to support data analysis (Bazeley, 2000; Jackson, 2019). Both inductive and deductive analysis were used.

Braun and Clarke (2016) suggest that the researcher can more easily discover more insights in the data, when attention is given to the six phase critical elements of a thematic analysis (Clarke and Braun, 2016). That is, familiarising with the dataset, coding, generating initial themes, developing and reviewing themes, refining, defining and naming themes and writing up (Braun and Clarke, 2021): This study

adopted this approach however, even though the phases are set out as if the process is logical and undertaken in a sequential order, in practice the research and analysis were not linear, and a cyclical and recursive approach was used to enable back and forth movement through the phases as needed (Braun and Clarke, 2022).

5.5.1 Familiarisation with the data

The ‘familiarisation' phase involved reading and rereading the complete dataset. This is required in order to find the pertinent data that might be related to the study question(s). In this regard, Byrne, (2021) suggests either manually transcribing data or using software that can be a beneficial and substantially aid in in-depth data analysis, taking note of interruptions, pauses or tones made by both the interviewer and the participant. In this study, manual data transcription was done, while NVIVO (version 14) was used to aid in organising and boosting the accuracy of the analysis process. To avoid the temptation of reading only some parts of the dataset or perhaps "skipping over" this stage entirely, all transcripts were given equal consideration (Braun and Clarke, 2006). This enhanced closeness to the data, immersion, and critical engagement. I read, reread, and listened to the audio recording for adequate familiarisation and immersion, while making notes as illustrated in figure 10.

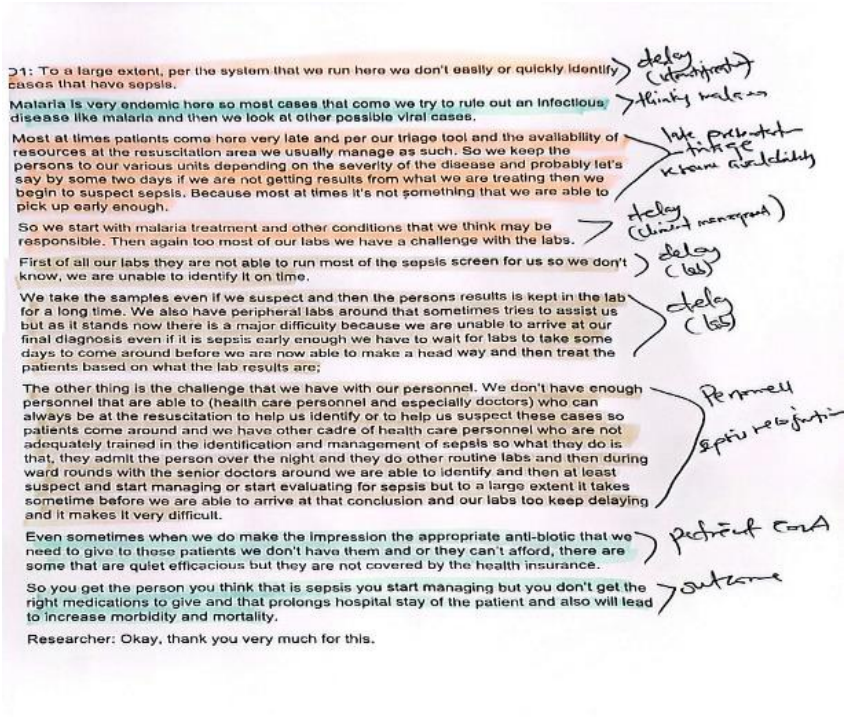

Figure 10: Initial ideas (familiarization stage)

5.5.2 Coding of the data

The essential building blocks of what would eventually develop into themes are codes. Hence, the coding technique provided concise, brief descriptive or interpretive labels for informational items relevant to the research objective(s). NVIVO version 14 (Bazeley, 2000; Edhlund, 2011; Hutchison et al., 2010b) was used to assist in organising the codes and ultimately tentative themes. A project book was created in NVIVO based on the research topic and transcripts imported into NVIVO. Based on the first familiarisation stage, initial nodes were created and an initial line-by-line coding performed. Afterwards, some of the nodes were collapsed into one another. This involved rereading and renaming the data. Any item that was useful to the research such as triage and payment were included as codes. The entire dataset was reviewed methodically, giving each data point equal attention and noting any intriguing information such as patients having to make payment before laboratory investigations and late identification of sepsis, as illustrated in table 12. I ensured that the code labels were succinct but included enough detail to stand alone as indicated in reflexive thematic analysis (Braun and Clarke, 2022; Byrne, 2021).

Table 12. Illustrative example of codes

Participant	Code - triage	Code - delays Lab, late presentation, clinical management	Code -patient cost	Code – shock management	Vital signs reassessment
D1 and P1	Most at times patients come here very late and per our triage tool and the availability of resources at the resuscitation area we usually manage as such. So we keep the persons to our various units depending on the severity of the disease and probably let's say by some two days if we are not getting results from what we are treating then we begin to suspect sepsis. Because most at times it's not something that we are able to pick up early enough.	Most at times patients come here very late and per our triage tool and the availability of resources at the resuscitation area we usually manage as such. So we keep the persons to our various units depending on the severity of the disease and probably let's say by some two days if we are not getting results from what we are treating then we begin to suspect sepsis. Because most at times it's not something that we are able to pick up early enough. The first bottleneck is with the resuscitation. The triage area where the staff, the clinical staff there including the nurses, the triage nurses are unable to suspect early enough whether this person coming is at risk of sepsis.	Cultures of some of the body fluids, they have to pay. And even if they don't pay up front, most of the labs are not covered by insurance, so will pay upon discharge but in a selected cases where our lab runs out we have to call other labs duals they come around and the patient have to pay up prompt before the sample is taken and it's even brought back and sometimes it becomes very difficult because relatives are not able to provide the money up front for these labs to be done so they come back with issues of our inability to determine exactly the organism that is causing the problem or to determine whether end organ damage is happening and is happening very fast. So yes, patients pay their investigations to help us detect or identify sepsis. They pay for them.	Yes the vasopressors that we have, our first line vasopressors for sepsis and especially when it becomes severe sepsis running into shock is noradrenalin. Yes, we have noradrenaline that we use but in the absence of noradrenaline we have dopamine that we give and then dobutamine. So our first line is noradrenaline then dopamine and dobutamine and in very rare cases if we don't have any of these available then we resort to giving an adrenaline infusion.	
D2	So when they come to the emergency first of all, they have to be triaged by our triage nurses and from the triage they come to see the doctor or the doctor comes to see them I mean either ways. The doctor comes to see them so based on what the patient presents with you will have to run some labs to confirm your diagnosis and then treat accordingly Okay, so when a patient gets to the triage, they will check the temperature of the patient, they will check	Some of them seek other alternatives especially herbal and religious. Some of them seek these avenues before they end up in the hospital. When all hope is lost that is when they come to the hospital for them to be treated. So during those times there's multiple organ damage and it becomes very difficult for them to be resuscitated.	we don't have all the laboratory resource so if there is an investigation that cannot be done in the hospital and the patient has to do it outside, for that one the patient will have to bear the cost by him or herself.	Yes, some of them do not respond to the fluids resuscitation. That is when most of them are in septic shock, so in such patients there might be the need for inotropes; the noradrenaline especially for noradrenaline, yes for septic shock.	okay, so we don't really have fix time. Depending on the state of the patient we can reassess as early as thirty minutes after, yes to see if parameters are improving but mostly if we have the staff on hand, we mostly have someone assigned to hat so that person keeps an eye on the patient at least even if the patient is reassessed thirty minutes later we could have any vitals checked about three or four times before the medical officer comes to

Participant	Code - triage	Code - delays Lab, late presentation, clinical management	Code -patient cost	Code – shock management	Vital signs reassessment
	the respiratory rate of the patient, the pulse of the patient, the blood pressure of the patient and sometimes too the random blood sugar (RBG) of the patient, yes.				reassess and if parameters are not improving they are alerted but for the medical officer to earliest we reassess is let's say, yes. But for the nurses they can reassess maybe every ten to fifteen minutes to see if the patient is responding well to management.
N2 & N3	When we are doing triaging, it's the vital signs that we do mostly the temperature, pulse, the respiration, BP and then we sometimes check the sugar as well. And then sometimes too you do your general assessment when the patient comes maybe the patient is having cold extremities, when the patient comes with low SP02, oxygen saturation when it's low let's say below 92% we also consider that are and then start monitoring. We also consider the respiration as well because we see all these vital as signs and symptoms of infection. So we also base on that one and then start with their plan.	because most at times when the patients reports late as I initially said if the patient comes in unconscious most at times you start the anti-biotic but it will take sometimes for anti-biotic to start working so maybe they base on the patients condition whilst you are resuscitating.	And sometimes too financially people may not have money to come to hospital but when it deteriorates or when it worsens they have no option than to come to the hospital	we give normal saline and ringers lactate, and then Dextrose in normal saline to patients with sepsis	as I initially said, most at times after treating the patient, after starting the sepsis is maybe after twenty four hours if we have beds we mostly trans the patients out to the ward and even after starting the first doses of the anti-biotic we normally do not reassess our patients to see whether they are responding to them because of maybe the continuity of care sometimes breaks. And then sometimes too mostly we do for those that are not responding to treatment but those that are responding to the treatment we do not reassess them to see how their condition is.
N5	so going by the triage that we are using, the South African Triage System, we consider the vital signs, the consciousness level of the patients, how mobile is the patient, is he walking	And the lab depending on the workload we have at hand, sometimes from what I enquire from them they can give us the base blood component within ten to fifteen minutes but because of the system we are	as I said earlier we only do it for specific patients, it's quite expensive so it's not everybody who will be able to afford so we it for sepsis patients and sometimes for patients who are not responding to the initial antibiotics	if it is identified that patient has deteriorated to the point that they score red or orange, IV fluids initiations are immediate. Immediately the IV lines are secured and blood samples are taken, IV fluid resuscitation starts. So we go	so depending on the case and the severity with which we are dealing with, it can be done every thirty minutes (30 minutes) after the initial triage. If it is not so severe

Participant	Code - triage	Code - delays Lab, late presentation, clinical management	Code -patient cost	Code – shock management	Vital signs reassessment
	by himself and then we use other discriminators such as the main complaints of the patients. Talking about sepsis in focus, we consider the pulse and the BP(blood pressure) specifically but our triage does not focus just on sepsis patients, its generalised for all the kinds of patients that comes in so we do triage for everybody, we don't just isolate sepsis patients.	operating, we tend to get the results sometimes twenty four hours when the sample gets there but if it's for the patient that we really need it immediately, we do a follow up to the lab and request for a copy of the printed lab results.	therapy that was initiated. So you have tried this, you have tried that the patient is not responding so let's do C/S (culture and sensitivity) and see if the patient will respond, we do it for such patients as well.	for the crystalloids especially the normal saline and ringers lactate. Normal saline 0.9% sodium chloride. They are the two main kinds of fluid we use for our septic patients.	then every four hours it can be done. If the patient is also responding and we move them to the wards then it becomes like six hours (6 hours) or eight hours (8 hours) every day. So it depends on how severe, in what state they find themselves.

5.5.3 Generating initial themes

As interpretation of aggregated meaning and meaningfulness throughout the dataset takes precedence (Creswell, 2014) over individual data items. This phase begins when all data have been coded. The coded data was analysed to determine how the various codes could be grouped based on common meanings to create themes and categories (Braun and Clarke, 2022; Braun and Clarke, 2021).

A specific code, such as blood sampling practices, was part of a larger story in the data and was used as a sub-theme for what became the process of resuscitation theme. Five initial themes evolved namely: sepsis process; factors contributing to delays in the sepsis process; triage and sepsis identification; components of usual care; and improving sepsis care, however these were reviewed in the next stage and finally three themes were constructed

Although there is no standard for the number of themes, many themes make analysis cumbersome and disjointed; while too few themes may not wholly examine the depth and breadth of the data (Braun and Clarke, 2016), hence, I considered this while moving to the next stage of the analysis.

5.5.4 Developing and reviewing potential themes

All candidate themes were reviewed in connection to the coded data. Initially, the links between the data items and codes that underpin each theme and sub-themes were reviewed (Braun and Clarke, 2022). Themes were examined again in light of the data set and dropped or merged to avoid repetition. For example, an initial theme named ‘’factors contributing to delays’’ was unpacked as delays and merged into two

different themes. This was because delays were identified in the triage as well as the process of resuscitation.

5.5.5 Refining, defining and naming themes

The next stage in the analysis process was to study the thematic framework thoroughly. According to Braun and Clarke (2021) it is necessary to express each theme and sub-theme in connection to the dataset and the research question(s). Also, each theme should offer a cogent and internally consistent account of the data that the other themes cannot tell (Patton, 2002). At this stage, the theme titles underwent the last change after thoroughly assessing the underlying data items defined in the themes. This helped me decide which to use as extracts when summarising the findings.

Each extract was considered in light of the theme it was linked to and in the larger context of the research question(s), resulting in an analytical narrative explaining what makes extract intriguing and why. Data extracts were then presented as part of the explanation of the themes, illuminating what has been interpreted about what participants said and contextualising this interpretation by illustratively giving a high-level description. For example, the theme ‘’triage and sepsis identification” was clearly defined with generated codes and clustered into subthemes. Overall, three themes were produced from all the preliminary and final codes, with additional categories explaining the data better. These themes were: (1) thinking and identifying sepsis; (2) process of resuscitation; and (3) improving sepsis care as illustrated in tables 13 to 15 below. The themes have further sub-themes, which is named categories.

Table 13: Themes and categories 1

Theme:	*Thinking and identifying sepsis*
Focus:	HCPs, patients
Sources:	Interview data
1. Category name 2. Category name	Triaging and clinical awareness This category relates to clinicians' inability to recognise sepsis from the beginning, however, considers malaria and other conditions without flagging sepsis. It also includes low level of awareness regarding the recognition and management of sepsis. Delays This category relates to patients waiting very long at home before reporting to the hospital. This also refers to patients visiting herbal or traditional healers or clinics, which further delays them before they finally arrive at the hospital in a deteriorated state. This also refers to patents having to make some form of payments before investigations or medications are being administered. HCPs delays relate to inadequate resources and poor clinician sampling practices, which also further delays the care process.

Table 14: Themes and categories 2

Theme:	*Process of resuscitation*
Focus:	HCPs
Sources:	Interview data
1. Category name	Components of care This category relates to the available treatment options for patients when sepsis is finally identified. This includes laboratory investigations, antibiotics, fluid management, focus of infection and patient outcomes (discharge, transfer, death)
2. Category name	Delays This category relates to HCPs delay in monitoring patient's vital signs after the initial triage, which makes them not identify deteriorating patients as early as possible. This also includes documentation and resources.

Table 15: Themes and categories 3

Theme:	*Improving sepsis care*
Focus:	HCPs
Sources:	Interview data
1. Category name 2. Category name 3. Category name	Sepsis protocols This category relates to standard operating processes, such as sepsis track and trigger or algorithm, to aid in prompt sepsis recognition and care. It includes vital signs frequency of monitoring standards. Resources This category relates to the availability and proximity of resources such as blood culture bottles closer to the nurses to facilitate sample taking when a patient is flagged for sepsis Training This category relates to taking clinicians through sepsis and the need to recognise sepsis as early as possible and to initiate interventions promptly. It includes both skills and simulation training as well as bedside teaching to improve care and outcomes. This also includes training on deteriorating patients, frequency of vital signs monitoring tool.

These themes and categories explain the sepsis process from the perspective of healthcare professionals from the study site.

5.6.0 Process mapping workshop

After the analysis of the interview data, SSVs were invited to a final process mapping workshop after gaining their consent to participate. This was undertaken to chart the current processes used for the identification and management of sepsis as reported in the interviews with HCPs and data collected to understand the usual patient journey through the ED for those with a suspected or confirmed diagnosis of sepsis. The mapping was confirmed through observational processes and compared to the

Sepsis Six interventions (Evans et al., 2021; Rhodes et al., 2017). See Appendix 8 for the final graphical representation of the current process. The finalised pathway (graphical representation) was presented to participants attending a final stakeholder meeting.

5.7.0 Rigour in mixed methods studies

The assessment of rigour varies between quantitative and qualitative research methodologies due to their inherent variances (Seale and Silverman, 1997). In quantitative research, the parameters for ensuring rigour encompass several key factors, namely, validity, reliability, replicability, and generalisability, which were assessed in this study (Bryman et al., 2008). Lincoln and Guba's criteria of credibility, transferability, dependability, and confirmability are often regarded as the benchmark for evaluating the quality of qualitative research (Lincoln et al., 1985)

In this project there was the chance that assumptions and personal impact on the interpretation of the qualitative data would be increased as a result of my direct involvement in participant in-depth interviews during the process mapping phase (Rolfe, 2006). As a result, some critics might claim that these influences can cast doubt on the credibility of the data and the interpretations (researcher bias) that were

Presented, arguing that this would not occur if standardised quantitative procedures were used (Bryman 2012). In order for readers to assess the robustness of the study for themselves, it is imperative to present reasoning for all decisions made during the research process (Rolfe, 2006; Hammersley and Oliver, 1996). Lincoln and Guba’s (1985) four criteria were utilised to assess the rigour in the process mapping interviews. The first was credibility, which is defined as the accuracy of the data as well as the researcher's interpretation and presentation of it (Ritchie et al., 2005).

The findings of this research were compared with the gold standard (surviving sepsis campaign guidelines) through triangulation of findings using the different methods to capture data to assess credibility and trustworthiness, including supervisors acting as second checkers verifying the data and analysis as it progressed.

Utilising a multi-professional team was another approach used to enable a deeper comprehension of current sepsis practices. Additionally, supervisor feedback was continuously sought after to improve various viewpoints and suggestions for further investigation and accurate data interpretation (Shenton, 2004).

To fulfil objectivity and dependability (Lincoln, 2000), reflexivity was used throughout the entire study and discussed in section 5.7.0. Transferability was the last criterion used to increase trustworthiness which relates to the applicability of the findings to various contexts (Lincoln, 2000). Given this, all the data were analysed independently. Two reviewers (AT and LLD) also coded 10% of the transcripts from each multidisciplinary transcript. After the two reviewers (supervisors) completed their independent coding, an online virtual meeting was arranged to discuss the initial codes. This was to ensure that the codes I had generated and that of the other two reviewers were largely comparable, and this was done to ensure the credibility and reliability of the codes and themes. After the codes were discussed and agreed, themes were generated and discussed in relation to how to present them and their appropriateness to the research questions.

The evaluation of rigour in mixed methods research is a challenging task that necessitates additional consideration due to the inherent disparities in assessing rigour in quantitative and qualitative procedures. The subjects of rigour and quality are currently of significant interest within the mixed methods literature, and there

remains a lack of consensus in these domains (Onwuegbuzie and Johnson, 2006; Onwuegbuzie and Leech, 2005). There is a lack of consensus regarding the quality concerns that are unique to mixed methods research compared to monomethod approaches, (Onwuegbuzie and Johnson, 2006). Nevertheless, a number of scholars delve into the significance of evaluating integration and the necessity of providing a rationale for employing mixed approaches, which has been discussed earlier (Curry et al., 2012; O'Cathain et al., 2008; Wisdom et al., 2012). Other researchers propose the use of Lincoln and Guba's criteria for trustworthiness to be used in mixed methods research. Irrespective, it is imperative for researchers to maintain transparency in their explanations of the research process. This entails offering comprehensive information regarding data collection, analysis, interpretation, and integration for all employed methodologies. By doing so, readers are empowered to assess the quality of the research (O'Cathain et al., 2007).

As a nurse in charge on study leave, I initiated preliminary discussions with clinical leaders, including the medical director, deputy director of nursing services, and the nurse and physician in charge of the accident and emergency unit, to establish foundational conversations and understanding in preparation for this study. The capacity for influence and compulsion in my position was evaluated.

Engagement with staff and patients for research within the accident and emergency department was not included in my previous clinical responsibilities and necessitated the establishment of a new framework to foster confidence with personnel (Buchanan et al., 1988). This established a significant distinction, mitigating (though not eradicating) the risk of coercion. Understanding these aspects allowed me to anticipate the potential problems of conducting research in the accident and emergency unit (Feldman et al., 2003) and to devise strategies for addressing them.

I intended to promote this over an extended duration prior to initiating the study by both informal and formal methods (Buchanan et al., 1988). The comprehensive formal methodology I proposed included various forms of contact. The informal and formal techniques were expected to enable my presence for staff to ask questions and express issues informally. These approaches encompass permission and procedural clarity concerning the individuals involved (staff and myself) in relation to the study's objectives, which are elaborated upon in the reflexivity section.

5.8.0 Reflexivity

Reflexivity entails a researcher critically considering how their location, values, opinions, and worldview influence decision-making and interpretation during the research process. Hence, a process of critically evaluating oneself as well as analysing and recognising one's own values that may have an impact on data gathering and interpretation (Polit, 2010). Reflexivity has been widely adopted in qualitative data collection methodologies (Finlay, 2002) and is demonstrated in the transparency of the information about any individual or professional circumstances that may have had an impact on data collection, analysis, and interpretation; either positively or adversely being reported.

However, because of the philosophical difference between qualitative and quantitative research methods, the use of reflexivity alongside quantitative research methods is uncommon (Mauthner and Doucet, 2003). In experimental design for example, every effort is made to distant the researcher from the research - such as double blinding, however, there is considerable debate about impartiality (Burns,

2001). Quantitative research is seen to be tightly controlled, where researchers take precautions to reduce the danger of bias, by attempting to be external from processes that could confound and seek to take the stance of objective observers.

Even though the application of reflexivity in mixed methods studies is often less evident in methodical conversations, it is legitimate to pose concerns regarding the role of reflexivity in a mixed methods study, such as whether reflexivity should be limited to only the qualitative components of the study or applied uniformly.

There are at least four reflexive strategies, including self-reflexivity (Pillow, 2003) (Akter et al., 2022). Self-reflexivity recognises the researcher's role(s) in the formulation of the research problem, the research setting, and the research findings, and emphasises the need for the researcher becoming consciously aware of these variables and considering their effects.

In this PhD study, a self- reflexive stance was taken throughout as a means of providing insight into the research activities, ideas, and interactions. A reflective diary (study journal) was kept from the start of this PhD journey, where, I reflected on the data collection phases, my role in the process and any underlying meanings made. In this situation, it helps in reflecting on events and provided a record of data collection contributing to trustworthiness (Thomas and Magilvy, 2011; Whittemore et al., 2001). As a PhD project is not just about conducting research, but also about providing the novice researcher with a set of ultimately transferable capabilities, recording professional transformation and progress in a research diary is consistent with the concept of fostering self-awareness in the research context (Freshwater and Rolfe, 2001).

By allowing for critical analysis of the ethics process, systematic review, case note review procedure and the process mapping, the diary gave the research a new dimension. It gave me the chance to document and assess my feelings, ideas, and reactions as the data were being gathered and analysed. Every day encounters with personnel and data, as well as thoughts and feelings that had surfaced over the day, were recorded. This method is in line with Finlay's (2002) definition of reflexivity as an activity in which scholars analyse their responsibilities in an explicit and self-aware manner (Finlay, 2002).

First, my status as an employee of the study site hospital, although on study leave yet conducting this research, meant engaging with former colleagues as well as new staff: this experience was documented. There were some worries about returning to where I worked because I spent several years there, had held a clinical leadership role, and got to know several staff members well. The reaction of staff to me as a researcher and what it would be like to enter the facility and interact with new staff members and previous co-workers were among the many questions that came to mind. Being a former colleague, did however, facilitate some fascinating interpersonal interactions, some of which were beneficial to the research and some of which were less so. Many staff members expressed a positive interest in the study, and this sparked a number of interactions that enabled me to access and find the necessary data in the hospital's electronic health record and to finish the process mapping exercise with ease.

These conversations were useful because, when the study was originally conceived, the hospital’s records were on paper. However, over the years of my study leave, the hospital had transferred its case notes to an electronic patient record (EHR) system. Some data were difficult to locate without insider knowledge of the system (Finlay,

2002). For example, the patient notes were not in an obvious place, but a member of staff p provided direction, by taking me through the processes taken to identify total admissions for the period and the selection of case notes identified with sepsis. This made it much easier to locate the data needed to carry out the research.

Furthermore, even though individuals had been diagnosed with sepsis, it was discovered during the collection of case notes that no blood cultures had been requested for them (Long and Koyfman, 2016). In this case, there was a sense that analysis-related notions had begun to emerge during the data collection phase, and that the relationship between data collection and analysis is not always linear or one way. Other interactions with former colleagues enabled me to learn about new innovations ongoing in the facility.

Reflexivity was used when reviewing the case notes for a number of reasons. First, to maintain a standard procedure for data collection and analysis, and second, to guard against jeopardising the method's robustness. The Just Say Sepsis Tool (JSST) NCEPOD, 2015), used in sepsis audit was used to as the basis for the retrospective data collection from the case notes in this study. On designing the study, the JSST which is used in sepsis audit in the UK, as mentioned earlier, appeared to be the suitable and reliable, therefore it was adopted. However, the information required to complete the UK JSST needed to be modified to fit the Ghanaian context. For example, consultant had to be changed to review by an ED doctor as there is no ED consultant in the context.

Professional boundaries such as being a former staff member and previously a charge nurse of the ED was considered. Hence, I became aware of the preconceived notions and unconscious biases I could bring to the field, including

those related to my background, education, and experience. This awareness helped limit the degree to which impressions captured in writing suffer from being filtered through the mind (Martin et al., 2007; Schensul, 2013).

In addition, I kept notes on my experiences, emotions, assumptions, and role in the research process. For instance, I conducted this study in Ghana, which meant that I was familiar with the local culture and perception of the society (Peirano, 1998). I am skilled in the Twi language (the most widely spoken language in Ghana), and English language (the country's second official language). I have worked as a registered adult emergency nurse for more than ten years. In many years of my practice, I have accumulated information, experience, and skills. This makes me an insider, a healthcare provider from Ghana, and a participant in this study. (i.e., healthcare professional). In this instance, participants may feel that disclosing information to me might mean betraying their colleagues and exposing their inefficiencies or even incompetence. However, my constant reassurance of confidentiality and the study being focused on developing a bundle to improve the quality care as well as an academic exercise (for a doctoral award) helped ease their concerns.

Additionally, I am aware of several organisational and cultural customs, such as the practice of addressing female nurses as "sister" and doctors as "doc," which may not be known to "outsiders." Although I am an insider, I am also an outsider because I spent the previous five years pursuing my further education in the UK (a master's degree and am currently enrolled on a PhD programme) and also having the opportunity to work in a UK ED setting (Mauthner and Doucet, 2003). As a result, I contribute a few unique qualities to my study. Particularly in my study and training in the UK, I have become more conscious of where people who make decisions about their health and treatment are encouraged to participate in the decision-making

process to the extent that they wish to. In this situation, patients are assisted in understanding the available care, treatment, and support options as well as the risks, advantages, and repercussions of those options during the treatment decision-making process. It entails assisting individuals to reach decisions about a preferred option, based on high-quality, evidence-based information and their own preferences. There is constant explanation of procedures and care to patients, which is not always the case in Ghana. This means patients in Ghana are often naïve about what is wrong with them and treatment options.

In view of this, when collecting and analysing data, I was more sensitive because of my experience with the UK healthcare setting. As a result of this, I decided to learn more about sepsis recognition and treatment at a Ghanaian ED (Evans et al., 2021). Without the experience, it would have been more difficult for me to analyse the case notes and interviews with the criticality and “new eyes" needed. Relationships I had in the workplace were influenced by who I was as a nurse. I was viewed by the HCPs as an insider (participant) in many ways because I am a nurse. My field roles were certainly impacted in a number of ways by this. I became a participant in the study after being introduced to the employees as the former senior nurse of the ED right away. In order to collect the data efficiently, for instance, I got access to conference rooms and offices, which would have been challenging for a non-HCP or an outsider.

Also, some participants would ask me questions about the research. For example, when conducting the interviews, participants inquired further about whether the research will persuade the institution to buy more equipment. I had to clarify that this study is purely research for academic and quality improvement purposes and outcomes will be communicated to the hospital management for further action.

In my reflective notes, I stated how saddened I felt when participants mentioned that patients had to pay for their prescriptions upfront. I feared some patients might not survive because of financial difficulties, which left me feeling sad. Another instance was when participants said that sepsis is not a condition that is watched out for, causing them to delay the patient until later. Despite being faced with scenarios that were so emotionally taxing like these, I found the entire experience to be worthwhile because the participant input may help to modify how practice and care is provided.

The ethical considerations process also provided a lot of insights into the processes of gaining an ethical approval both in Ghana and at the University of Birmingham. The process of the systematic review also gave excellent insights into gathering credible evidence.

I also kept in touch with my supervisors as I got feedback from them. My supervisors talked about the data and the analyses and interpretations I came to along the process, including the early data analysis. Due to their unfamiliarity with the Ghanaian context I was researching, my supervisors' verification was especially crucial because it gave them the opportunity to point out and raise concerns I had not fully thought through and that needed additional research. Hence, it can be concluded that to provide a comprehensive view of the study process, a reflective diary gives the research additional dimension. Signposting the reader to what happened in the research is very important and has been worthwhile in this study.

This doctoral research has several implications for practical application since it investigates the methods of identifying and managing sepsis. Sampling procedures will be enhanced due to the detection of unlabelled samples and inadequate sample

collection, which directly poses a risk to patient safety. Rapid identification of a deteriorating patient and timely interventions will be enhanced by closely monitoring vital signs, considering patient acuity and monitoring frequency to avoid delayed detection and consequent fatalities.

The research will provide insight into the additional trainings needed, beyond the standard basic life support (BLS) and Advanced Cardiac Life Support (ACLS) delivered by the facilities' training centre. In so doing the trainings will be included in the yearly mandatory training. The implementation of the locally designed standard operating procedures for sepsis, antimicrobial stewardship, vital signs monitoring, sample collection, and identification and treatment of a patient experiencing deterioration will also help improve clinical guidance and patient care. The cooperation of emergency and facility leaders will facilitate these impacts, therefore generating favourable influences that will lead to the necessary change and implementation outcomes. By using Kotter's eight step organisational change theory, this study intends to provide a gradual process in, bringing change while involving stakeholders in order to sustain any change proposed.

5.9.0 Ethical Considerations

Data collection for this study was initiated after ethical approval was secured from the Kintampo Health Research Centre Institutional Ethics Committee and the University of Birmingham (see Appendix 9) (Connelly, 2014). The Kintampo Health Institutional Ethical approval is a rigorous multi-staged ethical process where the researcher submits documentation for the scientific and ethics review process. Firstly, the researcher was called for an initial virtual scientific board interview on Zoom© (due to COVID protocols) on the 4th of October 2021. The scientific

committee reviewed the documents and made recommendations and comments, which I amended where needed. I subsequently returned the corrected documents back to the scientific committee, and when they completed their reviews, they confirmed approval of the study. This in effect was a scientific review not ethical. The ethical review committee invited me for a separate ethical review virtual interview through Zoom©. After the second review, I was required to make some amendments as recommended to meet the Ghana ethical requirements and afterwards. Full ethical approval was issued for the study to begin in November 2021. Ethical approval was also obtained from the University of Birmingham's before commencement of the study (Appendix 9).

5.10 Access to the Study Site

Initial meetings established willingness to participate at the study site, with approval confirmed by the Hospital Administrator in September 2020 and written consent given (see Appendix 10). Once ethical approval was received from both the University of Birmingham and the Kintampo Health Research Center Institutional Ethics Committee, formal study access through meetings with the site's Medical Director (MD) and Nursing Director (ND) was also obtained. Subsequently, the approved protocol information was shared, and ED access was negotiated with the nursing, medical, pharmacy and laboratory leadership. Even though I had previously worked in the ED I acted solely as a researcher throughout the study period, as discussed in section 5.5.0.

5.11 Assessment and management of risk

Assessing for risk and identifying the best measures to put in place is paramount in research, although it is unlikely all eventualities anticipated will occur (Terje, 2016). This study identified risks such as maintaining participants' anonymity, breaching confidentiality, exposing personal information and identifying a poor clinical practice (Appendix 11 contains the risk assessment and control measures), however, none of these were experienced in the course of the research.

5.12 Consent Process

Information about the study was disseminated to all staff in the ED after consultation with nursing and medical managers through leaflets and posters. This was specific participant information targeted to recruit SSVs and a separate participant information sheet (PIS) (Appendix 5) for (1) identified stakeholders who were interviewed face-to-face and (2) all participants who were involved in the process mapping workshops.

The researcher (AP) was available in the ED and/or by phone (details supplied) to discuss the various phases of the project and expectations with potential SSVs and stakeholder participants. Once an agreement was obtained, SSVs were invited to a Study Steering Group Meeting held in the study site conference room to discuss the roles and responsibilities and undertake research governance training. All the steering group members had the opportunity to be taken through the research governance training by the researcher.

All participants involved in the process mapping were asked to complete a consent form (see Appendix 5) once they had the opportunity to make an informed decision

about participating in the study. Participants were informed of their right to withdraw from the study if they wished - up to the point where data analysis had commenced. They were also assured of the strategies that would be used to maintain confidentiality and anonymity, which is fundamental to ethical research practice (Connelly, 2014). The researcher made every effort where possible to make sure data provided by participants could not be traced back to them in reports, presentations and other forms of dissemination of results (Wiles et al., 2008).

Participants throughout the study were allocated a unique non-identifiable code to maintain anonymity and confidentiality. The data management plan in Appendix 12 provides further details.

5.13 Data Management Plan (DMP)

The University of Birmingham ensures that all research data is collected and stored according to the university's policies, including confidentiality and anonymity. In Appendix 12, information on how data were collected and stored securely based on the University of Birmingham's principles in data management is provided.

5.14 Mixed methods Integration of Case Notes Analysis and Process Mapping

In this study, integration occurred at all levels. The study is considered a convergent mixed methods study at the design level. Using a retrospective case note review and process mapping interviews, the convergent mixed methods approach established the current sepsis identification and management practices in Holy Family Hospital, Techiman, leading to the design of a sepsis algorithm and an educational package.

At the analysis level, the integration was presented through narrative and joint displays (Draucker et al., 2020; Fetters et al., 2013; McCrudden and McTigue, 2019;

Shahhosseini and Hamzehgardeshi, 2015) to assess inferences and understand how sepsis is currently managed in the study site, the gap with Sepsis Six intervention, and the ideal intervention for implementation in the study site (see chapters 8 and 9)

5.15 Summary

The methodology and methods employed in a study are fundamental to the research process. This chapter has provided details of the methods used in this study and rationale for the chosen approaches. That is the processes used in gathering case notes data for the retrospective review and process mapping to understand sepsis recognition and care in a Ghanaian Emergency Department. Chapter six presents the results from the retrospective review of the case notes.

CHAPTER SIX

RETROSPECTIVE CASE NOTES RESULTS

6.1 Introduction

The previous chapter explored the methodology and methods for this study. This chapter presents the results from the review of case notes (RCN) relating to patients attending the ED at the study site between November 2019 and November 2020.

The case notes related to care received by adult patients 18 years and above who presented to the ED and their episode of emergency care was coded in the electronic health record as suspicion or diagnosis of sepsis.

6.2 Background

The NCEPOD (2015) audit tool “Just say sepsis! ”, which is used in the UK to review the process of care received by patients with sepsis, was used as the basis for retrieving data relating to usual care for sepsis patients. Data extracted included antibiotic, IV fluids, oxygen and vasopressor administration. Also, demographic and clinical data, including age, gender, mode of admission, admission location, source of infection and comorbidity were extracted. The usual care components were compared with the Sepsis Six items incorporated in the NCEPOD audit tool as the gold standard to identify gaps and areas that could be targeted for improvement in any intervention (NCEPOD, 2015). This chapter will present an analysis of the demographic characteristics of the identified patient cohort, usual care components and the patient outcome. The relationship between outcomes and variables extracted from the case note records is presented.

6.3 Demographic Characteristics of Patients' Records Reviewed

Patients ranged from 18-74 years, with a mean age of 43 years. Patients underwent triage on arrival at the emergency department (ED) and their status was categorised based on the South African Triage Scale (SATS). As mentioned in Chapter 3, a colour-coded system, classifying patients' status as red, orange, yellow and green is used in the study site. Red - cases require immediate medical attention; orange requires medical attention within ten minutes; yellow, within an hour; and green, four hours. Given the short time interval between the red and the orange categories, this study site adopted a combined approach for patients classified as red and orange, so all red and orange category patients may receive attention immediately or within ≤ 10 minutes in the red/orange areas (zones) of care. All green cases are referred and, seen during the day (8:00am to 8:00pm) in the outpatient department (OPD).

Almost all patients' records indicated a vital signs assessment was completed on arrival into the ED - vital signs were recorded in 72 (96%) case notes. The vital signs components assessed were blood pressure, temperature, pulse, respiratory rate, oxygen saturation (SPO2) and level of consciousness (Table 20). In addition to the standard vital signs/assessments, nine (9) case notes also had fasting or random blood sugars recorded for patients with pre-existing history of diabetes.

Demographic characteristics of the patient whose records were included are presented in Table 16.

Table 16: Demographic Characteristics of Patients categorised as Suspected Sepsis or Sepsis in the Emergency Department (November 2019 – November 2020).

	Criteria	Frequency (n=75)	Percent (%)
Age	Below 20	9	12.0
	20-49	36	48.0
	50 & >	30	40.0
Gender	Female	41	54.7
	Male	34	45.3
Type of admission (triage category)	Red	27	36.0
	Yellow	48	64.0
Mode of Admission	Home	63	84.0
	Referral	12	16.0
Comorbidity	Not recorded	52	69.3
	Present	23	30.7
Source of infection	Respiratory	20	26.7
	Urinary	15	20.0
	Abdominal	15	20.0
	Malaria	11	14.7
	Others	14	18.7

Forty eight percent (n=36) of case notes indicated that the majority of patients who were diagnosed with sepsis were within the age group of 20-49 years, the remaining 40% (n=30) were 50 years and above. Only 9 (12%) patients were aged 20 years or less precisely 18 and 19. The triage classification recorded on the 75 case notes indicated 27 (36.0%) were classified as red and 48 (64%) as yellow. Even though the majority of those aged between 20-49 years were diagnosed with sepsis (or suspected sepsis), they were classified as yellow category, whereas those 50 years and above were classified in the red category. Also, 41 (54.7%) of the case notes

related to female patients (non-pregnant), and 34 (45.3%) were males. Eighty-four per cent (n=63) of patients attended the ED directly from home with only 12 (16%) indicating referral from neighbouring clinics and hospitals for further management and care in the study site. Although few cases were referrals from other facilities, these were all categorised as red category and had the highest level of mortality (see table 26). Fifty-two (69.3%) case records had patients with no recorded comorbidity, and 23 (30.7%) had documented comorbidities. The majority of those with recorded comorbidities died 10/23 (43.5%) (Table 17).

Table 17: Comorbidities of Patients categorised as Suspected Sepsis or Sepsis in the Emergency Department (November 2019 – November 2020).

Comorbidity	Frequency (n-23)	Death
Hypertension and Diabetes	6 (26%)	2 (8.7%)
CVA, Hypertension and DM	3 (13%)	3 (13%)
Peptic Ulcer Disease (PUD)	3 (13%)	1 (4.3%)
Hypertension	2 (8.7%)	1 (4.3%)
Diabetes	2 (8.7%)	
Asthma	2 (8.7%)	
Retroviral infection (RVI)	2 (8.7%)	1 (4.3%)
Obstructive Uropathy	2 (8.7%)	2(8.7%)
Chronic Liver Disease (CLD)	1 (4.3%)	

From the table above, hypertension and diabetes were the most commonly recorded comorbidities representative of non-communicable disease profile of the Ghanaian population (Owusu et al., 2021).

The underlying source of infection was identified as of respiratory origin in 26.7% (n=20) case notes; pneumonia being the commonest diagnosis and the major cause of death. Other sources of infection include urinary tract infections 15 (20%), abdominal infections 15 (20%), malaria 11 (14.7%) and others 14 (18.7%). The 'other' 14 cases (18.7%) with infections resulting in sepsis were classified in the records as:

- Spinal lesion
- Tetanus
- Osteomyelitis
- Infected Wound
- Laceration
- Meningitis
- Tonsilitis

6.4 Management of sepsis in ED

The Surviving Sepsis Campaign (SSC) publishes evidence-based clinical guidelines for clinicians to adopt to improve patient outcomes (Evans et al., 2021). According to these guidelines, all interventions must be completed within an hour once a patient is suspected or confirmed for sepsis. This bundle of interventions recommended in the guideline include blood lactate estimation, blood sampling for blood cultures before antibiotics administration, administration of antibiotics within an hour, administration

of intravenous fluids, preferably crystalloids, as mentioned earlier in Chapter 1. In addition, vasopressors should be administered in cases of fluid refractory shock (SBP <90), and oxygen (target SPO2 above 92) if needed (Evans et al., 2021). These actions are undertaken alongside regular monitoring of patients. Although considered the international gold standard (Evans et al., 2021) the study site does not follow the SSC sepsis bundle guidance in entirety. At the time when this case note review was completed, usual care included antibiotic, vasopressor, oxygen (prn) and intravenous fluid administration only. In this review, usual care has been compared with Sepsis Six elements as the international gold standard to identify what is already in place, and any omissions or gaps in care that had potential for implementation in the future and what might be difficult to achieve.

From the results of this case note review, it was found that blood cultures were not routinely taken for patients presenting with suspected sepsis. When taken, it was usually in response to the patient failing to respond to initial treatment or antimicrobial therapy. In no cases were blood drawn for lactate levels assessment.

6.4.1 Vital signs/triage

Assessment of patient's vital signs is crucial in the identification of sepsis. In this study, vital signs were checked and recorded for patients in most (96% - n=72) case notes at initial presentation (Table 18), yet there were missing values in a number of cases except for temperature recording.

Table 18: Vital signs on arrival (n-75)

Characteristic	Category	Frequency (N=75; Unless otherwise stated)	Percent (100%)
Systolic Blood Pressure (SBP)	Below 100	12	16.0
	100 & >	57	76.0
	Not recorded	6	8.0
Pulse	Below 100	38	50.7
	100 & >	33	44.0
	Not recorded	4	5.3
Respiration	Below 20	39	52.0
	20-24	23	30.7
	25 and >	3	4.0
	Not recorded	10	13.3
Temperature	Below 37.2	39	52.0
	37.2 - 38.2	21	28.0
	Above 38.2	15	20.0
	Not recorded	0	0.00
SPO2	90 & below	8	10.7
	91-94	8	10.7
	95 and >	54	72.0
	Not recorded	5	6.7
Level of Consciousness	Alert	54	72.0
	Confused	4	5.3
	Unconscious	8	10.7
	Not recorded	9	12.0

As shown in Table 18, 12 (16%) case notes had patient's systolic blood pressure (SBP) below 100 and 6 (8%) had no SBP recorded on their initial presentation. These 12 case notes with low SBP were categorised as red zone on triage and had a sepsis diagnosis recorded. An initial pulse rate below 100 was recorded in 38

(50.7%) cases and 33 (44%) presented with an initial pulse rate of 100 and over. The records indicated these patients were triaged and allocated to the red and yellow zones. Four cases 4 (5.3%) had no pulse rate recorded on arrival, although designated to the yellow category. In the respiratory rate assessment, 23 (30.7%) case notes had patient's respiratory rate of 20-24 and 3 (4.0%) were above 25. Ten (13.3%) had no records of respiratory rate (1 from red, remaining 9 from yellow). The majority of patient records 39 (52.0%) showed a temperature recording below 37.2, 21 (28%) between 37.2 and 38.2 and 15 (20.0%) patients presented with a temperature greater than 38.2. 5 (6.7%). Those with higher temperatures recorded, which could indicate sepsis, were allocated to the red zone. Oxygen saturation (SPO2) was unrecorded in 7 (6.7%) patient's case notes and all were categorised as yellow. Sixteen (21.4%) case notes showed a reading of SPO2 below 94 and were all designated red category. The majority of records indicated that patients were oriented on presentation at triage with 54 (72.0%) of case notes showing the patients were alert on arrival, 4 (5.3%) confused, 8 (10.7%) unconscious, and 9 (12.0%) case notes had missing values. Repeat vital signs were not recorded for the majority of the patients. Table 19 below illustrates all records of 2nd vital signs observations for patient's codes as suspected sepsis or sepsis over the study period.

Table 19: 2nd Vital Signs (n=75) emergency department records of patients with suspected sepsis or sepsis (November 2019 – November 2020)

Characteristic	Category	Frequency (N=75)	Percent (%)
Systolic Blood Pressure (SBP)	Below 100	9	13.0
	100 and >	32	42.7
	Not recorded	34	45.3
Pulse	Below 100	24	32.0
	100 and >	19	25.3
	Not recorded	32	42.7
Respiration	Below 20	12	16.0
	20-24	16	21.3
	25 and >	5	6.7
	Not recorded	42	56.0
Temperature	Below 37.2	38	50.7
	37.2 - 38.2	4	5.3
	> 38.2	1	1.3
	Not recorded	32	42.7
SPO2	90 and <	2	2.7
	91-94	8	10.7
	95 and >	32	42.7
	Not recorded	33	43.9
Level of Consciousness	Alert	26	34.7
	Confused	1	1.3
	Unconscious	4	5.7
	Not recorded	44	58.7

Of the 75 case notes reviewed 32 (42.7%) patients had no repeat vital signs documented. Out of those with missing records 2/32 (2.7%) were designated to the red zone, and the remaining 30/32 (40.0%) to the yellow zone. From the case notes with records of repeat vital signs, 43 (57.3%) patient's time interval between 1st and 2nd recording was greater than one hour even for patients admitted to the red zone.

Systolic blood pressure was not recorded in 45.3% (n=34) of case notes after the initial vital sign assessment. The majority of the 34 patients with no 2nd SBP record were admitted to the yellow zone, although patients admitted to the red zone had recorded SBP assessment period between observations longer than the recommended one hour. Rates of non-completion of 2nd vital sign assessments were: 42.7% pulse rate; 56% respiratory rate; 42.7% for temperature; 43.9% respiratory rate; and 58.7% no documented level of consciousness.

In this case note review, initial vital signs assessment was completed for the majority of patients - this assessment would have been undertaken in the triage area on arrival to the ED. However, between 40-60% of subsequent observations were missed, not recorded or unrecorded in-patient records. These patients with missing values were most likely to be admitted to the yellow zone. Due to incomplete vital signs assessment, recognition of deterioration was probably delayed. There was a statistical significance, where patients who had delayed reassessment were likely to die ($p<0.05$).

6.4.2 Components of usual care provided for patients with sepsis at the study site

Fifteen patients (20%) who received oxygen administration were all triaged within the red category. The majority (73/75 - 97.3%) of cases coded for sepsis or suspected sepsis had antibiotics prescribed, however, 2 (2.7%) had no evidence in their records that antibiotics were prescribed; both these patients were categorised as yellow zone. Even though the majority of the cases had antibiotics prescribed, they were administered in more than an hour; this was not statistically significant with the outcome – discharge or death (p-0.433). There was variation in the antibiotics prescribed, although 57(76%) were broad-spectrum including ceftriaxone, amoxiclav

and cefuroxime; all consistent with SSC recommendations. These were mostly administered intravenously, with just 16 (21%) prescriptions provided orally. Most patients (54/72%) were prescribed crystalloids, however, others received 5% and/or 10% dextrose, administered based on their presentation (see Table 25). However, 5 (7.0%) patients who were allocated to the red zone received Dobutamine after 4L of IV fluids were administered. This suggests that even though some elements of the Sepsis Six bundle were present (antibiotics, IV fluids, vasopressors), others were not available – lactate checks (Table 20).

Table 20: Usual care provided for patients with sepsis/suspected sepsis at the study site

Sepsis Six criteria	Criteria assessed	Frequency (N=75)	Percent (%)
Oxygen administration	Oxygen	15	20
	Not recorded	60	80
Antibiotics prescribed	Yes	73	97.3
	No	2	2.7
Type of antibiotic	Broad spectrum	57	76.0
	Others	16	21.3
	Not recorded	2	2.7
IV fluid prescribed	Yes	54	72.0
	No	21	28.0
Type of IV fluid	Crystalloid	34	45.3
	Others	20	26.7
	Not recorded	21	28.0
Vasopressor administered	Yes	5	7.0
	Not recorded	70	93.0

6.4.3 Time to interventions

The time taken to carry out time critical interventions such as administering antibiotics is considered significant for improving outcomes in sepsis. Table 21 below illustrates the components of care and the time taken to carry these out.

Table 21: Comparison of care received at study site contrasted with Sepsis 6 criteria

Time Critical Sepsis Six Criteria	Criteria assessed	Frequency (N=75)	Percent (%)
Arrival and provisional	≤1 hour	54	72.0
sepsis diagnosis	>1 hour	21	28.0
Arrival to 1st	<5minutes	11	14.7
vital sign assessment	≥5minutes	61	81.3
	Not recorded	3	4.0
Arrival to 2nd vital signs assessment	≤1 hour	3	4.0
	≥1 hour	39	52.0
	Not recorded	33	44.0
Arrival to antibiotic administration	≤1 hour	10	13.3
	> 1 hour	62	82.7
	Not recorded	3	4.0
Arrival to IV fluid administration	≤1 hour	14	18.7
	>1 hour	38	50.7
	Not recorded	23	30,7
Outcome of patients	Died	20	26.7
	Discharged	55	73.3
ED length of stay	Within 24 hours	33	44.0
	More than 24 hours	42	56.0

Clinicians using the Sepsis Six guidelines are expected to identify sepsis or make a provisional diagnosis within 1 hour of arrival at the ED. In this study, 54 (72%) of the case notes had patient's being diagnosed of sepsis within an hour and 21 (28%) beyond an hour. All 21 case notes with sepsis diagnosed after an hour were within the red category. Even though the majority of the case notes had a record of a diagnosis of sepsis identified within an hour, this might be due to poor specificity inherent in the coding system adopted at the study site. Hence sepsis and septic shock recognition is delayed. In the case of administration of antibiotics, 62 (82.7%) case notes showed that administration of the antibiotics took longer than one hour. Only 10 (13.3%) received antibiotics within an hour, and 3 (4.0%) had no documented administration time, even though they received antibiotics. When it comes to intravenous fluid administration, 14 (18.7%) received the fluids within an hour, 38 (50.7%) recorded administration initiated in more than an hour, and 23 (30.7%) had no recorded IV fluids.

Most patients 55 (73.3%) were discharged home directly from ED, and a further 20 (26.7%) patients died in the ED. From the data extracted from the case notes, it was evident that those patients categorised as yellow following triage were discharged home, in contrast to those patients who died who were all categorised as red zone at triage. One case record indicated the patient was referred to a tertiary level hospital for further specialist care unavailable at the study site. ED length of stay was recorded as more than 24 hours in 42 (56%) cases; however, 33 (44%) patient stays were less than 24 hours until their final disposition due to lack of inpatient beds. To further breakdown the specific length of stay hours recorded in the case notes, 33 (44.8%) case notes recorded patient's stay within 0-24 hours, 6 (7.9%) within 24-

48hours, 20 (27.6%) within 49-72 hours, and 15 (19.7%) beyond 72 hours as illustrated in the bar chart below in Figure 11.

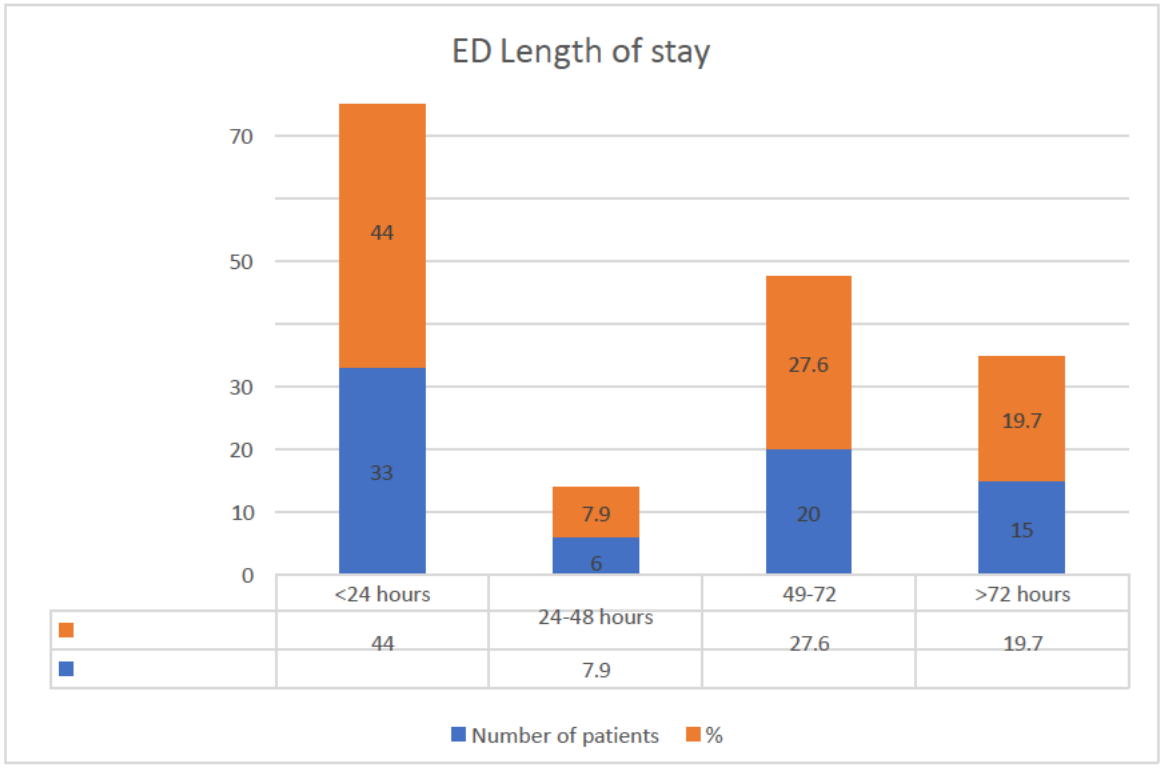

Figure 11. ED length of stay

6.4.4 Relationship between demographic characteristics and outcome

Table 22 presents the results using the Chi-Square test of independence applied to examine any associations between independent and dependent variables. These included: age of patients (p = 0.001); type/RAG status on admission (p= 0.001); mode of admission (p= 0.002); and comorbidity (0.029). All were significantly associated with the disposition of either the patient's discharge or death.

Table 22: Relationship between demographic characteristics and outcome (discharge or death)

Variable	Category	Died (n=20)	Discharged (n=55)	Total	P-value
Age	Below 20	0 (0.00%)	9 (100%)	9 (100%)	0.001
	20-49	5 (13.9%)	31 (86.1%)	36 (100%)	
	50 and above	15 (50%)	15 (50%)	30(100%)	
Gender	Female	9 (22.0%)	32 (78.0%)	51(100%)	0.226 (FET)
	Male	11 (32.4%)	23 (67.6%)	34 (100%)	
Type of admission	Red	15 (60.0%)	10 (40.0%)	25 (100%)	0.001
	Yellow	5 (10.0%)	45 (90.0%)	50 (100%)	
Mode of Admission	Home	12 (19%)	51 (81.0%)	63 (100%)	0.002 (FET)
	Referred	8 (66.7%)	3 (33.3%)	11 (100%)	
Weekend/day	Weekday	17 (28.3%)	43 (71.7%)	60(100%)	0.384 (FET)
	Weekend	3 (20%)	12 (80%)	15(100%)	
Source of infection	Respiratory	9 (45.0%)	11 (55.5%)	20(100%)	
	Urinary	3 (20.0%)	12 (80.0%)	15(100%)	0.069
	Abdominal	3 (20.0%)	12 (80.0%)	15(100%)	
	malaria	0 (0.00%)	11 (100%)	11(100%)	
	others	9 (64.3%)	5 (35.7%)	14(100%)	
Comorbidity	With comorbidity	10 (43.5%)	13 (56.6%)	23(100%)	0.029
	Not recorded	10 (19.2%)	42 (80.8%)	52(100%)	

All patients less than 20 years were discharged (n=9), none died. Patients aged 20-49 years were predominantly discharged 31 (86.1%), whilst around half of patients (n=15) in the age group 50 years and above died. Statistically, this review found that the greater an individual's age, the higher the likelihood of dying (95% CI, 0.3130 to 0.6870). There was no association (p=0.226) between gender and greater or lesser levels of morbidity. Even though 11 men (32.4%) died (95% CI:0.1739 to 0.5053) compared to (n-9 (22.0%) women (95% CI 0.1056 to 0.2195), there was no statistical difference in terms of likelihood of death or survival between males and females. For type or RAG status following triage, 15 (60%) of deaths were recorded of patients categorised as red zone and 45 (90%) of patients discharged were categorised as yellow zone.

Patients later coded as sepsis and categorised at triage to the red zone were more likely to die (95% CI, 0.3867 to 0.7887, proportion - 0.6000) than if categorised as yellow zone on triage. The majority of patients referred from another healthcare facility to the ED, died (n-8), whereas 51 (81.0%) of the patient case notes showed that patients who attended ED directly from home were more likely to be discharged (95% CI, 0.3903 to 0.9398). There was a statistically significant association between the presence of comorbidities and mortality. 10 out of 23 patient case notes with documented comorbidity died (95% CI, 0.2319 to 0.6551), whilst 42 cases of those with no documented comorbidity were discharged. These data would suggest that prognosis is affected by co-morbidity as patients presenting to ED with sepsis are more likely to die if they have an underlying health condition.

6.4.5 Relationship between time to interventions and outcome

The time interval between the first and second vital signs was significantly associated with final disposition (p=0.001) whereas the relationship between time from arrival to antibiotics administration with disposition was not overall statistically associated (p= 0.433 FET). The exception, however, was the patients that ultimately died (n=20) 18 received their first dose of antibiotics after 1 hour. Likewise, as shown in Table 23 the time from admission to first vital signs recording was not associated with either outcome – discharge or death (p=0.566), however, the second vital signs was significant.

Table 23: Time from arrival Sepsis 6 interventions and patient outcome

Variable	Category	Died (n=20)	Discharged (n=55)	Total (n=75)	P-value
Time of arrival to time antibiotics administered	An hour	2(20.0%)	8 (80.0%)	10 (100%)	0.433
	> an hour	18 (29.0%)	44 (71.0%)	62 (100%)	
Time of triage and first vital signs assessed	<5minutes	3(27.3%)	8(72.3%)	11(100%)	0.566
	5mins or>	17(27.9%)	44(72.1%)	50 (100%)	
Time between first and second vital signs assessment	An hour	1 (33.3%)	2 (66.7%)	3 (100%)	0.001
	>1hour	18 (46.2%)	21 (53.8%)	39 (100%)	
	Not recorded	1(3.0%)	32(97.0%)	33(100%)	
ED length of stay and outcome	Up to 24hrs	3(9%)	30(91%)	33(100%)	
	>24hrs	17(40%)	25 (60%)	42(100%)	0.002

6.5 Summary

From the results of this case notes review a number of findings warrant consideration. Firstly, sepsis identification was largely doctor-led; that is, the patient, irrespective of findings at triage, must be assessed and diagnosed by the attending physician before any actions can be delivered by the nurses and/other members of the team. Secondly, all patients attending the ED with an infection are coded in the electronic health record as sepsis. In the absence of a system to differentiate between an infection and sepsis may result in inappropriate treatment for sepsis in those with an infection and/or treatment of patients with sepsis not being managed at the pace required to achieve optimum outcomes. Thirdly, although most of the case notes had a record of vital signs completed at initial presentation, were triaged, and treatment initiated, some vital sign assessments were missing. Also, second and subsequent vital signs reassessment were frequently delayed (>1hour) or not completed. In some instances, 2nd assessment took more than three hours to be completed. Antibiotics administration also from the records was delayed beyond 1 hour in a number of cases.

Interestingly, ED length of stay was very high; patients had to stay in the ED for over twenty-four hours due to lack of inpatient beds. This could cause overcrowding in the ED, impacting on routines such as regular vital signs monitoring, identification of deterioration, and ultimately result in poorer outcomes. There was no information in any of the 75 case notes reviewed that blood cultures and/or lactate were tested normally as part of recommended sepsis pathways. This is something explored further through the process mapping described in Chapter 7. Likewise, the finding

that referral from another healthcare facility was likely to result in a poorer outcome for patients. Also, many patients had no documented comorbidity; hence it is not possible to confirm if they did or did not have comorbidities. Another thing to note is the number of mortalities from the case notes recording referrals from neighbouring hospitals and clinics. All these findings will be explored further in the next chapter.

CHAPTER SEVEN

PROCESS MAPPING

7.0 Introduction

This chapter has three components: the first describes the pre-study observation; the second explores HCPs' views on the sepsis care pathway through individual interviews; and the third explains the process mapping workshop.

7.1.1 Pre-study observation of the current flow of patients with sepsis:

A pre-study observation of two purposefully selected patients in the ED was conducted. One was observed on a weekday and the other on a weekend from their initial presentation until their final decision was made in the ED for an understanding of the flow of patients with sepsis prior to the interviews and workshops (graphical presentation presented in Appendix 13). Key findings from the observation include:

- A doctor was called to attend to the patients after triaging by triage nurses to assess, diagnose and decide on treatment for sepsis, however, there is only one doctor per time.
- Resuscitation nurses secured IV lines and took samples for FBC and biochemistry.
- Samples were sent to the lab by nurses and patient relatives.
- Resuscitation nurses picked up patients' medication from the pharmacy after the doctor’s prescription.
- Resuscitation nurses administered medications.
- The frequency of monitoring was done at the nurse’s discretion.
- Laboratory investigation results delayed reaching clinicians and ED staff did not follow-up.

It was observed that there were delays in the care process, such as time for sepsis diagnosis and the time it takes to receive the results of laboratory investigations. These have been explored further in the process mapping interviews and workshops.

7.2 Findings from interviews - Healthcare professionals' (HCP's) perspectives on the processes patients with sepsis undergo in the ED

7.2.1 Introduction

This section presents the findings from interviews with healthcare professionals (sepsis staff volunteers – SSVs as discussed in Chapter 5) regarding the care process for patients with sepsis. The outcome of the analysis of the transcribed data from interpretation and sensitivity to the subject were three themes: thinking and identifying sepsis; process of resuscitation; and improving sepsis care.

7.2.2 Methods

Fourteen HCPs (SSVs) who willingly volunteered and consented were interviewed using a conversational approach, as described in Chapter 5. Interviews were recorded using a password protected audio recorder. These interviews lasted between thirty to forty-five minutes. The interviews were transferred as audio files to a password protected laptop, data were transcribed by the researcher (AP), and audio recordings were deleted. Transcribed data were analysed using reflexive thematic analysis (Braun and Clarke, 2022), open coding and supported using NVIVO version 14 (see Chapter 5).

7.2.3 Interview findings

During 2021, a series of interviews were undertaken with ED healthcare professionals to better understand their roles and perceptions of how patients with sepsis were currently managed and what they perceived as the usual care pathway for these patients.

Four types of healthcare professionals were involved: doctors; nurses; pharmacists; and laboratory technicians. These professionals had been in their roles for four months to twelve years. Individual roles described by the SSVs, when asked included: taking care of the patient from their arrival and making a working diagnosis (doctors); taking samples (nurses, doctors, lab personnel); dispensing medications (pharmacist); administering medications (nurses); and processing samples (laboratory personnel). Other personnel, e.g. porters, as described by SSVs, have responsibilities such as receiving patients into the ED and they assist in taking patients for x-rays, depending on the available number per shift.

Some of these tasks were also undertaken by registered nurses, particularly out of hours or when porters were unavailable.

7.3 Themes

The three themes explaining the process of care for patients with suspected or diagnosed sepsis were: (1) thinking and identifying sepsis (categories – triaging and clinical awareness and delays); (2) the process of resuscitation (categories - components of care and delays); and (3) improving sepsis care (categories - sepsis protocols, training and resources). An overview of the elements within each theme and category is illustrated in Figure 12.

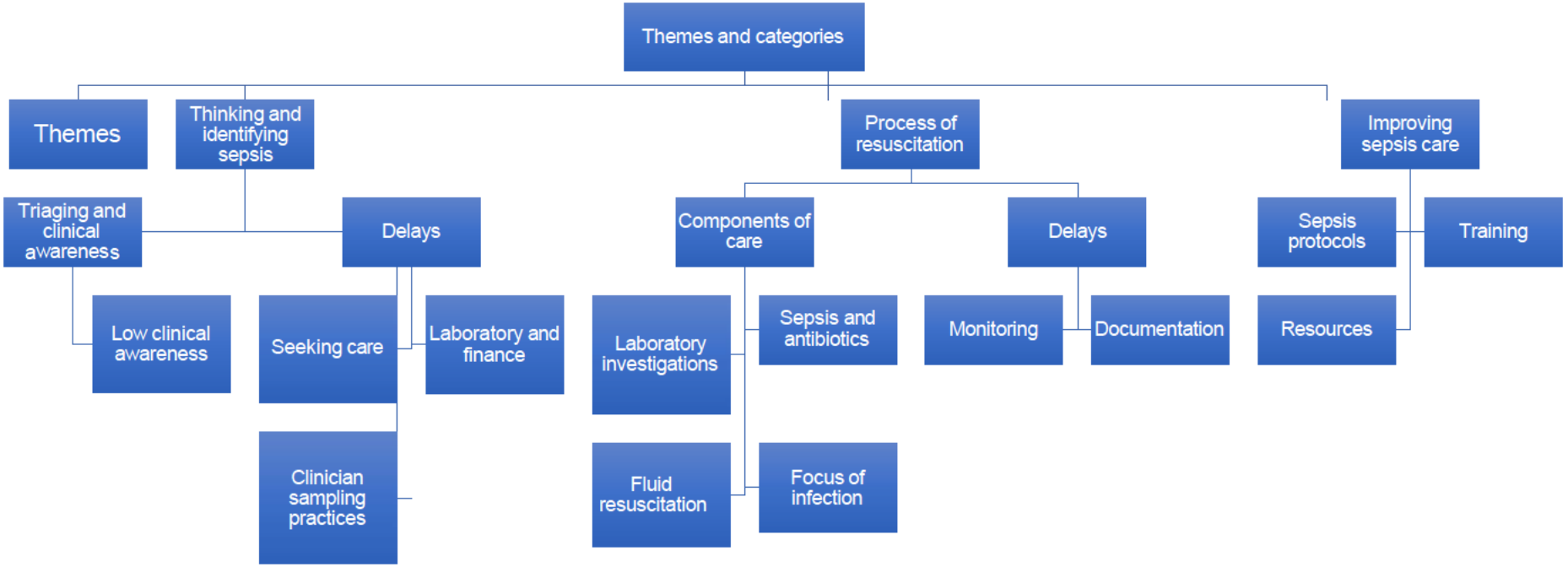

Figure 12. Themes and categories from interviews with participant healthcare professionals (SSVs)

7.3.1 Thinking and identifying Sepsis

Patient triage process, clinical awareness, and identification delays were significant categories of this theme.

7.3.2 Triaging and clinical awareness

In this theme, participants explained their perspectives of the triage process for patients suspected of having sepsis, their views on sepsis identification and their clinical awareness of sepsis as a clinical problem. Careful assessment of the information provided by the SSVs (MDT) who were interviewed revealed most of the time, doctors are required to examine and make a diagnosis of sepsis before any actions can be taken, as illustrated by these participants:

"so when the patient enters the ED, triaging is done by the ED Nurses, and then they alert the doctor about the case that has arrived. So, an initial assessment involving history and physical examination is made by the doctor and then through that suspicion of sepsis is also made.'' (D5)

" sepsis management begins when the doctor's examinations confirm, we realise that the patient is having sepsis we start the treatment from there and we continue when our investigations are there, so maybe for the first twenty- four hours at least we have to start base on our investigations but as I said, the lab investigations come in before the twenty-four hours so we continue or we discontinue when we get the lab investigation. So, it start from the time that the doctor assess and realise that the patient is having sepsis.'' (N3)

"The sepsis pathway is actually started after the doctor has finally seen the patient and taken his time and examined and he starts it.'' (N5)

These quotes above explain traditional team, doctor and nurse roles. Based on these illustrations, even though the doctor's role to diagnose and initiate a management plan of sepsis interventions is local custom and practice, this approach to sepsis identification and the care process might delay initiation of treatment. Only one doctor is on duty and is responsible for all incoming patients - between 30 to 40 patients per shift. In this case, this traditional role will not help in cases of sepsis. The triage system used by nurses for all patients is general and not specific to better identify sepsis. Hence, an opportunity to initiate interventions may be missed. This approach may lead to the patients reporting with sepsis being managed on the general pathway where cardiorespiratory assessments may take a long time.

"so going by the triage that we are using, the South African Triage System (SATs), we consider the vital signs, the consciousness level of the patients, how mobile the patient is, is he walking by himself and then we use other discriminators such as the main complaints of the patients. Regarding sepsis in focus, we consider the pulse and the BP (blood pressure) specifically, but our Triage does not focus just on sepsis patients; it is generalised for all the kinds of patients that come in, so we do triage for everybody. We do not just isolate sepsis patients." (N2)

In this case, there could be delays in instituting treatment and care provision, patient safety and mortality risk. For example, in contexts where a method of assessing for deterioration using an early warning scoring system such as the NEWs2 track and trigger is available, sepsis is more likely to be identified through the initial nursing assessment when a composite set of observations is taken to establish a baseline score. However, this generalised approach used in the study site may lead nurse clinicians to overlook sepsis when triaging, and even when identified, it may be based on individual judgements of what parameters qualify a patient to be

considered as having sepsis. Further, irrespective of whether they do or do not suspect sepsis, diagnosis requires medical assessment and ‘authorisation’ of a management plan.

The purpose of triage, however, is to complete an initial assessment to determine the severity of their presenting problem and determine the best or appropriate placement in the ED; arguably without adequate assessment, appropriate placement is misguided (Health 2012; Hayden et al., 2016; Rady, 1996; Safdar, 2010; Yurkova and Wolf, 2011). Creation of sepsis awareness is paramount as delays in treatment will produce a poorer outcome (Machado et al., 2017a). At the study site, task shifting with appropriate training and behaviour change will be needed to change the current ways of working.

Malaria is endemic in this area of Ghana and a common cause of patients presenting at ED with acute associated problems. Consequently, staff gravitate towards ‘thinking malaria first’ and tend in any diagnostic assessment to seek to rule out malaria before considering alternative interpretations of symptoms such as sepsis.

“To a large extent, per the system that we run here, we don’t easily or quickly identify cases that have sepsis. Malaria is very endemic here, so most cases that come, we try to rule out an infectious disease like malaria, and then we look at other possible viral cases. So, we start with malaria treatment and other conditions that we think may be responsible. Then again, too most of our labs, we have a challenge with the labs.” (D1).

“most at times, the doctor's suspicion is much later after they do their normal rounds, but we don’t have something that is an organised formal sepsis pathway at all, not at all.” (N5)

Normal rounds in the quote above refer to the routine reviews made by the doctors (example medical or surgical teams - usually in the morning). For instance, if a patient is assessed by an ED doctor and admitted for the medical team, the patient will have to wait for a review by the medical team the next day due to engagements at their outpatient departments. These further delays sepsis recognition, if it was missed by the ED doctor.

Even though the suspicion of endemic conditions could be clinically feasible, contextually, understanding and adopting other clinical protocols which might be more appropriate in some cases, such as the sepsis protocol, can go a long way to help in its identification and care as sepsis is one of the top ten causes of mortality. Normally the first step in assessment is differential diagnosis of all conditions that share similar signs and symptoms, but a definitive diagnosis is reached when tests and observations are completed and results for interpretation are presented.

However, because full set of vitals are missed and there are poor attitudes towards follow up of laboratory investigations, possible diagnosis may be missed in the absence of standard markers. Also, in possible diagnoses these are often considered in terms of likelihood, and this could facilitate the malaria choice as most likely.

7.3.3 Delays

This theme describes patient, clinician and organisational barriers that impede or delay the early recognition of sepsis (Mgawadere et al., 2017; Papali et al., 2015b). Here the patient's decision to seek care was reported by the SSVs as one of the key factors of delay, which leads to their condition worsening before they arrive at the hospital. These patient delays may be linked to financial, cultural and religious

practices as reported by SSVs. For the clinician's part, lack of clinical awareness (nurses and doctors) as mentioned earlier and poor blood sampling practices causes a delay in the process. The availability of resources was a further factor impacting organisational delays, such as inadequate blood culture sample bottles and non-availability of lactate checks as discussed below:

i. Seeking care

All SSVs expressed their frustrations that most of the patients stay at home, or seek alternative treatment options, before finally deciding to seek hospital treatment. Hence, on arrival their condition has already deteriorated, and little can be done to prevent death.

"sometimes they delay in deciding to come to the hospital, and sometimes some of the patients may also visit small facilities and then clinicians may detain them.

Conditions that they cannot manage, they will keep the patient and only refer when the case is in a very bad state. Also, for some patients who are non-insured sometimes they may want to gather money before they come to the hospital. And then some are also from places that coming to the hospital becomes a bit of a challenge, looking at the distance they are from a very far places. And then also organising themselves to come to the hospital becomes a bit of a challenge.

Notwithstanding that, the hospital continues to reach out to the communities in a form of advocacy, in a form of education to sensitive them that even when they don't have insurance, they should report to the hospital, and the hospital will be in the position to offer some help to them, and then arrangement is made for them to clear their bills later". (P3)

These scenarios offered by one clinician reveal that there is an awareness of a gap between patient awareness of signs and symptoms of sepsis (or severe illness) and the importance of seeking early urgent hospital treatment when experiencing these signs or symptoms.

ii. Laboratory and finance

The available pay-later policy in the ED (24–48 hours) can help facilitate expedited patient care, including that needed for patients with sepsis or suspected sepsis.

"as a hospital, our policy is to provide all immediate drugs and services for the first 48 hours without requesting for any payment." (P3)'

The initiative to treat then seek payment later is good when sepsis is recognised early, however, in situations when a diagnosis of sepsis is recognised late, patients may not fall within the "grace" period mentioned. In these cases, patients may have to make payment before investigations are conducted, which can delay care.

"Cultures of some of the body fluids, they have to pay. And even if they don't pay up front, most of the labs are not covered by insurance, so will pay upon discharge, but in selected cases where our lab runs out, we have to call other labs from outside and when they come around, and the patient have to pay up prompt before the sample is taken, and it's even brought back, and sometimes it becomes very difficult because relatives are not able to provide the money up front for these labs to be done, so they come back with issues of our inability to determine exactly the organism that is causing the problem or to determine whether end-organ damage is happening and is happening very fast." (D1)

“okay, so if the patient is on health insurance, the full blood count or complete blood count is free with the insurance and the blood grouping, so they do get that one.” (D4)

Even though some laboratory investigations, such as full blood count and urine for routine examination, might be considered fully under the national health insurance scheme, others, such as blood cultures, biochemistry, and chest x-rays, might require some form of payment before being carried out. This was a challenge reported in two of the reviewed papers where patients were unable to have blood cultures done due to financial constraints (Arie et al., 2019; Kassyap, 2018).

When the blood samples are sent to an outside laboratory, the required financial reimbursement further delays the entire process.

“sometimes, I mean because we don’t have these equipment’s in our facility to make things faster with the management for them, they go out and pay for labs outside before they are done and then for them to bring the results, it makes the whole management thing longer. It takes time for us to know the results that we are trying to look for.” (D2)

This means clinical decisions may be delayed if the patient does not have the money to make payment before the samples are investigated. Upgrading the capacity of the study site laboratory with frequent supplies to complete tests such as blood cultures can save the patient from any delays related to payment, especially when sepsis is recognised outside the ‘pay later period’.

Results from laboratory investigations also took a long time to be reported to the doctors. One of the reasons, even when lab investigations are completed early, was the access to an EHR within the lab to record, which tend to take longer than usual,

which delays the results from reaching the doctor to facilitate clinical decision-making and management plan. Inadequate personnel were also mentioned by participants as a cause of delay.

"The other thing is the challenge that we have with our personnel. We don't have enough personnel (health care personnel and especially doctors) that are able to who can always be at the resuscitation to help us identify or to help us suspect these cases when patients come around. to a large extent, it takes some time before we are able to arrive at that conclusion and our labs too keep delaying and it makes it very difficult." (D3)

This reinforces the limitations that one doctor per shift can cause. Role shifting through developing nurses to recognise deterioration and escalate concerns could support prompt identification and management. Resources such as the capacity to run blood culture and lactate were one of the challenges raised (none of the case notes reviewed had blood cultures done). However, it was mentioned that the laboratory could access blood culture bottles but not in the emergency. In this case, training the nurses on sampling and bringing these bottles closer to them will help inform the collection of blood culture samples.

iii. Clinician sampling practices

One major challenge that laboratory personnel identified as causing delays in the existing and any potential sepsis care pathway, was the existing approach for taking and handling blood samples. This led to occasional incorrect laboratory results, which needed to be repeated before proceeding with further clinical decisions for the patient and continuity of care.

“And at times, what I have also observe is that the sample is being poured into the EDTA container for the reagents/EDTA to mix with the sample for the hematology test then they later realise that they are supposed to use chemistry container. So certain times you go and the sample is not clotting, you do the electrolytes, all of them are high, and you will realise that it is the mixing of the reagent that caused it. I have observed that one, too more than twice. I always advise them, but they still do it. That is what I have observed. The second challenge is that the samples are not labelled during the emergency. Even if you tell the person please label this sample is like another extra work, they wouldn’t do it. So, most at times, it makes it difficult for you to know that actually the sample has been exchanged or it’s actually the right thing because they don’t label it.” (L1)

Interpretation of this account illuminates problems that could impact on patient safety. If a sample is mislabelled or is not labelled, it could result in the wrong diagnosis being made, creating unnecessary anxiety and possibly an incorrect management plan. The outcome, especially if not identified, could result in aggressive interventions being initiated. Staff in-service training on appropriate sampling practices would appear to be needed.

7.3.4 Process of resuscitation

This theme identified two categories: components of treatment and delays in treatment.

7.3.5 Components of care

The interventions carried out for patients with (suspected) sepsis were described by participants. First, the nursing team secure IV access and take routine samples, the doctor diagnoses and plans care, the registered nurse collects medications and administers them, sends specimens and chases laboratory results. Sometimes laboratory technicians assigned to the ED also assist with sample taking by collecting the samples and further sending them for the tests. In addition to other components mentioned above, oxygen administration was one of the interventions considered for patients whose SATS are less than 92% and often initiated by nurses:

''Yes, so if they come in severe distress, even if the saturation is normal, we support with oxygen because of the high respiratory rate to ease on the respiratory system, but most of them come with low saturation, so we start empirical oxygen support.

Then we start with the intranasal if it's not improving, then we go to the higher ones, the nonrebreather, and sometimes intubation comes in." (D4)

From this illustration, even though administration of oxygen therapy depends on oxygen saturation, nurses do not wait for doctors to prescribe oxygen before initiation as they perceive it as a life-saving intervention. However, they do discuss the decision to initiate treatment with the doctors to subsequently inform prescribing.

i. Laboratory investigations

From the stage of diagnosis, the laboratory investigations frequently requested included a complete blood count, biochemistry and urine for routine examination:

"we take samples for the full blood count. Full blood count that one will give you the HB (hemoglobin) of the patient, and then it will give you the WBCs (the white blood

cells), then it will give you other result like oenophiles, basophils so that it will also help you to know the type of infection. You know, in the case of infection, the WBC's level rises, so we also based on that one. Mostly we base on the full blood investigations. Then if we also want to do for further investigations, we take the urine to do the urine R/E (Routine Examination)." (N3)

Blood cultures are not part of initial laboratory tests requested. The issue of financial implications came to light regarding some brands of antibiotics.

"as I said earlier, we only do blood culture for specific patients; it's quite expensive, so it's not everybody who will be able to afford so we do it for sepsis patients and sometimes for patients who are not responding to the initial antibiotics therapy that was initiated. So, you have tried this, you have tried that the patient is not responding, so let's do C/S (culture and sensitivity) and see if the patient will respond; we do it for such patients as well.'' (N5)

"But for the blood cultures, sometimes it takes as much as three days or even a week when the person is not doing well with our current anti-biotic then we begin to wonder there may be problems with sensitivity then we begin to start doing the cultures otherwise most at times we start the anti-biotic about approximately four hours." (L1)

These illustrations imply that patients with sepsis might have received antibiotics for a couple of days before blood cultures are taken to identify the best antibiotic to use. This delay could impede culture growth and failure to produce an isolate, even though the patient might remain acutely ill. Even though administration of antibiotics should not be delayed if blood cultures are delayed (Evans et al., 2021).

ii. Antibiotics

Broad-spectrum antibiotics are normally prescribed and administered for all patients suspected or diagnosed with sepsis. The SSVs indicated commonly used broad-spectrum antibiotics were ceftriaxone and amoxiclav, which aligns with global guidelines (Evans et al., 2021). The choice of antibiotics normally depends on the suspected focus of infection:

"so in patients with sepsis, because normally we don't have the lab results immediately, we normally do broad spectrum antibiotics whilst awaiting for the culture and sensitivity results to guide us in the selection of antibiotics. When you are dealing with adults with sepsis, normally, these antibiotics are used as the first line. We have the amoxicillin clavulanic acid injection and cefuroxime injection; we have ceftriaxone injection. And then, when you are managing sepsis as a result of conditions like chronic ulcers or diabetes ulcers, then the choice of antibiotics sometimes differs where clinicians may sometimes want to prescribe flucloxacillin injection combined with either metronidazole or clindamycin based on our peculiar nature. That is for the adult's population." (P3)

All these antibiotics described in this account are broad-spectrum antibiotics. Since the local culture sensitivity pattern is unknown and cultures are hardly done, switching the patient to a more specific antibiotic might be challenging as they may not be readily available.

"When they come, we take the sample, and then we start with broad-spectrum antibiotics, so after a day or two, if they are not doing well on the broad spectrum, then we do the culture and sensitivity to identify which specific ones are causing the problems, and then they tackle it from there." (N5).

In cases where nursing empowerment is considered, timely recognition and interventions could be expedited. Antibiotics might have been initiated a day or two before any thought of sepsis and then have blood cultures taken as mentioned earlier. Local protocol for antibiotic stewardship was mentioned by SSVs to not be in place and yet to be devised, which makes antibiotic de-escalation not principled appropriately.

"so currently the institution is in the process of developing its own protocols, notwithstanding that fact we still rely on the standard treatment guidelines of Ghana which spells out various antibiotics to use in managing cases." (P3)

At least if there is a local protocol for antimicrobial stewardship, then taking blood cultures as soon as possible before administration of antibiotics might result in a well- informed treatment plan.

iii. Fluid management

SSVs indicated intravenous fluids such as ringers' lactate were often prescribed and administered:

"so as part of the management, they do hydrate the patient, and the various intravenous fluids that are normally prescribed include the ringers lactate and the sodium chloride infusion. Sometimes if the patient cannot be able to eat well that is when they give dextrose preparations, either 5% infusion or dextrose 5% in normal saline preparation, that is for the adults, for the new ones or the neonates; they give the one-fifth (1/5th) dextrose in normal saline preparation for the newborns or neonates." (P3).

"yes, when they are presenting with hypotension, especially when they come and we have tried IV fluids resuscitation, we have given four litres (4L), five litres (5L) and

BP (blood pressure) not rising, urine output not coming and so we resort to the vasopressors to get the vasoconstrictions." (N5)

"In most cases patients with DM (Diabetes Mellitus), and hypertension and heart failure, when you give them more of IV fluids it leads to worsen their condition so sometimes, we have to stop using the IV fluids and then start with the inotropes." (N3)

From these descriptions crystalloids are the most frequently administered IV fluids. Some patients, when clinically indicated, are given inotropes or vasopressors when fluid resuscitation fails or is contraindicated. This is good practice for fluid refractory shock, especially for patients whose comorbid state deteriorates with increased fluid resuscitation (Evans et al., 2021).

iv. Focus of infection

Participants expressed that one of the most important factors to be considered regarding sepsis is identification of the source of infection, which they seek to ascertain from admission and results in patients visiting other areas of care such as radiology for chest X-rays.

"okay, so I will say the commonest, we have chest infection (pneumonia, tuberculosis), and then so maybe I will place the UTI as second because they are quite common now and then brain infection too, we do have them. Ideally, if the patient can afford then we do a full septic screen, but we start with the cheaper ones first before we go to at least most patients can afford the chest x-ray, can afford the urine R/E, but not every patient can afford head CT, especially with contrast." (D4)

Without identification of the source of infection, optimum treatment will be missed and poorer outcomes ensue.

v. Outcomes

Participants were aware that patients presenting with sepsis were likely to have poorer outcomes.

"In fact, on our death certificate that I fill most of the times I noticed that majority of the cases at least about fifty percent (50%), they die from one form of sepsis or the other which probably wasn't detected or was detected late and some came in and they didn't have prolong hospital stay but they died because sepsis wasn't easily or properly identified earlier on for initiation of care." (D1)

This account suggests that sepsis can easily pass through the system largely unnoticed until their condition deteriorates and could lead to death. Age and the behaviour of patients were other factors clinicians expressed as contributing to the outcome of the patients ultimately diagnosed with sepsis. Sepsis is not among the top ten reasons for admissions, although, it is among the top ten reasons for death (HFH Annual Report, 2020).

7.3.6 Delays

In this theme, patient's vital signs monitoring and documentation were discussed. Participants stated that the frequency of vital signs monitoring varies from patient to patient, and that is based on the nurses' intuition. The non-availability of a standardised frequency of monitoring leads individual clinicians to use their judgement when monitoring patients, resulting in unrecognised deterioration until later.

"Well, it's variable. There are no fixed times. So, I would like to give a scenario a patient comes with low BP, and then, as a result of sepsis, when the initial

interventions are instituted, the vital maybe checked as often as half-hourly. Yeah, but those who may have normal BP, normal saturation but are pyretic, their vitals maybe checked the second time, maybe in an hour or more, but another thing that determines how often the vitals are checked is where the patient will move to. And when the patient will be moved from the resuscitation area, if the patient moved immediately like within twenty minutes, moved to a zone, red zone and yellow zone,

the vitals will be checked immediately because that is also part of the receiving protocol. So, the time for second reassessment it varies. It's not fixed. And every patient and their needs." (N5)

The implication is that clinicians may or may not complete further monitoring, unlike facilities where early warning systems are embedded.

7.3.7 Documentation

Missing vital signs and incomplete documentation was one of the challenges identified (see Chapter 6). SSVs offered several factors as reasons for why this occurs. First, switching from a paper-based to an EHR was mentioned as a contributory factor. Secondly, inadequate computer access to complete documentation was another factor.

"They were given earlier, but the charting on the system was often late. The whole AKSOFT was new, and people were now adjusting (N5) '' I think it's also due to poor documentation." (N5)

"some patients actually receive antibiotic therapy within the first one hour of admission, but due to inadequate machines like computers or laptops which the staff uses to chart and document every procedure carried out, these are charted and

documented later when every resuscitation measure is carried out for the patient." (N4)

7.4 Improving sepsis care

Three categories emerged from this theme: sepsis protocols; resources; and training.

i. Sepsis Protocols

The need for a sepsis protocol or care pathway in the ED was recognised by participants to standardise processes for identification and implementation of sepsis interventions.

"I think the emergency unit is a unit whereby we troop in with so many conditions, and attention is only given whereby the patient is unconscious. But sepsis upon, further studies shows that sepsis is one of the diseases that is killing about 40- 70 people (forty to seventy people). So, I think if we can segregate those cases, but through the prescriber, we can also know the drugs to store in order to kind of those kind of interventions." (P2)

"And then also I think there should be a protocol everywhere, especially in the emergency, there should be protocol everywhere, every corner that you pass there should be, or you should be able to see the management protocol for sepsis, it will make things easier for even new doctors who come around." (D2)

The HCPs interviewed were enthusiastic about using a standardised care pathway for sepsis identification and care.

A protocol for sample taking and handling was also proposed by SSVs to guide them to adopt appropriate sampling practices and to reduce sampling errors resulting in

inaccurate laboratory results. This, they indicated, would reduce patient safety concerns a consequence of clinician sampling practices.

"There should be a protocol in place, at least it will be uniform so that every clinician will know how to handle sepsis regarding the lab investigations and all those things. So that one too will really help." (L2)

The idea of a sepsis pack (where all medications and fluids are packed in one) was also raised by participants and the need to have a sepsis pack closer to the nurses to help them promptly deliver care.

"So that is something we can consider and pack the various medications that they need closer to the bedside or close to the nurse's station, but this can also be done when we have institutional protocols such that, that will guide us that for this particular cases, the pack should contain this number of drugs or this types of antibiotics so the team members should definitely have to speed up with the process of designing the institutional protocol for the management of sepsis and that will guide us to be able to prepare the pack. That will show us for this condition, but this particular antibiotic or this particular vasopressors in this particular pack. So, we will arrange a note on that." (P3).

This could lead to prompter initiation of interventions and consistent monitoring.

ii. Resources

Resources for blood culture and lactate were proposed to be made closer to clinicians, especially for blood culture sample bottles, to enable them to take samples as soon as possible while securing IV access before administering antibiotics. In this case, an appropriate culture and sensitivity can be carried out to help inform further clinical decisions. Furthermore, the need for additional clinicians

to help ease the pressure on clinicians and improve patients' timely recognition and care was mentioned.

"Number one, blood cultures because they are the good standard of diagnosis, so we need blood culture machines, we need if its new analysers or culture bottles or whatever that it is we need because blood cultures are empirical to the diagnosis. That means all the sepsis that we diagnose is presumed, which is not the best because we need the cultures to know the sensitive antibiotics, and it will help in our management." (D4)

"The lactate and the other investigations that we don't, at least if we are able to do it, all those ones will help in the management of the patients." (L2)

These quotes reiterate the need for human and material resources to enhance the care of patients with sepsis.

iii. Training

SSVs noted that training clinicians and the entire MDT to better identify and intervene in suspected sepsis and improved clinician sampling practices were needed. This could improve staff knowledge and change practice eventually improving sepsis identification and care.

"Well, I think there should be refresher courses for clinicians so that from time to time we will be on our toes or from time to time we will find it easy identifying sepsis because new staff, junior staff come in very often so these will help make them aware, make them I mean have knowledge about how sepsis is managed and for the old ones too it makes the knowledge we have already even better." (D5)

“training for the nurses and any other person who takes the sample. Secondly especially taking the blood C/S, the procedure is that you don’t open the bottle. There is a place you will pin the needle through and dispense the blood, but when you even tell them to do it later, you will come and see that they have open it and they are pouring it, so it means they have exposed the sample. So, all boil out now to training as to the different samples.” (L1)

7.5 Process mapping workshop

After the interviews, a process mapping workshop was undertaken to chart the current care process for patients with sepsis that reflects the usual' patient journey through the ED (Appendix 13). This workshop mapped the processes that patients suspected or diagnosed with sepsis are exposed to, from their initial presentation to the ED until their final disposition (discharge, referral or inpatient hospitalisation or death). This workshop was carried out at the study site's conference room. All SSVs who consented to participate in the workshop were present on the day, after reviewing the study information and confirming their willingness to participate. In all, 14 SSVs attended the workshop, comprising of doctors, nurses, pharmacists and laboratory technicians. Participants were asked a general question about how patients with sepsis flow through the ED from their initial presentation. All participants made meaningful contributions to the initial draft of the process mapping exercise using flip charts with pens and sticky notes, producing an initial draft of the process, as illustrated in Appendix 8.

7.5.1 Triage

All patients reporting to the ED go through a general triage without sepsis being flagged as there is no standardised sepsis track and trigger system in operation, as discovered in the interviews. It was also discovered that triage time could be lengthier, up to 15 minutes in some situations, depending on how busy the department is (that is when more than 5 patients report at a time). These delays only apply to patients considered to be in a stable condition after vital signs assessment. The critically ill, such as those having trouble breathing, are fast-tracked quickly though triage and managed. Since there was only one blood pressure machine in use at the ED at the time of this workshop, according to SSVs, it was challenging to triage several patients, even if additional staff members were present. It was also discovered that the ratio of patients who presented themselves at one time compared to the number of nurses was insufficient, most of the time leading to delays in interventions and monitoring.

7.5.2 Resuscitation

According to SSVs within the resuscitation area, just one nurse cares for all the new patients. This increases the waiting times for other patients. Also, because there are always new doctors running shifts in the ED especially during the weekends who are unfamiliar with how ED systems operate, running shifts in the emergency can lead to delays. Given this, some might want patients' identification numbers (patient records) to be ready before initiating interventions or all their laboratory investigations completed before the doctor on duty completes his assessment to establish a working diagnosis and initiating interventions.

7.5.3 Red and Yellow

According to SSVs, in the red zone, due to the limited number of computers for completing documentation, the interval from completing and recording interventions often took more than three hours. Even though vital signs had been done, the electronic system is time sensitive so if it takes longer than an hour they cannot enter an observation. This made it challenging to monitor the progress of patients, coupled with the absence of a deteriorating patient chart to help identify patients who need to be reviewed by the doctor.

ED overcrowding was also identified as one of the major challenges. As the inpatient wards had inadequate resources to provide further care for patients falling within the red category, coupled with an only 2 bedded high dependency unit, their ED stay tended to be prolonged. Given this, the red area is always congested with many patients who have spent more than 24 hours in the department, which explains why most sepsis-coded patients' ED length was more prolonged. This made it difficult to receive further red patients who needed close observation to go in from the resuscitation. One other challenge SSVs mentioned was the inadequate number of doctors to take care of the patients; hence, what happened was that after a medical officer attended to a patient, then the subsequent care was either taken over by physician assistants or house officers (newly qualified doctors on rotation) which delayed clinical decision making. The same findings were identified in the yellow zone, including overcrowding, which most times impedes nursing monitoring.

7.6 Summary

The results from the process mapping exercise revealed that several factors impact on the process of identification and implementation of sepsis interventions. One of the key factors was inadequate clinical awareness and the delay in diagnosing sepsis, such as suspecting other conditions like malaria, before thinking of sepsis.

Clinician blood sampling practices, including not following up on laboratory investigations, patient's delay in seeking care, financial reimbursements and issues of resources were all points of delays in the sepsis process.

Chapter eight will present the mixed methods integration of the retrospective review of case notes and the process mapping, which will provide a broader insight into the current practices, enabling the stakeholder discussions with regards to the design of a context-specific intervention in chapter nine.

CHAPTER EIGHT

MIXED METHODS INTEGRATION

8.0 Introduction

This chapter presents the mixed methods integration of key findings from the retrospective review of case notes (RCN - Chapter 6) and process mapping (PM-Chapter 7) through narrative, merging and connecting with joint displays (Fetters et al., 2013). Key findings from the RCN include late identification of sepsis after suspecting other conditions like malaria. In addition, blood cultures were not requested and done for the patients diagnosed with sepsis. There were also poor sampling practices and delayed laboratory results identified. Furthermore, re-evaluation of the patients' vital signs was not consistently done and recorded. The process mapping workshops and interviews also revealed similar findings, including inadequate knowledge of healthcare professionals in suspecting and managing sepsis. The decision to report to the hospital and financial constraints were also identified as patient factors contributing to delays. Given these key findings, the COM-B model has been used to discuss the key findings regarding the capability (psychological and physical) to identify and manage sepsis, the opportunities (physical and social) available to them and the motivation (automatic and reflexive). In doing so, individual and organisational behaviours needing change is identified to enable a stakeholder discussion aimed at improving recognition and care.

8.1.0 Capability Opportunity Motivation-Behaviour (COM-B) Model

For a behaviour to occur, it is necessary for the individual to possess both the ability and the opportunity to engage in that action (see Chapter 4). These factors, in conjunction with motivation, contribute to the individual's propensity to modify their behaviour in accordance with the COM-B model. The process of evaluating these elements is commonly known as behavioural diagnosis according to Michie et al., (2014). Given this, the study utilised the COM-B components to evaluate behaviours related to the recognition and management of sepsis, as illustrated in Table 24 below.

Table 24 – Understanding sepsis recognition and care using the COM-B

COM B	Behaviour diagnosis
Psychological capability	Knowledge about sepsis - not thinking sepsis - initial thought of malaria. Omission of vital signs reassessment. Poor documentation practices.
Physical capability	Patients' health seeking behavior – reporting late to the hospital. Delay in antibiotic administration. Poor sampling practices – HCP.
Physical opportunity	Resource availability - sample bottles not close to nurses, lactate, blood culture sample bottles and their proximity to nurses. Standardised tools for sepsis, vital signs monitoring tool, organisational antibiotic protocol. Laboratory tests for sepsis - patients having to make some form of payment.
Social opportunity	Nurses not given the opportunity to request laboratory investigations after sample collection. Patients being delayed at nearby clinics.
Automatic motivation	Willingness to adopt recommendations.

The study revealed several key factors related to capability such as vital signs re-evaluation (Asiimwe et al., 2014) and healthcare workers' knowledge in sepsis, identification which were related to psychological capability. Regarding physical capability, antibiotic administration, poor sampling practices and patient health seeking behaviours were identified. The lack of established protocols for identifying sepsis, and antibiotic administration, limited availability of resources, including financial concerns for patients, were recognised as key factors contributing to physical opportunity, consistent with findings from Africa (Keeley and Nsutebu, 2021). Social opportunity involved ED nurses' inability to request laboratory investigations after samples are taken until the doctor on duty does, which is always delayed, and patients being delayed at nearby clinics. In terms of motivation, the willingness to adopt recommendations was identified in the process mapping. These factors are discussed below:

8.1 Capability

The capability to recognise and manage sepsis have been classified as psychological and physical, as discussed below:

8.1.0 Psychological Capability

Regarding the psychological capability in identifying and managing sepsis, various human factors such as limited awareness, poor recognition of sepsis, poor sampling techniques and poor monitoring of vital signs on the part of the healthcare professional (in hospital cause of delay) and delay in seeking care on the part of patients were identified in both data sets. Similar findings were reported in the

papers reviewed (Machado et al., 2017a; Ndadane and Maharaj, 2019). These could be classified as appraisal, illness and treatment delays according to Anderson's model of delay, which is also backed up by the three delays in sepsis recognition where there is failure to recognise sepsis, both on the part of the patient and the healthcare professional, contributing to treatment delays (Mgawadere et al., 2017; Papali et al., 2015b; Walter et al., 2012).

i. Vital signs assessment

Assessing vital signs is a primary aim of nursing and crucial to providing safe, high-quality care. Vital sign patterns can predict survival independently and give early warning of imminent sepsis and respiratory failure (Churpek et al., 2014; Papali et al., 2015a). Determining whether an individual has sepsis and initiating appropriate therapy can be challenging without the appropriate assessment of vital signs.

As a result of this, it is necessary for all clinicians, especially nurses who are often the first contact HCP, to understand and recognise the clinical manifestations and initiate appropriate response and treatment for sepsis, especially in the ED. In this study, most patients had their vital signs assessed on arrival; however, this was a general triage for all patients without flagging sepsis until the attending physician examined and provided a working diagnosis (Chapter 7). After this initial triage, reassessment of the vital signs is frequently omitted (Papali et al., 2015a), which makes it impossible to recognise deterioration at its early stages.

ii. Re-assessment of vital signs

Patients with severe sepsis may have better outcomes if closely monitored over time since this can help identify patients at risk of deterioration, leading to early and appropriate interventions (Dellinger et al., 2013; Jacob et al., 2012). As a result of

this, a purposeful and progressive monitoring frequency is required to ensure that objectives established in advance have been achieved (Oglesby et al., 2011; Rivers et al., 2001).

Unfortunately, evidence has found that vital signs are not consistently assessed, documented, or interpreted, which makes it more challenging to provide effective interventions promptly for patients whose conditions are deteriorating (Oglesby et al., 2011). This study identified that even though initial vital signs were taken for most patients on their presentation during triage, subsequent monitoring was insufficient, omitted or not documented most of the time, as illustrated in Table 25 below. These findings are consistent with global literature (Elliott, 2021; Machado et al., 2017a; Papali et al., 2015a).

Table 25: Joint displays from retrospective case notes and process mapping

Retrospective case notes				Process mapping	Interpretation
Characteristic	**Category**	**Frequency (N=75; Unless otherwise stated)**	**Percent (%)**	Frequency of monitoring "Well, it's variable. There is no fixed time, So I would like to give a scenario where a patient comes with low BP and then, as a result of sepsis, when the initial interventions are instituted, the vital may be checked as often as half-hourly. Yeah, but for those who may have normal BP, normal saturation but are pyretic, their vitals may be checked the second time, maybe in an hour or more, but another thing that determines how often the vitals are checked is where the patient will move to. And when the patient will be moved from the resuscitation area, if the patient moved immediately, like within twenty minutes, moved to a zone, red zone and yellow zone, the vitals will be checked immediately because that is also part of the receiving protocol. So, the time for a second re-assessment it varies. It's not fixed. And every patient and their needs." (D5) Missed vital signs "I think it is due to poor documentation. The whole AKSOFT was new, and people were adjusting N5." Blood sugar- "I think they were checked but not documented as it does not affect the triage N5."	Confirmation The qualitative data excerpts confirm that most case notes had no recorded vital signs. There was no standard monitoring frequency, hence they tended to be omitted, leading to missing important cues needing immediate intervention. As stated earlier, this will affect patients whose parameters qualify to go through the sepsis care pathway. The poor documentation of procedures also contributes to BM not being documented even when taken. This will affect the care progress when handing over needs to be done.
Systolic Blood Pressure (SBP)	Below 100	9	13.0		
	100 and above	32	42.7		
	Not recorded	34	45.3		
Pulse	<100	24	32.0		
	100 and >	19	25.3		
	Not recorded	32	42.7		
Respiration	Below 20	12	16.0		
	20-24	16	21.3		
	25 and >	5	6.7		
	Not recorded	42	56.0		
Temperature	Below 37.2	38	50.7		
	37.2 - 38.2	4	5.3		
	Above 38.2	1	1.3		
	Not recorded	32	42.7		
SPO2	90 and below	2	2.7		
	91-94	8	10.7		
	95 and >	32	42.7		
	Not recorded	33	43.9		
Level of Consciousness	Alert	26	34.7		
	Confused	1	1.3		
	Unconscious	4	5.7		
	Not recorded	44	58.7		

Frequency of monitoring

"Well, it's variable. There is no fixed time, So I would like to give a scenario where a patient comes with low BP and then, as a result of sepsis, when the initial interventions are instituted, the vital may be checked as often as half-hourly. Yeah, but for those who may have normal BP, normal saturation but are pyretic, their vitals may be checked the second time, maybe in an hour or more, but another thing that determines how often the vitals are checked is where the patient will move to. And when the patient will be moved from the resuscitation area, if the patient moved immediately, like within twenty minutes, moved to a zone, red zone and yellow zone, the vitals will be checked immediately because that is also part of the receiving protocol. So, the time for a second re- assessment it varies. It's not fixed. And every patient and their needs." (D5)

Missed vital signs

"I think it is due to poor documentation. The whole AKSOFT was new, and people were adjusting N5." Blood sugar- "I think they were checked but not documented as it does not affect the triage N5." Confirmation

The qualitative data excerpts confirm that most case notes had no recorded vital signs. There was no standard monitoring frequency, hence they tended to be omitted, leading to missing important cues needing immediate intervention. As stated earlier, this will affect patients whose parameters qualify to go through the sepsis care pathway.

The poor documentation of procedures also contributes to BM not being documented even when taken. This will affect the care progress when handing over needs to be done. One of the reasons expressed by SSVs during the process mapping workshop

was the absence of a standardised protocol outlining recommended practice for the frequency of monitoring. In this case, a repeat assessment of vital signs is left to the nurses' discretion, even though they do not need any instruction before monitoring. This makes it challenging to identify deterioration as early as possible (missed care) (Brekke et al., 2019) to enable the introduction of life-saving interventions to improve patient care.

The introduction of a paperless system or poor documentation practices on the part of the HCP was also attributed to these findings. Due to the human-led nature of the EHR, there are no red flags to prompt clinicians when there is time to monitor the next vital signs. This draws on the problems with the implementation of EHR and its impact on autonomy of work (Jedwab et al., 2022). However, this is not the case in other systems, where the EHR bleeps an alarm when the next vital signs are due. This means HCPs must understand that not all computer systems are identical. Hence, they should ensure that they adapt these new systems and consider new ways of working to achieve the Nursing and Midwifery Council's (NMC) requirement that we perform and document all procedures, and everything done for a patient as when not documented, then it is taken as not done (NMC, 2018).

iii. Knowledge of healthcare professionals in recognising sepsis

The premise underpinning the Surviving Sepsis Campaign making available a wide variety of educational materials and resources was to raise awareness and educate clinicians. In addition to this, the UK Sepsis Trust and CDC also publish educational materials to inform both healthcare systems and patients. Education and training of all HCPs helps to increase awareness of sepsis and the need for

prompt intervention (Evans et al., 2021). In this study, the general awareness and knowledge of HCPs regarding identification of sepsis was inadequate based on the process mapping workshop and interview results. Clinicians therefore tend to consider malaria before thinking sepsis, which is identified later mostly after deterioration.

"To a large extent, per the system that we run here we don't easily or quickly identify cases that have sepsis. Malaria is very endemic here so most cases that come we try to rule out an infectious disease like malaria and then we look at other possible viral cases. So, we start with malaria treatment and other conditions that we think may be responsible." (D1)

It is therefore obvious that sepsis identification is always delayed to the last minute, when less can be done. In addition, sepsis was not recognised at triage, hence, the only doctor who is available to see all incoming patients, might delay or overlook a case of sepsis until later. However, studies have demonstrated that effective techniques for controlling sepsis include enhancing the knowledge, attitude and practice of pre- and post-registration nurses and physicians (Fernandez et al., 2006; Machado et al., 2017a; Robson et al., 2007). Even when identified, controlling the source is one of the key factors to consider in sepsis management.

iv. Source control after sepsis recognition

Identification of the source of the infection following sepsis screening and initial management is essential. Pneumonia (50%), urinary tract infection (UTI) (20%) and intraabdominal infections (15%) have been documented in the literature as the commonest sources of infection (Daniels, 2019; WHO, 2018) resulting into sepsis globally. This study found similar results, where the common source of infection was

of respiratory origin, particularly pneumonia, and this was associated with a higher mortality rate. These findings concur with most LMICs, including the findings from the systematic review in this study (El Khuri et al., 2019; Machado et al., 2017b; Westphal et al., 2011) where the most common origin of infection is respiratory. Hence, identifying the source as early as possible could prompt additional diagnostic investigations to be undertaken and care initiated. As healthcare professionals in this study did not think sepsis from the beginning, source control could also be delayed. For example, in cases of abdominal sources that needed surgical interventions, 5 out of 9 of these cases died without surgery.

However, in sepsis, many severe presentations do not stabilise or improve without adequate source control, despite rapid resuscitation and administering appropriate antimicrobials. Prolonged efforts at medical stabilisation in lieu of source control are generally not helpful, especially for severely ill patients, particularly those with a septic shock (Solomkin et al., 2010). Hence, concurrent medical stabilisation of the patient and controlling the source would be beneficial (Evans et al., 2021). While there is insufficient evidence to support the timeframe in which source control should be obtained, within 6–12 hours have been documented to be beneficial in terms of preventing further deterioration or death (Bloos et al., 2014; Chao et al., 2013; Karvellas et al., 2016). Beyond this timeframe, most studies show a lower chance of survival (Evans et al., 2021). Hence interventions to ascertain source control in sepsis and septic shock should be implemented as soon as medically and logistically possible after the suspicion or diagnosis (Bloos et al., 2017).

Although malaria is common in sub-Saharan Africa and Ghana (38% of outpatient and 35% of inpatient), most of the patient's case notes with a diagnosis of malaria had good outcomes, that is, the patient was discharged home. In contrast, most of

the patients who died (n=9) had an infection of respiratory origin and developed sepsis. This implies that thinking about, recognising sepsis and the source is paramount as this could help direct focused investigations and new clinical protocols (which would require testing). They may not be necessarily ‘extra’ investigations but focusing on the correct identification rather than requesting a plethora of inappropriate tests, where the patient may have to pay.

8.1.1 Physical Capability

Antibiotic administration and sampling practices have been identified as the physical capability and discussed below:

i. Antibiotic administration

Studies on sepsis and septic shock have demonstrated that delaying the introduction of antibiotics is linked to negative outcomes (Ferrer et al., 2014; Kumar et al., 2009; Martínez et al., 2020), whereas other studies have not established the link between early antibiotic administration on the outcome of sepsis (Ko et al., 2020; et al., 2011; Silber, 2003).

Even though most patients received broad-spectrum antibiotics, such as ceftriaxone, in this study, the timing of antibiotics was not statistically linked to the outcome of the patients (P-0.433). However, out of the patients who died, 18 of them received antibiotics after one hour. This means that early administration of antibiotics should still be considered. Castaño et al. (2019) reported same findings. Contrastingly most studies have proven the link between early administration of antibiotics and its relation to mortality according to the SSC guidance (Evans et al., 2021). The switch from a paper-based to an electronic system was attributed to delayed documentation of antibiotics as nurses were still adapting to the system when the case note record

review phase of this study was undertaken. Antibiotics might have been initiated earlier and the time documented on papers (nurses own initiative and not part of the system) waiting to be transferred to the EHR. However, the AKSOFT software in use at the time of the data gathering does not allow an hour late documentation. This means that the time stated on the system might not be the actual time. This highlights some common challenges when changing to an her and the need to transition healthcare professionals for the change.

The SSC, however, strongly advise giving antibiotics within one hour to those patients with higher chances of sepsis and septic shock (Evans et al., 2021). Moreover, for those with probable sepsis, within three hours, so further assessment and investigations can be conducted to rule out sepsis.

Antimicrobial stewardship is described as he optimal selection, dosage, and duration of antimicrobial therapy that results in the best clinical outcome for the treatment or prevention of infection, with low harm to the patient and minimal impact on the emergence of recurrent resistance (Gerding, 2001). This is very important when it comes to sepsis. The optimal antimicrobial therapy consists of the four D's: "appropriate drug, right dose, de-escalation, and suitable duration (Joseph and Rodvold 2008).

One of the concerns raised from this study was about the local approach to antimicrobial prescriptions and stewardship. Even though Ghana has guidelines on antimicrobial stewardship, this has not been contextualised to or implemented in local facilities. Given this, reviewing patients on broad-spectrum antibiotics and de-escalation lies in the prescribing clinician’s judgement. For example, due to the lack of an antimicrobial stewardship policy at the study site, none of the case notes

reviewed had blood cultures carried out. Those prescribed antibiotics only received those from their initiation to final disposition (discharge, transfer out of ED or death). This was particularly evident in those deteriorating patients on intravenous antibiotics.

ii. Poor sampling practices

The issue of poor sampling practices, leading to delayed and sometimes unreliable results, was discovered in this study. Substandard sampling practices pose a healthcare safety issue (Ndadane and Maharaj, 2019; Söderberg, 2010). Similarly, researchers have reported haemolysis of samples taken by clinicians, sometimes leading to unreliable laboratory results (Vernoski, 2013).

"And at times what I have also observed is that, the sample is being poured into the EDTA container for the reagents/EDTA to mix with the sample for hematology test then they later realise that they are supposed to use chemistry container." (L1)

Taking blood samples, however, is a routine procedure, and the accuracy achieved during the blood sample procedure has a bearing on the quality of care provided to patients (Vernoski, 2013). Given this, sampling practices are highly important for sepsis, as inappropriate contamination of the samples can lead to false results, which is not exclusive to sepsis samples.

iii. Patient health seeking behaviours

Patient's decision to attend the hospital or visit other points of care are also a contributory factor in the prompt recognition and management of sepsis. Patients preferred to seek herbal treatment, making them delay arriving at the hospital, according to healthcare professionals during the process mapping workshop and interviews.

"sometimes they delay in taking a decision to come to the hospital and then sometimes they go for herbal treatment." (P3)

This means there is further deterioration when they arrive at the hospital. Further HCP delay in recognition, will eventually compound the problem. Similar findings were found in Malawi, where patients decided to consult traditional healers before finally arriving at the hospital, accounting for 14.9% of sepsis-related deaths (Mgawadere et al., 2017).

8.1.2 Opportunity

Standardised tools for sepsis, resource availability, payments and request for investigations have been discussed under physical and social opportunity below:

8.2.1 Physical Opportunity

Factors identified as physical opportunity were absence of standardised tools and policies regarding sepsis recognition and care, resources and payment processes.

i. Standardised tools for sepsis

From the two datasets, it was apparent that there was no formal sepsis track and trigger, which is embedded at triage (Papali et al., 2015b).

"so going by the triage that we are using, the South African Triage System, we consider the vital signs, the consciousness level of the patients, how mobile the patient is, is he walking by himself and then we use other discriminators such as the main complaints of the patients. Talking about sepsis in focus, we consider the pulse and the BP (blood pressure) specifically, but our triage does not focus just on sepsis patients; it is generalised for all the kinds of patients that come in, so we do triage for everybody, we don't just isolate sepsis patients." (N5)

“we don’t have a formal sepsis pathway in place at all; most at times, the doctor's suspicion much later after they do their normal rounds, but we don’t have something that is an organised formal sepsis pathway at all, not at all.” (D1)

This means all patients are assessed using a general triaging approach as discussed in chapters 2 and 7 which may contribute to, delayed recognition and possibly further deterioration.

In addition to the lack of formal sepsis track and trigger, ongoing vital signs monitoring is frequently delayed or omitted, as discussed earlier, possibly because no formal frequency of monitoring tool as compared to the NEWS2 is available. In addition to this limitation, there was no institutional antimicrobial guideline.

ii. Resource availability in managing sepsis

LMICs often have very limited availability of resources available to support healthcare (Abdu et al., 2018; Baelani et al., 2011; Baker et al., 2013; Bataar et al., 2010; Taki, 2017). Blood cultures and lactate are needed to facilitate diagnosis of sepsis, guide resuscitation and the selection of appropriate antimicrobials in ongoing care (Fan et al., 2016). These investigations are primarily available in HICs but might not be the case for LMICs (Evans et al., 2021). Even when available, they tend to have lengthy turnaround times (sometimes more than 24 hours) based on the setting, equipment used, the number of patients or location (Adu, 2021). Case notes from this study (n- 75) had no blood cultures or lactate requested, which was attributed to the limited supply of blood culture bottles and the proximity to clinicians as well as the non- availability of an ABG machine. Considering this, antibiotics are frequently initiated before blood culture samples are taken, that is even if the cultures are requested at a point.

“the lactate levels, we do not do it here, arterial blood gases, I mean all those things are important.” (D2)

In view of this, the entire sepsis bundle may not be applicable in LMICs, including Ghana, due to limited equipment (Abdelwahab et al., 2017; Abdu et al., 2018; Baelani et al., 2011). Hence, components of the bundle such as timely antibiotics, IV fluids in cases of hypotension in consideration to comorbidities may have more potential as other components, such as lactate checks, may not be available, limiting full bundle implementation (Abdu et al., 2018; Bataar et al., 2010; Dunser et al., 2012).

iii. Payment for investigations and some medications

Even though Ghana has a national health insurance system, patients must make payments, whether insured or not, prior to some investigations being undertaken including medications, as explained in Chapter 7. This can contribute to delays in clinical decisions and management (Arie et al., 2019; Kassyap, 2018; Mgawadere et al., 2017). Literature from Ghana acknowledges this and also advocates for the revision of the health insurance policies at the national level as the poorest or sickest may not receive the appropriate care, even though they may be on health insurance (Drislane et al., 2014).

iv. Requesting of blood samples by nurses

Although samples may be collected in advance, nurses need to wait for doctors to request laboratory investigations before samples can be sent for testing. This may not be the case in other emergency departments or contexts, where nurses collect and send samples to the laboratory as part of overall patient episode of care. This accelerates clinical decision-making as there is no need to wait for the doctor to

complete other tasks prior to completing the investigation order (Mattison et al., 2016; Tromp et al, 2010).

8.2.2 Social Opportunity

Some patients seeking treatment in nearby clinics who may not have the necessary knowledge in recognising sepsis may delay until deterioration before initiating further referral of the patient (Mgawadere et al., 2017; Papali et al., 2015b).

"some of the patients may also visit small facilities and then clinicians may detain the patients. Conditions that they cannot manage they will keep the patient and only refer when the case is in a very bad state (P2)."

Hence, patients may arrive at the study site in a worse condition, to result in resuscitation success.

8.3.0 Motivation

Regarding motivation, there was willingness to embrace recommendations from the outcome of the study to improve care.

8.4.0 Summary

In summary, integrating the datasets from the retrospective review of case notes and process mapping using the components of the COM-B has given much more understanding of how sepsis identification and management have been practised in Ghana. This revealed barriers and facilitators regarding clinical practice and education concerning sepsis, bringing clarity into understanding sepsis in the study site, which was discussed with stakeholders to improve care. These include patient monitoring, assessing a patient for deterioration, recognising and managing sepsis,

blood sampling practices and antimicrobial stewardship (including formulation of local policies from national guidelines) (Evans et al., 2021). Chapter nine will discuss the coproduction workshops with stakeholders.

CHAPTER NINE

CO-PRODUCTION OF SEPSIS INTERVENTION

9.0 Introduction

This chapter describes a series of 3 co-production workshops; the aim of these was to examine the results following the integration of the case notes and process mapping. Stakeholders involved in the co-production included emergency nursing leaders, emergency physicians, medical officers, nurses and interventions after call scientists. Areas of discussion included: sepsis identification and interventions; sampling practices; and identification of deterioration. This aided in gaining unique insights, providing opportunity for participation and engagement and commitment to understanding organisational processes and individual practices regarding care for patients with sepsis. The ultimate goal being to design an intervention fit for context and for hospital staff involved with sepsis care to (better) identify patients with sepsis and manage their care in accordance with the findings of the case notes review, process mapping and literature review.

Several models of change have been synthesised to facilitate staff awareness, engagement and cooperation including the COM-B and Kotter's 8 step organisational change model, as discussed in Chapter 4. The COM-B model, including behaviour change techniques (BCTs), identifies a stepped approach for behaviours to achieve proposed change (De Franceschi, 2011; Michie, 2014; Michie et al., 2011). COM-B and BCTs are used for the design of health interventions notably, for the improvement of the Sepsis Six bundle implementation in the UK (Steinmo et al., 2016) and used in this study to facilitate engagement with changing practices. The TIDIER checklist for designing interventions, is used here to organise

and report the outcomes from co-production workshops throughout the chapter (Rhon et al., 2022) . The checklist adopts a what, why, who and how approach, included in chapter headings.

9.1.0 Co-production

Over the last two decades, global interest in co-production within healthcare research has grown (Graham et al., 2019; Slattery et al., 2020). Co-production incorporates cooperation with stakeholder at all phases of the research process and enables use of effective healthcare technologies and interventions while avoiding the overuse of ineffective ones (Jull et al., 2019). Engaging with stakeholders from the development stage of a study ensures the results fit with the context where the investigation occurred (Graham et al., 2019).

This approach also integrates Kotter's eight step organisational change concept (Newcomb, 2008) (Table 26), as discussed in Chapter 4, which considers the urgency of the problem, formation of a team, creation of a vision and effectively communicating the vision, empowering the action, creating short term wins, not letting up and making the change stick. As the study utilised the development phase of an intervention design according to the MRC framework (Skivington et al., 2021a), four steps out of eight of Kotter's organisational change model were employed (see Table 26). Kotter's model was selected over other models such as Lewin's change theory based on its effectiveness in facilitating change in different contexts (Harrison et al., 2021; Newcomb, 2008).

Table 26: Kotter's organisational change framework

Step	Application in this research
1. Create a sense of urgency	Sepsis is one of the top ten causes of mortality at the study site. From the review of retrospective case notes 20 out of 75 patients died. There were several missed opportunities in vital signs reassessment, causing further deterioration of patients.
2. Form a powerful guiding coalition	As the ownership of the intervention is intended to come from within, SSVs staff within the department, formed a steering group to lead the change process in the ED. This group comprised of representatives from all disciplines in the MDT (see Chapter 5).
3. Create a vision	A vision was created by discussing the outcome of the retrospective review of case notes and the process mapping. This was done through SSVs workshops. Omissions, barriers and facilitators were discussed providing an action plan for sepsis recognition. Subsequently, an educational package was designed.
4. Communicate the vision	The final ambition (to change practice and attitudes towards care of patients with sepsis, even though had been revealed in the beginning of the study) was communicated on the last day of the workshop to clarify the things to be done.

These four elements of Kotter's framework (Newcomb 2008, Appelbaum et al., 2012) helped identify that there was a need to consider improving sepsis care (process mapping and RCN). After the need for a change was identified, a study steering group from the ED comprising of clinical staff was formed by the team, including team leaders of doctors, nurses, laboratory and pharmacy personnel, as discussed in Chapter 5, to facilitate the change process.

9.1.1 Why - Rationale for Co-production

Several considerations led to the notion of creating an intervention to enhance the identification and care for patients attending the ED with sepsis. This notion was sparked by a number of important factors, such as issues with capability (poor sepsis identification from initial presentation) and opportunities (doctor led approach to sepsis interventions) available to staff, as discussed in Chapter 8. For example, a working diagnosis needed to be established by the doctor before beginning any interventions which is often delayed, though time – 'the golden hour' is considered the optimum period to reduce poor outcomes when it comes to sepsis recognition and care (Kalantari and Rezaie, 2019).Again, practices associated with blood sampling and antimicrobial stewardship also needed careful thought as was a matter of patient safety concern. Nurses rarely repeated vital sign observations of patients, further delaying recognition of deterioration. Given this context, involving stakeholders in the co-production exercise significantly contributed to developing context specific strategies aimed at improving the quality of care for patients who present with sepsis in the ED (Grill, 2021)

9.1.2 What

Given the motivation for the co-production, it was necessary to review evidence for implementation as well as best practices from all over the world. The findings from the systematic review, the SSC guidelines (Evans et al., 2021), the UK Sepsis Trust (Daniels et al., 2019), CDC guidelines and the WHO sepsis education materials informed stakeholders on the available guidance that could be adopted. This information led to a series of three days workshops at the study site to support the co-production process for a context-specific intervention, as shown in Figure 13.

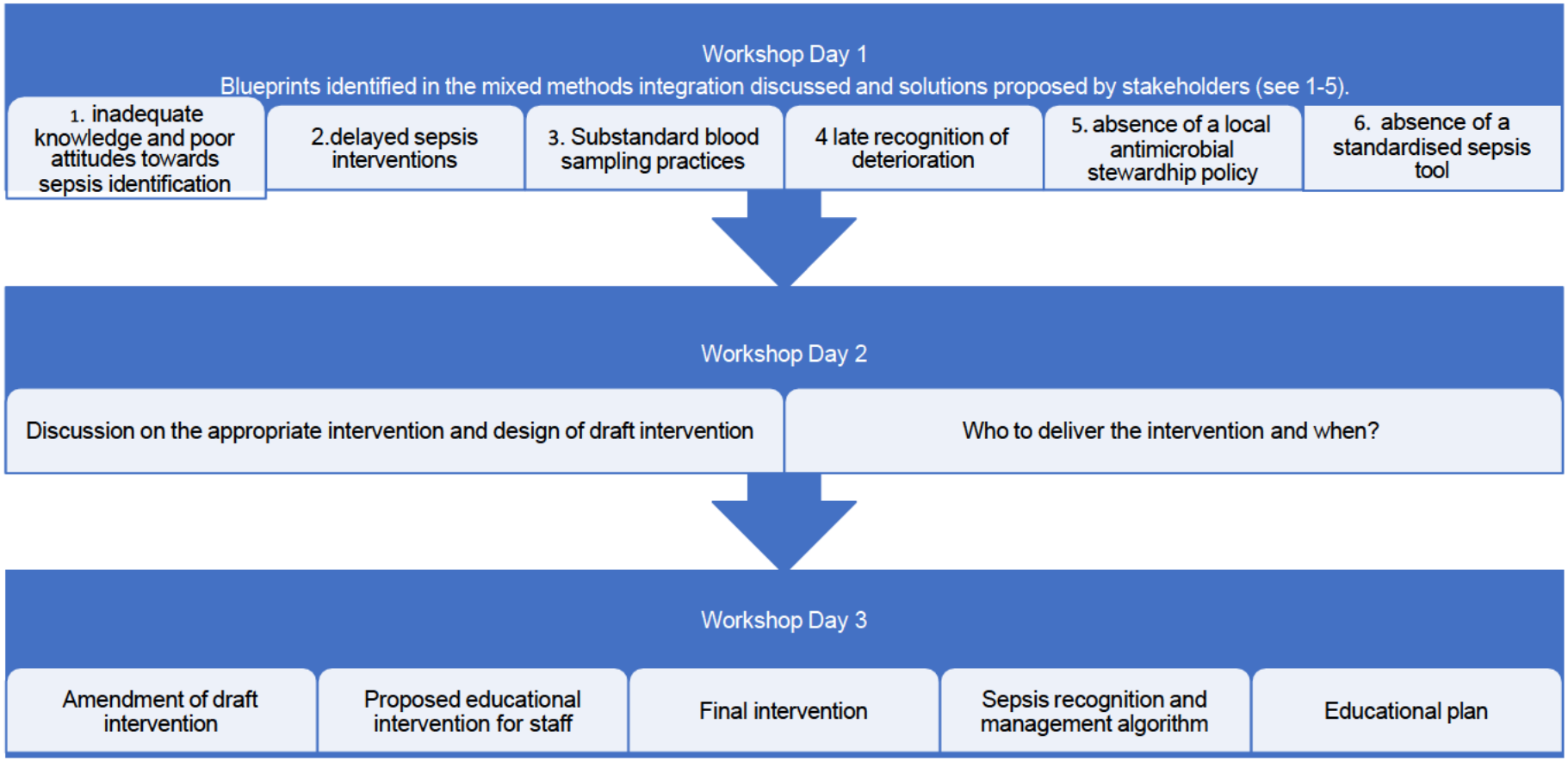

Figure 13. Stakeholder workshops

9.1.2.1 Workshop Day 1:

The results from the systematic review, retrospective review of case notes and the process mapping was presented during the first co-production session. Here, stakeholders (doctors, nurses, laboratory and pharmacy professionals) were made aware of the observed omissions in sepsis care. This includes evidence-based interventions evidenced as solutions to address these omissions (Burrell et al., 2016). In this case, the COM-B aided in identifying the barriers to implementing sepsis interventions, and possible solutions (Table 27), as has been used in other studies focused on behaviour change (Colquhoun et al., 2017; Croot et al., 2019).

Stakeholders were divided into 4 homogeneous sub-groups to discuss and develop the optimal intervention that might help enhance clinical care for sepsis (Aml et al., 2016). Following feedback from each group, evidence was used to build a context- specific standard operating process for sepsis collaboratively (Evans et al., 2021).

Ideas suggested in the groups included the attending triage nurse using the triage colour code (SATS Manual, 2012), qSOFA (AlQahtani et al., 2017), the SIRs criteria (AlQahtani et al., 2017), and clinical suspicion to identify sepsis during the triage process. Following identification, appropriate communication with the doctor on duty and commencing interventions within an hour was advised. Stakeholders then decided to adopt the NEWs2 guidance on the frequency of monitoring and reassessment as it informs prompt identification and actions to enable fast escalation of care to improve results (Pankhurst et al., 2022; Smith et al., 2019). In a systematic review assessing the impact of

sepsis education for healthcare professionals and students, it was identified that teaching methods embedding sepsis simulation and games were more effective in knowledge acquisition and retention than the traditional presentations (Choy et al., 2022). Moreover, content for delivering sepsis education was in accordance with the SSC bundle. Given this, it was also agreed that an educational intervention that included the sepsis identification and management pathway, as well as taking and handling samples, antimicrobial stewardship and identifying patient deterioration could be helpful. In addition, embedding varied teaching methods such as simulations to inform learner experience, knowledge attitudes and skills regarding sepsis recognition and care was explored (Breuer and Hassinger, 2020; Bridges, 2017). This was to ensure that any designed intervention is fit for purpose, context and acceptability (Grill, 2021; Kroese et al., 2021).

9.2.0 Behaviour Change Consideration

Some individual behaviours, such as most HCPs from the study site not identifying sepsis from the point of admission, informed the design of the intervention as recommended by the MRC framework (Craig et al., 2013). The BCW which encompasses three stages was utilised at this stage, as illustrated in Figure 14 (Michie, 2014).

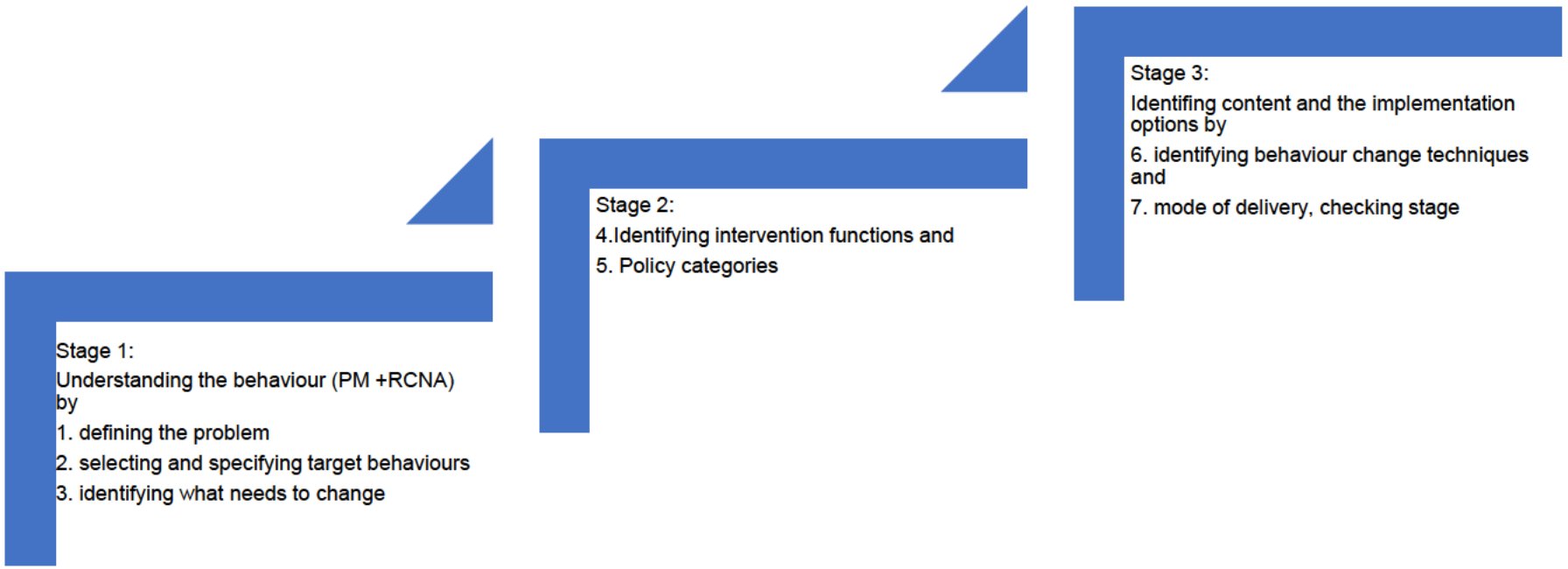

Figure 14. Stages of behaviour change

9.2.1 Designing the Intervention: MRC Framework - Stage 1 – Understanding the Behaviour

The first stage for consideration when behaviour change is needed is to understand the behaviour (Michie, 2014). The first problem established from the review, notes analysis and process mapping, was that HCPs did not consider sepsis when a patient presented in ED; they did so only when the patient had already deteriorated (Mgawadere et al., 2017; Papali et al., 2015). Repeat vital signs were omitted most of the time. Also, blood cultures were not requested for patients with sepsis, even though laboratory technician expressed the availability of blood culture bottles in the lab.

This issue was compounded by substandard blood sampling practices, such as pouring samples from full blood count bottles to biochemistry bottles, contravening infection prevention practices, not labelling samples before transporting them to the lab and a lack of local antimicrobial policy. Also, requesting for blood tests was solely done by the ED doctor, which is mostly delayed. Finally, issues with patients' decision-making about travelling to hospital due to considerations including searching out for alternate treatments and financial constraints was identified in the process mapping, resulting in deterioration before finally reporting to the hospital. Hence, the need to concentrate on changing behaviours (Gould et al., 2017; Michie, 2014).

Considering these issues, five primary desired behaviours are suggested (Michie et al., 2011b), specifically:

- Improve patient and HCP awareness of sepsis
- Use sepsis algorithms to inform standards of care

- Identify deterioration through frequent monitoring of vital signs
- Enhance sampling procedures
- Standardised protocols for antimicrobial policy.

The process of behavioural diagnostics involves determining the precise changes required to stimulate new behaviour (Michie, 2014). Given this, the identified behaviours above were mapped onto the components of COM-B to enable a contextually fit intervention, as demonstrated in Table 27.

Table 27. Mapping of barriers to COM-B elements and Behaviour Change Techniques

Barriers to identifying and implementing sepsis interventions	COM-B	Intervention function	Policy Category	BCTs and its application in changing behaviours in sepsis recognition and care
Inadequate knowledge on recognition and implementation of sepsis interventions Inadequate knowledge on recognising deterioration (patient monitoring frequency) Inadequate knowledge in drawing samples (substandard sample collection technique) Patients lack of knowledge on sepsis and the urgency to report to hospital	Psychological capability	Education Training	Communication /marketing	Instruction on how to perform the behaviour – HCPs will be presented with study days and presentations on identifying and carrying out sepsis interventions. This includes working on scenarios, roleplay/simulations Skills training – HCPs will be trained on standards on sample taking. That is following infection prevention strategies and the best appropriate technique. Simulation – HCPs will be given scenarios to act on sepsis identification, implementing interventions. Demonstration of behaviour – HCPs to observe and participate in t simulation activities. Prompts and cues – HCPs will be reminded at point in time using reminders and bedside prompts. Running sepsis awareness events throughout the hospital
Late administration of antibiotics Poor sampling practices	Physical capability	Training Education	Communication	Skills training Simulation Instructions on sampling practices and antibiotic administration in sepsis

Barriers to identifying and implementing sepsis interventions	COM-B	Intervention function	Policy Category	BCTs and its application in changing behaviours in sepsis recognition and care
Absence of protocols to support recognition and care regarding sepsis care. • Institutional guideline on adult sepsis recognition and care including requests of blood cultures in sepsis recognition. • Guideline on patient monitoring • Guideline on antimicrobial policy Inadequate resources to aid in implementation. Absence of blood culture bottles in the ED	Physical opportunity	Enablement/ Training	Guidelines Regulation-Establishing principles Fiscal measures Service provision	Information on antecedent – HCPs will be made aware and taken through the context specific sepsis algorithm designed. In addition, ensuring that the intervention is made available to the ED staff. Action planning – HCPs will be encouraged to have a plan and set goals to inform performance such as ensuring 95% compliance from HCPs and goals towards reducing mortality from sepsis and reducing serious untoward incidents related to sepsis by 40% for example. Adding objects to the environment – Providing the guidelines for sepsis interventions in the ED. Displaying posters with the guideline for easy read. For example, using the nudge theory (guiding individuals towards making better decisions such as sending prompts and reminders. – Provision of paper version of the algorithm for staff to complete and providing a sepsis pack. Making blood culture sample bottles available in the ED for staff to use.

Barriers to identifying and implementing sepsis interventions	COM-B	Intervention function	Policy Category	BCTs and its application in changing behaviours in sepsis recognition and care
				Feedback and monitoring – To identify patients who have been treated with sepsis and their outcomes and feedbacking to staff to identify performance.
Nurses in ED's not permitted to request blood samples	Social opportunity	Enablement Restrictions	Regulation provision	Social support – practical –Work with hospital policy makers to allow ED nurses to initiate blood sampling and request blood investigations for suspected sepsis to speed up decision making. Social support unspecified – pairing nurses and doctors with SSVs to ensure that they understand the sepsis interventions appropriately.
Willingness to embrace change	Reflexive and automatic motivation	Modelling Persuasion – telling stories of people who died of sepsis	Environmental/ social planning Communicatio n/marketing	Reward and threat – material reward, material incentive, incentive (outcome) - Encouraging staff with vouchers after completing the sepsis guidelines and awarding best sepsis nurse/doctor/laboratory technician/pharmacist either for the week or month.

Barriers to identifying and implementing sepsis interventions	COM-B	Intervention function	Policy Category	BCTs and its application in changing behaviours in sepsis recognition and care
		Incentivisation		Using examples of case notes who were diagnosed and died of sepsis through debriefing and review meetings. Information about health consequences -HCPs to be provided with leaflets of sepsis including the effects of not identifying sepsis early and how to prevent these. This information can also be shared through messaging on phones. Identifying self (staff)as role model Encourage staff to set good examples for their colleagues to follow. Feedback on behaviour Monitoring and provision of feedback on the use of the sepsis pathway.

9.2.2 Stage 2 – Identify intervention function

In order to make it easier to choose the most suitable and effective broad classification of things that could be done to change behaviours, the nine broad categories (named intervention functions) guiding behaviour change as proposed by Michie et al. (2014) were linked to the COM-B elements (see Table 27). In doing this, seven intervention functions, namely, restriction, education, training, facilitation, modelling, motivation, and persuasion (Michie, 2014) were identified to facilitate any proposed behaviour change (Table 27), which are explored further in section 9.4.

9.2.3 Policy categories

The final stage of identifying intervention functions is to establish the categories of policy which the desired behaviours are best aligned/categorised. Guidelines, regulation, communication/marketing, fiscal measures, and environmental/social planning are areas identified (Gould et al., 2017). This was considered in the light of the context to ensure its relevance to the population and also to ensure the allocation of appropriate resources. For example, regarding communication/marketing, strategies that had already been used were explored. Given the involvement of stakeholders in this conversation, it was agreed that all these policies are appropriate for this change to occur.

9.2.4 Stage 3 – identification of content and intervention functions

Behaviour Change Technique (BCT)

The components of an intervention, such as action planning and physical environment remodelling, are known as behaviour change techniques (Michie et al., 2013). The BCTs are made up of 93 taxonomies that assist in determining the optimal strategy for behaviour change (Michie et al., 2013; Michie et al., 2012).

Connecting these taxonomies with the COM-B components as illustrated in Table 27. Stakeholders collaborated to identify skills training, teaching on how to perform the behaviour, simulation, prompts and cues, as related to improving psychological capabilities. In terms of physical capabilities, information on the antecedent and action plans were recognised. Other strategies included social support, the addition of things to the environment, and feedback and monitoring. These are detailed in Table 27.

9.3 COM-B – ANALYSIS

9.3.0 Psychological capability

For clinicians to be psychologically capable in identifying and managing sepsis, knowledge was identified to be a key factor, as discussed below:

Knowledge

To have the psychological capacity to change practise, healthcare personnel need to increase their knowledge and abilities in the areas of sepsis awareness, identification, and intervention implementation (Steinmo et al., 2016). This increased awareness, and education should encompass sepsis recognition and management, recognising deterioration of a patient's condition, antibiotic stewardship, and effective

blood sampling practises. In addition to providing instructions to healthcare professionals, there is a need to educate patients about sepsis, especially how to identify and the importance of seeking prompt treatment if they identify any of the indicators of it.

As explored in the co-production workshop with SSVs, behaviour change strategies, such as instruction on how to carry out the behaviour, skills, and simulation training, including demonstration of how to perform the 'optimum' behaviours, must be used. This approach has been shown to aid in improving knowledge and skills (Akselbo, 2023).

In terms of instruction on how to carry out the behaviour, HCPs will be released to attend study days, including presentations, on recognising and carrying out sepsis interventions (Choy et al., 2022; Liaw et al., 2011). This will be followed by skills and simulation training on the relevant topics, including blood sample taking and antimicrobial stewardship (Lewis et al., 2019). Clinically relevant scenarios will thus be used to carry out these tasks. Following that, HCPs will be reminded to utilise prompts and signals at specific points in time through reminders and bedside prompts.

9.3.1 Physical capability

In order to offer healthcare professionals with the appropriate physical capability, there is a need to train them on proper sampling practices through skills and simulation training to enable them to have the hands-on training to carry out these procedures safely (Choy et al., 2022). In addition to this, education on antimicrobial administration when it comes to sepsis and the need for timely administration needs to be considered.

9.3.2 Social opportunity

It is a good first step in developing practice to encourage and consult with hospital policy makers that will allow ED nurses to request for blood tests after obtaining samples in order to hasten the decision-making process as has been done in most EDs (Ahmad et al., 2011). Additionally, partnering staff members with SSVs will help them better comprehend sepsis interventions in practice while also boosting their confidence, which will increase their likelihood of implementing the tool.

9.3.3 Physical opportunity

One of the problems highlighted by SSVs was the absence of a standard operating procedure (SOP) for diagnosing and treating sepsis. Given this, it is advisable to provide the ED with sepsis intervention guidelines while also adding objects to the environment, such as putting up posters that are easy to read and understand (Machado et al., 2017a; Papali et al., 2015). The algorithm designed as part of this study (see figures 16 and 17) will be made available on paper for staff to complete, and a designated sepsis kit made available, providing staff in the ED ready access to blood culture sample bottles (Malhotra et al., 2021). To make sure that those standards are being followed in this situation, feedback and monitoring will be essential. Accordingly, sepsis-treated patients' prognoses will be assessed, and clinicians (overall team) will receive feedback on them in order to gauge performance. In addition, guidance on monitoring frequency, as illustrated in Appendix 3, will be made available while re-orienting staff through the South African Triage Scores (SATS).

In order to offer healthcare practitioners with the physical opportunity, it is necessary to provide them with information regarding sepsis recognition and care (Michie,

2014). Healthcare providers (HCPs) will be provided with information and guidance regarding the context-specific sepsis algorithm (see page 240). Healthcare professionals (HCPs) will also be incentivised to develop a strategic plan and establish specific objectives to direct their performance towards the improvement of care (including this in quarterly appraisals (Rello et al., 2016). These objectives may include achieving a compliance rate of 95% of initiation and completion of the bundle among HCPs and setting a target for the ED to decrease mortality related to sepsis and serious adverse events associated with sepsis by 25%, for example.

9.3.4 Motivation – Reflexive and automatic

The fact that employees accept the gap and the willingness to change practices is a big motivation. In view of this, encouraging HCPs to perceive themselves as champions (role models) in sepsis identification is critical in bringing to their consciousness what is best practice, when a case of sepsis is identified (Michie, 2014). Furthermore, encouraging workers to set positive examples for their colleagues to follow by adhering to the sepsis standards is critical. Finally, monitoring and feedback on the utilisation of the sepsis pathway is paramount to monitoring the progress of the usage of the sepsis algorithm.

Appreciating employees after fulfilling the sepsis guidelines and awarding the best sepsis clinician (nurses, doctors) for the week or month is something to consider and has been done in other sepsis studies successfully (Steinmo et al., 2015). Furthermore, HCPs could be given leaflets outlining the consequences of failing to detect sepsis early and how to avoid it. Finally, reviewing case notes of people who were diagnosed and then died from sepsis could draw their attention to the health repercussions of late detection of sepsis and help in improvement and learning.

9.3.5 Workshop 2

The instructional pathway and educational intervention were explored in groups by the team at the second stakeholder meeting. Here, stakeholders discussed how to tailor the draft algorithm to the context. The pathway for sepsis was improved and agreed upon by the team here (figures 15). This pathway was adapted using findings that were identified through the systematic review conducted as part of this study, the SSC guidelines (Evans et al., 2021) and a study conducted in Malawi (Chesire et al., 2022). In recognition of the characteristics of the context, the local triage scoring system which is similar to the NEWs2 (RCP 2017) was added to the recognition of sepsis parameters. In recognition of the unreliability of resources for assessing lactate levels, it was recognised that this test cannot be offered consistently but could be completed when available. This investigation has been included ‘’if available’’ due to the context. In view of the inconsistent availability of lactate testing, education of staff will include the assessment of physiological parameters for determining resuscitation success including the use of capillary refill time (CRT) in the absence of lactate (Sebat et al., 2020). Regular vital signs monitoring was also added, based on the NEWs2 clinical response thresholds (RCP, 2020) for each SATS score obtained. These adaptations have the support of the SSVs and are anticipated to enable HCPs to identify patients who need systematic observation of signs of sepsis and/or deterioration, intervene speedily and initiate onward escalation using a sepsis pathway.

Furthermore, strategies for staff education on sepsis detection and intervention implementation, detecting deterioration (with focus on the frequency of monitoring),

obtaining and handling blood samples, antimicrobial stewardship, and resource availability in managing sepsis were discussed.

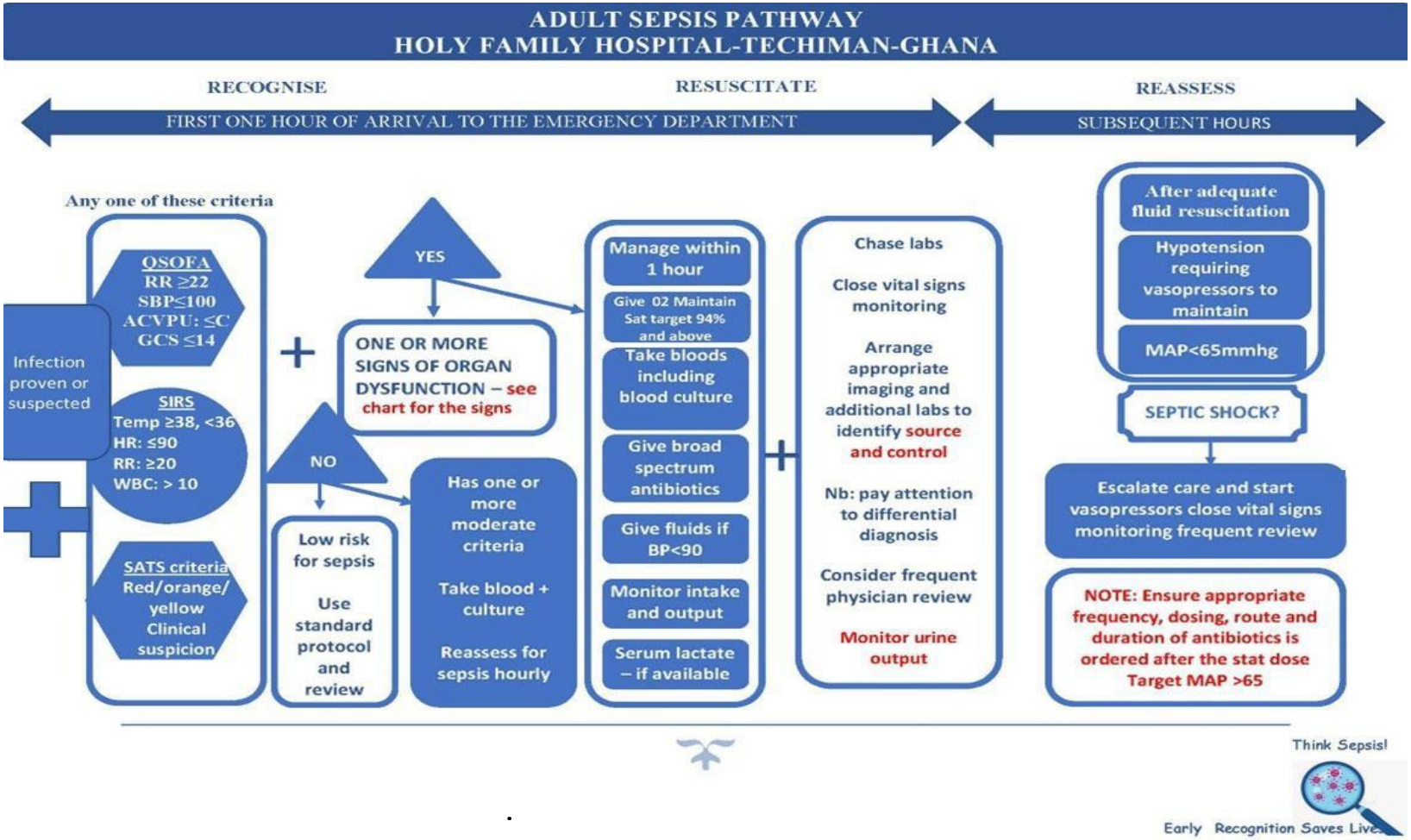

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Figure 15. Proposed adult sepsis pathway (Source: adapted from Cheshire et al., 2022, Evans et al., 2021).

9.4 Checking stage

As with all discussions regarding organisational change, stakeholders assessed the intervention's usability based on the available resources and the context. This was done to guarantee that the intervention was locally adaptable and practical (Morgan et al., 2016).

9.4.1 Workshop 3

The final workshop was to conclude on the various planned activities such as who to deliver planned sessions and timelines (figures 17 and 18). As part of the workshop, a logic model was also created to guide actions and activities (Table 29).

9.4.1 a Who and How

The multidisciplinary stakeholders involved in the co-production workshop and would be engaged with the delivery of the intervention included emergency physicians, emergency nurses, registered general nurses, medical officers, pharmacists, biomedical scientists, and laboratory technicians, as mentioned earlier (Jabbour et al., 2013; Steinmo et al., 2016). These HCPs have either received extensive training in emergency medicine or worked collaboratively in the ED and are in the position to advise on a context specific intervention which is practical and help to facilitate the training as illustrated in Table 28.

9.4.1 b Mode of Delivery

In identifying the possible mode of delivery of the content (Michie, 2014), stakeholders agreed to face-to-face sessions in smaller groups (Table 28). In addition, radio presentations, flyers, leaflets and posters will also be used as part of

the intervention to enable reach to patients and the community (audience) as much as possible and also create awareness (Machado et al., 2017a).

Table 28. Process of intervention delivery

Who	What (intervention components)	Where/mode of delivery	When/how often
Hospital management (medical director and director of nursing)	Confirmation of usage of tool for sepsis identification	Management meeting Face-to-face Resources	After PhD examination
Doctor and nurse in charge of ED	Setting goals and objectives Getting vouchers and rewards available for staff Giving congratulatory notes	Meeting rooms and ED Face-to-face	TBC
Doctors and nurses	Presentations on the identified topics	Training centre Face-to-face	TBC
Doctors and nurses	Simulations	Training centre and ED Face-to-face	TBC Ongoing
Doctors and nurses	Practical sessions in the ED on the use of the sepsis tool	Emergency department Face-to-face	TBC
Laboratory personnel	Presentation on standard sample taking processes	Training centre, skills training, ED	TBC
Pharmacist	Training on antimicrobial stewardship Designing local antimicrobial stewardship policy	Training centre Practical sessions in the ED	TBC
Any of the members of the team	Bedside cues	ED	Always

Table 29. Logic model

Input	Activities	Output	Outcome	Impact
➢ Staff ➢ Time ➢ Refreshments ➢ Venue/Space ➢ Supplies ➢ Training materials and assessment tools ➢ Vouchers ➢ Leaflets ➢ Sepsis awareness promotional materials	➢ Train all emergency staff on the created sepsis interventions	ED staff trained on sepsis recognition and interventions.	Improved awareness and knowledge of sepsis	To improve the recognition of sepsis and timely implementation of interventions
	➢ To train all staff on blood sampling practices	Trained staff on sampling practices	Improved practical application of standard Sampling practices improved.	To improve clinician knowledge and practicality in sampling practices
	➢ To train staff on mandatory laboratory	HCPs trained on mandatory	Improved knowledge on requesting for	To improve staff knowledge on recognising

	investigations to do in cases of sepsis.	laboratory investigations.	mandatory labs when needed.	deterioration with emphasis on the frequency of monitoring
	➢ To train staff on recognising deterioration with emphasis on the frequency of monitoring of patients	Trained ED staff on recognising deterioration	Improved knowledge and practicality in recognising deterioration	To improve the practicality of nurses recognising deterioration and escalating care as early as possible
	➢ To train staff on antimicrobial stewardship	HCPs trained on antimicrobial stewardship.	Improved antimicrobial practices including de-escalation.	To prevent antimicrobial resistance in patients diagnosed or suspected with sepsis.
	➢ Create a platform for the study steering group and	Study steering group created, and constant meetings conducted.	Steering wheel created to discuss progress.	To ensure continuation and sustainability of the use of sepsis of the sepsis bundle

	monthly meetings with the study steering group.			
	➢ Conduct talks for patients and communities.	Patients and communities educated on sepsis and the need to report early to hospital	Improved community and patients' knowledge on sepsis	To improve patients and community's knowledge on sepsis and the need to seek timely attention

9.5 Educational package

A continuous bespoke education programme will be conducted for all staff working in the ED (doctors, nurses, nurse assistant clinical and porters) of the study site, using the materials designed in Chapter 9 (Rechter et al., 2022). In addition, educational materials will be available to staff and new starters (Evans et al., 2021). It is anticipated that finally, the sepsis bundle (adapted) will be one of the mandatory trainings for all categories of staff, including national service, house officers and students.

9.6 Summary

A unique, practical and theory-informed intervention was systematically designed by following the Behaviour Change Wheel guide (Michie, 2014), alongside stakeholder input, RCN and PM, and existing literature and recommendations. This sepsis intervention was developed primarily to improve HCP practice associated with sepsis recognition and care.

CHAPTER TEN

DISCUSSION

10.1 Introduction

The previous chapters have provided insights into the conduct of the entire study, including the context, theoretical and methodological frameworks and the findings of the literature review and the empirical study. This chapter highlights the contribution of the unique study to current practice associated with sepsis recognition and management in EDs. The implications for theory, clinical practice, policy and research have been presented.

10.2 Summary

10.2.1 Addressing a concern: Understanding sepsis recognition and management in a Ghanaian emergency department

This study was initiated in response to increased mortality among adult patients reporting to an ED: these sepsis-related deaths are at consistent levels reported in the African literature (Keeley and Nsutebu, 2021). Upon reviewing the wider literature on the identification and initiation of sepsis interventions in LMICs, it was identified that the full SSC bundle potentially could be implemented in LMICs. However, application needs to be context-specific and planned in relation to the available resources. Bundle interventions have been major concerns for many LMICs due to contextual limitations (Abdu et al., 2018). However, improvement in the quality of care might be possible if the context is taken into consideration (Evans et al, 2021; Malhotra et al, 2021). In this study, current practices in Ghana were conceptualised using the SSC bundle as a baseline to inform differences and contextual application through process mapping and retrospective review of case

notes (Evans et al., 2021). This involved a process mapping and retrospective review of case notes to understand the current practices regarding sepsis recognition and care in a Ghanaian ED and estimate the gap with the ‘gold standard’ SSC.

The principal research question was ‘’what are the current practices regarding adult sepsis recognition and care in a Ghanaian ED?’’ The main empirical findings from this part of the study were presented in chapters 6 and 7 and an integrative process was reported in Chapter 8 using the COM-B model with stakeholder discussions in Chapter 9. The key findings such as delayed sepsis recognition and initiation of interventions are discussed here.

10.3.1 Delayed sepsis recognition

One of the key findings from this study suggests HCPs do not consider sepsis until a patient deteriorates, to the point where they are exhibiting substantial indicators of irreversible organ malfunction.

In LMICs, delays in seeking medical attention are typically caused by patient centred factors, such as the patient’s decision-making process, insufficient understanding of the symptoms of sepsis and financial constraints. All these factors are consistent with literature from other LMICs such as in Malawi (Abdu et al., 2018). These factors all lead to patients reporting late to the ED in a deteriorated state. After an already existing deterioration, when there is delay in HCPs recognition, this compounds the situation.

10.3.2 Challenges at site level regarding sepsis interventions

Most of the components of the Sepsis Six bundle were available at the study site, namely antibiotics, IV fluids and vasopressors/inotropes. However, because of the delay in diagnosing sepsis, this had a cascade effect, delaying the initiation of bundle components, adversely affecting patient's care and in some cases, eventual outcomes (Machado et al., 2017a).

Lactate levels were not routinely assessed due to non-availability of an arterial blood gas analyser or point of care lactate checks, even though they are needed to guide resuscitation. However, SSC recommends the use of physiological parameters in the absence of lactate checks (Abdu et al., 2018; Kassyap, 2018).

Even though blood cultures are hugely important to stratifying and treating sepsis, interestingly, none of the case notes assessed indicated that blood cultures had been requested. All the patients diagnosed with sepsis, or suspected with sepsis, were on the same antibiotics until they reached their final outcome, especially those prescribed with intravenous antibiotics. Moreover, local guidelines regarding antimicrobial stewardship were not available.

One major limiting factor in the process related to permission to request investigation, e.g. this is needed to be completed by the attending physician, despite the nurse being responsible for drawing the sample, which delays clinical decision making. These key findings were significant to delays in the recognition of sepsis and the initiation of interventions.

10.4 Unique contribution to sepsis knowledge in LMICs

This study is the first of its kind conducted in Ghana to assess current practices regarding sepsis care in non-pregnant adults. The study demonstrated how contextual factors in the process of care delivery can adversely affect patient care. Examining the case notes and HCPs' perceptions of sepsis care brought to light to major deficiencies in care, which was used a basis to design study interventions. For example, inadequate HCPs' knowledge to recognise sepsis following triage adversely impacted on the time to initiate interventions and ultimate outcome of patients (Kalantari and Rezaie, 2019). This study is also one of the few studies that has examined sepsis in real-world settings using a mixed methods approach to explore patients journey to improve care.

10.5 Strengths and limitations

All research studies have inherent limitations. Although some researchers contend that a mixed-method approach enables the drawbacks of one method to balance or cancel out the limitations of the other method (Creswell, 2004; Creswell, 2011; 2014; 2018), using more than one method of data collection still leaves room for alternate explanations and insights. Employing mixed methods, as done in this present study, allowed one methodological standpoint to complement and explain the findings from another, providing a more granular understanding of the current practices regarding sepsis identification and care (Fetters ultimately 2013). The limitations and strengths of the applied quantitative and qualitative approaches have been discussed below.

10.6 Strengths

This research produced an innovative, practical evidence-based intervention contextually sensitive to local health needs and this is one of the study's greatest strengths. That is, focusing on patients with sepsis from predominantly poor socio-economic backgrounds and the dearth of research with, and for, this population in Ghana, especially with regards to sepsis detection and care.

The study's methodological rigour by using a mixed methods approach also added to the study's strength (Creswell, 2018). First, fulfilling the trustworthiness criteria of qualitative studies (Shenton, 2004), using the Just Say Sepsis tool (NCEPOD, 2015) and inter-rater reliability checks (Mason, 2015) in the quantitative aspects. The inter-rater reliability check ensured that the data collected were a correct representation of the measured variables and can be replicated (Hollingworth et al., 2006). Data integration also enabled a better understanding of the current practices from qualitative and quantitative data regarding sepsis care.

By using the mixed methods appraisal tool (MMAT – Appendix 14) (Hong et al., 2018), the study explored both quantitative and qualitative data, including integration of the two datasets as mentioned earlier. This facilitated a broader understanding of different views regarding the processes of care. In addition, the audio recording of interviews enabled me to listen to the interviews continually during data analysis for a deeper understanding. To enhance the credibility of the study, supervisory team suggestions was sought throughout the entire process of the research. Being reflexive throughout the research process also revealed the confirmability and

dependability of the study (Akter et al., 2022; Finlay, 2002; Freshwater and Rolfe, 2001).

Having practiced in the ED of the study site as the nurse in charge and practicing in the UK could have potentially caused bias in the data collection. Hence, I set out to ensure that I adopted a reflexive approach in my role as a researcher and kept a reflective diary to document the study process. While the findings from this study were linked to the existing literature in order to maintain congruence between the literature and the empirical study (Craig et al., 2013), an appropriate theory was used to frame the study throughout to enhance transferability.

Stakeholder input from hospital staff was sought throughout the research process, from research design, development and use of data collection instruments to intervention design. Engaging with these stakeholders was innovative in the Ghanaian setting and a practical method that led to the successful design of a useful and usable instrument to improve practice (Jull et al., 2019; Slattery et al., 2020). The impact of stakeholder involvement has been reported to be beneficial, noting how the perspectives of various stakeholders contributed to the formulation of intervention content (Coupe and Mathieson, 2020). Incorporating stakeholder perspectives not only improves research quality but helps to grasp user perspectives throughout the process. It also increases the likelihood of success during subsequent evaluation and implementation stages (O'Cathain et al., 2019; Turner et al., 2019).

10.7 Limitations

One limitation is that the study was conducted in a single secondary level hospital, as mentioned in Chapter 2. Even though this might be the case, as the Ghanaian

government tries to ensure all EDs are equipped similarly, with basic resources, it is unlikely that this ED varies substantially from others in Ghana. This suggests the implementation plan, after further testing/modification, might be appropriate for wider knowledge sharing and implementation.

Patients and the public (PPI) were not involved in the design or execution of the study (Morgan et al., 2016). Hospital staff stakeholders, however, were involved as they were the focus of the improvement, and the intervention was intended for use by them in the treatment of patients while they were in the hospital. Going forward, PPI will be involved with the dissemination of findings and in the design of any communication strategy to inform community education. Every attempt to garner their opinions will be sought prior to any further feasibility testing or implementation of this intervention.

From the retrospective review of the case notes, people who had sepsis but were coded using a different differential diagnosis were not reviewed and therefore were included or excluded on the basis of the recorded diagnosis. This means some cases may have been missed, particularly since the process mapping indicated that failure to “think sepsis’’ was systemic. In the future, common sources of infection that could lead to sepsis, such as pneumonia or UTIs, could be explored and added to the inclusion criteria to provide a more complete picture of sepsis practices.

Even though the study was conducted in the period of the COVID-19 pandemic, which impacted on my travels and the ED of the study site being closed for two weeks due to staff COVID status, it did not have a particular impact on the study as some of the data were related to pre-pandemic activity. However, during periods of

fieldwork, all public health measures for COVID-19 protocols were followed throughout the study.

A final limitation is that because a statistician was involved after the data collection, this did not allow for further advanced statistical analysis to be performed

10.8 Implications of study findings

This research implications have been explored as they apply to practice, research and policy, as discussed below:

10.8.1 Clinical practice

The most significant implications of this PhD are on practice, through the development of an algorithm and education package to support sepsis recognition and care to be employed in an ED setting in Ghana. Indeed, the leaders of the ED and the entire hospital were thrilled about the research and asked for the prospect of its usefulness to inform and guide their future practice. A further feasibility study would allow for examination of the acceptability of each facet of the proposed bundle and establish if the algorithm could be used in or outside of the environment in which it was produced (Craig et al., 2013). Beyond the intervention itself, concerns about patient payment, National Health Insurance Scheme (NHIS), and the decision to seek care are very significant to practice, hence a review of the health insurance system needs to be considered by policymakers to enable the poor to be able to access healthcare.

Even though it is recommended that interventions should not be evaluated outside of the context in which they were intended due to variances in context, there is still a need to demonstrate transferability as the Ghanaian local hospitals may have similar

circumstances (Moore and Evans, 2017). However, some revisions may be required to ensure it is adequately customised and acceptable to any new contexts or demography. For example, any pre-defined goals will need to be adjusted to ensure applicability and implementation success.

Improving sampling practices is also crucial, especially as it is a patient safety concern. This, in turn, could ensure greater efficiency so that appropriate laboratory investigations are requested and followed up to inform timely clinical decision-making. This might involve using HCP workforce differently and giving nurses permission to request, take and monitor blood test results to speed up clinical decision-making.

With widely varying rates of delayed and incorrect diagnoses, misdiagnosis represents a significant form of error in healthcare but is less investigated. For instance, pneumonia and other associated conditions are commonly misdiagnosed in underdeveloped countries due to overdiagnosis of malaria; this results in inadequate or inappropriate treatment and possibly higher rates of morbidity from the underlying ailment (Amexo et al., 2004). This problem was clearly evident in the data in this study, confirming sepsis recognition and care still needs to be prioritised.

Inaccurate diagnosis, for instance, accounts for 10% to 15% of cases of sepsis globally, even in the most technologically advanced nations (Graber et al., 2002; Graber et al., 2005). Considering this, the figures from developing and transitional nations are unquestionably higher and almost certainly add significantly to financial expenditure, as well as high patient morbidity and mortality. Considering these factors, patient safety should be key when it comes to emergency care services (Jha et al., 2010) especially for patients presenting with sepsis.

The imperative need to receive time critical tests also seems to be a persistent challenge (Jha et al., 2010) and there seems to be poorer follow-up of significant tests in LMICs, including Ghana and the study site. Data from HICs indicate that only approximately half of critically significant laboratory results indicating potentially life-threatening illnesses were promptly followed up and the proper therapy initiated (Darragh et al., 2018; Tate et al., 1990).

Other implications for practice include:

a) Improving HCPs knowledge on the identification of sepsis and management:

Considering the nurse's role in identifying sepsis, being able to differentiate between sepsis and other more common presentations during triage has the potential to accelerate treatment initiation. There is evidence that “thinking sepsis”, as a possible diagnosis of patients at initial presentation, helps in care escalation to instigate prompt treatment (Papali et al., 2015b). In view of this, a sepsis track and trigger tool for clinicians, especially for triage nurses, to enable them to identify sepsis more accurately, escalate to the MDT and interventions initiated promptly, was designed.

b) Improving vital signs reassessment and documentation:

Ongoing standards for repeated monitoring of vital signs needs to be adopted by nurses. Monitoring frequency could be added to the EHR to enable the system to remind nurses to complete repeat vital signs in a timely manner. Alternatively, documentation of vital signs needs to be paper based. These paper documents can be scanned into the EHR or attached to the patient's notes. This strategy may be necessary when there is limited access to computers (IT), as is the case currently in the ED. With everyone on this team working together, better sepsis management programmes can be developed.

There is a need for good documentation practices and the ability to understand when to initiate optimum frequency and ongoing monitoring patients' vital signs to help bridge this gap (Aragon, 2014; Mok et al., 2015). At the system level, a two-way system could be adopted where the paper version is used alongside the electronic one until HCPs becomes fully adapted to the system. In doing so, when there are insufficient computers for documentation, nurses can document on a paper version and transfer it to a computer when available.

c) Following standard recommendations:

Ensuring that all patients suspected or confirmed with a diagnosis of sepsis have blood cultures taken to inform antibiotic related decisions is paramount. This means blood culture sample bottles must be readily available to facilitate sample collection once there sepsis is suspected. Reviewing initial sepsis patient identification and initiation of resuscitation target time to 1 hour with subsequent monitoring to improve care and outcomes.

A well-organised orientation for new doctors working in the ED is likely to promote faster patient evaluations.

There is also the need for a medical officer on each shift in the ED, especially during the weekends, an appropriate orientation for house officers, and a process in place for managing diverse conditions.

d) Training:

- Creating clinical awareness, educating and changing attitudes of HCPs and patients will be necessary to enhance the recognition of sepsis and improve outcomes in Ghana (Calvello et al., 2013; Howell and Davis, 2017).
- Training clinicians on best practices regarding sample taking, especially blood cultures, is essential, including simulations and clinical observations.
- Sepsis training to be included to yearly mandatory training for all staff.
- Training of referral centres on sepsis identification and prompt initiation of interventions.
- Bespoke training for newly recruited staff and students working in the ED on "think sepsis".
- Training on the identification of the deteriorating patient through close and repeat vital signs, monitoring the patient to improve their knowledge and expertise in caring for patients with sepsis.
- Improving infection prevention practices

e) Improving resources:

Hospital management to consider procuring an Arterial Blood Gas (ABG) machine, if possible, to guide clinicians on the progress of resuscitation. Protocols for antibiotic stewardship and formalising monitoring frequency as part of the existing triage needs to be considered. Point of care testing (intradepartmental) could be a consideration in LMICs to reduce waits for essential results (Baig et al., 2017; Gaieski et al., 2013).

f) Assigning additional personnel, computers and patient monitors for triage. This has already been requested in the study site following the co-production

workshops. Patient and community education on the signs of sepsis to inform prompt reporting to the hospital are necessary.

10.8.2 Future Research

Individual findings from this study have the potential to influence future research. The following could be considered in future research:

a. Identification of context specific sepsis identification tools

b. Resource availability in EDs in identifying and managing sepsis

c. Local antibiotic sensitivity patterns and local application of antimicrobial stewardship is needed. For example, in the UK, the start SMART policy guides clinicians in controlling administration and de-escalation of antibiotics (Llewelyn et al., 2015). This could be adopted, and its feasibility tested to determine its applicability in the Ghanaian context.

d. Assessing the community's knowledge on sepsis identification is paramount in understanding the type of education to give them.

e. Quality improvement clinician sampling practices across the nation, as discussed in Chapter 7, is an urgent need to inform patient safety practices.

f. Improving HCPs in EDs knowledge of sepsis identification and care nationwide.

g. Further research into clinician sampling practices, especially the techniques in LMICs, is needed to tailor education and change practice policies.

10.8.3 Future Directions and further research

To foreground potential future steps, this PhD study and findings should be recognised as a work in progress. After designing an intervention, the MRC Framework recommends feasibility testing of the intervention. First, to assess the viability of the intervention itself, and second, to assess the viability of the evaluation (Craig et al., 2013) before the decision for a full implementation is made. The next step after this PhD study, therefore, would be to conduct a feasibility study, which would help fulfil the two aims of feasibility (Craig et al., 2013). That is to analyse and modify the intervention and choice of outcome measures including economic concerns, as none of these are addressed in this study.

10.8.4 Policy

Obstacles, such as resource availability, to correctly identify and treat sepsis lies in the hands of the broader organisation and are not something that HCPs are able to address. Nevertheless, it is crucial for caregivers, both nursing and medical staff, to be aware of the socio-cultural and personal barriers and take them into account while giving care. In view of this, addressing any obstacles and the necessity for support for training initiatives that raise healthcare professionals' understanding of sepsis needs to be emphasised by policymakers. Policies at the hospital, ministry of health, Christian health association of Ghana and educational institution levels are discussed below:

At the hospital facility level, policies for sepsis identification and management need to be instituted. This is good practice if sepsis care is to be taken forward. In addition, monitoring and evaluating the care of sepsis needs to be prioritised. An audit might be particularly valuable in providing feedback to clinical teams.

Empowering ED nurses to request laboratory investigations will aid in faster clinical decision making for patients. As much as possible, all national protocols need to be locally adopted to suit the context, especially for antibiotic policies.

At the Ministry of Health and Christian Health Association of Ghana level, policies such as those listed below could be considered:

- Prioritising sepsis identification and interventions in non-pregnant adults by the government nationally. Ensuring that all EDs across the country have resources to identify and manage sepsis accordingly.
- Antimicrobial stewardship local policies and campaigns need to be considered. Ideally, strict policy on localising antimicrobial stewardship and sampling practices among clinicians working in all categories of hospitals needs to be implemented.
- Revisiting of the national health insurance policy is key as financially challenged Ghanaians presenting at ED may not be able to access quality healthcare.
- Policy around resource capacity to manage sepsis and securing its application in individual facilities needs to be in place.
- Policy on community education on sepsis identification and timely care seeking behaviours need to be considered.
- Regional policies can include sepsis identification, scheduled training programmes and timely reporting to hospital to inform care.
- Research policy implications which will support evidence-based practice.

At the educational institution level, sepsis identification and management could be embedded in nursing training curricula, as recommended by the WHO.

10.9 Personal Reflection

Understanding the researcher's personal background and situation aids in the development of self-awareness. As a certified emergency nurse specialist, I have worked with qualified nurses, nurses on rotation, and student nurses for many years. In addition, working in Ghana and the UK has exposed me to a variety of healthcare difficulties and insights. Starting this PhD in December 2019 has given me the opportunity to learn and has provided me a great deal to reflect on. My insider knowledge was useful in conceptualising and designing the study, but it also affected my thoughts and viewpoints. As I began my work, I was aware of the necessity to suspend my biases and preconceptions. To guarantee that my own values and ideas were not imposed on the analysis, I kept a notebook in which I recorded and reflected on my viewpoints and new understandings. In many ways, this was a successful strategy. Despite my resolve to keeping an open mind, it was not until I began collecting data that I understood my viewpoints and understandings were, in many ways, limited and superficial regarding sepsis. Both the systematic review, review of case notes and process mapping produced such illuminating and important data that I was taken aback and became a naiver researcher. The research journey helped me gain a fresh and exhilarating energy, and I became more receptive to and accepting of the new insights that were surfacing. As I pulled new interpretations from the data, I had numerous opportunities to challenge and re-evaluate the validity of my previously held beliefs. Throughout this process, I became actively aware of the significance of allowing the viewpoints of the participants to prevail rather than

my own throughout the analytic and interpretative phases; it was their story that needed to be told, and they were the people most able to tell it (Mauthner and Doucet, 2003).

The major question that guided the interviews with HCPs was, "Can you walk me through the care pathway for patients with sepsis?" Even though there are good nursing practices, when it comes to sepsis, the participants' descriptions of some form of substandard nursing were one of the most personal and professionally hard components, based on the narratives. I was particularly concerned about improper sampling and patient monitoring practices. As a professional nurse committed to quality treatment, I was deeply worried, especially because there was nothing to do at that point. Although I thought that the stories recounted were not isolated incidents, I did not feel I could expose any of the personal information that had been revealed to me. As I had anticipated scenarios like this, in which I could be inclined to revert to my previous role as a nurse when interviewing, I was conscious of the importance of maintaining my identity as a researcher before I began collecting data. The positive factor about this was the stakeholder involvement afterwards, which informed the design of an intervention package to improve practice. In all, I would say that this study was timely in improving sepsis care and provided good exposure for future research. Overall, this PhD study has been a really great learning experience, in theory, practice and research.

10.10 Conclusion

This thesis provides some new insights into the current practices regarding sepsis recognition and care and provides the co-production of a context specific intervention to aid practice. It identified barriers to identifying and caring for patients with sepsis. It combined theory, literature and the findings from earlier stages of the PhD, and following the behaviour change wheel in guiding intervention design (Michie, 2014b). A practical algorithm was, therefore, adapted to enhance sepsis identification and care. Stakeholder involvement throughout the process enhanced the design and contributed towards the development of some useful resources for involving stakeholders in this doctoral research. Future research should look at the feasibility of the intervention. If feasible and effective, it may have the potential to be implemented and transferable to other similar organisations; tailored further to their context.

This study is the first to use a mixed methods approach in identifying the process of examining the recognition and care among adults with sepsis in Ghana. This study has also demonstrated that the decision in recognising and intervening for sepsis does not solely fall on the doctor. It is also the responsibility of the multidisciplinary team, hence empowering clinicians, especially nurses, to think and identify sepsis as soon as possible from triage and communicating to the remaining team, which will aid in initiating prompt interventions. Notwithstanding, bespoke educational and training intervention through these recommendations is very important, which was designed as part of this study. One of the key features in working in an ED is the ability to collect safe blood samples and recognise a deteriorating patient. Without

these, clinical outcomes might not be favourable. In view of this, keen interest with regards to these needs to be taken in high esteem to improve care and outcomes.

Finally, a key factor is for policymakers to revisit the national health insurance policy as one of the concerns in patients seeking and experiencing delayed care was financial constraints.

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Appendices

Appendices

Appendix 1a – Triage sheet

Source - Ministry of Health

A&E SERVICES

Appendix

A. Triage Sheet

Patient Name:.....
Age.....**Sex: M F**

Chief Complaint:.....

Date.....**Time of Arrival**.....

Part 1: Triage Early Warning Score (TEWS)

Triage Parameter	Measured Value	TEWS Score
Mobility		
Respiratory Rate		
Heart Rate		
Blood Pressure		
Temperature		
AVPU		
Trauma		

TEWS SCORE:.....

Initial Triage Colour: RED ORANGE YELLOW GREEN BLUE

PART 2: The Discriminator List

1. **Does the patient need to be triaged to a higher colour based on the discriminator list?**

   YES NO

2. **What was the discriminator?**.....

Part 3: Final Triage Colour:

RED ORANGE YELLOW GREEN BLUE

B. Triage Scale (TS)[2]

Introduction

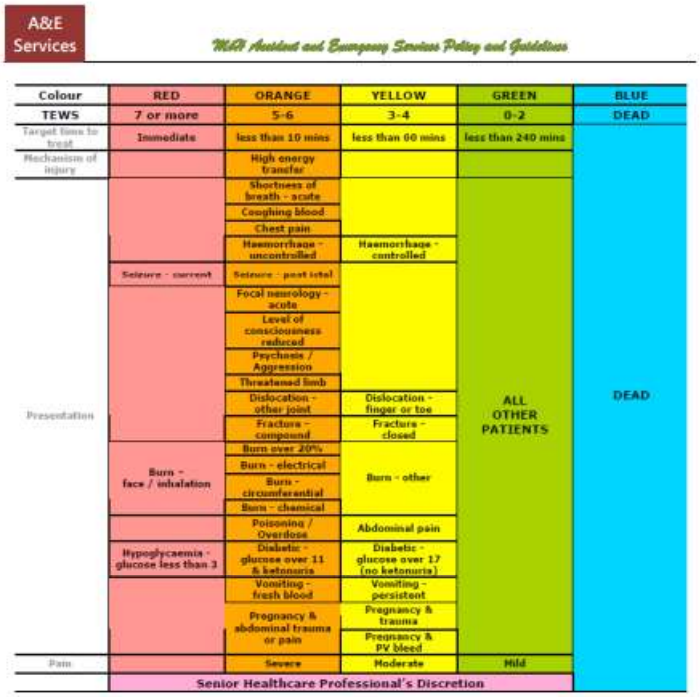
[2] The TS is an adopted version of the South Africa Triage Scale (SATS) which has among other scales proven to have stood the test of time, has shown to reduce mortality and morbidity, is easily taught and understood is practical and user-friendly, is reliable and accurate.

Appendix 1b: Adult Triage scores
Source: MOH A&E services

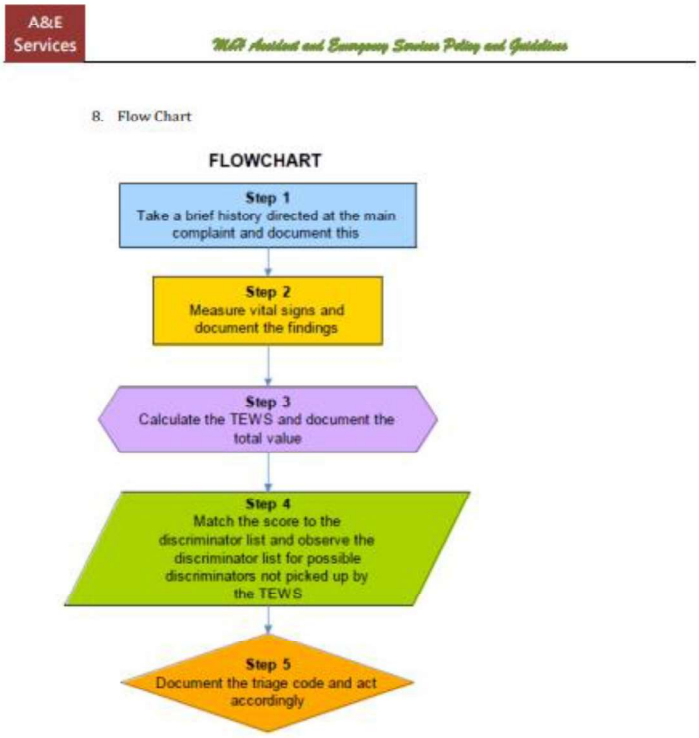
1. Adult Triage Score. (TEWS)

	3	2	1	0	1	2	3	
Mobility				Walking	With Help	Stretcher/ Immobile		Mobility
RR		less than 9		9-14	15-20	21-29	more than 29	RR
HR		less than 41	41-50	51-100	101-110	111-129	more than 129	HR
SBP	less than 71	71–80	81-100	101-199		more than 199		SBP
Temp		Cold OR Under 35		35-38.4		Hot OR Over 38.4		Temp
AVPU		Confused		Alert	Reacts to Voice	Reacts to Pain	Unresponsive	AVPU
Trauma				No	Yes			Trauma
over 12 years / taller than 150cm								

Appendix 1c: Adult Discriminator list
Source: MOH A&E services



Appendix 1d: Triage flow chart
Source: MOH A&E services



Appendix 1e: SATS Priority levels - Source: SATS manual

Priority COLOUR	Target time	Management
RED	IMMEDIATE	Take to the resuscitation room for **emergency** management
ORANGE	< 10 mins	Refer to majors for **very urgent** management
YELLOW	< 1 hour	Refer to majors for **urgent** management
GREEN	< 4 hours	Refer to designated area for non-urgent cases
BLUE	< 2 hours	Refer to doctor for certification

Appendix 1f: Adults SATS chart: Source: SATS manual

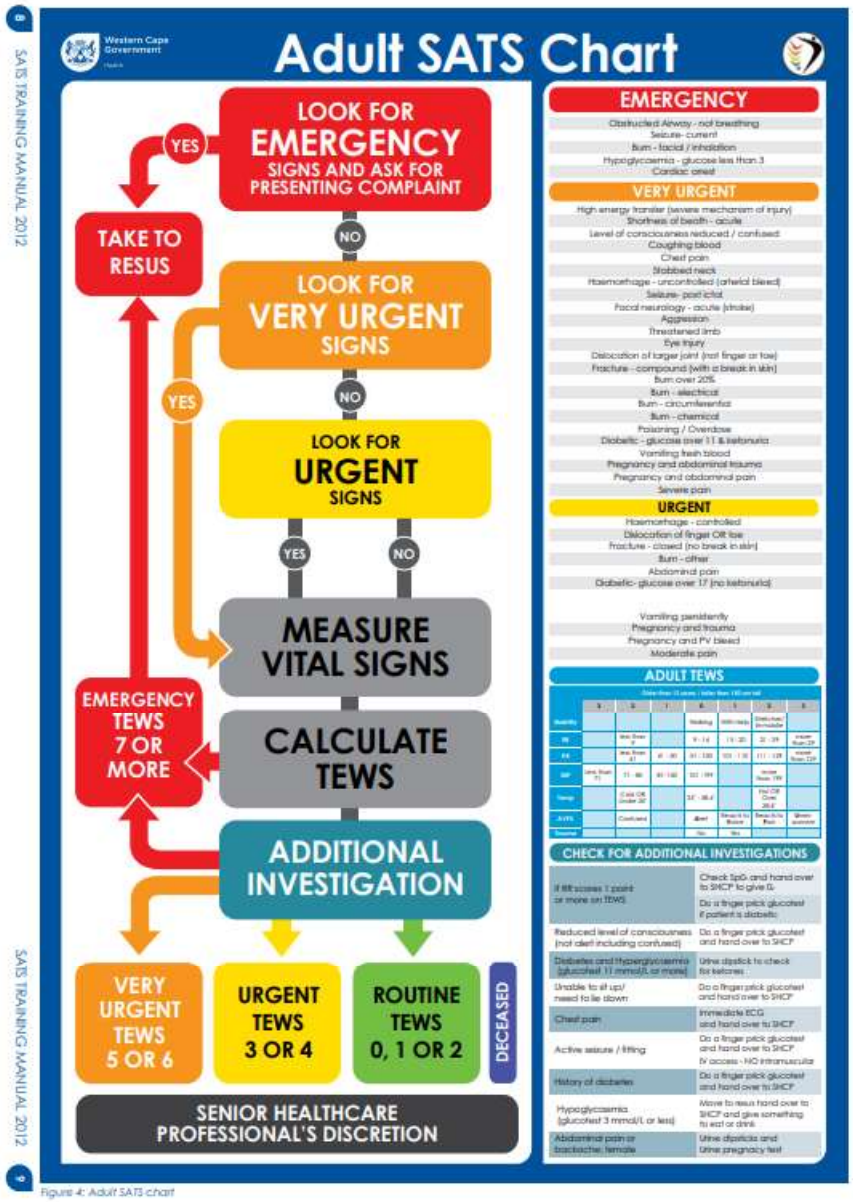


Figure 4: Adult SATS chart

Appendix 2a: Electronic database searched and search terms

Electronic database	Search terms/Strategy
Medline CINAHL EMBASE Web of science Pub Med Google scholar	1. ("sepsis" or "severe sepsis" or "septic shock").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 2. ("sepsis bundle" or "sepsis protocol" or "sepsis interventions").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 3. ("sepsis one" or "sepsis three" or "sepsis six").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 4. ("surviving sepsis campaign" or "early goal directed therapy").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 5. 1 or 2 or 3 or 4 6. Adult/ or exp Emergency Service, Hospital/ 7. (("low and middle income country") or "developing country").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary

	concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 8. exp Clinical Competence/ or exp Clinical Deterioration/ 9. (" national early warning score" or sequential organ failure assessment" or quick sequential organ failure assessment" or "systemic inflammatory response").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 10. ("recognition" or "detection" or "identification").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 11. 5 and 6 and 7 12. 5 and 7 and 10 13. 5 and 7 and 8 14. 1 and 6 and 7 15. 2 and 3 16. 2 and 3 and 4 and 6 and 7 17. 6 and 7 and 9 18. 4 and 6 and 7 19. 3 and 7 20. 1 and 6 and 7 21. 1 and 2 and 3 and 6 and 7 22. ("sepsis" or "severe sepsis" or "septic shock").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 23. ("sepsis bundle" or "sepsis protocol" or "sepsis interventions").mp. [mp=title, abstract, original title, name of

	substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 24. ("sepsis one" or "sepsis three" or "sepsis six").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 25. ("surviving sepsis campaign" or "early goal directed therapy").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 26. 22 or 23 or 24 or 25 27. Adult/ or exp Emergency Service, Hospital/ 28. (("low and middle income country") or "developing country").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 29. exp Clinical Competence/ or exp Clinical Deterioration/ 30. (" national early warning score" or sequential organ failure assessment" or quick sequential organ failure assessment" or "systemic inflammatory response").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word,

	protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 31. ("recognition" or "detection" or "identification").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 32. 26 and 27 and 28 33. 26 and 28 and 31 34. 26 and 28 and 29 35. 22 and 27 and 28 36. 23 and 24 37. 23 and 24 and 25 and 27 and 28 38. 27 and 28 and 30 39. 25 and 27 and 28 40. 24 and 28 41. 22 and 27 and 28 42. sepsis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 43. sepsis bundle.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 44. sepsis protocol.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 45. (lower and middle income countries).mp. [mp=title, abstract,

	original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 46. developing countries.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 47. emergency department.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 48. 45 or 46 49. 43 and 47 and 48 50. 43 and 48 51. 43 and 48 and 50 52. 44 and 48 53. 43 or 44 54. 48 and 53 55. sepsis recognition.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 56. 48 and 55 57. acute care settings.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease

	supplementary concept word, unique identifier, synonyms] 58. 55 and 57 59. emergency department.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 60. 55 and 59 61. 42 or 43 or 44 62. 48 and 59 and 61

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PROSPERO
International prospective register of systematic reviews

Identification and implementation of sepsis interventions in emergency departments in low and middle income countries: A systematic review.

Angela Prah, Liz Lees-Deutsch, Anne Topping

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Review question

This review will examine the following questions;

1. What processes are used to recognise sepsis in emergency departments in low and middle income countries (LMICs)?

2. What screening tools for sepsis detection are in use in emergency departments in LMICS?

3. What are the component parts of any interventions or bundles for sepsis in use in emergency departments in LMICs?

4. How effective are measures to recognize and manage sepsis in emergency departments?

5. What is the impact of sepsis interventions used in emergency departments on patient mortality in LMICs?

6. What are the enablers or barriers to sepsis pathway/bundle management in emergency departments in LMICs?

7. What are the optimum timelines for implementation of sepsis interventions?

8. What are the roles and responsibilities of different health care workers in the operationalisation of any sepsis bundle or interventions in use in emergency departments in LMICs?

Searches

MEDLINE, PubMed, CINAHL, EMBASE, Web of Science, Google Scholar. Hand searching will also be done

Language restrictions: Only articles written in English will be included.

Number of years restrictions: Articles from the year 2002 to present will be included as this was the date the global Surviving Sepsis Campaign (SSC) was launched.

Types of study to be included

Cross sectional studies/surveys, randomized controlled studies (RCTs), controlled trials, non-controlled experimental studies, observational and cohort studies.

Condition or domain being studied

The identification and management of sepsis is the domain under investigation. Sepsis is a ‘a life-threatening organ dysfunction due to a dysregulated host response to infection’ (1). This systematic review will focus on the identification of sepsis in adults (18 years and above) and the timely implementation of interventions including actions during the first hour following presentation at the emergency department, often referred to as the sepsis ‘golden hour’.

1. Singer M DC, Seymour CW, Shankar-Hari M, Annane D, Bauer M, et. al. The third international

consensus definition for sepsis and septic shock. JAMA. 2016;315:801-10.

Participants/population

Patients attending emergency departments (ED) in LMICs with sepsis. In the context of this study, an emergency department will include accident and emergency, casualty or emergency room, that specialises in the care of patients with acute, severe or urgent illnesses or injuries who arrive by ambulance or their own means without prior appointment. EDs are usually found in hospitals, other primary care centres or health centres and operate a 24 hour service. Majority of these patients require immediate attention

Inclusion criteria:

Emergency departments in LMICs.

Interventions carried out including the first hour of sepsis recognition.

Adult (18+ years) attending an emergency department who are identified as potentially experiencing sepsis.

Deteriorating patients whose status is related to sepsis.

Impact of sepsis interventions on patient mortality.

Barriers and enablers to the implementation of sepsis interventions.

Screening instruments used in the identification and management of sepsis-for example, sequential organ failure assessment (SOFA), quick sequential organ failure assessment (QSOFA) and national early warning score (NEWS).

Exclusion criteria:

Studies conducted in developed countries.

Studies that relate to deteriorating patients only will be excluded unless the data is related to sepsis.

Studies conducted outside emergency departments.

Conditions other than sepsis or relating to maternal sepsis.

Intervention(s), exposure(s)

Interventions and/or bundles of interventions used to identify and manage sepsis in patients attending emergency departments in LMICs.

Comparator(s)/control

No intervention(s) or bundles or locally adapted interventions to identify and manage sepsis in patients attending emergency departments in LMICs.

Main outcome(s)

1. The interventions or bundle of interventions used to recognise sepsis in emergency departments in LMICs.

2. The screening tools in use in emergency departments in LMICs to detect sepsis.

3. The component parts of any interventions or bundle of interventions used in the identification and management of sepsis in emergency departments in LMICs.

4. Optimum timeline for sepsis interventions.

5. The impact of sepsis interventions in emergency departments on patient mortality in LMICs.

* Measures of effect

Depending on the outcome measures and the data available, risk ratio, odds ratio, time to sepsis interventions and mortality rate will be extracted.

Additional outcome(s)

1. The effectiveness of measures used to recognize and manage sepsis in emergency departments.

2. Enablers or barriers to the introduction of interventions or bundle of interventions for the identification and management of sepsis in emergency departments in LMICs.

3. The roles and responsibilities of different health care workers when operationalising interventions and/or bundles in emergency departments in LMICs.

* Measures of effect

This would be considered based on the data available and the outcome measures.

Data extraction (selection and coding)

Selection: A two stage process will be used. First, titles and abstracts identified through the searches will be screened against the inclusion and exclusion criteria by two independent reviewers. Second, full text articles that meet the eligibility criteria will be obtained. Two review team members will independently assess the eligibility of the full text articles for inclusion. Any disagreements will be arbitrated by a third reviewer. Software will be used to support the screening processes. A Prisma flow chart will be developed to represent the conduct of the review.

Extraction: Data extraction will be undertaken, using the Participant, Intervention, Comparator, Outcome, Study site and Study design (PICOSS) framework (3) after critical appraisal of the studies. A standardized data extraction tool will be used. Summary tables, extraction of the major concepts, understanding of disagreements between the various papers, and how they relate to each other will be illuminated. Gaps in the included literature will be identified to inform future research.

3. Boland A, Cherry MG, Dickson R. Doing a systematic review : a student's guide / edited by Angela Boland, M. Gemma Cherry, Rumona Dickson. 2nd edition. ed: London : SAGE, 2017.

Risk of bias (quality) assessment

The risk of bias will be assessed by the use of the Newcastle Ottawa quality assessment tool for non-randomized studies and critical appraisal skills programme (CASP) for randomized studies (3, 4). Tidier checklist (5) will also be used for the description of interventions if any are identified. Rating of subparts will also be done by the use of the standard quality assessment criteria for evaluating primary research papers (Qualysyst) (6) .

The quality of included studies will be assessed independently by two reviewers. The inter rater agreement will be calculated using the percentage method and disagreements will be arbitrated by the third reviewer following discussion within the team.

3. Boland A, Cherry MG, Dickson R. Doing a systematic review : a student's guide / edited by Angela Boland, M. Gemma Cherry, Rumona Dickson. 2nd edition. ed: London : SAGE, 2017.

4. Bettany-Saltikov J. How to do a systematic literature review in nursing : a step-by-step guide, Second edition. ed: London : Open University Press/McGraw-Hill Education, 2016.; 2016.

5. Cumpston M, Li T, Page MJ, Chandler J, Welch VA, Higgins JP, et al. Updated guidance for trusted systematic reviews: a new edition of the Cochrane Handbook for Systematic Reviews of Interventions. Cochrane Database of Systematic Reviews.10(10).

6. Leanne M. Kmet, Robert C. Lee, Cook LS. Standard quality assessment criteria for evaluating primary

research papers from a variety of fields. AHFMR. 2004.

Strategy for data synthesis
All included studies will be presented in summary tables. A narrative synthesis reporting the findings of the included studies will be undertaken. This will illustrate the characteristics of the emergency department settings such as geography of unit, number of beds/ trolleys, triage or categorisation for acuity of patients, characteristics of the workforce, skill mix. The interventions used and the component parts of any complex interventions or bundles (including deteriorating patient chart, blood tests conducted, antibiotic protocol, intravenous fluid administration), training and any task re-allocation. A summary of intervention effects including sepsis identification, time to treatment and mortality, will also be examined. Meta-analyses will not be undertaken as the interventions described in included studies are likely to be heterogeneous with variable outcome measures reported in included studies.

Analysis of subgroups or subsets
Studies examining deterioration in relation to sepsis and studies examining screening tools used in the identification and monitoring of patients experiencing sepsis.

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Type and method of review
Systematic review

Anticipated or actual start date
15 May 2020

Anticipated completion date
30 October 2020

Funding sources/sponsors
University of Birmingham

Conflicts of interest

Language
English

Country
England

Stage of review
Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Developing Countries; Emergency Service, Hospital; Humans; Income; Sepsis

Date of registration in PROSPERO
03 June 2020

Date of first submission
08 May 2020

Details of any existing review of the same topic by the same authors
N/A

Stage of review at time of this submission
The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions
03 June 2020

Appendix 3 NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE

COHORT STUDIES - Source: https://www.ohri.ca/programs/clinical_epidemiology/oxford.asp

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

1) Representativeness of the exposed cohort
   a) truly representative of the average _____ (describe) in the community ✸
   b) somewhat representative of the average _____ in the community ✸
   c) selected group of users eg nurses, volunteers
   d) no description of the derivation of the cohort

2) Selection of the non exposed cohort
   a) drawn from the same community as the exposed cohort ✸
   b) drawn from a different source
   c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure
   a) secure record (eg surgical records) ✸
   b) structured interview ✸
   c) written self report
   d) no description

4) Demonstration that outcome of interest was not present at start of study
   a) yes ✸
   b) no

Comparability

1) Comparability of cohorts on the basis of the design or analysis
   a) study controls for _____ (select the most important factor) ✸
   b) study controls for any additional factor ✸ (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

1) Assessment of outcome
   a) independent blind assessment ✸
   b) record linkage ✸
   c) self report
   d) no description

2) Was follow-up long enough for outcomes to occur
   a) yes (select an adequate follow up period for outcome of interest) ✸
   b) no

3) Adequacy of follow up of cohorts
   a) complete follow up - all subjects accounted for ✸
   b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) ✸
   c) follow up rate < ____% (select an adequate %) and no description of those lost
   d) no statement

Appendix 4: Source: Critical Appraisal Skills Programme (CASP - RCT)

CASP Randomised Controlled Trial Standard Checklist:

11 questions to help you make sense of a randomised controlled trial (RCT)

Main issues for consideration: Several aspects need to be considered when appraising a randomised controlled trial:

- Is the basic study design valid for a randomised controlled trial? (Section A)
- Was the study methodologically sound? (Section B)
- What are the results? (Section C)
- Will the results help locally? (Section D)

The 11 questions in the checklist are designed to help you think about these aspects systematically.

How to use this appraisal tool: The first three questions (Section A) are screening questions about the validity of the basic study design and can be answered quickly. If, in light of your responses to Section A, you think the study design is valid, continue to Section B to assess whether the study was methodologically sound and if it is worth continuing with the appraisal by answering the remaining questions in Sections C and D.

Record 'Yes', 'No' or 'Can't tell' in response to the questions. Prompts below all but one of the questions highlight the issues it is important to consider. Record the reasons for your answers in the space provided. As CASP checklists were designed to be used as educational/teaching tools in a workshop setting, we do not recommend using a scoring system.

About CASP Checklists: The CASP RCT checklist was originally based on JAMA Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL and Cook DJ), and piloted with healthcare practitioners. This version has been updated taking into account the CONSORT 2010 guideline (http://www.consort-statement.org/consort-2010, accessed 16 September 2020).

Citation: CASP recommends using the Harvard style, i.e., *Critical Appraisal Skills Programme (2021). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: insert URL. Accessed: insert date accessed.*

CASP
Critical Appraisal Skills Programme

Study and citation: .....

Section A: Is the basic study design valid for a randomised controlled trial?

1. **Did the study address a clearly focused research question?**
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ☐	No ☐	Can't tell ☐

2. **Was the assignment of participants to interventions randomised?** *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ☐	No ☐	Can't tell ☐
3. **Were all participants who entered the study accounted for at its conclusion?** *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ☐	No ☐	Can't tell ☐

Section B: Was the study methodologically sound?

4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ☐	No ☐ ☐ ☐	Can't tell ☐ ☐ ☐
5. **Were the study groups similar at the start of the randomised controlled trial?** *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ☐	No ☐	Can't tell ☐

6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ☐	No ☐	Can't tell ☐

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ☐	No ☐	Can't tell ☐
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ☐	No ☐	Can't tell ☐
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ☐	No ☐	Can't tell ☐

CASP
Critical Appraisal
Skills Programme

Section D: Will the results help locally?			
10. **Can the results be applied to your local population/in your context?** *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ☐	No ☐	Can't tell ☐
11. **Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?** *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ☐	No ☐	Can't tell ☐

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Appendix 5a

Participant information sheet (process mapping)

Title of Project: Sepsis bundle implementation in a Ghanaian Emergency Department: a convergent mixed methods pre-implementation study.

Principal Investigator: Angela Prah

Invitation paragraph

You have been invited to participate in a research study. Before you decide whether to take part in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it if you wish to. Feel free to ask the investigator any question if there is anything that is not clear to you or if you would like to know more about the study. Take time to decide whether you wish to take part or not. Thank you for reading this.

What is the study about?

Sepsis is a result of a dysregulated host immune system due to infection and can lead to organ failure. The early identification of sepsis, and the initiation of timely interventions, helps prevent progressive deterioration and improve patient outcomes. Evidence based care practices known as care bundles of care have been used elsewhere to speed the recognition of these patients and manage their care better.

The overall aim of this research is to develop a sepsis package for the emergency department that will help in the timely recognition and management of patients presenting with sepsis. Introducing change is complex and involves a number of stages. This research seeks to help introduce a sepsis bundle and evaluate its implantation. The first phase, the focus of this research, involves a process mapping exercise and analysis of case note analysis. The outcome of this phase will be

design of the care bundle (an intervention) to be piloted and then the actual implementation will be monitored called a process evaluation. You are being invited to take part in the process-mapping workshop and individual interviews to help identify the current process used in managing patients with sepsis.

Who does the study involve?

Healthcare professionals working in the ED of Holy Family Hospital, Techiman who have given consent to participate in the study willingly will be invited to join one or two process mapping workshops as well as stakeholder interviews. This process mapping seeks to understand the current processes used to recognize and manage sepsis in the emergency department.. Interviews will be audio recorded and would last for 30-45 minutes.

Why have I been chosen?

You have been chosen because you have experience of the management of patients with sepsis through working as a healthcare professional working in ED.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide not to take part you are still free to withdraw and without giving a reason.

I am interested in taking part, what do I do next?

You can contact me through.

Telephone: +233503288115

Email: axp902@student.bham.ac.uk

Angela Prah

What if I agree to take part and then change my mind?

You are free to withdraw from the study at any time, without giving any reason.

What is the procedure that is being tested?

This a qualitative study in which we are going to seek answers on the current process of recognising sepsis

What are the possible disadvantages and risks of taking part?

Giving your time to participate in this study will be a possible inconvenience to you. In the event of any possible physical, psychological or emotional disturbance during the course of data collection, the appropriate intervention will be used be it medical intervention, counselling etc. .

What are the possible benefits of taking part?

If you decide to take part in this study you would be adding a valuable resource to the work to facilitate a policy that would serve as a guide for future guidelines in recognising and managing sepsis

Is the study invasive?

The study does not involve any invasive procedure and therefore does not provide any compensation arrangements. However, the researcher will prioritise the welfare of participants throughout the study. Research participants will not be subjected to any form of exploitation.

Who can I complain to?

If you have any questions regarding anything to do with this study, you can contact the lead investigator (Angela Prah) or supervisors (Prof Anne Topping and Dr. Liz Lees- Deutsch) or focal point for the study at the participating hospital. If this achieves no satisfactory outcome, you should then contact the Ethics Administrator for the study.

Their details are below:

Name: Prof Anne Topping

University of Birmingham

Dr. Liz Lees-Deutsch

University of Birmingham

Name: Angela Prah (PI)

Telephone: +233503288115

Email: axp902@student.bham.ac.uk

Name: Mrs Ophelia-0549629341 (Ethics Admin)

Study site Supervisor

Tobias Ninnang Gebhard

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept on a password protected database and is strictly confidential. You will be given an ID code which will be used instead of your name. Any identifiable information you may give will be removed and anonymised.

According to ethics policy, your information will be kept for 5 years after the study has been completed at the University research repository. The supervisors of this study will also have access to the data and members of the faculty human research ethics committee may also have access to your information because they have the right to check that the study has been conducted in accordance with the approval.

What will happen to the results of the research study?

Information that will be gathered after analysing all data as per the objectives of the study will primarily be published in selected peer-reviewed journals and on participating hospitals' websites.

Who is organising and funding the research?

Funding of the study is done by the Ghana Scholarship secretariat as well as the University of Birmingham

Who has reviewed the study?

This study has been reviewed and approved by the University of Birmingham ethical approval committee, Kintampo Health Research Institute and the study site.

Thank you for volunteering to take part in the study.

Appendix 5b

Process Mapping Consent Form for Healthcare Professionals

Version 1.0, 7th July 2021

Title of Research Project:	Sepsis bundle implementation in a Ghanaian Emergency Department: a convergent mixed methods pre-implementation study
Researcher details:	***Angela Prah*** ***Email :***

Please tick and initial all boxes if you have read and understood the following:

1. I confirm that I have read/ had read to me the Patient Information Sheet for the above study (version ____) and have had the opportunity to consider the information and ask questions and these have been answered satisfactorily. I agree that researchers have provided me with a copy of the participant information sheet to keep.	
2. I understand that participation is voluntary. I also understand that as a participant, I am free to withdraw from the study upto data synthesis without giving any reason and without there being any negative consequences.	
3. I agree to take part in the process mapping workshop as well as stakeholder interviews and also acknowledge that the interview will be digitally audio recorded. I understand I can decline to answer any particular question	
4. I understand that data collected during the study may be looked at by individuals in regulatory authorities in UK and Ghana. I give permission for the regulatory authority to have access to my data.	
5. I agree to anonymized study data being stored securely.	
6. I understand that the data collected may be published as part of this research project. My identity will not be revealed in any publication or report.	
7. I understand that University of Birmingham/ Ghana Health Services have reviewed and approved this study. Ethics No	
8. I understand that the information collected during the data collection will be anonymized before it is looked at by all members of the project team and the University of Birmingham as well as the Ghana Health services ethics Committees who may require access to check that the study has been conducted in accordance with the approval.	
9. As a participant I agree to be contacted by the researcher named above	
10. I agree to take part in the above study.	

A copy of this document must be retained by both the participant and researcher *Applicant use*

Print name of participant			
Contact details of participant (e-mail)			
Participant signature		***Date***	
Researcher name and signature		***Date***	

Participants Rights; If you have any ethical concerns during or after your participation in this study, please contact the Administrator of the Kintampo Health Research Centre Institutional Ethics Committee on **0556847860**

Consent statement:

I have read the above study information, or it has been read to me. I have had the opportunity to ask questions about it and questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study. I also understand that the information collected will be treated confidentially and will be used only for the purpose informed. I will be given a copy of this informed consent form.

…… ……

Name of Participant Signature or thumb print

Date ……/……/……

Witness (Witness to Consent Procedures if Participant cannot read)

A witness's signature and the participant's thumbprint are required only if the participant is illiterate. In this case, a literate witness must sit throughout the entire period of the consenting process, write his or her name, date and sign this document.

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely".

…… ……

Name of Witness Signature

Date ……/……/……

Person conducting Consent

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the potential participant. I have answered all questions that have been raised and have witnessed the above signatures on the date indicated above.

Name: …….. Date: ……../……../……..

Signature: ……..

Appendix 6 - UNIVERSITY OF BIRMINGHAM / HOLY FAMILY HOSPITAL DATE 12/2021

STAFF SIGNATURE AND DELEGATION LOG

Study Number/Short Title	Understanding sepsis recognition and management in a Ghanaian Emergency Unit	**Protocol Number:**	KHRCIEC/2021-26
Principal Investigator:	ANGELA PRAH (PhD STUDENT)	**Study Site:**	HOLY FAMILY HOSPITAL, TECHIMAN, GHANA

NAME	STUDY ROLE	TASK PERFORMED	STUDY INVOLVEMENT	INITIALS	SIGNATURE AND DATE	PI SIGNATURE AND DATE	CV
A.T. A	SSV	Inter rater reliability	Checked 8 case notes independently and compared with the PI	ATA	ATA 12/2021	ANGELA PRAH	

DELEGATED TASKS

1. Inter rater reliability

Appendix 7: Case notes extraction template

Q1	Q2	Q3	Q4	Q4
Patient	**Age**	**Sex**	**Date of admission**	**Time of admission**

Q5	Q6
Mode of admission	Was sepsis suspected or confirmed?

Q7

Was set of observations conducted for the patient on arrival?

Q8	Q9	Q10
What time was the observations conducted	Temperature	Pulse

Q11	Q12	Q13	Q14
Respiration	SPO2	BP	GCS

Q15

Was early warning scoring system used ?

Q16

Was a standardised sepsis protocol/care bundle used?

Q18	19
whats the name of the EWS	Was the patient assessed by an ED doctor on arrival

Q19a

what time did the doctor assess the patient

Q20

was serum lactate requested, sent and results retrieved

Q20a

if yes to number …, time requested, time sent, time results retrieved, results

Q21

was blood cultures obtained before leaving the ED

Q21a

if yes, was this done before administering antibiotics

Q21b	Q21C
what time was blood culture requested	what time was it sent

Q21d	Q22
what time was it retrieved and the time	was the patient prescribed antibiotics

Q22a	Q22b
what type of antibiotic	was the antibiotic administered within an hour

Q22c

what time was the antibiotics prescribed

Q22d	Q22e
what time was it picked from pharmacy	what time was it administered

Q23	Q23a
did the patient receive IV fluid	state the type of IV fluid prescribed

Q23b	Q23c
state the time it was prescribed	state the time it was started

Q24d

amount received before leaving the ED

Q25

Did the patient have repeat observations done

Q25a	Q25b	Q25b	Q25b
what time was the repeat observations done	Temperature2	pulse2	respiration2

Q25b	Q25b	Q25b	Q25b
SPO22	**BP2**	**GCS2**	**FBS/RBS**

Q26	Q26a
Did the patient receive O2 before leaving the ED	what time was O2 set up

Q26b	Q26c
mode of O2 delivery	what time was O2 set up2 and what time was the patient weaned off

Q27	Q27a
did the patient receive vasopresors	if yes, what type of vasopressor

Q27b	27c
time vasopressor was prescribed	time it was administered

Q28	Q28a
was consideration given to the likely source of infection	what was the source of infection

Q29	Q30
did the patient have an ongoing mgt plan	Date of sepsis identification/diagnosis

Q30a

time of sepsis identification/diagnosis

Q31

is there evidence of a structured handoverthroughout all the shifts

Q32

what was the final outcome of the patient

Q32a	Q33	
what date and time was the final outcome	results of lab results	Further comments

Appendix 8a

CONVERSATIONAL DEPTH TOPIC GUIDE FOR STAKEHOLDER INTERVIEWS (WP2) PROCESS MAPPING

Before the interview

Introduction of the researcher to the interviewee and the purpose of the interview

During the interview:

Questions

To start, can you tell me your title and role here at (Holy Family Hospital)?

P

R: How long have you been in this role?

P

b. What is your role in the care of patients with sepsis?

R (Nurse or doctor): Tell me about the journey/processes of patients with sepsis who present to the emergency from your perspective as well as any barriers observed. OR

In your perspective, what are the processes of a patient who comes to the emergency with sepsis. OR

How do you manage sepsis in your department from their initial presentation.

R (laboratory personnel): Tell me the processes in which the sample of a patient with sepsis goes through right from the point of collection to the time the results are ready in your perspective as well as any barriers that is being encountered whiles the samples are in the process.

R (pharmacy personnel) : Tell me how the medications of a patient diagnosed with sepsis are collected from the pharmacy in your perspective and any barriers that are encountered in the course of that process

Additional prompts based on individual roles

R: Could you please walk me though the process of triaging, admitting, caring for and the final disposition of the patients presenting with sepsis. I would like to know the step-by step process and what takes place at each step, staff involved and the time it takes to complete the step.

R: How does the sepsis process takes place?

R: What happens when a patient arrives in the triage area and what time does it take to triage

R: How is sepsis identified (is it at the triage or as diagnosed by the attending physician)

R: When does the sepsis identification and management begins?

R: Who (what staff roles) is involved in getting the sepsis pathway carried out

R: Who specifically begins the sepsis pathway

R: What interventions are carried out once sepsis has been recognised/suspected.

R: Is lactate or blood culture requested, done and retrieved to inform the diagnosis of the patient.

R: Is there a sepsis pathway in place in the ED

R: Are blood cultures taken before the administration of antibiotics

R: What are the timelines for these activities mentioned.

R: What time does it take for sepsis to be diagnosed

What time does it take for the interventions to be carried out

R: Which areas of care does the patient visit and what time does it take to get these done.

R: What are the roles of individual healthcare professionals in identifying sepsis

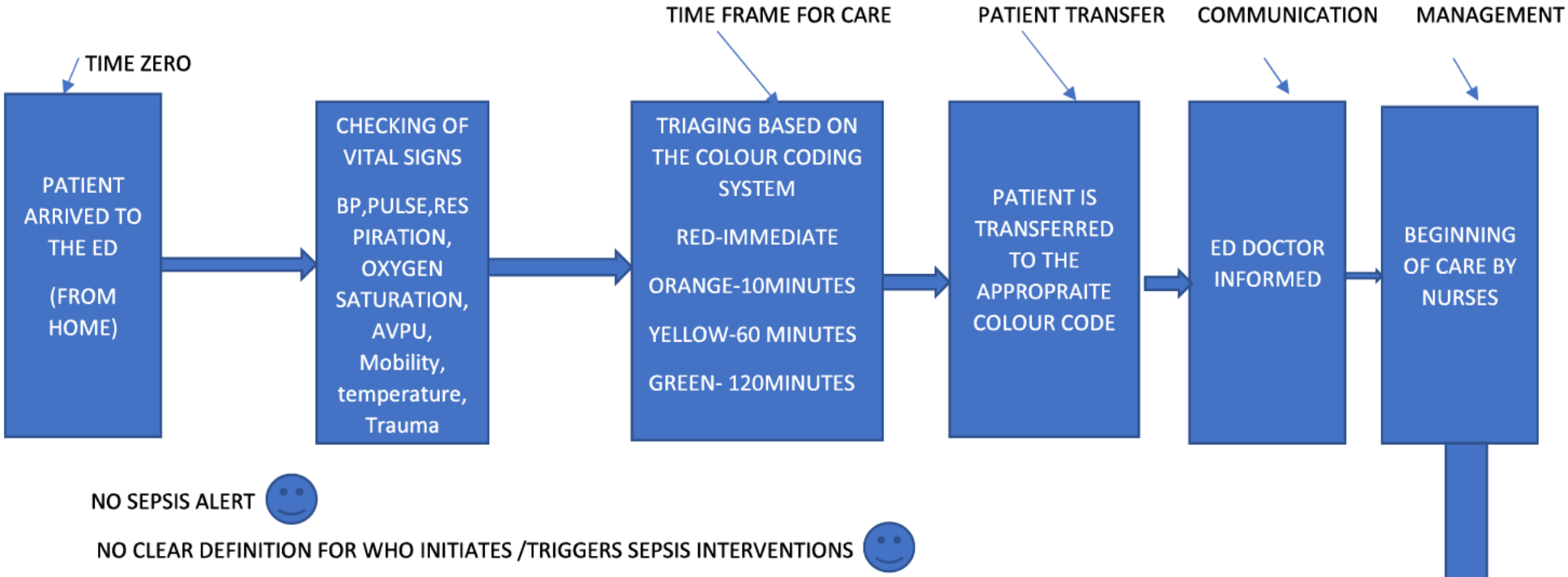
R: What are the outcomes of patients presenting with sepsis based on the care rendered to them.

R: Do patients have to pay before their laboratory investigations?

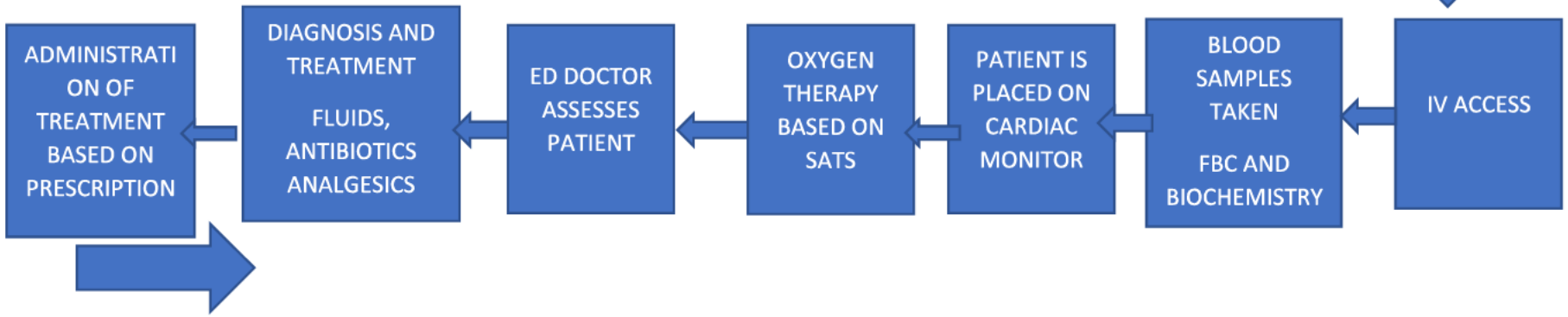
R: Do patients have to pay before their medications are served?

PROCESS MAPS FOR SEPSIS IN HOLY FAMILY HOSPITAL, CURRENT SITUATION

TRIAGE(This is done based on the South African Triage Scoring System(SATS)

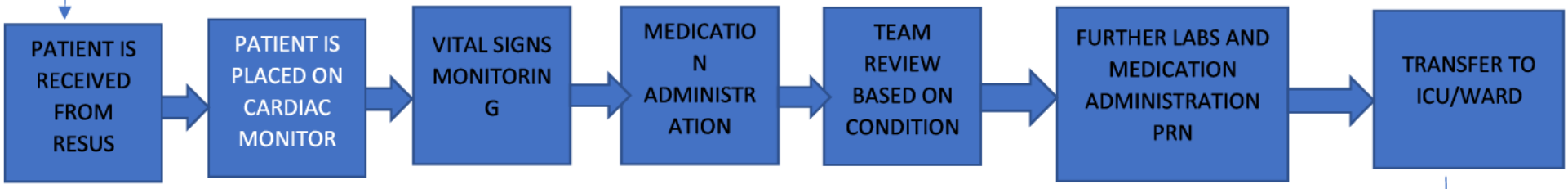


RESUSCITATION AREA/INITIAL TREATMENT AREA-PATIENT KEPT FOR 4 HOURS FOR LABS, RX AND RADI GY



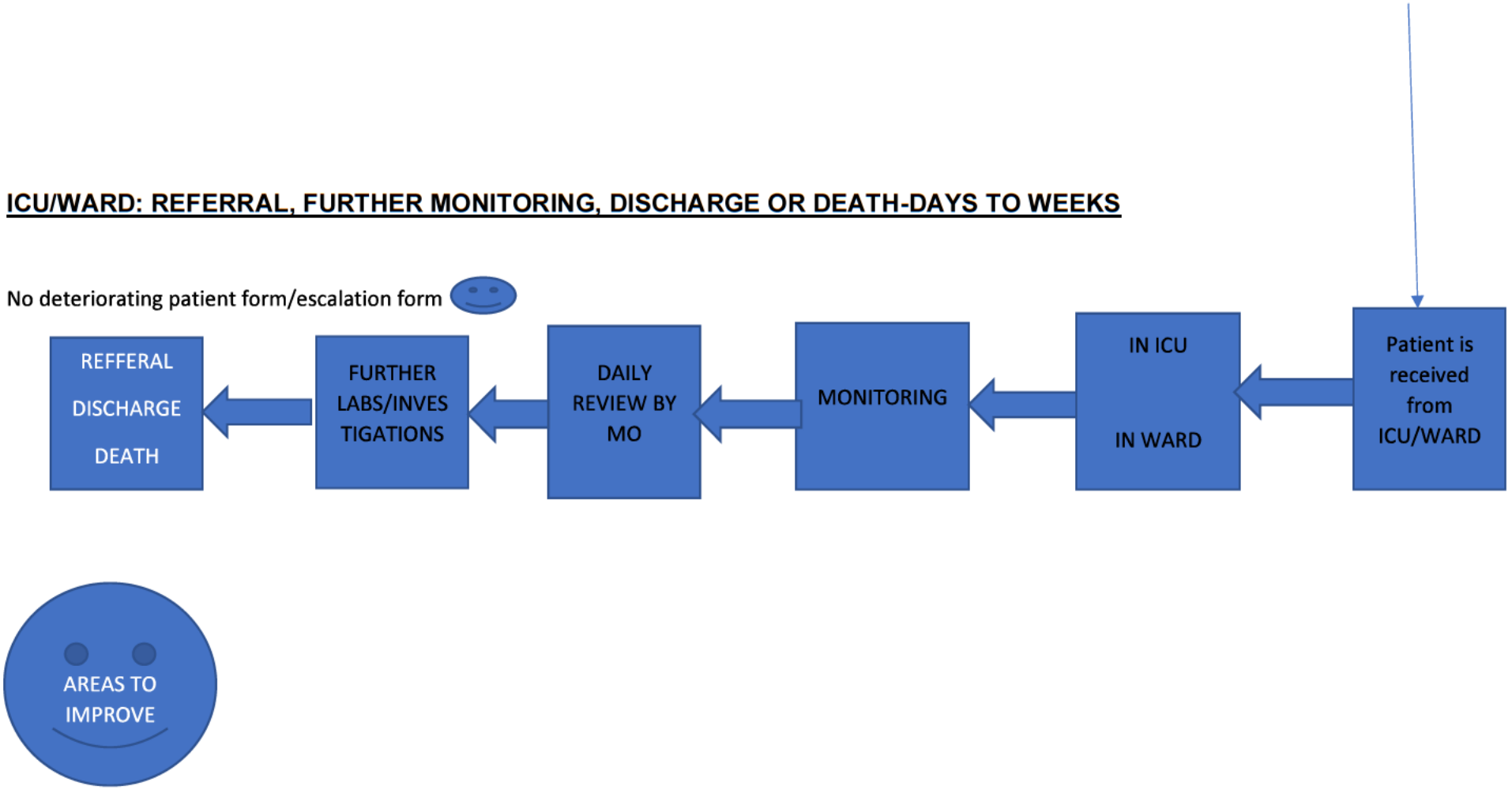
1. Sometimes broad spectrum antibiotics is prescribed before arrival of laboratory results
2. Blood culture is not taken before antibiotics but requested
3. Fluid resuscitation is done based on vital signs and doctor's prescription
4. Lactate is mostly not done
5. Patient is placed on cardiac monitor for continuous monitoring
6. Scheduled vital signs monitoring and documentation is based on the discretion of the assigned nurse
7. Urine output monitoring

RED/ORANGE: OBSERVATION AND MONITORING FOR 24 HRS

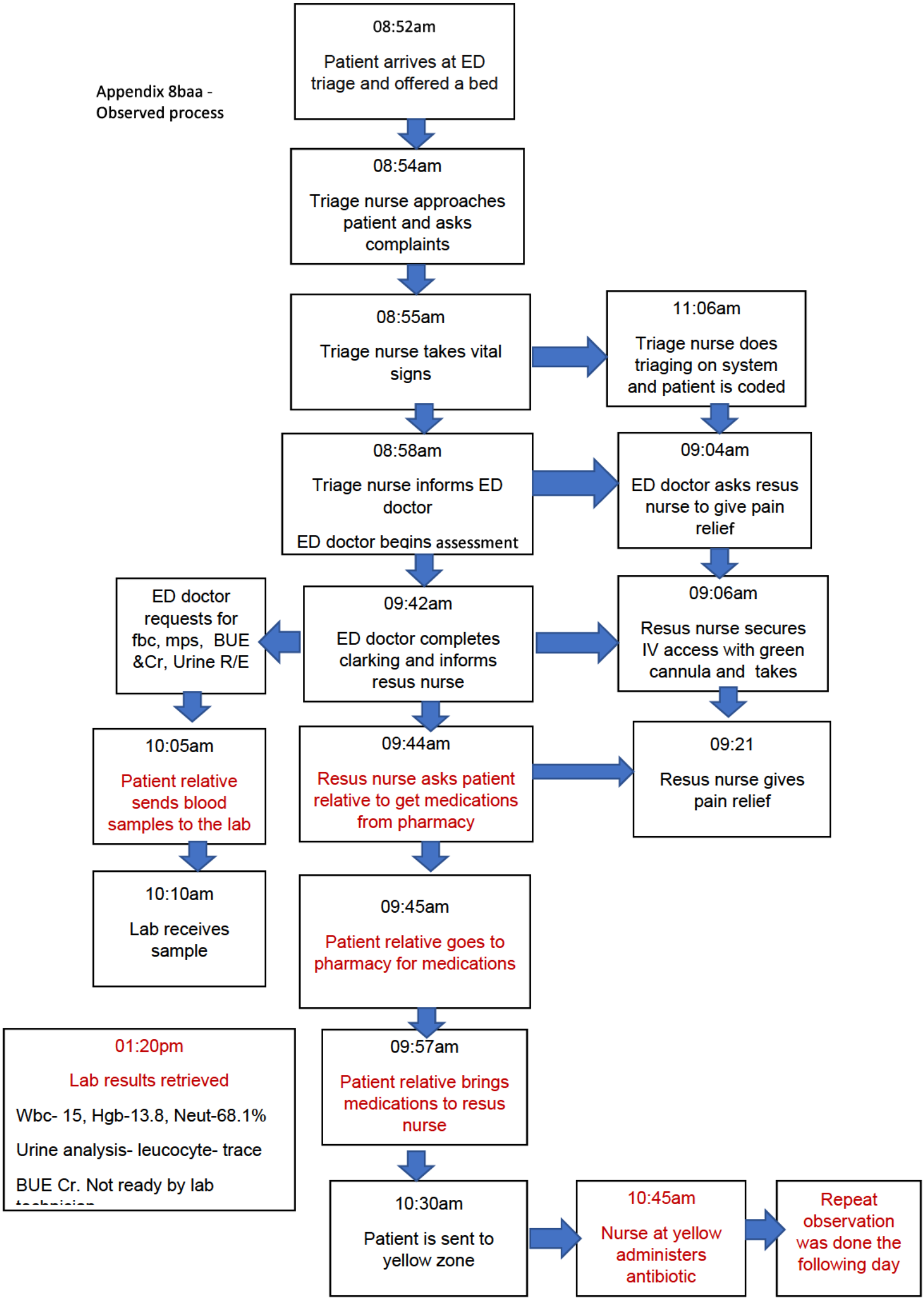


No deteriorating patient form/escalation form

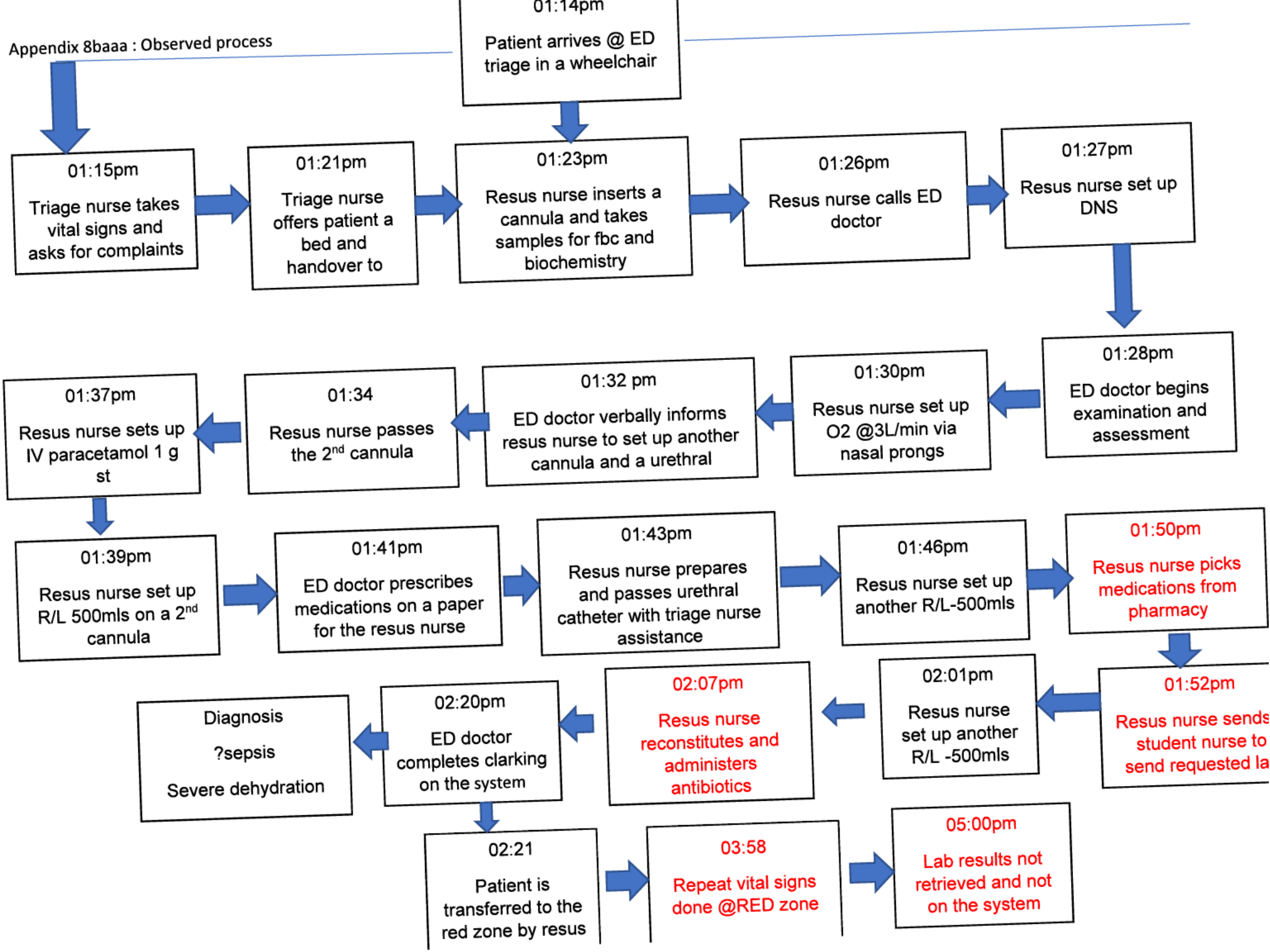
ICU/WARD: REFERRAL, FURTHER MONITORING, DISCHARGE OR DEATH-DAYS TO WEEKS



Appendix 8baa - Observed process



Appendix 8baaa : Observed process



In case of reply the Number and date of this letter should be quoted.

My Ref.
Your Ref. No.

Kintampo Health Research Centre
Ghana Health Service
P. O. Box 200
Kintampo
Bono East Region
[redacted]

October 21, 2021

The Principal Investigator
Sepsis Bundle Study
Kintampo Health Research Centre
P.O. Box 200
Kintampo
Bono East Region, Ghana

Dear Principal Investigator,

Decision on your protocol

The KHRC Scientific Review Committee reviewed your protocol titled **"Sepsis Bundle Implementation in A Ghanaian Emergency Department: An Explanatory Sequential Mixed Methods Study"** on Monday, 4th October 2021.The committee received your responses to the comments and based on confirmation by the main reviewers, we are pleased to grant your study full approval.

You are also required to submit a copy of the final protocol to the Kintampo Health Research Centre Institutional Ethics Committee for ethical approval before the study commences.

Accept my congratulations.

Thank you.

Yours faithfully,

[redacted]

(David Dosoo)

Appendix 9: Ghana ethics

Kintampo Health Research Centre (KHRC) Institutional Ethics Committee (IEC)
P.O Box 200
Kintampo, B/A
Ghana, West Africa

Tel:
E-mail

FULL ETHICAL APPROVAL CERTIFICATE

Holy Family Hospital
P. O. Box 36
Techiman, Bono East Region
Ghana

Date: 15th November 2021

Study ID Number:

Title of study: Sepsis Bundle Implementation in a Ghanaian Emergency Department: An Explanatory Sequential Mixed Methods Study.

Principal Investigator: Angela Prah (PhD Candidate)

Supervisors: Professor Anne Topping, Dr. Liz Lees-Deutsch

Type of Review: Full Board Review

Approval Date: 15th November 2021

Expiration Date: 15th November 2022

1. The Kintampo Health Research Centre Institutional Ethics Committee (IEC) is constituted and operates in conformance with requirements of 45 CFR 46, 21 CFR 50, 21 CFR 56, and section 3 of the International Council on Harmonization Guidelines, as well as all applicable regulatory, legal, and other ethical requirements governing human subject research in Ghana. The OHRP Federal Wide Assurance number for the committee is 00011103; the IRB registration number is 0004854.

2. On November 9, 2021, the IEC reviewed the above-mentioned study in the title and granted it conditional approval.

3. The Committee acknowledges receipt of the response to the conditional approval letter as well as the submission of the updated documents. The response and revised documents were reviewed and found to be satisfactory. As a result, the Committee gives you full ethical approval for the study's implementation.

4. The following documents were reviewed and approved for use;

    4.1 Sepsis Bundle Implementation in a Ghanaian Emergency Department: An Explanatory Sequential Mixed Methods Study. Dated 12th November 2021

Study File number: 2021-26

THE CHAIRMAN
KINTAMPO HEALTH RESEARCH CENTRE
INSTITUTIONAL ETHICS COMMITTEE.

Appendix 9: Ghana ethics

Kintampo Health Research Centre (KHRC) Institutional Ethics Committee (IEC)

P.O Box 200
Kintampo, B/A
Ghana, West Africa

4.2 Information Sheet and Consent Form (Process Mapping – Healthcare Professionals). Version 1, dated 12th November 2021
4.3 Information Sheet and Consent Form (Case note extraction - Patient and or relative). Version 1, dated 12th November 2021
4.4 Information Sheet and Consent Form (Process evaluation for Healthcare Professionals). Version 1, dated 12th November 2021
4.5 Data collection tools
4.6 Study Budget
4.7 Curriculum Vitae of study Investigators.

5. During study implementation, the IEC must be informed within 72 hours by the principal investigator (PI) of learning of any (a) unexpected, serious, study-related adverse events; (b) disclosed adverse events, or (c) unanticipated problems with the study which may pose risk to study participants or others (if applicable).

6. All safety monitory reports, including DSMB summaries and reports, must be submitted to the IEC as soon as they become available to PI(s) (if applicable).

7. Changes or modifications to this research activity must be submitted and approved by the IEC before they are implemented.

8. PI(s) would be required to apply for renewal of this approval certificate (if the study lasts for more than 12 months) plus a progress report.

9. PI(s) is required to notify the IEC of study completion (end of data collection/last follow-up) or early termination of the research project.

10. Submit the final report of the study three months after the approval certificate expires (study closure).

11. Before the conduct of the study, submit the original/final copy of your informed consent forms for **authentication stamp** before making photocopies for your consent process.

12. Regulated study records, including IEC approvals and signed consent forms, must be securely maintained by PI(s) and available for audits for three years after the study is closed with the IEC.

Sincerely,

THE CHAIRMAN
KINTAMPO HEALTH RESEARCH CENTRE
INSTITUTIONAL ETHICS COMMITTEE.

Nana Franklin Fei
Second Vice-Chair
Institutional Ethics Committee
Kintampo Health Research Centre

Study File number: 2021-26

Appendix 9: University of Birmingham ethical approval

Re: "Sepsis Bundle Implementation in a Ghanaian Department: A Convergent Mixed Methods Study"
Application for Ethical Review ERN_21-1847

Thank you for your application for ethical review for the above project, which has now been reviewed by the Science, Technology, Engineering and Mathematics Ethical Review Committee.

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for your project, subject to your adherence to the following conditions:

- That insurance is in place prior the commencement of the study. A member of the governance team will be in touch shortly to confirm if additional insurance information is required (ctinsurance@contacts.bham.ac.uk)

For clarification, as long as the conditions above are met and the details of the proposed work do not change, your project has ethics approval and no further action is necessary.

I would like to remind you that any substantive changes to the nature of the study as described in the Application for Ethical Review, and/or any adverse events occurring during the study should be promptly bought to the Committee's attention by the Principal Investigator and may necessitate further ethical review.

Please also ensure that the relevant requirements within the University's Code of Practice for Research and the information and guidance provided on the University's ethics webpages (available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Links-and-Resources.aspx) are adhered to and referred to in any future applications for ethical review. It is now a requirement on the revised application form (https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx) to confirm that this guidance has been consulted and is understood, and that it has been taken into account when completing your application for ethical review.

If you require a hard copy of this correspondence, please let me know.

Appendix 10: Hospital consent

NATIONAL CATHOLIC HEALTH SERVICE

Post Office Box 36
Techiman
Brong - Ahafo Region
Ghana, West Africa

DIOCESE OF TECHIMAN

Telephone numbers:

September 08, 2020

Miss. Angela Prah
Holy Family Hospital
Techiman.

Dear Madam,

RE: IMPLEMENTATION OF SEPSIS PACKAGE IN AN EMERGENCY DEPARTMENT(I-SEE) IN GHANA: A COMPLEX MIXED METHODS STUDY.

With reference to your letter requesting for permission to collect data in this facility, approval has been given to you to use our hospital as study site.

You are required to give a copy of your final study to the hospital upon completion.

Your on-site Supervisor is Dr. Tobias Ninang

Thank you.

Yours faithfi

.....

CHRISTOPHER AKANBOBNAAB
(Hospital Administrator)

CC : Dr. Tobias Ninang

Appendix 11: Risk assessment

University of Birmingham

RISK ASSESSMENT

Title of research: Understanding sepsis recognition and management in a Ghanaian Emergency Department: A convergent mixed methods study

SECTION A: AIM OF THE RESEARCH

The study seeks to examine how sepsis has been recognised and managed in a Ghanaian emergency department. This study will look at the following specific objectives which are classified in phases.

Phase 1: recruit a group of staff to act as sepsis volunteers who will assist in the design of a context-specific sepsis bundle and implementation plan. To map existing systems and model processes for recognising and managing sepsis in a Ghanaian ED

Phase 2: after mapping existing systems and model processes for recognising and managing sepsis at the ED of Holy Family Hospital, Techiman, Ghana, to co- design an intervention and provide education for staff.

Proceeding with worldwide public liability without cover for participants.

This research is part of a quality improvement (QI) programme designed to help healthcare professionals manage sepsis using best practises. Simply defining best practises does not guarantee that they will be implemented, so it is crucial to conduct parallel research evaluations of strategies for effective uptake and implementation. The Holy Family Hospital in Techiman, Ghana will receive this QI programme.

Holy Family Hospital, Techiman will receive a copy of the best practise guidance and QI intervention, which is an educational programme aimed at clinical staff and a protocol to be used in identifying and managing sepsis, after participating (co designing) in the design of the best practise sepsis guidance. We are obtaining institutional and clinical staff consent for participation in the study because it will only use data that is regularly

collected about patients. The hospital recognises the intervention as a QI measure and a component of their standard clinical care, that is implementing best practises to enhance patient outcomes.

SECTION B: THE POTENTIAL RISK(S)

Scoring system:

High Risk 3	3	6	9
Medium Risk 2	2	4	6
Low Risk 1	1	2	3
	Low Probability 1	Medium Probability 2	High Probability 3

Activity or operation 1:	Retrospective case note review	Probability	Risk Severity	Score
Risk:	The risk of maintaining anonymity of participants. Breaching of confidentiality and exposure of personal information. Identification of poor clinical practice	1	1	1
Control measures:	• Allocation of unique identifiers to each case note. • No names or hospital numbers used in the data collection or analysis. • The use of password protected data extraction tools • Following the hospitals policy if there is any. • Following UoB guidelines in data storage. • In the unlikely event of identification of poor clinical practice, the medical director will be informed to serve as learning. This will inform the facility in providing re training for the staff.			
Remaining risk:				

Activity or operation 2:	Process mapping workshop and interview of Multidisciplinary team (doctors, nurses, pharmacist, biomedical scientist)	Probability	Risk Severity	Score

Risk:	The risk of maintaining anonymity of participants. Breaching of confidentiality and exposure of personal information. Identification of poor clinical practice	1	1	1
Control measures:	• Allocation of unique identifiers to each interviewee. • Following UoB guidelines in data storage (Storage of data on OneDrive temporarily as discussed with IT due to BEAR retiring and later transferred to RDS). ✓ Use of password protected voice recorder. ✓ Transcription of data and permanent deletion of voice recording. ✓ The use of password protected transcription. ✓ Data not shared with third parties except supervisory team when necessary. ✓ Informed consent • Following the hospitals policy if there is any. • In the unlikely event of identification of poor clinical practice, the medical director will be informed to serve as learning. This will inform the facility in providing re training for the staff.			
Remaining risk:				

Date Risk Assessment carried out by Research Team: 10/10/2021

Approval by: Kintampo Institutional Ethics Committee (Ghana) / Study site supervisors
Date 12/11/2021

Plan Overview

Appendix 12: Data Management plan (DMP)

A Data Management Plan created using DMPonline

Title: Understanding sepsis recognition and management in a Ghanaian emergency department: a complex mixed methods study of organizational change

Creator: ANGELA PRAH

Principal Investigator: ANGELA PRAH

Data Manager: ANGELA PRAH

Contributor: Dr Liz-lees Deutsch, Prof Anne Topping

Affiliation: University of Birmingham

Template: UoB short template

Project abstract:

This PhD study seeks to ascertain how sepsis has been identified and managed in an emergency department in Ghana, using a convergent mixed methods approach. A systematic review has been conducted to identify sepsis identification and management in low and middle income countries. A process mapping and a case notes analysis will also be conducted to identify the current situation to tailor the intervention. Afterwards, an intervention will be designed with stakeholders of the emergency department. Training and education will be conducted and then a feasibility pilot study will be conducted. The intervention will then be evaluated to observe the effectiveness, barriers and facilitators. Ethical approval will be sought from the University of Birmingham and from Ghana to enable them actualise the research which is going to be undertaken. This will be a single centre multi phased study.

ID: 62250

Last modified: 25-11-2023

Grant number / URL: AS/H/UK/100/VOL2./20/040B

Understanding sepsis recognition and managment in a Ghanaian emergency department: a complex mixed methods study of organizational change

Data description

What types of data will be used or created?

Ethical approval was sought from the university of Birmingham and Ghana before the commencement of the project.
All participants were given participant information sheet to read, understand and ask questions. Consent forms were then issued to participants to sign, after they have consented to partake in the research. These were locked securely in the University cabinet until scanned. Once scanned, they were stored on oneDrive and Research Data Store(RDS). Data that came out of the systematic review was stored on OneDrive and RDS. All quantitative data were collected securely and stored on oneDrive and RDS. Qualitative data were collected through an encrypted voice recording. These were converted to digital format on OneDrive and deleted after transcription. Transcribed interviews were password protected and stored on OneDrive and RDS.
Information such as below were collected;
Patient identification number, age, sex, admission date, admission time, mode of admission
Vital signs; Temperature, Pulse, Respiration, SPO2, BP) Mental status, glucose level, sepsis protocol in use, early warning scoring system in use, time of doctors assessment, lactate test requested/done/results, antibiotics administered, time in administering these medications, blood culture done, IV fluids administered, repeat observations, oxygen prn, vasopressors given, consideration given to the source of infection, source of infection, date and time of sepsis identification, structured handover, final disposition and further comments
All data collected were anonymised, that is the use of unique study identification number which excludes participants identifiable number. All documents such as consent forms that contains personally identifiable coded such as name and date of birth which is not anonymised were stored securely on oneDrive and RDS.

How will the data be structured and documented?

File naming was agreed with PGR and supervisors in advance before being stored on OneDrive and RDS.
All information gathered were password protected(encrypted) and kept confidential

Data storage and archiving

How will your data be stored and backed up?

The University of Birmingham provides a Research Data Store (RDS); access to the RDS is restricted to project members. Backup copies of data are taken on a daily basis and data is stored in separate buildings from the live data. The RDS has a backup and retention policy on how it looks after the data including archiving of primary data here :
https://intranet.birmingham.ac.uk/it/teams/infrastructure/research/bear/research-data-service/RDS/BackupRetentionPolicy.aspx
Interview recordings were stored on an encrypted audio recorder and backed up with a password protection. Audio recordings were deleted once transcription was completed.
Any publication of a paper will be transferred to the UOB Research Data archive

Is any of the data of (ethically or commercially) sensitive nature? If so, how do you ensure the data are protected accordingly?

Data was stored securely on OneDrive and RDS with a password protection.
Anonymity of data was done.
The research data included personal data taken from human subjects. All personal data which was gathered was handled confidentially.
Participants could leave the study at any time without consequences if they wish to. When a participant withdraws, they can decide if the data collected before withdrawal from the study will be included in the study. The data of participants who withdraw will be used wherever possible. in the situation whereby a participant requests all of their previously collected data is excluded from the study, all

of this data will be excluded from the study and destroyed. If a participant withdraws during the study or the recruitment phase, a new participant will be included.

In a situation whereby there is data protection breach, all UOB and study site protocols will be followed to ensure a proper reporting and management of such incidence(None of these happened in this study).

Where will your data be archived in the long term?

This would be done by following the university's guidelines on data archiving.
The data in this study will be used to submit a thesis, which is part of a PhD. Publication of one or more data will be done by this data.

Data sharing

Which data will you share, and under which conditions? How will you make the data available to others?

Audio recordings were not shared. Audio transcripts and the remaining data was shared among PGR and supervisor due to reasons of analysis.
Data will be shared through the University of Birmingham's eData repository (https://edata.bham.ac.uk/) which makes the datasets discoverable through search engines like Google. eData uses Dublin Core as a metadata standard and the minimum metadata provided for published datasets will cover amongst others title, type of data, creators, publication date and related publications.
Monitoring may be carried out by UOB and the Ghana Scholarship Secretariat. This will include visits and monitoring to ensure accuracy of files and informed consent. No plans have been made to share the data with other institutions

Appendix 13 Clinical response to the NEWS trigger thresholds

NEW score	Frequency of monitoring	Clinical response
0	Minimum 12 hourly	• Continue routine NEWS monitoring
Total 1–4	Minimum 4–6 hourly	• Inform registered nurse, who must assess the patient • Registered nurse decides whether increased frequency of monitoring and/or escalation of care is required
3 in single parameter	Minimum 1 hourly	• Registered nurse to inform medical team caring for the patient, who will review and decide whether escalation of care is necessary
Total 5 or more Urgent response threshold	Minimum 1 hourly	• Registered nurse to immediately inform the medical team caring for the patient • Registered nurse to request urgent assessment by a clinician or team with core competencies in the care of acutely ill patients • Provide clinical care in an environment with monitoring facilities
Total 7 or more Emergency response threshold	Continuous monitoring of vital signs	• Registered nurse to immediately inform the medical team caring for the patient – this should be at least at specialist registrar level • Emergency assessment by a team with critical care competencies, including practitioner(s) with advanced airway management skills • Consider transfer of care to a level 2 or 3 clinical care facility, ie higher-dependency unit or ICU • Clinical care in an environment with monitoring facilities

Appendix 14 – mixed methods appraisal tool (MMAT) – Hong et al., (2018)

Part I: Mixed Methods Appraisal Tool (MMAT), version 2018

Category of study designs	Methodological quality criteria	Responses			
		Yes	No	Can't tell	Comments
Screening questions (for all types)	S1. Are there clear research questions?				
	S2. Do the collected data allow to address the research questions?				
	Further appraisal may not be feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening questions.				
1. Qualitative	1.1. Is the qualitative approach appropriate to answer the research question?				
	1.2. Are the qualitative data collection methods adequate to address the research question?				
	1.3. Are the findings adequately derived from the data?				
	1.4. Is the interpretation of results sufficiently substantiated by data?				
	1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?				
2. Quantitative randomized controlled trials	2.1. Is randomization appropriately performed?				
	2.2. Are the groups comparable at baseline?				
	2.3. Are there complete outcome data?				
	2.4. Are outcome assessors blinded to the intervention provided?				
	2.5 Did the participants adhere to the assigned intervention?				
3. Quantitative non-randomized	3.1. Are the participants representative of the target population?				
	3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?				
	3.3. Are there complete outcome data?				
	3.4. Are the confounders accounted for in the design and analysis?				
	3.5. During the study period, is the intervention administered (or exposure occurred) as intended?				
4. Quantitative descriptive	4.1. Is the sampling strategy relevant to address the research question?				
	4.2. Is the sample representative of the target population?				
	4.3. Are the measurements appropriate?				
	4.4. Is the risk of nonresponse bias low?				
	4.5. Is the statistical analysis appropriate to answer the research question?				
5. Mixed methods	5.1. Is there an adequate rationale for using a mixed methods design to address the research question?				
	5.2. Are the different components of the study effectively integrated to answer the research question?				
	5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?				
	5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?				
	5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?				