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An emergent theory of clinical engagement in relation to implementing Quality Improvement methodology. A grounded theory study in intensive care units in Scotland.

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Abstract

It is well recognised in the quality improvement literature that understanding context is essential to successful quality improvement. Yet, there is a lack of evidence within the Quality Improvement (qi) literature describing a definition of context. Additionally, clinical engagement is offered as another important influence on successful implementation of qi and achieving aims. This study set out to understand if there was a relationship between staff perceptions of clinical engagement when reducing ventilator associated pneumonia and how this relates to the System of Profound Knowledge framework central to the model for improvement methodology?

Utilising a constructivist grounded theory approach, 18 nursing, medical and managerial staff were interviewed in four Scottish intensive care units to understand their perceptions of clinical engagement and whether it influenced their ability to achieve the Scottish Patient Safety Programme (SPSP) Ventilator associated pneumonia (VAP) reduction aim.

This study has made it possible to develop a working definition of Clinical engagement which resonates with staff working in intensive care units. Staff in all units, irrespective of achieving the SPSP VAP aim, described clinical engagement in a similar matter, highlighting the requirement to actively engage all staff groups. Where staff responses differed between the units was in the language used when referring to each other – in non-achieving units there was increased reference to person dependency and evidence of decohesion within teams.

The use of a constructivist grounded theory approach can support intensive care staff to share their perceptions of clinical engagement and facilitate the development of a working definition which has meaning in practice for staff. It is also possible to develop operational definitions of context as described by staff and to use this to inform the four lenses of the System of Profound Knowledge.

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Glossary of terms

Term / phrase	Meaning
Healthcare Improvement Scotland	Healthcare Improvement Scotland (HIS) was set up by the Public Services Reform (Scotland) Act 2010 and took over the functions of NHS Quality Improvement Scotland and the regulatory functions of the Care Commission in relation to independent healthcare services.
Intensive care unit	An intensive care unit is a specifically staffed and equipped hospital ward dedicated to the management of patients with life threatening illnesses, injuries or complication (Oh, 2003)
Level three care	Patients requiring level three care are cared for by a team of staff including specialist intensivists, critical care nurses and allied health professionals. The intensive care unit is in a tertiary referral hospital. (Oh, 2003)
Measurement plan	A document developed and utilised by the improvement team to articulate the measurements being used to support their improvement activity. The measurement plan includes detail of where the data is being collected from i.e. what is the data source, when it is being collected and what calculations are being used to generate the output.
Model for improvement	A framework developed to support a system of improvement. The Model for improvement is based on three fundament questions, which are combined with plan-do-study-act cycles.
Quality improvement	The ISO definition of quality improvement states that it is the actions taken throughout the organization to increase the effectiveness of activities and processes to provide added benefits to both the organization and its customers. In simple terms, quality improvement is anything which causes a beneficial change in quality performance. (http://transition-support.com/Quality_improvement.htm)
Scottish Patient Safety Programme	The Scottish Patient Safety Programme (SPSP) is a unique national programme that aims to improve the safety and reliability of healthcare and reduce harm, whenever care is delivered.
Ventilator associated pneumonia	A complication of mechanical ventilation, due to the breaching of the patent's natural immune defence during intubation. A hospital acquired infection associated with mechanical ventilation. Diagnosis required the patient to have been receiving mechanical ventilation for more than 5 days.

Chapter 1 – Introduction

1.1 The history of quality improvement

> *"The greatest outstanding problem before the medical profession today is that involved in the delivery of adequate, scientific medical service to all people ..."*
>
> (Olin West 1928 cited by Lee and Jones 1933. pg. 3)

This quote attributed to Olin West and cited by Lee and Jones in their publication "*The Fundamentals of good medical care"* sums up the ever-present search by healthcare providers to deliver quality, evidence-based health care to all patients. Indeed, since the mid 1800's medical literature in North America and the United Kingdom provides evidence of this continual effort to improve patient care. Ignaz Semmelweis and Florence Nightingale are commonly cited as being the fore runners of quality improvement in the healthcare setting. With Semmelweis, a Hungarian doctor reported to have introduced hand hygiene to obstetric practice to reduce post-partum mortality rates (Best and Nuehauser 2004) and Nightingale, an English nurse being credited with making the connection between mortality rates among soldiers receiving care for injuries during the Crimean war and the poor living standards experienced within the hospitals (Marjoua and Bozic 2012).

David Colton in 2000 published an article detailing the conceptual and historical foundation of *"Quality Improvement in Health care".* In the paper, Colton sets out the relationship between industrial development, management theory development and the introduction of quality improvement methodology into the American healthcare system. Colton proposes the development of quality improvement has been driven by the industrial revolution, is associated with the American Civil War and the development of assembly line industry. Frederick Taylor is credited with first identifying the lack of structured work in factories, first introducing the concept of systems engineering in the removal of inefficient steps and the need to understand the system to improve processes and therefore improve outcomes. Taylor also introduced the application of scientific methods to training the work force.

Within the healthcare setting the British Medical Association had been established in 1832 initially as a mechanism for doctors to share medical knowledge; but by 1858 had assumed the role which brought about the medical reform activity, with the membership being involved in the drafting and passing of the Medical Act 1858. While in North America, early changes focused on establishing standardised education systems, resulting in the emergence of the American Medical Association in 1847 (Chassin and O'Kane 2010). In 1910, Abraham Flexner an educator by profession introduced the concept of evaluating medical schools, concurrently the American College of Surgeons was established in 1913; the establishment of evaluation of medical schools and the American College of Surgeons ultimately resulted in accreditation processes for healthcare organisation and the development of standards of care and treatment of patients in hospitals introduced in 1917. The drive to establish standards of care is credited to Ernest Codman and Edward Martin, with Codman being recognised as the first surgeon to pioneer the link between process and patient outcome. Martin advocated evaluation of process and outcome as an approach to assess the quality of care in American Hospitals. The Hill Burton Act 1946 is considered to have been the catalyst required for healthcare organisations to adopt organisational management and change methodologies which had been further developed by Fayol, Weber and Barnard. Their respective theories related to understanding how the organisation created the effective environment for change, Management Theory and understanding of Organisational Systems. These were considered to have supported the proviso that the organisations would be able to meet specified fiscal conditions set out in the Hill Burton Act in exchange for Federal Assistance.

The Hawthorne Study which took place between 1923 – 33, is a well-recognised study reflecting the impact of staff observation on their behaviour. It is recorded as having influenced organisational thinking and practice during the 1940s and 50s. Yet, there are no records that the findings from this landmark study impacted healthcare delivery at the time. Simultaneously, Edward Deming and Walter Shewhart were developing mechanisms to collect and record data prospectively; gathered throughout processes rather than waiting until the end to retrospectively determine outcome – again this activity was occurring out with healthcare. Joseph Juran was also developing his theory which would become known as "The Juran Trilogy" relating to quality management and the combination of planning, cost and improvement, brought together in his "*Quality*

Control Handbook" first published in 1951. Despite this considerable resource in the field of quality improvement being developed in North America and the development of the Joint Commission which brought together the American College of Physicians, American Hospital Association, American Medical Association and the Canadian Medical Association, in 1951 quality improvement was still not adopted within healthcare organisations. The move to introduce quality improvement into healthcare is attributed to Avedis Donabedian in his 1966 paper *"Evaluating the quality of healthcare"* (Reproduced in Millbank Quarterly in 2005), where he introduces the concept of Structure + process = outcome. This is generally recognised as the introduction of quality improvement concepts within healthcare literature.

What was the situation in Britain?

Over a similar period, in addition to establishing the British Medical Association and the Medical Act, there had also been movement towards improving services for patients as communities. The Sheppard Tower Act in 1921 improved access to Maternal & Child Health Service and the British Ministry of Health review of maternal mortality and morbidity in1928 lead to the provision of ante-natal clinics as well as clinical meetings and dialogues; all focusing on improving service provision for individual patients. A change of focus in national policy is commonly associated with the publication of large government commissioned reports evaluating the quality of service delivered to patients. In the UK one such drive was the result of the Department of Health commissioned *An Organisation with a Memory* (DoH, 2000). In this publication Donaldson et al highlight the need for the health care system to learn from errors and mistakes, recognising that *"... serious incidents and failures in service are uncommon ..."* but when they do happen *"... they can have disastrous implications for patients and their families."* In addition, Donaldson et al emphasised that review of the serious problems leading up to the incident reveals *"... similarities to incidents which have happened before."* (DoH 2000, pg. 1)

Publication of *"An Organisation with a memory"* followed 11 years after the introduction of clinical governance, which had been established as a concept to systematically and critically evaluate the quality of care delivered. Clinical governance was introduced to evaluate several aspects of patient care including diagnosis and treatment, patient outcome and quality of life as well as resource use (Morrell and Harvey 1999).

The central feature of the clinical governance approach is audit, which is described by Morrell and Harvey as a process which can be used to benefit patients, providing opportunities to improve standards of care as well as the development of more effective services. Clinical governance was purported to be the mechanism to improve patient care, raise standards of care as well as identify aspects of existing excellent care. Within the UK healthcare system whole departments of staff were employed to manage and deliver this methodology. However, Donaldson et al (DoH 2000) identify examples where this did not occur; they document examples which highlight where lessons and recommendations from audit and investigation of adverse events were slow to bring about change in patient care. Donaldson et al state that this is due to individual healthcare services and individual practitioners being left to implement change rather than through a co-ordinated organisational approach. This is not exclusive to the UK; in the same period similar finds were emerging from the US with the *To Err is Human* (Kohn et al 2000) and *Crossing the Quality Chasm* (IoM 2001) reports. Both reports were commissioned by the Institute of Medicine, an American organisation with a congressional charter to advise the federal government on issues in medical care, research and education. Like the Donaldson et al report, these accounts highlight the need for healthcare systems to learn from errors, to deliver consistently reliable evidence-based care and reduce harm to patients receiving health care. However, IoM (2001) go further stating that it is essential for healthcare organisations in the USA to consider approaches used by high performing organisations including defence, chemical industry and manufacturing to improve practices and results. There is a compelling body of evidence which supports improvements in quality and value including streamlining processes, removing redundant steps as well as data management systems to review data in meaningful and timely fashion.

There is evidence which shows that the Scottish healthcare system was not dissimilar in the need to improve care. Following the passage of the Scotland Act in 1998 The Scottish Executive Health Department (SEHD) produced several publications, including *Towards a Healthier Scotland* (SEHD 1999) and *Our National Health* (SEHD, 2000), both of which set out a need to improve the nation's health as well as improve the care delivered within the National Health Service (NHS). This approach was supported by the publication of *A guide to service improvement* (SEHD 2005), within this document is

a reference to a change methodology which staff could use to *"... support service improvement and redesign ..."* (SEHD 2005. pg. 87)

The methodology recommended in this Government document is the model for improvement which had been used successfully in the United States of American (USA) health system. The methodology is first described in a rudimentary form by Nelson et al in their 1998 paper titled *"Building a quality future"*, where they describe an approach which is aimed at:

> *"... caregiver microunits that can find ways to improve quality and value and can be replicated throughout an entire healthcare organisation..."*
>
> (Nelson et al 1998. pg. 18)

Nelson et al (1998) acknowledged and further built on the contribution of Quinn (1992) in the introduction of micro-unit or micro-system thinking to healthcare. Quinn is credited with bringing business performance techniques from manufacturing to healthcare to increase quality and productivity. The additional thinking brought to the development of the methodology at this point has already been identified earlier as having been generated by Deming and Juran with their theory on quality improvement and Quality Trilogy theory respectively, both again developed within industry. Deming and Juran's methodologies are referenced in the *To Err is Human* (2000) publication as potential avenues for exploration within healthcare to achieve improvement in the quality of care and improved outcomes for patients. In addition, the *To Err is Human* and *Crossing the Quality Chasm* publications both recommended a need for healthcare to look to external industries to improve quality and safety of the delivery of patient care.

The recognition of the model for improvement as a change model which can be used to bring about rapid improvement in service while maintaining the need to focus on quality and safety was formally brought into the Scottish healthcare system in 2007 when the Scottish Patient Safety Programme (SPSP) was established. Rather than the model being a suggested change model, there was now an expectation that all territorial health boards in Scotland use this model. The introduction of SPSP occurred following the publication of the *Better Health, Better Care Action Plan* published in 2007; in this

document the Scottish Government recognised reductions in waiting times and mortality rates but also identify that:

> *"The Scottish people need and deserve care that is safer, more reliable, more anticipatory and more integrated as well as being quicker still."*
>
> Scottish Government 2007, pp, 41

The Action Plan had been developed following a health service user consultation process where patients, relatives and carers had identified unreliable and poor standards of care as being an issue within existing healthcare provision. In response to this feedback the Scottish Government established the Scottish Patient Safety Alliance – which brought together Scottish Government, NHSScotland, the Royal Colleges, other professional bodies and the Scottish Consumer Council. The Institute of Healthcare Improvement (IHI) was also brought into the Alliance to act as technical experts on the use of the advocated change methodology.

The purpose of the Scottish Patient Safety Alliance was to build on anecdotal success achieved through the Safer Patient Initiative (SPI); which had been previously utilised in NHS Ayrshire & Arran, NHS Dumfries & Galloway and NHS Tayside to improve safety standards within acute adult care settings. The formal reports published by the Health Foundation (2011a) indicated that despite there being no systematic measurement, anecdotal evidence suggested that the Safer Patient Initiative had *" ... highlighted the need to reduce variation and increase reliability of clinical practice..."* with the view to reducing harm to patients. *"For the first time in the UK real-time data was available to describe levels of harm..."* as well as describe *"... practical approaches to measurement and evidence-based interventions designed to improve patient safety"* (Health Foundation, 2011a). In addition, evaluation of the methodological approach of collecting process measurement revealed that participating teams found this a helpful exercise to develop understanding of cause and effect, established engagement with improvement work as well as allowing staff to see if they were indeed delivering reliably consistent standards of care (Health Foundation 2011b). Please refer to Appendix 1 for more detail of Model for Improvement and context of Scottish implementation including capacity and capability building.

My Reflection 1 ***Capacity & capability in Model for Improvement methodology***
Based on my experiences of being an integral member of an improvement team in critical care, providing logistical support to SPSP as well as being an improvement advisor there are four issues I perceive in relation to the approach taken with sharing the model for improvement:

Having been involved in the Scottish Patient Safety Programme for some time both at a logistical level of setting up learning sessions and learning opportunities such as SPSP Fellowship, IA programme and Improvement Skill in Action as well as actually delivering sessions within the "taught programme" opportunities it is apparent that delegates have a varied experience of the content delivered. Different people deliver the same content with their own interpretation, this can be beneficial as a variety of examples offered can be helpful for different staff groups. However, this can sometimes result in the actual meaning of the content being altered and delegates are misinformed. One of the most frequent misconceptions leads to delegates assuming that the model for improvement is the PDSA cycle – this results in a fundamental misunderstanding of the methodology, a gap in practitioners understanding and an inability to bring about sustained and evidenced improvement. As well as incomplete understanding of the importance of the system of profound knowledge.

In addition depending on which taught programme that delegates attend they can be exposed to more or less of the theory supporting the methodology, for example the IA programme has an increased focus on measurement while the Fellowship programme focuses predominantly on the "softer skills" associated with improvement such as building relationships within and across teams. Although the system of profound knowledge was integral to both programmes there was a heavier focus in the Fellowship curriculum on all four lenses.

There had been an expectation in the early days of the programmes that all boards would eventually have a pool of both Fellows and IAs to support improvement activity. However, this was not always achieved. As a result across the country there are teams with varying understanding of or access to knowledge of the systems of profound knowledge.

It became apparent when speaking with delegates that there were varying opportunities for delegates to apply their learning when they returned to their everyday role. If their post did not offer the opportunity to utilise the model for improvement, this skill was often lost before they could start an improvement project. Alternatively, often the internal infrastructure to support improvement activity was lacking with staff not having time to practice the skill while having support from someone who already has the skill to guide practice.

In the early iterations of both the fellowship and the improvement advisor course some candidates who secured posts had done so merely to improve their curriculum vitae and had not used their learning on returning to their clinical post.

Systems thinking and achieving quality improvement

Fundamental to the effective delivery of quality improvement and therefore the model for improvement (MfI) is the consideration, understanding and application of Deming's *"System of Profound Knowledge*[1]*".* The System of Profound of Knowledge (SoPK) was developed by Deming and Dr Barbara Lawton as an approach to transform management within institutions - industry, government, or education - into a thriving, viable, competitive organization (Deming, 1994: Kaizen 2016). Deming describes the system of profound knowledge as *"… a map of theory by which to understand the organisation that we work in."* (Deming 1994, pp, 92). Appendix 2 provides a graphic of the system of profound knowledge (SoPK) as it is commonly displayed in improvement methodology text.

Without this way of thinking and learning it is suggested that improvement will not bring about the systemic and cultural changes required to sustain practice change (Pettigrew et al 1992: Kaplan et al 2010: Berry 2016). There are four essential parts of this concept (also referred to as four lenses).These will be explored in more depth in the next section. The order of discussion does not reflect any order of importance or hierarchy, Langley et al (2009) suggest that each lens is an important as the others, but they may need to be prioritised depending on the circumstances found by the improvers. However, for effective improvement all lenses must be addresses.

1. **Appreciation of the system:** this lens promotes the consideration that services are usually delivered within a complex system of interactions between people, procedures and equipment; understanding these interactions is essential to bring about and sustain change. Without understanding of the interactions and interdependency within the system it is not possible to effect change which will maximise effectiveness and efficiency and in the case of healthcare improve patient outcomes (Langley et al 2009).
2. **Understanding of variation:** this lens was developed by Deming from his knowledge of Walter Shewhart's theory of understanding variation. By plotting data over time in dynamic prospective time series rather than interrupted

[1] The System of Profound Knowledge is also referred to as the Lens of Profound Knowledge – the terms are used interchangeably in the improvement texts to refer to the same theory / model.

retrospective time series it is possible to determine if there are predictable patterns or not within observed processes and / or outcomes. It is this predictability which improvers want to analysis, understand and interrupt, aiming for change in a positive way. The data visualisation tools traditionally used alongside the MfI are run charts and statistical process control (SPC) charts[2]. When teams can tell the difference between variation which is natural / random and therefore inherently part of their existing system and variation which is unusual or non-random influencing their system they are able to decide if the changes they are making are making improvements to outcomes.

3. **Building knowledge:** this lens proposes that understanding the system within which a process sits allows teams to be able to predict what the impact a change will make to the overall outcome. Improvement activity requires that the team involved continually learn and develop new knowledge about their system and this is only possible through continuous study. Teams can only build this knowledge because of having adequate *"appreciation of their own system"*; they are able to give meaning to the lived experience for themselves.
4. **Human side of change**: this lens suggests that the first step in any transformation within an organisation begins with the individual perceiving a new meaning of life, events, numbers and interactions between people and this individual will help others to move away from their current practice and beliefs moving to a new philosophy (Deming 1994). Langley et al (2009) describe the need to attract people to the proposed change as well as develop understanding of the need for the change for both the organisation and the individual. Understanding the assumptions and beliefs behind decisions and actions as well as sharing information are required for any change to be successful. Rogers (2003) proposes that this individual is operating as a "near peer" and is more important in persuading colleagues than an external change agent.

The SoPK is an integral component of the quality improvement and MfI; improvement is thought to be impossible without taking consideration of the four lenses (Deming 1994: Langley et al 2009: Kaplan et al 2012). From these short descriptions offered above it is possible to begin to understand the inter-relatedness of the lenses; the lens should not be considered as discrete, in addition they should be considered as having a

[2] Refer to Glossary for a definition of SPC charts

synergistic relationship with each other. Yet, no reference is made in relation to the strength / weighting of the individual lenses – in any illustration of the SoPK it is usual that the lenses are all illustrated as being the same size and sitting within a magnifying glass. As indicated earlier in this section there is no reference or recommendation to the order that the lenses should be addressed for improvement activity. However, recognition of and acting to address the four lenses is required to drive the organisational culture change which is needed to support and embed quality improvement activity. This is one of the main findings shared in the Health Foundation paper published following the Safer Patients Initiative (SPI): several of the contributors to the evaluation process indicated that culture change had been one of the strategic outcomes resulting from involvement in the initiative (Health Foundation 2011b). It is important to recognise that there is no explicit recognition of the link with SoPK and the change in culture described in the evaluation reports.

During the work to present this thesis I looked for evidence to support the use of the SoPK in literature; much of the early literature references acknowledge authors speaking with and communicating with Deming to explore thinking around the topic. Deming is credited with first introducing SoPK as a framework guiding managers in their pursuit of quality management (Berry 2016). Although there are currently no meta-analyses of the SoPK, there is evidence available relating to the different lens topics. It is this evidence which will be explored and presented in the next section.

Appreciation of the System.

"A system is described as a network of interdependent components working together to accomplish the aim of the system" (Deming 1994. Pg. 50). In addition, the system must have an aim, without an aim there is not system. In man-made systems the aim will be a value judgement. The components may not be clearly defined and not everyone will be aware of the extent of the system, however for effective management of the system there needs to be knowledge of the interrelationships which exist between all the components including the people working within the system(s).

Bertalanffy published a collection of papers introducing systems thinking to engineering science in 1968. Systems' thinking was described at the time by Bertalanffy, as having been pre-eminently a mathematical field of study, but now necessitated within engineering by the complexity observed in the modern technology

of the time. Bertalanffy attributes this to the increased complexity of both technology and social structures of the modern world. To take a systems approach individuals or teams are required, according to Bertalanffy *"to consider alternative solutions and to choose those most promising optimisation at maximum efficiency and minimum cost in a tremendously complex network of interactions."* Bertalanffy proposed that studying systems as an entirety rather than a group of parts confined or defined by narrow context is more likely to result in successful change. Peter Senge in his "*Fifth Discipline*" text of 1990 is credited with presenting the seminal work related to systems thinking in change management. Senge referring to the development of learning systems and understanding quality management highlights that *"… systems are bound by invisible fabrics of inter-related actions."* However, *"… we tend to focus on snapshots of isolated parts of the system…"* Senge proposes that systems thinking needs to be supported by building a shared vision, mental models and team learning to be effective in achieving improvement. By appreciating the system within which you are working supports a discipline of seeing the structures which underlie complex situations.

It is important to recognise that systemic and systematic thinking are different. The Mosaic Project in their 2010 White Paper *"Systems Thinking"* emphasise the point that thinking systematically encourages linear, event oriented thinking while systemic thinking requires the understanding of feedback loops and system behaviour emerges from the structures of the feedback loops.

McNary (1997) published in the leadership and management literature, indicates a need to have an oversight of the entire organisation as well as the individual sub-components to deliver quality within. Having an effective system approach facilitates optimisation of each component to deliver to the maximum of its capacity. This is achieved by having a constancy of purpose which everyone is working towards supporting a synergistic effect rather than encouraging diversity. This is compounded by the fact that the bigger an organisation the more complex it becomes and the reduced ability of anyone person to hold a system overview and understand the impact of improvement across the whole system. Within the nursing literature Philips et al (2016) further develop this concept, describing how systems thinking can support nursing leadership in quality and safety in healthcare. Philips et al highlight the need for teams undertaking quality and safety activity to understand the relationships

between structures and behaviours of a system as being essential if there is to be a change in behaviour patterns. Systems have their own behaviours which is driven over time by the people, environment and structures within which they exist.

The additional literature provided here highlights the on-going recognition within improvement and change management of the need to understand the system within which teams are working. Through the lens of "appreciating the system" Deming is advocating teams undertaking improvement to fulfil these requirements on their journey towards improvement.

Understanding variation

Variation exists all around in professional life as well as our personal lives, variation is related to the individual's ability to perform tasks, the resources available to perform tasks as well organisational influences. As individuals and groups, we are constantly making decisions based on variation we encounter – determining whether to make changes based on the variation or to treat it as random and therefore not requiring action (Nolan and Provost 1990).

One of the fundamental aspects of improvement is to understand and control variation (Deming 1994). Much of Deming's theory relating to understanding variation which influences this lens was developed in collaboration with his long-time colleague Shewhart. Deming met Shewhart when he first joined Western Electric Company in 1925. Shewhart first introduced the concept of special cause and common cause variation when working on the quality of telephone production. He identified that without the ability to predict how a process will "behave" and treating all variation as special, results in an inability to reliably manage or improve processes (Deming 1994). Shewhart (1931) writing on the importance of understanding "tolerance" and its influence in producing high quality and standardise machined components reminds the reader that understanding variation and how it is manifest within processes is essential. Shewhart writes of the importance of recognising when tolerance / variation needs to be minimised and when there can be more flexibility in the range of tolerance. Although referring to manufacturing industry, Shewhart highlights the concept that only by observing and understanding the degree and sources of variation can we then determining the limits / parameters we wish to set.

More recently in 1991, Berwick again reinforced Shewhart's thinking writing *" … that variation is a thief. It robs from processes, products and services the qualities they are intended to have."* It is also evidence of waste, loss of information and confounds the ability to predict outcomes. Provost and Murray (2011) writing on the concept of variation indicate that change is not always an improvement and it is only possible to determine improvement or otherwise through the activity of measurement. The use of measurement in improvement activity allows observation of variation within processes and outcomes, identification of intended and unintended variation as well as identification of inefficiencies, waste, rework, errors and harm for those on the receiving end of healthcare activity.

By including variation as one of the four lenses of the SoPK, Deming is advocating that improvers using his framework have a means to observe, question and develop understanding of the variation affecting their existing systems as well as observe the intended and unintended impact of their improvement activities.

Theory of Knowledge

Deming states that knowledge is built on theory and that theory is knowledge, by conveying knowledge it is *"… possible to predict the future and that it fits without failure observation from the past."(*Deming 1994 Pg. 102*)* Rational prediction requires theory to build knowledge, this is achieved through systematic revision of established theory based on observation over time. It is important to acknowledge that one cannot exist without the other; if there is no theory there is nothing to build knowledge on and vice versa without knowledge it is not possible to confirm a theory (Goldman 1999). Having a theory facilitates the development of predictions – it is only then that questions have meaning and therefore learning opportunities. Deming advocates that one of the mechanisms to establish the ability of prediction through the development of knowledge is using data – which relates to the lens "understanding variation." This is supported by Provost and Murray (2011) who state that knowledge is built on the iterative process of developing theory, making predictions based on existing theory, testing those predictions with data and then adapting the theory based on the results. This recurring cycle of testing theory and understanding the fit with predictions is the premise of the model for improvement, answering questions raised by the theory

based on subject matter expertise and conclusions resulting from data analysis from previous cycles of testing.

Human side of change or Psychology of change

Deming proposes that the psychology of change directs us to understand people, their interactions, the circumstances of those interactions including with other people and the system within and with which they are interacting. Deming expands this by adding that people are different to each other; learning in different ways, having different intrinsic and extrinsic motivations and having different needs from their relationships and interactions with others around them (Deming 1994).

Randall et al (2010) writing on work psychology supports Deming's thinking, proposing that people within organisations do not perform their duties and roles in a value-free vacuum. Rather performance is governed by the organisational culture observed in the values, beliefs, customs and systems unique to each organisation. The organisational culture of the NHS according to Davies et al (2000) emerges from the sharing of beliefs, attitudes, values and norms of behaviour between colleagues and the management of organisational culture is a means of improving healthcare. Culture is dynamic, resulting from movement in organisational norms; importantly organisational culture is transmitted to new members of staff by established staff both implicitly and explicitly. Kotter (2012) writing in his text *"Leading change"* develops this further directing those interested in leading change to recognise that there is a need to overcome tradition and inertia, passive resistance and a prevalence to turn improvement into additional bureaucracy by those either resisting change or not understanding the need for change. Kotter emphasises the need to root new behaviours in the organisational social norms and shared values.

In their Thought Paper "*The Habits of an Improver*" published in 2015, Lucas and Nacer describe 5 dimensions of improvement. One of the 5 dimensions offered by Lucas and Nacer is *"influencing"* – influencing they propose is the ability of the improver to influence people and this is only possible by understanding them, being able to read them and see where they are coming from. Improvers need to be able to see things through the eyes of others, walk in their shoes and seek to understand other's perspectives.

These observations from Randall et al, Kotter and Lucas and Nacer reflect Deming's remarks in *"The New Economics"* when he refers to the activities required of a manager of people is to establish and maintain engagement in quality activities. Deming also makes the link between psychology of change and effective leadership, proposing that both are linked to the development of effective teams.

In this section I have sought, in the absence of any meta-analysis of the system of profound knowledge, to offer other evidence which supports the four lens model presented by Deming. Although it has been difficult to specifically demonstrate the efficacy for the use of the SoPK as a model supporting quality improvement. I consider that I have presented evidence which supports the inclusion of the different lenses and how these support change management and quality improvement. I consider the components of the system of propound knowledge provide quality improvement practitioners with fundamental building blocks to use as guiding principles and I propose should be utilised as a framework to support the understanding of teams working in improvement.

1.2 Contextual factors in quality improvement

Literature review - Background

Nothing exists nor can be understood in isolation from its context. Context gives meaning to what we think and do. When things do not work as anticipated or planned inevitably it is context which is the invisible variable (Bates 2014). Pettigrew et al in 1992 cited that off the shelf solutions and individual competencies may only have limited impact on the success of change while the real success related to change is understanding the context. According to Pettigrew et al, context refers to the why and when of change and concerns itself with influence from prevailing economic, societal and political environments as well as local resources, capabilities, structures and cultures.

In 2014 the Health Foundation published a series of essays on *"Perspectives of Context"*. These are a collection of papers by recognised writers in the field of quality improvement and change management. This publication is advertised as *"Original Research,"* however by Øvretveit's own admission this is an opinion piece and a review of selected literature. In the collection of four papers the writers were all invited to reflect on "Defining context," offer consideration on the "Key themes and focuses of

concern in the literature" and "Models, taxonomies and frameworks for context." From this publication, it is apparent that each of the five contributing authors – Paul Bates, Professor Glen Roberts, Professor Naomi Fulop, Professor John Øvretveit and Professor Mary Dixon all define context differently.

Bates indicates in his contribution *"Context is everything"* that context has not been formally studied and it is not possible to find an explicit or well-articulated theory of context. The evidence cited by Bates suggests that context can be considered from either an objective phenomenon as something real and tangible which can be manipulated and shaped, or a subjective constructivist perspective where it is important to understand how people attend to, interpret and attach significance to what they perceive as context. With Roberts and Fulop adding in their paper *"The role of context in successful improvement"* that the conceptualisation of context is shaped by the belief that management of change is complex and multi-faceted. Highlighting that context should be considered in these terms to counter the Universalist and prescriptive perspective that there is only one right way to approach change.

In relation to context and delivering quality improvement interventions, Øvretveit (2004), wrote that results observed are dependent on the conditions surrounding them, and these may support or hinder the intervention potentially impacting on the *"depth of implementation."* Similarly, Powell et al (2009) providing a systematic narrative review of quality improvement models, propose that the application in the local context needs to be considered in a programmed and sustained way, with information provided through the life time of a project describing the local context and importantly how that has potentially impacted on the outcomes of improvement interventions. These requirements are supported in the guidance document developed for reporting quality improvement activity for publication in the SQUIRE 2.0 guidelines (Ogrinc et al 2015). Authors are reminded of the importance of describing their local context within the *"What did you do?"* section, where they are asked to set out the contextual elements considered important at the outset of introducing the intervention(s). SQUIRE guidelines suggest that context is considered as:

> *"*Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the

> interpretation of these factors ("sense-making") by the healthcare delivery professionals, patients, and caregivers that can affect the effectiveness and generalizability of intervention(s)."

Additionally, in the discussion section of the SQUIRE guidelines writers are expected to set out their interpretation of outcome; providing reasons for any differences between observed and anticipated outcomes, including the influence of context.

Within quality improvement literature context factors are recognised as impactful on the outcomes of quality improvement interventions. Dixon-Woods et al (2011) develop the observation by Lomas in 2005 that early iterations of quality improvement interventions are difficult to replicate, suggesting that this is due in some way to the context of the initial project not being replicated and / or understood. Øvretveit (2014) however suggests that the ability to determine between the boundary of improvement intervention and context is an arbitrary construct, dependent on the writer's ability to provide precise description of interventions and any evidence of additional context. Gabby and Le May (2010) propose in their writing on contextual adroitness that cognisance of context and contextual factors may be related to the practitioner's progression for novice to expert, with novices being so busy learning the practical skills of a new task that they are unable to attend to the elements of situational awareness and therefore unable to accurately reflect and report on the impact of context.

In summary recognising and understanding context and its influence on quality improvement is an essential part of the quality improvement journey. Øvretveit (2014) suggests that decision-makers at all levels, strategic and operational, need to be able to identify if the planned improvement / intervention is likely to be effective in their setting as well as know how to implement it. Kaplan et al (2010) in their systematic review paper provide evidence that there are certain context factors which can be related to delivering quality improvement success, including organisational characteristics, leadership, organisational culture, years involved in QI and data / information structures. This led to the development of the MUSIQ Tool which is an assessment tool utilised by quality improvement teams to understand the relative "force" of enablers and barriers to local quality improvement activity (Kaplan et al, 2012). Yet, Kaplan et al (2010) again highlight a recurrent issue in available literature

that due to conceptual ambiguity and methodological weakness it remains difficult to clearly define context factors and their influence on quality improvement activity.

Taking into account the commentary presented here relating to context factors and to ascertain if the situation remains the same some 10 years later a literature review was conducted of available literature.

Literature Review

The literature review was conducted using the *"Search for Evidence and Critical Appraisal: Health Service Research"* (Van de Voorde and Léonard, 2007). Van de Voorde and Leonard describe a methodology to conduct a review of literature on health service research topics. This methodology sets out a systematic approach to achieving uniformity in retrieval and quality of content. Their document identifies that the main goal of health service research is the identification of the most effective ways to organise, manage, finance and deliver high quality care, reducing medical errors and improving patient safety. Van der Voorde and Leonard propose that due to the heterogeneity of health service research evidence undertaking systematic reviews of complex and heterogeneous solely based on protocol driven search strategies may not identify important evidence. Challenges with appropriately identifying evidence relating to quality improvement interventions has already been discussed in this thesis, for this reason the structure offered by Van der Voorde and Leonard's approach was considered advantageous to this literature review process.

Review question

What evidence is presented within available literature describing context factors in relation to quality improvement?

Search strategy including search terms and resources to be searched

The following electronic data bases were searched: PubMed, CINAHL and EBSCO.

The search was limited to literature published in English Language until 2019.

Search terms utilised were:

Quality initiative*	Context*
Quality improv*	Factor*
Quality implement*	Barrier*
Patient Safety	Enabler*

Study selection criteria and procedures

Deduplication was carried out where the facility was available within the databases and manually during reference collation.

A two-phase screening process followed detailed in Figure 1

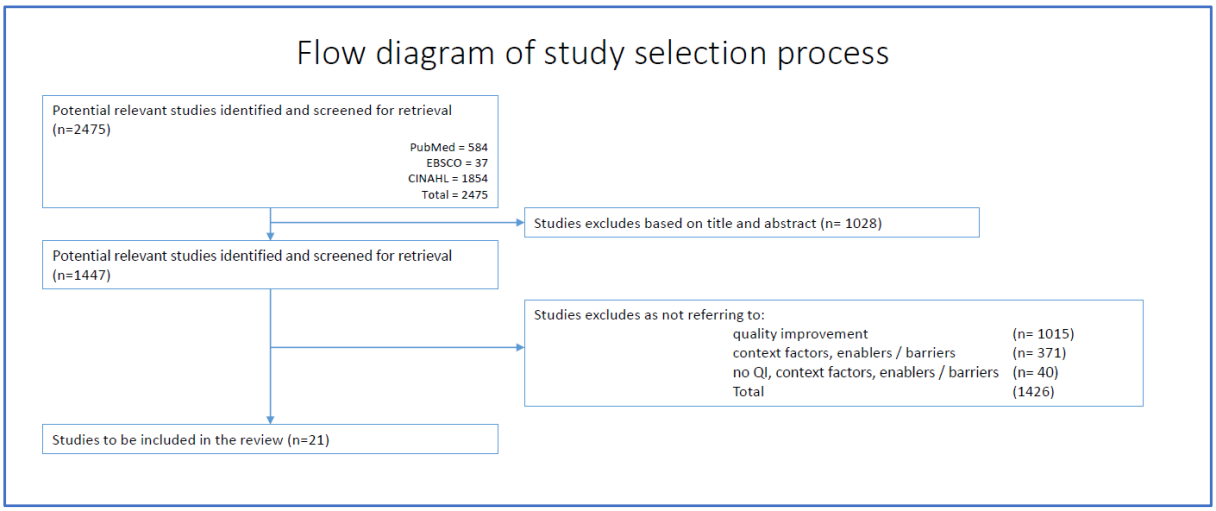


Figure 1
Flow chart of study literature selection process (context)

Initial screening was based on title, abstract and key word details. A second screening was carried out reviewing the full text for detail of quality improvement, enablers & barriers and context factors, articles were removed from the review where they did not describe enablers & barriers or context factors in the results section. Articles described as literature reviews were also removed where further analysis of the methods section resulted in lack of understanding of the author(s) process to identify how they had selected the papers they had included in their review.

The remaining articles were reviewed for the purpose of understanding the methodology utilised to identify and describe context factors in quality improvement activity, to understand the context factors described in these studies and to understand the limitations experienced by authors reporting these studies.

Data extraction strategy

The data extraction strategy for any review process is essential to guarantee continuity across the life of the review process, ensuring inter-relater reliability where there are

multiple reviewers as well as ensuring reliability in the review process if it takes place over an extended length of time.

Van der Voorde and Leonard recommend setting out clearly defined categories for reviewing articles to ensure consistency in the approach; the following data extraction template was developed to address the review question: *"What evidence is presented within available literature describing context factors in relation to quality improvement."* Please refer to Appendix 3 for associated operational definitions which were utilised to ensure consistency in data analysis over the period time taken to review the 21 articles.

Synthesis of the extracted evidence

Van der Voorde and Leonard recommend providing both descriptive analysis of the literature reviewed, therefore the results sections will provide both descriptive, non-quantitative and quantitative synthesis of the extracted data.

Descriptive, non-quantitative synthesis

The descriptive non-quantitative synthesis will be summarised here, and the extended tabular collation is provided in Appendix 4

Twenty-one articles were included in the literature review, each article was reviewed, and information collated guided by the data extraction template described above and in Appendix 3.

Table 1 sets out the different study designs described in the context literature:

Number of studies	Percentage of studies	Study design	Paper Reference
6	29%	Qualitative studies utilising interviews / focus groups	Parand et al 2010; Speroff et al 2010; Ijkema et la 2014; Burston et al 2014; Lyndon and Cape 2016; Canaway et al 2017
4	19%	Systematic Literature review	Minkman et al 2007; Halbesleben et al 2008; Powell et al 2009; Kringos et al 2015;
4	19%	Literature review	Masso and McCarthy 2009; Lekka 2011; Piscotty and Kalisch 2014; Gilhooly et al 2019
3	14.3%	Delphi – expert panels	Taylor et al 2011; Øvretveit et al 2011; Dy et al 2011;
2	9.5%	Quantitative – postal survey	Alexander et al 2006; Krein et al 2010;
1	4.7%	Ethnographic – staff experience	Aveling et al 2016
1	4.7%	Discussion Paper	Weiner 2009

Table 1
Summary of study designs included in the Context literature review

The geographic location of more than 3/4 of the literature reviewed related to either North American or European health care settings - 16 (76%), with the remaining 3 (14.2%) based in Australia, and 1(4.7%) reported on English and African healthcare settings. An additional 1 (4.7%) article related to International Health & Safety literature,

The reported studies were generally conducted in acute care settings, including critical care with 3 relating to community or chronic care settings. The Health & Safety paper relates to High Reliability Organisations including healthcare, is included with the 4 Literature Reviews.

Of the 21 articles reviewed 103 words and phrases used to describe influence on quality improvement were identified; please refer to Appendix 5 for the list of raw data extracted for the purpose of this review. The terminology used to describe and define these words and phrases varied across the papers reviewed, with authors categorising them as *"factors", "enablers and barriers", "context", "contextual factors", "indicators," "dimensions" and "themes"*. Six (28%) of the studies reviewed (Masso and McCarthy 2009: Parand et al 2010; Speroff et al 2010: Ovretveit et al 2011: Burston et al 2014: Pitscotty and Kalisch 2014) did not provide descriptions of what constituted context factors in their findings but referred to the importance and impact of context factors in delivering quality improvement.

Study limitations were not identified in 6 (29%)of the articles reviewed; Masso and McCarthy (2009), Powell, Rushmer and Davies (2009), Øvretveit et al (2011), Piscotty and Kalisch (2014) and Aveling et al (2014) make no reference to potential limitations within their study design, research approach or analysis. Weiner (2009) in his debate paper does not refer to limitations but does highlight the challenge of identifying measurement to support evidence of context factors and their impact on quality improvement delivery.

Three (14.2%) papers, Krein et al (2010), Dy et al (2011) and Taylor et al (2011), make some reference to limitations. Krein et al (2010) refer to their use of a qualitative approach and the resource intensive nature of this approach resulting in them only providing information from 6 hospitals. Krein et al consider this reduces the ability to generalise findings yet still provides a *"richness"* of information. The inability to generalise findings of qualitative research is a common critique in general (Robson 2011). Limitations identified by Dy et al (2011) refer to the challenges experienced in the development of their framework and that this was exacerbated by the lack of existing definitions of the dimensions created within the framework. Dy et al propose this may have led members of the panel to interpret their dimensions differently in the survey and consensus process. If this is a possibility among an expert panel, for practitioners with less experience and knowledge of the subject, it could be an increased probability. Taylor et al (2011) in a paper linked to the DY et al publication, provide commentary on study limitations within their discussion section; referring to

the process of identifying contexts discussed by their selected panel *" … as having been subjective."* In addition, Taylor et al state that the actual expert panel selected was also based on subjective selection, *"… such that another set of experts might have derived another set of context domains…"* The lack of operational definitions described by Dy et al and the subjectivity of the *"expert panel"* identified by Taylor et al highlights the lack of consistency associated with the study and description of context factors, potentially leaving the reader with more questions than answers and therefore remaining unable to definitively describe context factors.

In the remaining 12 (57%) papers, where limitations are discussed, limitations referred to availability of data as well as the challenges of combining historical data sets to facilitate data analysis (Alexander et al, 2006, Halbesleben et al, 2008 and Burston et al, 2014) and identification of outcomes (Minkman et al 2007), difficulties in defining outcomes from quality improvement activity (Parand et al 2010: Lyndon and Cape 2016), inability to generalise findings from the study populations (Speroff et al 2010: Lekka 2011: Ijkema et al 2014: Canaway et al 2017: Gilhooly et al 2019) and an inability to reliably define context factors (Kringos et al 2015). Kringos et al specifically identify an inability to define and assess context factors as a limitation of quality improvement reports generally. So, what does this mean in terms of the findings – how reliable/trustworthy are the findings?

Qualitative synthesis.

All the articles reviewed highlighted the challenge of being able to specifically name aspects of context which were identified directly in relation to the quality improvement activity. Reading the papers as a collection of reference material it became evident that there is no consistency in defining context, context factors and influencers of patient safety. These are terms which were used interchangeably across the literature: context, context factors, dimensions and enablers & barriers. The next section of this paper provides analysis of each of the papers included in the literature review; this review has been set out by the groupings indicated in Table 1:

- Qualitative Studies
- Systematic Literature Reviews
- Literature Reviews
- Delphi
- Quantitative studies
- Ethnography
- Discussion Paper

This will be followed by a summation of the information gathered and how this supports my research study.

Qualitative Studies:

(Parand et al 2010: Speroff et al 2010: Ijkema et al 2014: Burston et al 2014: Lyndon and Cape 2016: Canaway et al 2017)

Utilising semi-structured interviews Parand et al (2010) sought to identify factors affecting doctors' engagement with the Safer Patient Initiative (SPI), where 34 interviews took place across the 4 UK countries taking part in the initiative. Transcripts were analysed using NVIVO to determine if medical engagement had taken place, with medical engagement being defined as *"… doctors displaying active interest or a positive role of involvement within the programme."* Although not defined within the paper a grounded theory approach was used to develop axial codes facilitating emergent themes, iterative refinement was achieved through discussion among the research team. Seven *"Factors affecting medical engagement"* were identified as *"Quality improvement track record," "Resource allocation", "Perception of the purpose of SPI", "Evidence of efficacy", "External expertise", "Local programme champions" and "Management involvement."* Parand et al conclude from their study that medical engagement with quality improvement initiatives is a:

> *"… complex socio-political and motivational issue … underpinned by a series of inter-related factors associated with organisational context…"*

This statement therefore suggests that the seven core themes identified by Parand et al are additional to organisational context, and the core themes should be considered as enablers and barrier to engagement in quality improvement for medical staff.

To investigate if an organisation with group culture is better aligned with quality improvement compared to bureaucratic culture, Speroff et al (2010) undertook cross-sectional analysis of surveys sent to 61 American acute care hospitals. Surveys were sent to the adult and paediatric intensive care units in the hospitals over a 10-week period with the intention being the assessment of staff perceptions of 5 characteristics 1) organisational character, 2) management 3) cohesion, 4) emphasis and 5) distribution of awards.

Speroff et al refer to quality improvement literature which suggests *"… that the ability to make improvements depends on organisational context."* Yet, they make no reference to context or contextual factors until their conclusion section where they state that *"The influence of context on quality improvement … is widely appreciated."* And that *"… studies cite contextual factors involving the micro and macro systems …"* There is no attempt to indicate how their study contributes to the understanding of context and context factors as they themselves instead refer to organisational characteristics and structures. Their study identifies that hierarchical structuring, team functioning and staff morale, patient satisfaction and over all safety climate all have impact on the efficacy of the organisation. But they do not indicate if or how these characteristics relate to or interact with organisational context or contextual factors.

Ijkema et al (2014) reporting on the implementation of the Frail Elderly Programme in Dutch healthcare interviewed physicians, nurses and members of the Policy team to understand what factors impede and facilitate the implementation of a complex multi-component improvement initiative in hospitalised older patients. Using a qualitative design and semi-structured interviews, they analysed transcripts with the intention to structure responses under 1) process, 2) content and 3) context in relation to quality improvement activity. 19 hospitals were eligible to participate with the intention being to interview 4 people per hospital, 65 interviews were conducted in total providing an 85% response rate. 28 (43%) participants were nurses or geriatric nurses and 18 (28%) were physicians or geriatricians, the remaining participants were involved in Policy, research or were a physiotherapist.

Ijkema et al utilised a template with 3 existing topics identified from literature to determine how to analyse their data, this framework was developed by Pettigrew and Whipp (1993) to understand *"Strategic change and Competition"* in private sector organisations in the early 1990's. Ijkema et al use the framework process, content and context categories to code transcripts of the interviews with staff. It is not clear from the paper how analysts determined the difference between process and context bearing in mind from the background section above that Øvretveit included the process of implementation as context. Ijkema et al identify three topics of context – social, organisational and practical but there are no accompanying definitions of each provided. Stetler et al (2007) who also used this framework to identify key contextual

elements in organisations utilising evidence based practice, highlighted that although users *"…may interpret each term in a slightly different way"* … overall the framework focuses researchers on why, what and how of strategic change processes. Yet, this again raises the question of consistency in definitions of context between studies if there is no consistency.

From their study Ijkema et al determined that there were three broad context factors identified, these being "*Insight into effects*," "*Knowledge*," and "*Guidance*." From the associated narrative provided for each of these it is difficult to determine if they are considered positive and / or negative influences, and there is no reference to how these relate to social, organisational or practical context that Ijkema et al refer to in their abstract.

An Australian study by Burston et al (2014) designed to examine *"The relationship between the implementation of a transforming care initiative and two patient outcomes, inpatient falls and hospital acquired pressure ulcers"* reported variation in patient outcomes between participating units. Burston et al used historical data from two surgical wards in an acute hospital in Australia where 13 different interventions had been introduced, 10 of the 13 interventions had been introduced in both wards. The interventions described as a "bundle of interventions" by Burston et al, are all considered to be nurse-sensitive interventions and contribute to the outcome measure of reduced inpatient falls and reduced hospital acquired pressure sores. There is no definition of what Burston et al consider to be nurse-sensitive interventions or how this definition has been determined.

Using interrupted time series statistical process control charts, Burston et al report that fall rates in both units in the pre-intervention period are "in control," although this is an accurate interpretation for Unit 2 – where all pre-intervention data points remain within the control limits. It is inaccurate for Unit 1 as there are 6 data points outside the upper (3) and lower (3) control limits in the period determined as pre-intervention. This suggests from a statistical perspective that the system observed was not stable and was experiencing episodes of statistically different outcomes. In addition, Pronovost and Murray (2011) indicate where there are less than 20 data points available *"trial limits"* should be applied to the data until sufficient data is acquired, suggesting that the interpretation of "in control" pre-intervention is

inaccurate and determined from too few data points. Burston et al's interpretation of hospital acquired pressure ulcers remaining "*in control*" through-out the study period in Unit 1 is correct however Unit 2 chart illustrates special cause variation in the pre-intervention period using trial limits.

It is difficult to follow the results section in the paper as the special cause variation noted by Burston et al in the text does not correspond to the data illustrated in the chart in relation to meeting special cause variation rules for SPCs. In addition, misinterpretation of the shift rule[3], has led to the conclusion that there has been an episode of special cause variation post intervention. The control limits in Figure 1a have been miscalculated at one standard deviation from the mean, when this should have been 3 standard deviations from the mean and this may be the contributing factor for some of the misinterpretation of the data.

Notwithstanding the issues described above relating to data interpretation, Burston et al suggested the variable impact observed in this study may be due to various reasons including 1) *issues with the data coding processes*, 2) *the number of interventions being implemented at the same time*, 3) *inappropriate outcome measures,* 4) *the processes related to intervention implementation not being the same across the two units and potential issues with consistency of intervention application*, 5) *issues with the implementation strategy and engagement of staff* and 6) *different clinical contexts*. The different clinical contexts described by Burston et al include different clinical profile of the patients using the two units, potential differences in culture, values, beliefs, teamwork and team leadership – all of which Burston et al consider may have impacted levels of engagement and openness to the practice changes required. These findings are similar to evidence published by Dixon-Woods et al (2011) and Davidoff (2019) who write that understanding the cultures, belief and values within any team as they have an influence on the outcome of quality improvement activity. Burston et al suggest that incorporating evaluation into future interventions would help develop understanding of staff readiness for change, engagement levels as well as how interventions are adapted and implemented locally. It is interesting to note that Burston et al have identified issues with implementation strategy and engagement of

[3] where 8 consecutive data points below or above the centre line to denote a shift

staff as being different to clinical context yet cite these within their determination of clinical context.

Lyndon and Cape (2017) published the findings from a descriptive qualitative study relating to the implementation of an obstetric haemorrhage toolkit in a 31-hospital quality improvement learning collaborative in California. Lyndon and Cape identified barriers and facilitators to implementation of the toolkit, key to implementation according the Lyndon and Cape is the organisational context defined as 1) "*local culture within the organisation," 2) "local structure and experience of the implementation team," 3) "degree of administrative support – including data collection support," 4) "existing resources," 5) "clinical engagement," 6) "quality of communication"* and *7) "degree of hierarchy in existing relationships*." Lyndon and Cape provide from their interview transcripts both enabling and hindering examples for all seven of these common issues, however they do not provide evidence of how or why these have been determined to be *"organisational context."*

Also in 2017 Canaway et al sets out *"Medical directors' perspectives on strengthening hospital quality and safety."* This is a qualitative study using thematic analysis of interviews with public health medical directors in Australia intending to provide better understanding of contextual factors which situate and impact on hospital quality and safety. Using a pre-existing framework[4] Canaway et al provide evidence from their interview transcripts to support each of the seven identified themes.

The output from these themes were then reassigned into unique domains: *1) organisational culture and perceptions, 2) Governance, 3) Resources, 4) Education and training and 5) Reporting systems and technologies*. Although Canaway et al indicate that understanding context factors is one of the aims of their work there is little reference made within their findings section to contextual factors. Context is noted once within their findings table within the domain: *"Reporting systems and technologies"* and the need for dynamic indicators / metrics to *"… accommodate emerging ideas and changing context…"*

References to "context" and "contextualisation" is introduced in the discussion section as a consideration when understanding the "mixed effectiveness" of quality

[4] Developed for an Australian Government commissioned review of hospital safety and quality assurance "Targeting Zero"

improvement strategies and the fact that there are limitations in the reporting of the impact of context in quality improvement. These references are not related back to the data gathered through this study and Canaway et al indicate that due to the need to maintain hospital anonymity it was not possible to contextualise the information provided as the hospitals would become readily identifiable. However, despite setting this out at the beginning of the paper, providing understanding of contextual factors has not been done. Canaway et al have been unable to meet one of their project aims and therefore have not been able to add anything to the existing body of knowledge relating to context.

Systematic Literature Review:

(Minkman et al 2007: Halbesleben et al 2008: Powell et al 2009: Kringos et al 2015)

Minkman et al (2007) undertook a systematic literature review with the aim of understanding the empirical evidence related to improving performance in chronic care provision. They used four different quality improvement implementation approaches and found that a third of the 37 studies reviewed reported three or more context factors. However, it is not clear what process / framework was used to identify context factors from their results as a definition framework was not created prior to commencing the study – this is identified by the authors as a limitation of this study. They report that:

> *"There is a lack of insight as to which models' elements contribute the most to performance and to which confounding and context variables are present."*

Minkman et al described enabler elements and performance dimensions in their findings; referring to enablers of good quality care, covering processes, structures and mean values of an organisation. Two of the papers reviewed by Minkman et al are specifically highlighted as having *"explicitly including statistical analysis on context factors."* Yet, on review of these two papers (Shortell et al 1995: Le et al 2002) it is noted that although both papers have conducted statistical analysis of quantitative data relating to continuous quality improvement neither paper specifically refers to context factors. Both papers refer to "factors" influencing implementation, with Shortell et al referring to organisation and environmental factors while Lee et al identify influencing, enhancing, internal, cultural, multi-dimensional organisational and

structural factors. Neither Shortell et al nor Lee et al refer to these as context factors. Minkman et al do however identify that *"few"* studies discuss the influences of context factors on performance measurements and highlight two papers specifically where performance is determined to have been positively impacted by a foundation of quality improvement culture and strong physician leadership (Landis et al 2006) and visionary clinical leadership and financial conditions (Bodenheimer et al 2002).

Minkman et al indicate that their review identified the need to develop more knowledge on the relationship between organisational development, context factors and improved performance. It would also be appropriate to add that understanding what constitutes context factors as there is no clarity in this paper around definition.

Halbesleben et al (2008) reporting a literature review relating to *"Work-arounds in health care settings"* found that there was little literature referring specifically to work-arounds, yet work-arounds are frequently referenced in quality improvement literature. Work-arounds are defined as mechanisms workers use to expedite their work and reduce disruptions when they encounter blocks. They commonly involve substituting alternative, informally designed, and inconsistently applied work processes. Resulting in inconsistent working practices and potentially reduced reliability in processes.

Halbesleben et al do not refer to context in their paper rather they describe blocks outlining these as policies / laws / regulation, protocols / guidelines, work process design, technology, and people. These blocks have also been identified by other authors referring to context including Wideman et al (2006). Halbesleben et al indicate that blocks can be considered as intentional and unintentional, with intentional blocks being put in place to improve quality and safety. An example of an intentional block provided by Halbesleben et al is the need to independently carry out drug calculations for chemotherapy dosages.

However, intentional blocks which are put in place to protect employees and patient are frequently bypassed as they are perceived by staff as unnecessary demands on time. They provide this observation in relation to protocols and guidelines; describing the violation of protocols and guidelines as a decision taken by individual practitioners

when they consider guidelines to be wrong or not applicable to their patient and therefore a block to delivering care.

Understanding organisational and professional cultures and their impact on shaping normative beliefs are offered by Halbesleben et al as avenues for further research in relation to work-arounds and understanding process blocks which create them. These factors are not themselves identified as blocks to delivering care but rather a potential outcome of an organisation's acceptance or otherwise of violations / workarounds and therefore considered by Halbesleben et al important factors to understand.

NHS Quality Improvement Scotland recognising the importance to understand the essential elements required to improve patient care commissioned Powell et al (2009) to provide understanding on the interaction between local context and quality improvement approaches. This was achieved using *"A systematic narrative review of quality improvement models in health care."* Powell et al were guided by work previously published by Health Foundation in 2008 *Quest for Quality and Improved Performance Programme* to identify 5 quality improvement approaches to explore their use and the effect of use. Powell et al report that the success of any quality improvement approach is dependent on many factors including specific local contextual factors. It is proposed that as well as being influenced by local context, quality improvement approaches are also influenced by the contextual process of implementation. The methods used to understand and evaluate quality improvement initiatives must therefore be able to describe how context and implementation interact within organisations. Without this level of description, it is not possible to tailor quality improvement activities to local context. Powell et al provide a summary of *"Characteristics of Healthcare Organisations"* – provided in Appendix 6, which they offer as an additional broader context within which specific local context sit. This has been generated from several *"...influential..."* texts published 1996 – 2006, but it is not clear how they have been identified as influential texts.

This is an added level of complexity which Powell et al describe as interplay between organisational characteristics and local context with the potential to *"... impede, disrupt or derail application of any ... quality improvement approaches ..."* Powell et al propose that the choice of approach should be influenced by the local context to determine best fit, with local managers having to rely heavily on understanding contextual constraints.

Yet, it is also identified that implementation is challenged where *"Insufficient attention to developing receptive contexts …"* and successful quality improvement needs supportive contextual factors. But Powell et al do not provide evidence from the literature as to the definition of context or contextual factors beyond their adverse or supportive property.

In a paper published in 2015 by Kringos et al, which specifically sets out the *"… influence of context factors on the effectiveness of hospital quality improvement…"* as the topic of their review of systematic reviews, have used one of the recognised quality improvement assessment tools, the MUSIQ tool (Kaplan et al 2011) to evaluate readiness for change as their framework to identify context factors. The MUSIQ tool was created using a Delphi study approach with 10 quality improvement experts developing the content through iterative rounds of conversation and debate. Kringos et al have used the domains of the assessment tool to align context factors identified in their review articles. However, there has been minimal validity of the MUSIQ tool provided in the literature, the evidence provided supporting the MUSIQ tool by Kringos et al are two articles published by the group who originally developed the tool. Using this tool as their framework Kringos confirmed that quality improvement studies do describe context factors under the MUSIQ tool domains, they also identified additional context factors but do not include them in the main paper as these are considered to be additional to existing knowledge, raising the question why these have not been provided.

Literature Review:

(Masso and McCarthy 2009: Lekka 2011: Piscotty and Kalisch 2014: Gilhooly et al 2019)

A literature review undertaken by Masso and McCarthy in 2009 to understand the factors which support implementation of evidence-based practice in residential aged care, appraises 17 articles. Masso and McCarthy determined that their findings are equivocal – with factors identified supporting both negatively and positively in relation to their influence on implementation. Masso and McCarthy highlight that previous literature reviews have determined that studies have not been of sufficient quality to be included in literature review, and as a result previous authors have concluded that it is not possible to identify *"What works."* Focus should therefore be on "*How and why*"

interventions work – leading to the requirement to understand context and its influence on implementation. Masso and McCarthy identify the main gap in the literature as a *"… lack of understanding which factors are important in which circumstances and how the various factors interact with each other."* Masso and McCarthy used a matrix concept to identify 8 categories they refer to as "key factors"

These are defined as 1) "*Adequate resources*," 2) *"Demonstrable benefits of change,"* 3) *"Model of change / implementation,"* 4) *"Receptive context,"* 5) *"Staff with necessary skills,"* 6) *"Stakeholder engagement, participation and commitment,"* 7) *"Systems in place to support the use of evidence"* and 8) *"The nature of change in practice."* In their findings, Masso and McCarthy have interspersed the results of their literature review with evidence from supporting texts resulting in the reader becoming unclear what evidence has been provided from the literature review and what evidence is offered from additional articles and papers. Reviewing the results section of this paper it appears that the 8 key factors have been generated from 7 of the 17 papers included in the review with each key concept having been generated from just one of the publications except *"receptive context"* and *"stakeholder engagement, participation and commitment"* which have been identified from the same paper. The evidence presented relating to context in the results sections is mainly a summary of additional texts beyond the papers included in the literature review, of the 20 references cited only 6 are from the original literature search conducted by Masso and McCarthy, the reader is therefore left questioning the purpose of the literature review in guiding the discussion.

Notwithstanding these challenges however, Masso and McCarthy identify that context remains a poorly understood facilitator of change and innovation due to the interactions between actors and the system within which they operate. Similar to other authors identified in this literature review, Masso and McCarthy reference Pettigrew et al and their 1992 publication *"Shaping Strategic Change"* as the seminal reference to context and organisational change, Pettigrew et al describe context as being the *"… why and when of change…"* concerning itself with the influences of outer context – economic, social and political influences as well as inner context – resources, capabilities, structure, culture and politics. Despite this observation, Masso and

McCarthy have called out resources, capability and structures as being separate to receptive context in their key factors.

High reliability organisations are frequently used as an example of areas of effective safety culture and exemplars for quality improvement activity in healthcare settings. This has been previously highlighted in the introduction of this thesis where the Institute of Medicine are noted to have identified in both *"To Error is Human"* and *"Crossing the Quality Chasm"* texts. Lekka (2011) undertook a literature review on high reliability organisations to identify the characteristics and processes which account for their high safety and reliability levels. Lekka does not indicate how the literature review was undertaken nor how the papers were identified and selected for inclusion. Lekka describes the literature reviewed as *"… empirical papers … employing qualitative, case-study approaches offering rich descriptions …"* Lekka concludes that the rich descriptions offer understanding in specific contexts which may not be transferrable to more mainstream organisational contexts. Lekka refers to characteristics of high reliability organisations, highlighting that authors have been researching three "error free" organisations for 20 years and are able to identify several characteristics and processes that enable these organisations to achieve excellent safety records. Lekka also notes that there needs to be more research to provide evidence of links between safety measures and safety performance and how these would perform in different organisational contexts. Yet, there is also evidence provided which suggests that applying high reliability organisation principles may be ineffective and it is likely to be context dependent. Organisational context is referred to multiple times through the paper, with healthcare being cited as an unpredictable organisational context. Yet, there is no definition in the paper allowing the reader to understand what is being referred to when the term context is being used.

Piscotty and Kalisch (2014) published a literature review focusing on *"Nurses' use of clinical decision support."* Piscotty and Kalisch refer to four themes which emerged from their literature review these being 1) nurse factors affecting CDSS[5] use, 2) patient factors affecting CDSS use, 3) technology design factors affecting CDSS use and 4) organisational factors affecting CDSS use. Within these four themes Piscotty and

[5] Clinical decision support systems

Kalisch identify both positive and negative influences relating to the application and utilisation of clinical decision support systems.

> *"Given that the social and cultural organisations within healthcare settings are generally recognised as influencing clinical outcomes, more exploration of this context … is required."*

This is the last sentence in the discussion section of the paper and context has not been introduced earlier in the results section, this is a strong statement to include without supporting evidence from their study. Reviewing the results table presented by Piscotty and Kalisch, it is possible to perceive when comparing the factors set out in this paper to other evidence identified in this review which replicates context descriptors (Minkman et al 2007: Krein et al 2010: Parand et al 2010: Dy et al 2011: Gilhooly et al 2019). Leaving the reader wondering why Piscotty and Kalisch have not recognised them as context factors in their text?

Gilhooly et al in 2019, published a systematic review of *"Barrier and facilitators to the successful development, implementation and evaluation of care bundles in acute care in hospital: a scoping review."* Gilhooly et al indicate that this is an area of extensive literature and therefore utilised a *"scoping review"* in preference to a systematic literature review. Using this approach 28,692 articles were identified, following screening this was reduced to 348 and following further screening reduced to 99 quantitative study reports which were included in the final analysis. Gilhooly et al identified several strategies which supported compliance with care bundles 1) *advisory boards*, 2) *steering committees*, 3) *on-going training*, 4) *educational meetings* and 5) *use of audit and feedback*. In addition, Gilhooly et al report that the use of an implementation strategy / quality improvement strategy was also associated with improved compliance with care bundles. Where an implementation or quality improvement strategy was reported there were also references made to champions, multidisciplinary teams, Plan, do, study, act cycles, Root Cause Analysis and reminders.

Delphi – Expert Panel

(Taylor et al 2011: Øvretveit et al 2011: Dy et al 2011)

A series of articles published by Taylor et al (2011), Øvretveit et al (2011) and Dy et al (2011) report on an expert panel approach to describing context factors. Taylor et al

report on findings from a larger[6] study incorporating literature review and expert panel consensus to determine *"What context features might be important determinants of the effectiveness of patient safety practice interventions?"* Using interviews and group meetings they developed 4 broad domains of context features 1) "*Safety Culture, teamwork & leadership involvement"* 2) "*structural organisational characteristics"* 3) "*external factors"* and 4) "*availability of implementation & management tools*." These 4 had been distilled down from a longer list of 42, but it is not clear from the paper how the 42 context factors are aligned under the domains which had originally been described as 9 conceptual domains. For the reader the process of aggregating data from a targeted literature review through interviews and formal group discussions to such an extent that the 4 identified domains are so high level that definitions are required to clarify what they mean. In addition, at no point during the deliberations to develop the 4 domains does there appear to be consideration of using outcome measures of quality improvement programme / activity to support or direct the inclusion of specific context factors.

One of the associated studies from the Taylor et al (2011) paper is published by Øvretveit et al (2011). The aim of their paper which is described as "Original Research" is to articulate *"How does context affect interventions to improve patient safety? An assessment of evidence from studies of five patient safety practices and proposals for research."* This paper reports on the literature described in Taylor et al's paper and is defined by Øvretveit et al as having originated from a literature scan, expert input and other sources. However, it is not clear how the literature scan was carried out, the description offered by Øvretveit et al of *"… method involved compiling a comprehensive list of PSP[7]s from different sources."* and circular reference to the Taylor et al and Dy et al papers for more detail in the approach; it remains unclear as there is no reference made to search terms, databases examined or the number of articles retrieved. Øvretveit et al do provide evidence of context factors described by papers included in their review, of the 41 papers included in the review Øvretveit et al provide mixed evidence of context factors being reported, with some studies providing no context

[6] This paper is not available to review due to membership being required to access – Shekelle, Pronovost, Wachter et al. the PSP Technical Expert Panel. Assessing the Evidence for Context-sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria (Prepared under contract No HHSA-290-2009-10001C) Rockville, MD: Agency for Health Research and Quality, 2010.

[7] Patient safety practices

factors, some consideration of context factor and other studies providing good evidence in relation to the impact of context factors on the success of quality improvement activity. Øvretveit et al concluded from their review that:

1) There is little evidence that context factors influence implementation or effectiveness and

2) Lack of evidence about context is not evidence that context does not influence implementation or effectiveness.

Øvretveit et al propose that this is a result of research not being designed to investigate different context influences, rather it is designed to control for context. Taking this into consideration in relation to writing up quality improvement studies for publication this presents a problem as most quality improvement projects are not set up as research studies and these considerations are not addressed during the design of projects.

The third paper in this series published by Dy et al (2011) does not as suggested by Øvretveit et al provide evidence of a systematic review being carried out. Supporting evidence was identified purposefully which related to high-impact and diverse safety problems from the North American healthcare systems, including review of national reporting databases to target literature retrieval. The same expert panel was accessed and asked to contribute with the purpose being to develop *"A framework for classifying patient safety practices."* Using the same interviews and formal consensus group, the expert panel was tasked with developing classification dimensions for patient safety practices. These discussions again highlighted the importance of including context within the dimensions. Dy et al suggest that patient safety practices should be reporting on the perceived *"sensitivity to context"* with this being defined as understanding whether PSP implementation is dependent on issues such as context. The examples of context the panel suggested should be included in these determinations were leadership, culture, institutional financial status, or quality improvement structure. However, Dy et al do not provide evidence to support identifying these examples as context nor how these would be measured when determining the efficacy of patient safety practices. Within their results section they do note that studies are frequently poorly reported, with limited and low-quality data including little information on context nor underlying theory on the impact of context

on effectiveness. This section is not referenced raising the question if this is opinion from the panel or presented from the literature reviewed. Dy et al propose that their 11 key dimensions describe elements important for classifying patient safety practices as well as exploring issues of context sensitivity, yet one of the dimensions is "sensitive to context" which suggests context is already understood and defined to be able to determine if the outcomes are context sensitive. Considering the other dimensions proposed by Dy et al it could be argued that these should be considered as contextual factors in themselves, *"Setting"* is offered as a dimension, with examples offered being *"Hospital, nursing home, ambulatory"* yet, Minkman et al (2007) identify setting as a specific context factor from their literature review. This highlights the inconsistency within the quality improvement community and literature of context identification and definition.

Quantitative Study:

(Alexander et al 2006: Krein et al 2010)

Alexander et al (2006) reporting their North American based study examining the association between the intensity of care management (CM) implementation, patient safety indicators and relationships with hospital organisational and environmental context found inconsistent support for their hypothesis that greater implementation of CM resulted in increased patient safety. This study's data collection process was based on a postal survey of CEOs across 6150 hospitals with a response rate of 38% (n=2300). The survey itself had been developed almost 10 years before with the specific purpose of determining the extent of hospital involvement in quality improvement activity. The administrative data which the researchers used to cross reference with the survey results and determine a contextual relationship also related to 1997 – 1998. Although Alexander et al do note three limitations – merging of existing datasets potentially not being representative of the study population, issues relating to *"… endogeneity in cross sectional studies…"* and limited ability to measure patient safety Alexander et al do not comment on the appropriateness of re-analysing data with a different focus.

The authors provide four hypotheses to be addressed in their paper however, none of them relate to the second aim of the paper to examine if there is a relationship between CM implementation, patient safety and context. This therefore makes it difficult to

understand how they were able to determine that *"forces external and internal"* … including quality of care data, use of statistics and process measurement tools, focus on process and system improvement, guideline use and years involved in quality improvement "*… condition the impact of … CM activities on patient safety indicators."* Alexander et al indicate in their methods section relating to statistical analysis, that they

> *"… made the CM intensity variables interact with the moderating variables … to test the conditional effect of market and organisational context …"*

Yet, it is not explained how these contexts where identified to test against. There is no definition within the paper which clarifies what Alexander et al have determined as "context" it is not possible from the paper to state what hospital organisational context nor environmental context are in any concrete way to describe to others.

Krein et al (2010) undertook a multi-centre qualitative study to understand *"The influence of organisational context on quality improvement and patient safety efforts in infection prevention."* Using semi-structured interviews Krein et al spoke with 86 members of staff across six hospitals in USA from nursing and medical professions, focusing on practices aimed at reducing CLABSI[8], VAP[9] and CAUTI[10]. Krein et al used content analysis, specifically descriptive qualitative analysis of interview transcripts and concurrent data collection. Through this process they identified key themes from their data 1) *"leadership, culture and resources,"* 2) *"people issues"* and 3) *"champions,"* which were then used to summarise the findings from each participating site. Krein et al determined that the common organisational challenges identified by Bate et al, 2008 mapped well onto their results and were therefore used as an interpretive framework. Although Bate et al had identified 6 challenges Krein et al used only four – "*structural, political, culture and emotions*" as they considered these closely aligned with their key themes as identified above. It is not clear from the paper whether Krein et al verified either their initial three key themes with participants or if the revision to the 4 domains and then organisation context reflected participant perceptions. This could

[8] Central line associated blood stream infection
[9] Ventilator associated pneumonia
[10] Catheter associated urinary tract infection

then lead the findings set out by Krein et al to be in a similar circumstance to Taylor et al; findings being subjective and a reflection of the analysis and analyst(s) rather than matching the perceptions of participants. There is considerable literature available relating to validation of qualitative research finds; Leung (2015) proposes that this is a considerable challenge to the quality and trustworthiness of qualitative research and that it is only through robust validation processes that researchers can ensure the participants perceptions have been captured accurately. Birt et al (2016) noted that trustworthiness of results is the bedrock of high-quality qualitative research citing Tong et al (2007) who describes validity checking as ensuring findings are not constrained by researchers' existing knowledge.

It is also evident within the Krein et al paper the switching between terminologies in writing about context – Krein initially refer to key themes then move to the use of domain, then later to organisational context - but it is not clear how or why this progression of nomenclature occurred.

Ethnographic Study:

(Aveling et al 2016)

In 2016 Aveling et al published a multi-site ethnographic study reporting on the role of individual accountability in patient safety. Introducing the concept of a "Just Culture" where individuals and systems are both held accountable and accountability is balanced between both when considering patient safety errors. Aveling et al introduce context as a concept for consideration when apportioning accountability, with context in this instance referring to system design and functionality.

Accessing 5 large acute hospitals, 2 in low-income countries in Africa and 3 in high-income settings in England. The case studies were selected from two previously conducted research project with similar aims and designs. Project 1 provided 4 case studies: 2 African and 2 English and Project 2 provided 1 English case study. Project 1 had been set up to examine quality and safety in high and low income countries, however the data collected in the English site *"… was less extensive than from the African site …"* and so was supplemented with data from participation in Project 2 which was a study on culture and behaviour related to quality and safety. An additional case study was selected from Project 2 resulting in 2 African and 3 English case studies, with one of the English case studies being a merger of two data sets.

Data was collected through interviews (126) and observations (664 hours) with healthcare providers from the multi-disciplinary teams across medical, surgical and maternity services. Observations were made in managerial and clinical meetings and of clinical activities, the interviews; individual and group-based, were carried out with 124 members of staff. Purposive sampling was used to recruit participants to ensure diversity in study population. Interview topics covered perceptions of influence on and challenges of achieving patient safety. However, given that these are case studies from two different research projects Aveling et al do not discuss or refer to the potential similarity or diversity of interview questions and how this may have impacted the results of their study. Aveling et al refer specifically to their approach being to compare and contrast cases from diverse context, yet they do not set out what they are considering to be context to allow the reader to understand what they are comparing. There is reference to diverse contexts *"… of resources, history and environments."* but again this is not expanded on in the text.

Aveling et al provide evidence of individual's errors – poor outcomes or near misses being blamed on the individual and the systematic challenges of organisational context not being considered. There is evidence provided that the individual's ability to assume responsibility for a poor outcome or near miss is *"shaped … by organisational contexts … and … the prevailing cultural norms."* However, Aveling et al do not provide detail of what they consider as organisational context or cultural norms, the reader is left to determine what these are themselves. This is the same for the reference made to social context, which is again not defined in the paper and considering that this study involves hospitals from Africa and England it is not clear from the findings if Aveling et al are referring to African or English social context, how they have determined what is a social context for each of the study sites and how this has been measured against.

Aveling et al make reference to "context(s)" 25 times throughout their paper including historical, systemic, symbolic, economic, organisational and institutional contexts, without making reference to what they mean by context nor what they consider to be encapsulated within each of these distinct context. The reader could be left realising that context is important and is multi-faceted but still not able to describe or define it.

Debate Paper:
(Weiner 2009)

Weiner (2009) in a debate paper published in *Implementation Science* describing "*A theory of organisational readiness for change"* suggests that for change to be effective the organisation must create and display a more receptive context for innovation and change. As identified previously by Halbesleben et al (2008) this requires effective policies and procedures which support individual engagement and participation in change activity. Alongside this the organisational structures and resources need to be supportive for both the individual and teams to participate and contribute. Weiner provides supporting evidence for this from Pettigrew et al in their 1992 text *"Shaping Strategic Change."* In 1992 Pettigrew et al identified that most research relating to organisational change at the time was conducted without taking account of history, process or context, this according to Pettigrew et al prevented the studies being able to provide a holistic and dynamic analysis as is required to adequately understand change process.

Weiner refers to context and context factors frequently throughout his paper, expressing that there is a link between organisational readiness and context and that *"… receptive organisational context may be a possible determinant of readiness …"* Weiner proposes that generating a shared sense of organisational readiness is required to implement complex organisational change. To address this, Weiner provides a diagram facilitating visualisation, and incorporates possible context factors. Weiner proposes context factors which contribute to both the informational assessment and the change valence, with change valence being the perceived value placed on an impending change by members of the organisation. However, it is not clear what evidence Weiner has used to identify the context factors included. Although Weiner provides evidence that context factors have an important role in understanding organisational readiness for change and propose they may be more important than readiness in itself, he suggests that they are not the focus of the theory being discussed and does not elaborate.

Conclusion

As set out in the introduction to this qualitative exploration of the reviewed literature, it became evident that there is no consistency in defining context, context factors, themes and dimensions. These terms were used interchangeably across the literature; what one author defines as a theme another may define as a context factor.

Where context factors are identified these can be categorised as being either strategic, describing the structure within an organisation for example leadership, staff education and financial constraints. Or operational, frontline context factors for example skills in decision-making, participant willingness and clinician engagement. There are also examples where specific topics i.e. staff engagement and readiness for change are cited as being separate to context factors as cited by Burston et al 2014.

Summarising the descriptive analysis suggests that the study of context factors was commonly undertaken using qualitative methodology within North American and European healthcare settings, however this observation may reflect the search inclusion criteria to only include English Language articles.

The evidence suggests that context can be described as *"factors", "enablers and barriers", "context", "contextual factors", "indicators," "dimensions" and "themes"*; however there is no accompanying clear definition of the term offered within the papers.

In conclusion, considering a summary of the qualitative studies suggests the use of semi-structured interviews of a Delphi methodology allows the identification of multiple context factors relating to the micro (wards), meso (directorate) and macro (organisational) levels. Yet, due to lack of analysis frameworks or working definitions offered during the analysis processes there are no operational definitions to refer to. These studies are also unable to make links between the identified context factors and quality improvement activity outcomes.

Overall, all studies identified multiple context supporting the early work by Pettigrew et al, Pettigrew and Whipp and more recently Kaplan et al; there are aspects of context including leadership, social, organisational, cultural and levels of engagement identified across the literature which may be important to consider. The overall understanding of 'context' within qi is limited as it is based upon poor quality evidence

and it is not a well-defined, nor well understood, term within the qi literature. The importance of understanding the context and what factors should be considered when considering a qi approach, whether at an organisational, and/or individual project level, needs further exploration. Early evidence suggests that by managing context factors, the qi approach would have more chance of success in improving outcomes.

1.3 The Scottish Patient Safety Programme (SPSP)

From the previous section it is apparent that although there is inconsistency in describing and reporting context and context factors there is agreement that understanding context and context factors is important to the successful delivery of change management. The Scottish Patient Safety Programme (SPSP) was formally introduced into Scottish healthcare settings in 2008 and the purpose was to develop a collaborative community across Scotland all working towards a common aim of improving patient outcomes. For each of the identified clinical areas there were explicit outcome measures to be worked towards over the 5 years of the programme. The acute patient care delivery areas identified were:

1. general ward,
2. peri-operative care,
3. medicines management and
4. the critical care unit.

For each of these areas a driver diagram had been developed, the content of the driver diagrams had been developed following feedback gained during the SPI programme and in collaboration with IHI - technical partners. The driver diagram sets out procedures and practices, some of which was evidence-based; the thinking was that by reliably delivering to every patient every time as they were required, patient outcomes would be improved. The driver diagrams also contained the outcome measures associated with each of the clinical areas Appendix 7 details the four driver diagrams developed for the clinical areas involved in SPSP.

Driver Diagrams

Driver diagrams are described by Langley et al (2009) as a useful mechanism for improvement teams to illustrate their current theories and ideas related to their project as it sets out current hypothesis of the activities which are believed to be required to achieve the improvement outcome. Driver diagrams display the ideas which the team think will assist them to achieve their outcome as well as setting out the concepts and ideas which they can work on. The driver diagram should be developed by the improvement team as a collective as this encourages ownership of the activities detailed and improves the likelihood of success (Langley et al 2009). However, it is important to recognise that for SPSP teams the driver diagrams had been

developed through the testing phase of SPI as well as in the USA in earlier improvement programmes.

The driver diagram also provides clarity for the improvement team(s) as it incorporates the aim of the piece of work; the project aim is clearly articulated within the document. Integral to the driver diagram are change ideas which are the activities improvement teams think will support them to achieve their desired change(s). Improvement teams identify change ideas from available evidence-based activity where it is available and from using common sense approaches to developing solutions to existing problems. Within the SPSP driver diagrams are also examples of care bundles, which will be described in the following section.

Care Bundles

Care bundles are described by Resar et al (2005) as a set of activities which every practitioner providing a specific care for patients should be doing every time they interact with the patient. Care bundles are considered to describe the critical elements required to provide safe, reliable and effective care and are usually a collection of evidence-based practices. Within the SPSP critical care area driver diagrams there are several care bundles including: hand hygiene, central venous catheter care bundle, peripheral venous catheter care bundle, urinary catheter care bundle and ventilator associated pneumonia (VAP) prevention care bundle. The purpose behind these care bundles is for teams to establish reliable evidence-based care which will in turn reduce the incidences of infection and harm for patients requiring and receiving this type of care.

My Reflection 2 ***Setting the context of the Ventilator associated pneumonia Bundle***

When SPSP was first introduced to the critical care community there was considerable push back from clinicians in relation to the ventilator associated pneumonia prevention bundle. The bundle which had been developed in the USA incorporated proton pump inhibitor (PPI) prescription and the administration of DVT prophylaxis. There was considerable clinical debate about these two components as there was no evidence to support the inclusion of DVT prophylaxis to prevent VAPs and there was a growing body of evidence to suggest that PPI administration could increase the patient's risk of acquiring VAP due to altered gut pH.

To engage the critical care medical community in SPSP, the Scottish Intensive Care Society Audit Group (SICSAG) worked with units to develop the Scottish VAP prevention bundle – provided in Appendix 8 - which did not have these two components. This link contains the current VAP prevention bundle - http://www.sicsag.scot.nhs.uk/hai/VAP-Prevention-Bundle-web.pdf

By working with the critical care medical community, the SPSP strategic team was able to engage a group of clinicians who could have been influential in the non-up-take of the programme within the critical care patient setting. This I consider would have prevented the expected improvements in patient outcomes as most of the outcome measures required multi-professional input to be successful. This positive engagement I consider had two beneficial outcomes for patients:

1. *it ensured the medical community engaged and participated in the programme, as they developed a sense of ownership and control of the activity within the critical care driver diagram and*
2. *it ensured that the multi-professional team worked together to achieve the aims of SPSP resulting in improved outcomes for patients requiring critical care*

Care Setting

As is often the case when programmes of work are introduced system wide; some areas can adapt to the methodology more quickly than others, this had been previously alluded in the Michigan Project reports, Pronovost et al (2006) indicate that some units found engaging with the project easier than others. This ease of engagement is attributed to several factors including perceived "top-down" mandating of improvement activity, lack of perceived need to make changes to current performance and challenges with IT infrastructure to support data gathering. SPSP was not immune from these challenges, as identified in *"My Reflection 2"* there was considerable "push-back" from the critical care community especially in relation to the components of the VAP prevention bundle, Appendix 8 presents the VAP Prevention bundle. In addition, there were challenges related to the operational definitions to be used for diagnosis of the infections – including Ventilator Associated Pneumonia (VAP) and Central Venous Catheter related Blood Stream Infections (CRBSI).

The driver diagram specifically relating to Critical Care Units (Appendix 7), details the outcome as *"Improve Critical Care Outcomes. (Reduce mortality, infections and other adverse events)."* Sitting within the measurement plan supporting this work were specific measures relating to reducing ventilator associate pneumonia (VAP) as well as central venous catheter related blood stream infections (CRBSI). Both measures indicated that teams should be aiming to reduce VAPS and CRBSI to zero or 300 days between infections by December 2012. However, as SPSP became established as an improvement methodology it became apparent that the ability to achieve the outcome measures across ICUs was variable with some units achieving the 300 days between infections within a two-year period and others finding this more challenging. It was also evident within the data that some units although able to achieve a reduction were also experiencing periods of reduced improvement i.e., they were observing a return to rates reported in the early days of the programme's introduction. An additional confounding factors was the lack of historical data for ICU teams to compare themselves against. At the introduction of SPSP there were very few units where they

had well established and reliable mechanisms for collecting VAP and CRBSI infection rates[11].

Context factors in Intensive care units

The literature review presented earlier in this paper has highlighted the challenges in relation to understanding context factors due to the lack of operational definition used in quality improvement literature. But, it is also clear from the available literature that authors consider context to be an influential aspect of the success of quality improvement, Powell et al (2009) Dixon-Woods et al (2014) are just two authors who have highlighted this.

My area of clinical expertise is Adult Intensive Care, and it is for this reason that it was identified as the area of study – this will be discussed further in the Study Population section of this paper. The challenge to describe context is observed in the literature available relating to quality improvement in critical care environments too. Much of this literature is heavily influenced by the North American quality improvement community – this reflects the influence of programmes such as the 5000 lives led by the Institute for Healthcare Improvement (IHI) and the Keystone Project (Goeschel, C. A and Pronovost, P. J No date) both of which were early interventions aimed at specifically improving patient care in the critical care setting. In the early 2000s quality improvement focused literature had a predominance in before-after study design with quantitative results being the focus of reported results. Considering this in relation to the System of profound knowledge most of the literature provided description and detail relating to the *"understanding variation"* lens but with little or no reference to the other three lenses.

There is however, reference within discussion sections of many papers where authors refer to the possibility of influencing factors which they considered supported or enabled their improvement activity (Longmate et al 2011: Pinto et al 2011: Sexton et al 2011: Pronovost et al 2008), some authors do refer to these as context factors specifically. Reflecting on the literature presented earlier in this study relating to context factors it was highlighted that there is inconsistency in the terminology used by

[11] One was a large teaching hospital in Central Scotland and the other was a smaller unit also within the Central belt. Both units had introduced a surveillance post within their nursing compliment, these posts were introduced with the sole purpose of collecting and analysing ICU nosocomial infection rates, with a view to reducing them and improving outcomes for ICU patients.

authors when describing quality improvement activity. Yet, considering the descriptions in the literature review provided it is possible to see that the authors are describing / identifying context.

The influencing factors commonly identified are listed in Figure 2:

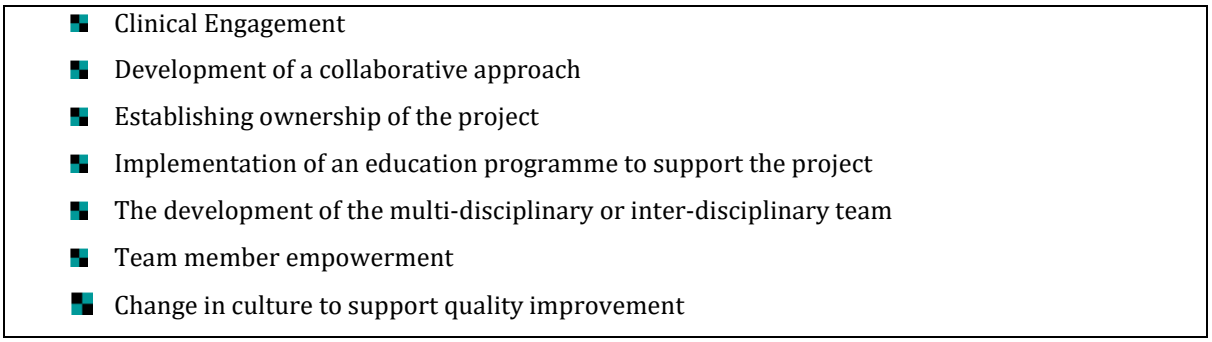


Figure 2
Influencing factors cited in quality improvement literature

Due to the relationship between the reliable delivery of intensive care and VAP rates within SPSP described earlier, together with my experience of witnessing push-back on the implementation of the bundle, I was acutely aware of the importance of clinical engagement within improvement projects. Therefore, from the seven factors identified in Figure 2, I decided to focus on the aspect of clinical engagement as this was the area I felt that I had experience of. It is intended in the next section to explore this further; by reviewing available empirical research literature which provides an opportunity to describe, assess, theorise and identify any research gap.

The following electronic data bases were searched: PubMed, CINAHL and EBSCO and the search was limited to literature published in English Language until 2019.

To identify relevant data a search strategy was developed using the following key word: Clinical Engagement and limited to English language, original articles and review articles. This strategy was used in preference to combining Clinical AND Engagement as this approach returned a volume of articles which was unmanageable to review 178788.

- Clinical Engagement returned 1012
- Adding “limit to English Language” returned 1007
- Adding “limit to original articles” returned 678

- Adding “limit to review articles” returned 233
- Following de-duplication this was reduced to 212

A two phase screening process followed and is detail in Figure 3

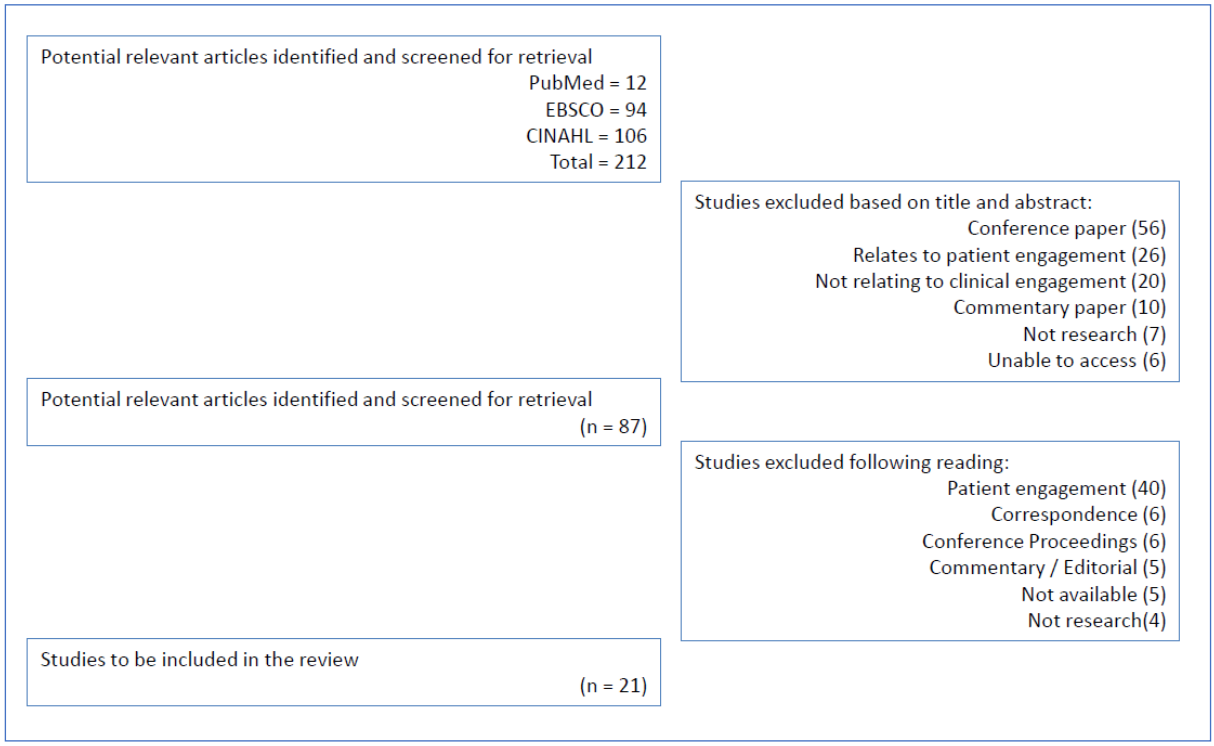


Figure 3
Flow chart of study literature selection process – clinical engagement

Initial screening was based on title, abstract and key words. A second screening was carried out reviewing the full text for detail of clinical engagement.

Study design	Paper Reference	Percentage (& number of papers)
Literature Review	Benn et al 2009: Kirkpatrick et al 2009: McLeod and Clarke 2009: Wilkinson et al 2011: Best et al 2012: Braithwaite et al 2014: Pannick et al 2016: Knight 2018: Melder 2020	43% (9)
Quantitative	Croft et al 2007: Da Silva 2016: Spurgeon et al 2011: Detwiller and Petillion 2014	19% (4)
Qualitative	Burnett et al 2010: Parand et al 2010: Jeffs et al 2018	15% (3)
Discussion Paper	Guthrie 2004: Alimo-Metcalfe and Bradley 2008: Patel et al 2010	15% (3)
Delphi Study	Donaldson et al 2015	4% (1)
National Report	Maybin and Thorlby 2008	4% (1)

Table 2
Articles included in the Clinical Engagement literature review

Table 2 details the percentage and number of articles within each study design type. This literature will be summarised in the next section.

Summary of the literature

In 2008, McLeod and Clarke were commissioned by the UK, Secretary of State for Business to undertake an in-depth analysis of employee engagement; this was specifically to understand if enhanced engagement approaches would positively impact UK competitiveness and performance during difficult economic times. Although this was primarily in relation to private businesses, McLeod and Clarke incorporated public sector organisations – including NHS and charity organisations in their report. From their research McLeod and Clarke (2009) suggest that having engaged employees provides them with a sense of personal attachment to work but, this is only achieved if employees *"… feel respected, involved, heard, well led and valued by those they work for and with."* They suggest that rather than being a one-way relationship i.e. for the expectation that an employee engages with work related activities, it is a two-way relationship where the organisation has a responsibility to actively engage employees and employees therefore having a choice about the level of engagement to offer the organisation.

The Health Foundation commissioned and funded research to help identify where and how quality improvement in healthcare quality can be made. A paper produced from this research was published by Wilkinson et al (2011), provided *"A review of literature on healthcare professionals' views on quality improvement initiatives."* This paper had several intended outputs including a focus to understand the relationship between clinical engagement and quality issues with the purpose of identifying trends in clinical engagement, activities related to clinical engagement as underlying beliefs and attitudes which may be precursors to engagement.

In a similar vein to McLeod and Clarke, Wilkinson et al identified that the available literature indicated the clinical engagement is important. Wilkinson et al identify clinical engagement as an influential aspect of successful quality improvement activity and that a "top-down" approach to quality improvement acts as a barrier to establishing clinical engagement. Spurgeon et al (2011) in their paper exploring the link between medical engagement specifically and performance data, stating that although there appears to be a correlation between levels of engagement and performance it is not always possible to make a direct causal link due to engagement being a multifaceted complex construct. Spurgeon et al reflect that medical engagement is required for any improvement or change activity to ensure that service change is carefully planned and effectively implemented. This is reinforced by Jeffs et al (2018) describing a qualitative study aimed at enhancing clinicians' abilities to use data to bring about patient care improvements. It is not immediately apparent from the paper that Jeffs et al are reporting on a study which had focused on non-medical clinicians – Nurses, occupational therapists, physiotherapists, ward clerks and ward managers. However, Jeffs et al identified in their discussion section that not involving their medical colleagues was a costly error as the project lacked the understanding of the whole system and potential impact of changes until it was too late. This was also noted by Detwiller and Petillion in 2014 who identified the lack of a medical champion from the outset of their study to introduce a clinical information system adversely impacted the success of their work and should have been considered much sooner in their activity. Da Silva (2016) suggests this approach enforces silo-working which is known to lead to low engagement due to limited understanding of expectations and progress.

Similarly to Spurgeon et al, Parand et al in 2010, reporting on the Safer Patient Initiative which had been introduced in the UK in the early 2000s, identified that engaging doctors in particular when undertaking quality improvement activity is an essential factor in success. Parand et al indicate that medical engagement is achieved when *"... doctors are displaying active interest or a positive role of involvement."* Yet, Burnett et al (2010) indicate that there is an important distinction between active engagement and passive acceptance. This was also an aspect of engagement identified by Melder et al (2020) who undertook an overview of systematic and narrative reviews and meta-analysis relating to the complexities of healthcare improvement. Melder et al indicate that clinical engagement, leadership and healthcare improvement roles are critical to achieve improvement, it is only possible through credible and active leadership that clinical engagement improves. Melder et al also identify interdisciplinary, social networks as well as a blended distribution of leadership being an influence on successful improvement. This aspect of social networks is explored further by Knight (2018) studying student engagement in clinical teaching at university. Knight describes the three socio-cultural influences determining engagement in activity being 1) environmental factors, such as having the opportunity to actively engage, 2) relationship based; the status of the individual with peers and superiors and 3) community and cultural aspects, what are the values and priorities of the individual to engage and does the activity meet those? Knight proposes that engagement is the publicly observed outcome of an individual's private unobserved motivational processes and is closely aligned with self-determination theory. Self-determination theory according to Knight aligns with engagement or lack of engagement depending on the experiences for the individual. If the experience of engaging satisfies a psychological need for autonomy, competency and relatedness this tends to stimulate engagement for the individual and suppress the potential for disaffection and non-engagement (Ryan and Deci 2000).

1.4 Summary

The provision of high quality, reliable patient care has been a vision and goal for healthcare providers since the early 1900's. Concurrently, advances in mechanisms to drive quality improvement in manufacturing industries had been demonstrated to improve quality and reliability in processes and products. However, it was not until 1990's following the publication of several documents in both North America and the

United Kingdom highlighting the levels of harm being experienced by patients receiving healthcare that quality improvement was introduced as an approach. The published literature relating to quality improvement predominantly relates to acute care setting in North America and Europe and early quality improvement literature is often reported by teams in critical care setting. The quality improvement methodology of choice introduced to the Scottish healthcare setting in 2008 is the model for improvement. This methodology utilises and blends the teaching of Deming, Shewhart and Juran and incorporates the system of profound knowledge as a framework for clinical staff and quality improvement practitioners to develop understanding of the projects they are working on.

This literature frequently identifies challenges replicating successful quality improvement in other similar organisations and clinical areas. The reason commonly attributed to these replication failures are reported to be differences in the context and contextual factors. Yet, although authors indicate that they understand context and context factors to be important influencing factors, there are no standard definitions available for teams using quality improvement methodology to work with. There are seven elements of context factors identified within the literature as clinical engagement, development of a collaborative approach, establishing ownership of the project, Implementation of an education programme to support the project, the development of the multi-disciplinary or inter-disciplinary team, team member empowerment and change in culture to support quality improvement.

The available quality improvement literature published by teams working in critical care settings commonly identify clinical engagement as one of the important influencing factors alongside multi-disciplinary working. There is consensus in the wider literature that engaging staff in change management and quality improvement specifically has a positive impact on health outcomes for patients. McLeod and Clarke (2009) introduced the concept that there is a difference between engagement and participation, with engagement being active and participation being passive. Depending on the organisations' ability to establish active engagement or passive participation will have an impact on the outcome of any improvement activity. Positive outcomes being related to active engagement, which is dependent on a two-way relationship between the organisation and individual employees.

Clinical engagement within a multidisciplinary team is poorly researched and understood. It is often noted through anecdotal commentary its importance within quality improvement literature. The term lacks a clear definition, and it is not clear which members of the multidisciplinary team need to be actively engaged in QI to result in an effective and sustainable change project. Therefore, it is essential to understand the concept of clinical engagement as a context factor that can underpin the success or failure of a QI project.

The purpose of this study therefore is to explore:

How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

Chapter 2 - Methodology, Research Design and Methods.

This chapter intends to set out the aim and research objectives of this thesis and to describe the research design which was used to develop understanding of how intensive care unit staff perceive the concept of clinical engagement in relation to implementing quality improvement methodology.

2.1 Aim

The aim of this study is to develop an emergent theory to understand intensive care unit staff perception of clinical engagement supporting the use of quality improvement methodology.

Research Objectives

To explore:

1. How different staff groups working in intensive care units describe clinical engagement?
2. The influence of clinical engagement on implementing quality improvement.

2.2 Research Methodology

Background

Adopting the correct methodology to undertake any research project is fundamentally important in being able to answer the research question.

The overall aim of this study is to develop an emergent theory of clinical engagement in relation to implementing quality improvement methodology in Scottish intensive care units. To do this a qualitative research methodology was adopted, as this allows the exploration of social constructs. Rather than developing a general understanding of situations, qualitative research can afford detailed description of how things work in context (Mason 2002). Using a qualitative approach also facilitates the inductive development of themes from individual participant's data with the researcher interpreting meaning from the gathered data (Creswell 2009). Where research aims to find out or understand information on a topic which has little existing evidence or represents complex relationships, qualitative methods are considered by Bowling (2014) to be the most appropriate approach.

A qualitative Approach

A qualitative methodology will allow the researcher to utilise rich descriptions offered by participants to develop the meaning of clinical engagement for clinical staff in intensive care units in Scotland. Without an understanding of the perceptions of establishing clinical engagement for successful implementation of the quality improvement methodology it is impossible to understand what this concept is and may reduce the potential to replicate effective clinical engagement across the country.

Quantitative methodology according to Robson (2011), offers the opportunity to test existing theoretical ideas and concepts, focusing on measurement and quantification of the aspect being studied. Importantly objectivity is sought, with the researcher remaining distant from the participants. However, due to the lack of evidence available to support the definition of clinical engagement it was not clear from the outset of the study what would be measured in a quantifiable manner and therefore a quantitative approach would not be the appropriate methodology to use.

During the development of the research approach several qualitative approaches were considered including case studies, phenomenology and ethnography before identifying that a grounded theory approach would be used. Although a case study approach could have potentially been used, the need to have a set of questions available to interrogate sources of evidence was a challenge as I was not clear from the literature what questions should be asked of data sources. Fundamental to this approach is also the requirement for multiple data sources (Creswell 2009). At the outset of this study I was not clear where the data could be found to answer the questions, I had set. Perry (2011) indicates that cases chosen to study are selected due to their ability to illuminate and extend understanding about relationships between existing constructs. Again, due to the lack of available definitions of clinical engagement I did not consider that it would be possible to select cases to study in a reliable manner. Ethnographic and phenomenological approaches were both considered as potential approaches to undertake this study and could potentially have added considerable insight into the research topic, however as both methodologies are utilised to describe experiences or phenomena and not to support the development of theory they were considered inappropriate. Indeed, ethnography was considered as an approach as it facilitates studies of group culture in a detailed manner, but as I was looking for variation in care, I

needed to study more than one group. But, due to my being a part-time student and the feasibility of conducting long term observational studies it was decided these would not be approaches I could consider.

Following these deliberations described above I decided that using a qualitative approach which follows constructionist grounded theory methodology would allow me to develop a theory which describes clinical engagement; using the language offered by clinicians utilising the qi methodology in clinical practice. Corbin and Holt (2005) suggest that the use of a grounded theory approach allows the researcher to understand how people, organisations or communities experience and respond to events that occur within their context. A grounded theory approach allows the researcher to develop "good concept – indictor links" as it emphasises and supports the creation of theoretical statement(s) from the data as described by the participants (Seale 2002). I consider that the use of grounded theory would allow the development of a theory explaining the meaning of clinical engagement as held by nurses, doctors and managers within the Scottish critical care setting and begin to examine clinical engagement as a social construct.

Grounded Theory

Originally introduced as a research technique by Glaser and Strauss in 1967; Grounded Theory as a qualitative research approach has been adapted in the intervening years, both by one of its original developers – Straus and by others. Grounded theory is a research approach which integrates both data collection and data analysis phases – with both occurring simultaneously. Data analysis informs the data collection phase as the researcher considers and compares the most recent and previously collected data to direct and inform the questions asked of the next participant; the "proactive" nature of data analysis assists the researcher in identifying the most appropriate next participant and questions. There are several different approaches associated with grounded theory; Glaser and Strauss first introduced grounded theory in 1967 as an alternative to quantitative research methods, with the data obtained systematically from social research. They described grounded theory as*: "... the discovery of theory from data – which we call grounded theory – is a major task confronting sociology today."*

Glaser and Strauss (1967)

Originally it was suggested that the researcher should come to the field naive to the topic area, with no preconceived ideas or existing theory (Glaser 1992):

> *"... scholarship in the study area should start after the emergent theory is sufficiently developed; allowing the researcher(s) to be firm in his own discovery and not forced"*
>
> Glaser 1992. Pg32

However, as with any research study the researcher frequently has substantial knowledge and experience in the subject area as it is commonly this which drives the interest and desire to better understand the area of study. The researcher having subject knowledge provides orientation and direction to the study but should also be mindful to have an open-mind and maintain objectivity when reviewing the gathered data. Being a reflexive practitioner ensures that the researcher is aware of the extent of their knowledge and how their clinical experience may influence the data gathering and analysis. Strauss and Corbin (1990 and 1998) developed a more pragmatic approach which took account of the researchers experience and the existing literature to support the identification of area to study, requiring the researcher to work through a pre-determined set of categories to analyse the gathered data. However, by having pre-determined categories the research could be at risk of forcing the data to fit the codes and to dismiss data which did not conform to these categories (Hunter et al 2011).

Grounded theory provides an opportunity to develop a systematic but flexible approach to collecting and analysing data to construct theory which is grounded in the data gained from participants. Grounded theorists attempt to learn what occurs in research settings and what the experience is for participants located in that setting; constructing data from observations, interactions and gathered material about the topic and setting. Charmaz (2006) proposes a more flexible approach on the use of grounded theory which allows the researcher to learn about the world they are studying and develop theories from that learning. Glaser and Strauss previously proposed that the theory [somehow] emerged from the data, while Charmaz introduces the concept that the theory is constructed from the researchers past and present involvement and interaction(s) with people and perspectives. Using this knowledge and experience leads

the researcher to identify potential ideas and questions to begin the process of data collection with a loose framework from which the first step into data collection can be taken. It is essential that the researcher remains open and sensitive to adaptation of the framework as data begins to be collected. The resulting theory is an interpretation of the studied environment, which may not necessarily be the same interpretation presented by another researcher (Charmaz 2006) this is referred to as a constructivist approach. The main purpose of the approach is to make sense of experiences shared by participants, with the researcher(s) fundamentally being one of the participants and contributing to the data gathered, hence the main reason I chose to use a constructivist approach.

2.3 Research Design

Appropriate research design selection is essential to ensure that the research study achieves its intended outcome i.e. to contribute to the development of knowledge (Urquhart 2013). There is little theoretical understanding of the construct that is 'clinical engagement' in relation to implementing quality improvement and therefore the use of grounded theory to build that knowledge and understanding was the most appropriate research design to use in this study.

Philosophical Position

It is generally recognised that there are different philosophies which can be held by researchers and that the philosophical position held by the researcher and research supervisors can influence the research approach selected for a study according to Creswell (2009). The philosophical position guiding this study is described by Urquhart (2013) as an interpretive paradigm – where the researcher has constructed an interpretation of the social practices as described by staff sharing their perceptions of improving patient care using a quality improvement approach within critical care units in Scotland. Using an approach which elicits participant perceptions is more likely to pay attention to and recognise the differences offered by participants (Touskas and Chia 2002). Creswell (2009) describes such an approach as a social constructivist overview where researchers seek out the complexity of participants' views rather than attempting to narrow meanings into a few categories or ideas.

Gathering the data

The process inherent in the grounded theory of constant comparison and referring to the available literature also ensured my biases were checked and potentially challenged. There is a close relationship between data collection and analysis in grounded theory with analysis occurring during data collection. Throughout collection and analysis, the researcher is asking "*what is going on here*?" *"How does it fit with previous data?" "Can I describe the social processes being shared by participants?"* and *"What meanings do participants attribute to the processes?"* But the resulting theory is far more than a description of what was happening for the participants as perceived by the researcher, by relating the perceptions offered by participants the researcher can develop a theory of the social construct as it exists for the participants. Yet, it is also important for me to recognise that my interpretation of the participants' shared perceptions using interviews then rewording and synthesising into a theory is ultimately merely a reflection of my understanding which has been influenced by my pre-conceived experiences and knowledge. James proposed in his philosophical writing in 1909 that there is however no way to overcome this if the reader acknowledges and allows for this in developing their unique understanding from the presented evidence.

Data collection methods

Theoretical Sampling

Sampling is a technique used within both quantitative and qualitative research methodologies to gather data from a subgroup of a large population. Sampling allows the researcher to gather information relating to a wider population without having to go to the expense from a time or financial perspective of approaching every single person (Bowling 2014).Theoretical sampling can be used in qualitative research methods as an important tool to facilitate the researcher to make determinations about the extent that findings generated in any particular situation or time can be applied more generally with the study population (Robson 2009). The sampling framework used tends to be more targeted to ensure the researcher gains access to individuals relevant to the research question being asked (Bryman 2016a)

When using a grounded theory approach rather than having a structured sampling process the researcher uses the data from previous participants to help guide the direction of both the enquiry and sampling processes. Charmaz (2006) indicates that by

using theoretical sampling the researcher can pursue avenues uncovered in interactions with participants. Theoretical sampling enabled me to extend and broaden the scope of the emerging categories and core categories from the data collected. Seale (2012) proposes that by actively choosing the cases to study and the people to interview the researcher is afforded the opportunities to gather findings which supports the emerging themes as well as challenge the limitations of their existing theory with the purpose of developing it further. The data collection process is controlled by the emerging theory and encourages the researcher to constantly ask the question *"what group or subgroup should I turn to next to collect data from?"* It is important to recognise that the use of theoretical sampling is not a single time point exercise but rather it is an activity which occurs iteratively throughout the lifetime of the study (Bryman, 2016a).

Theoretical sampling was utilised for this study not only to guide the selection of participant groups as described in the introduction, but also the intensive care units to be approached as well as the clinical condition to considered. The process for identifying study units and patient condition will be discussed further within study population.

Theoretical saturation

It could be argued that using theoretical sampling the researcher could continue finding new participants to approach ad infinitum. However, as the researcher collects, analyses and assimilates data using the grounded theory approach it becomes apparent that a point has been reached where no additional data is being found or presented to add to inform the properties of the categories being explored. With the representation of similar instances being repeatedly identified, the researcher can be confident that saturation point has been reached for the category. (Seale 2012). Charmaz (2006) describes this as saturating the categories with data until no new properties emerge. Theoretical sampling can be and is confused with data saturation, data saturation occurs when no new findings are being generated (O'Reilly and Parker 2013). However, Strauss and Corbin (1998) emphasise that theoretical saturation can be also be considered when the category is well developed in relation to the properties and the dimensions demonstrating variation as well as when relationships between the categories are well established and validated.

Data collection and analysis process

From a practical perspective data were gathered using a Dictaphone to record the conversation. This approach was used to ensure that I could engage fully in the conversation rather than trying to write notes and think about what my next question was going to be. Much of the evidence relating to note taking within research relates to ethnographic studies where field notes are recognised as an integral part of the data collection process. Burnett et al (1998) in their study of note taking in interview situations found that the process of note taking interfered with rather than enhanced the processing of attending to the information being presented and also resulted in the loss of information from the short-term memory of the note taker. Piolat et al (2005) suggest that this is due to the complex processes required for the note taker to be able to pay attention, comprehend the information being shred and to produce a written representation. However, it is recognised that there is little evidence relating to the experience from the perspective of the participant. Although, Doody and Noonan (2013) suggest that for novice researchers note taking is a mechanism to ensure that nothing is missed it is also acknowledged that note taking can be distracting for both the researcher(s) and participant(s). Montgomery and Bailey (2007) suggest that jotting notes in the presence of participants may be disruptive to them telling their story.

Miller and Crabtree (2005) indicate that field notes provide the researcher with a rich description of variables under study and can act as an aide memoire during the analysis process. During this study, field notes were created immediately post-interview, generally containing my first thoughts of the interview process, how I considered the interviewee had responded to the process as well as any immediate thoughts of what to include in the next interview. Lofland and Lofland (1999) recommend that field notes are created as soon after the observation or interaction as possible to ensure that the resulting note contains as rich a description of the episode as possible. Forgetting is endemic to the human condition and is eroded by the acquisition of new experiences and additionally too much time between the incident and the writing of field notes increase the likelihood that the research will not capture their own personal thoughts.

For example, on conclusion of the interview with Participant 412 one of my field notes noted her reference to the *"I mean for example… scrutiny of an individual patient at the bed side"* as well as the organisational scrutiny captured in the comment *"…when they*

are not compliant with the process element of scrutiny." I was interested by the participant's use of the term *"scrutiny"* in these two different contexts – I personally would not have considered that when reviewing patient care at the bed side. As a result, I was prompted to make a note to myself "To look out for reference of scrutiny in next interview with a manager." This became a specific question added into the questions posed to manager participants. This will be explored further in the section relating to the interview schedule.

Interview transcriptions

Following transcription each interview was analysed using an open coding technique. These open codes were developed through iterative review of the data and refined to selective codes representing the perceptions of participants.

This description may suggest a linear process with the progress from open coding to selective codes being a compartmentalised process, i.e. moving from one to the other, however this was not the case in practice. Open coding was reviewed and often revised for each of the transcripts on the completion of additional interviews during the data analysis phase.

> An example of this is the open coding term assigned to a passage in transcript from participant 431 *"… key of the senior charge nurse role to make sure that clinical engagement happens at all levels."* which was initially labelled as "facilitator" this code later became integrated into the selective code of "enabler." This integration was the result of further exploration with subsequent participants around the topic of facilitation, review of literature on facilitation. When explored with participants reference was made to the assumed responsibility within roles to "enable" the development of clinical engagement.

The constant review of transcriptions was done for consistency in analysis as well as generate the topic areas for discussion with the next interviewee. This process is illustrated by Alemu et al (2015) in Figure 4; Alemu et al illustrate this very well as not being a linear process. Although the intent is to progress from point 1 to 11; there are many backwards steps to revisit previously analysed data following the discovery of codes in subsequent transcripts. This was the process I followed for this study.

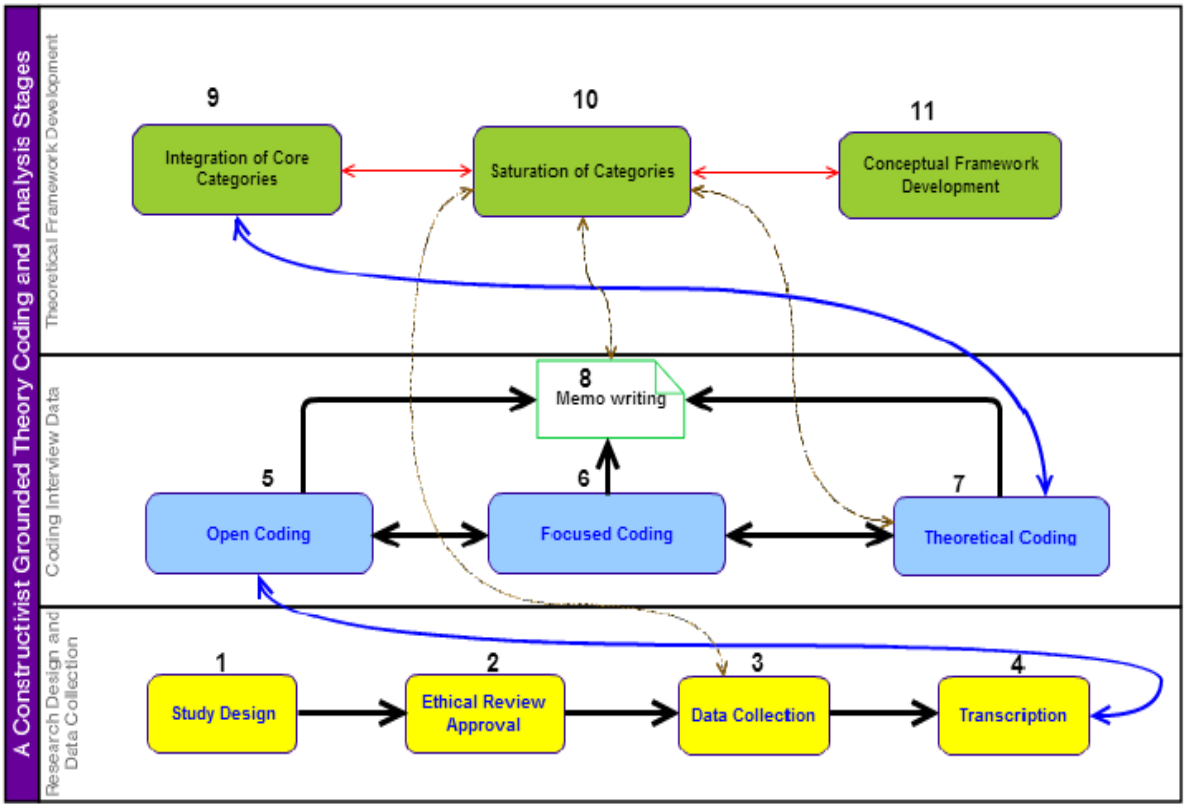


Figure 4
Illustration of the process used to generate open codes from the raw interviews data (Alemu et al, 2015)

Yet, on reflection having undertaken this study I would propose to include an additional connection between memo writing which is indicated by Alemu et al at step 8 and data collection which is indicated as step 3. I would propose that steps 5,6 7 & 8 should be linked by double ended arrows as I found that I frequently retraced these steps during the coding phases.

During the writing and review of memos created, I frequently found myself returning to the data to review transcripts as well as the open codes to help inform the topics I would be exploring at my next interview. An example of this is a memo created from the field notes[12] and interview notes for participant 412. This resulted in the Memo detailed in Figure 5:

Scrutiny focus

Memo

This is the first interview with a service manager, she referred to scrutiny and performance management activity related to quality improvement activity quite a few times in the interview. An example of her response is: levels of "scrutiny" are required and staff need to be recognising the improvement in patient care. She also referred to the need "… to demonstrate improvement to management and to national bodies."

It would be good to explore this further with subsequent managers. Is this a common aspect shared by managers? Make sure this pursued with the next manager interviewed.

Further development of this memo:

Several participants have spoken about the use of data to support improvement and to encourage engagement in improvement activity. Although this initially appeared to be a scrutiny focus and that this could be a barrier to improvement other participants have suggested that using data can help to get others involved. Participant 137 reflected that once they saw the difference it was making others were more likely to participate.

Figure 5
Example of a memo generated during the data analysis phase, illustrating the iterative category generation and theory development.

The original memo was generated from a single transcription but was then developed as additional interviews took place – addition to the memo is in italics in Figure 5. This constant revisiting of transcriptions, helped me to reflect on the data being generated from the interviews, identify questions for future interviews and assisted in the development of categories. This reflects the constructivists approach advocated by Charmaz, where the constant revisiting and reviewing of the data as well as the relationships between codes and categories, helps with the development of questions subsequent interviews as well as the development of categories and eventually core categories. The coding within individual transcriptions facilitates the researcher to achieve depth in their understanding and the action of coding across multiple

[12] This relates to the example provided on page 75

transcriptions provides additional width to this deep learning (Charmaz 2014). This concept goes some way to explain why I found that the relationships between writing memos and data coding was not a one-way process, where I frequently found myself returning to the codes having written a memo or having reviewed a memo from a previous data analysis session. This revisiting of the codes did in some instances result in rewording or defining the codes both open and selective – Charmaz indicates that this is normal and to be expected if the researcher is using the methodology correctly as iteration and constant comparison are fundamental components of the grounded theory method. These field notes as previously described included references to the physical environment, my perceptions of the participant and their engagement during the interview as well as my first thoughts immediately post interview. I found these notes particularly valuable when revisiting transcripts of early interviews, finding them useful in refreshing my recollection of the interview and the participant. These notes also provided me with the opportunity to critically reflect on my biases and theoretical standpoint which may have influenced my interpretation of the data. This is referred to as reflexivity and is discussed in the following section.

Reflexivity

Schwandt (2007) describes reflexivity as being more than merely an inspection of potential biases and their control. Rather it is suggested that using critical reflection the researcher is indicating and acknowledging that they are an integral part of the setting, context and social phenomena being studied. This is characterised by the existence of "messy text" signified by constant movement back and forth between description, interpretation and the inclusion of multiple voices within the text. Charmaz refers to this as the need to tolerate ambiguity. However, although I recognised the need to do this, as this is similar to the approach in quality improvement, I was also conscious of the need to check this. I therefore developed operational definitions for my selective codes, themes, categories and core categories as they emerged, this was not for the purpose of fixing them at an early stage but rather to be able see what my thinking had been at the time of development and to help me understand how thinking changed over time. This was also driven by my recognition that data collection and analysis could often be "interrupted" due to the length of time between interviews and not being able to work on the data continuously. Also realising that the analysis would take a considerable length of time, I wanted to develop a mechanism to prompt my thinking to

return my train of thought to previous sessions. My strategy to support this was to write definitions down – the concept of operational definitions will be discussed further on page 107, ensuring consistency of approach and are noted in the extended findings in Appendix 31.

This reflexivity applied not only to the development of categories and their properties but also to the actual data collection – interview preparation and interview, analysis and theory generation activity. Using critical reflexion on the perceptions shared by my participants, examination of my pre-existing knowledge and how these fitted or did not fit together I was able to develop a theory related to staff perceptions of how clinical engagement was established in Scottish intensive care units. In addition, this resulted in me being able to describe adaptations to Almeu et al model of *"theory coding and analysis phases"* which I included in my data analysis process. The adaptations are indicated by the orange dotted lines in Figure 6.

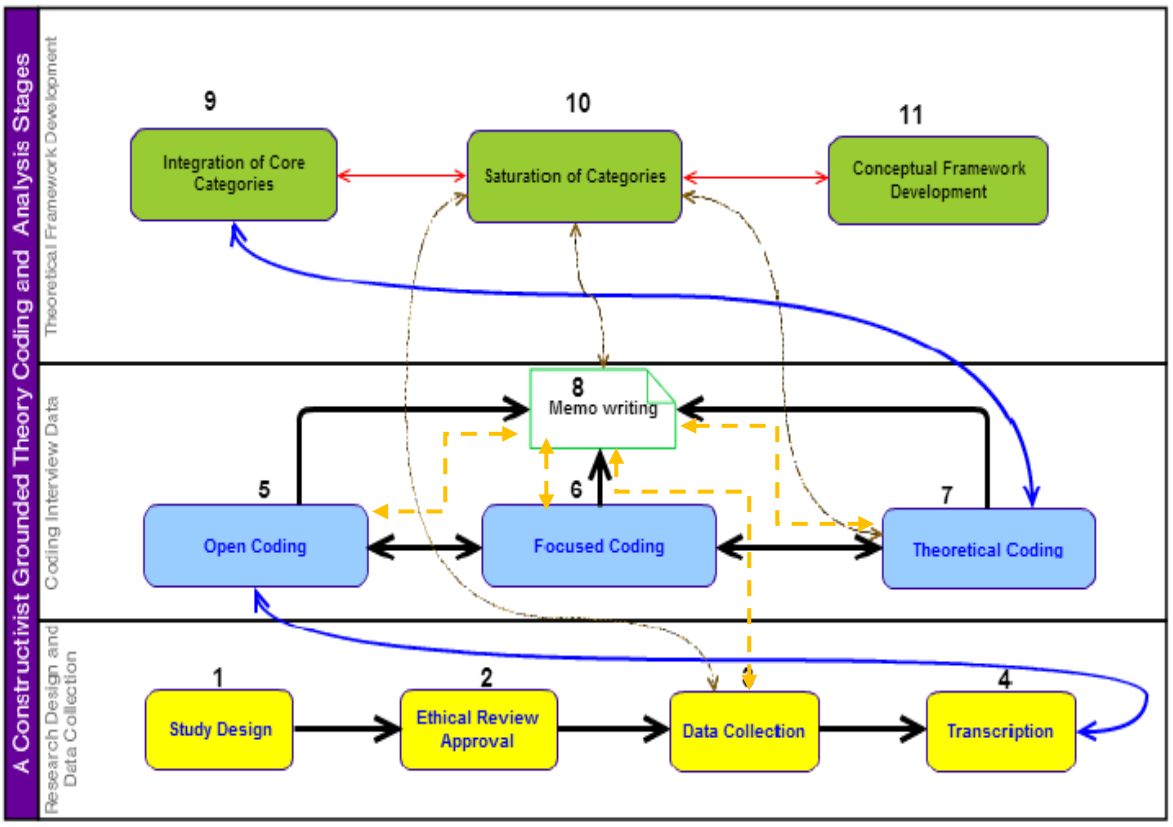


Figure 6
Illustration of the process used to generate open codes from the raw data generated from interviews with additional steps in the analysis process I perceived should be added to the diagram following reflection of the process. (Adapted from Alemu et al, 2015)

An additional element of reflection which have been incorporated into this study is the use of personal reflection, Charmaz (2014) suggests that reflection should include the opportunity to examine how the researcher's interests, position and assumptions influence the research enquiry process. To make this explicit and transparent I have included sections of text which I refer to as *"My Reflection*." I have included these as a mechanism to facilitate the reader to develop understanding of what I have brought to the data gathering and analysis process as well as to help understand what I have observed and how my observations have been shaped. By engaging with and examining my own preconceived theories during the process of data collection, analysis and writing up as recommended by Charmaz (2014) as well as making these explicit for the reader I hope has deepened and enhanced the resulting grounded theory. From a practical perspective all reflective accounts are clearly set out in the text within a text box as per My Reflection 3[13] below:

My Reflection 3 ***My contribution to context setting***

As a registered nurse with 10 years of critical care experience now working as an improvement advisor within one of the Special Health Boards in Scotland, Healthcare Improvement Scotland (HIS), I explored with participants, working in critical care, the meaning of clinical engagement for them within their unique context. Within my role as improvement advisor I provide practical and coaching support to teams utilising the model for improvement change methodology adopted by the Scottish Government to bring about improvements in patient care. I can provide this support and coaching as I have utilised the methodology within quality improvement teams providing direct patient care in critical care settings and have developed my knowledge of not only the model for improvement but also the supporting theories of change through working collaboratively with many different professional groups as well as a diverse range of clinical settings. This development of skills in the use of the methodology has been further developed during the life time of this study as I have worked for 18 months supporting the delivery of an improvement programme to teachers both primary and secondary as well as working for the last 18 months within mental health services in Scotland. I am also aware that the body of evidence supporting the use of the methodology is still developing and there are often gaps in our knowledge of how best to apply the supporting theories.

[13] There are two earlier My Reflections within the paper.

Data Analysis

Data analysis commenced following each interview when I created a short post interview note, called field note, which included detail of my initial perceptions of the interview, how the participant had interacted, the environment of the interview and perhaps most importantly my first thoughts of the conversation. In most instances this was immediately after the interview, commonly in my car where I would re-listen to the recording of the interview. However, if I had several interviews scheduled one-after the other, this was not possible, and the post interview note would be completed as soon as possible afterwards. The photograph in Figure 7 illustrates one of these post interview notes; there are 18 in total. These notes were revisited prior to each subsequent interview to help inform potential topics for conversation with future participants as well as during the processes to develop theory.

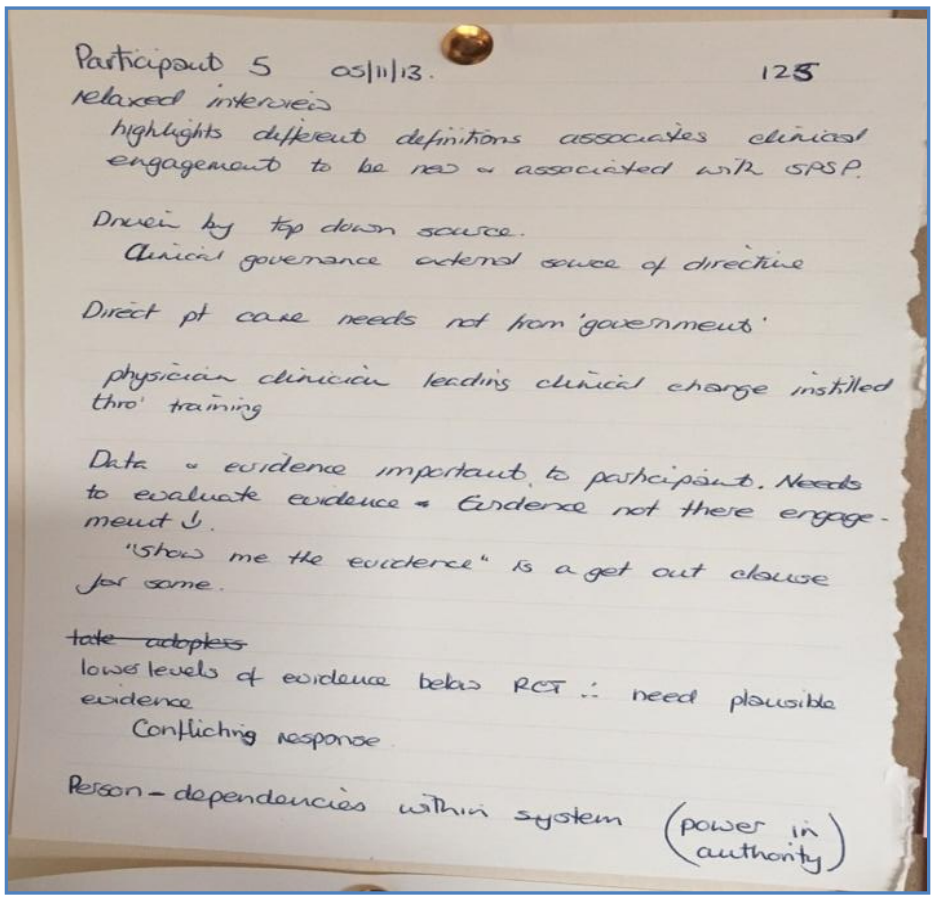


Figure 7
Post interview note – after each interview, a field note was taken of immediate thoughts and reflections on the interview, setting and participant engagement.

On completion of the transcription process described earlier on page 76, I went through each transcription reading it without making any notes in the text but creating memos which came to mind.

Charmaz (2014) suggests that memos provide the researcher with material to ponder, follow up and review later – these memos acted as a record of my initial thoughts and reminder of topics to pursue. Figure 8 illustrates two memos taken while reviewing transcript 123, both memos were from the initial data review and helped me to identify aspects of the study topic which had not initially occurred to me during the post-interview note taking.

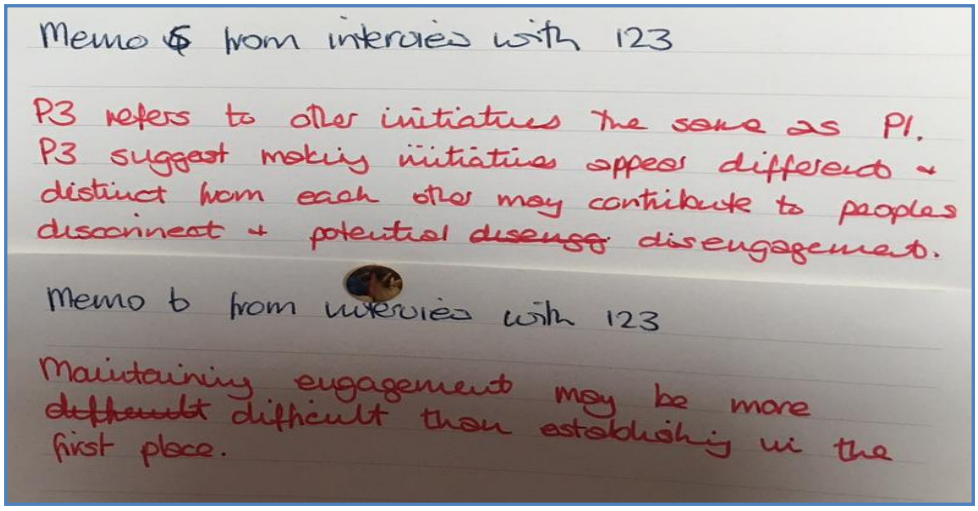


Figure 8
Initial transcription review memos – examples of memos taken during first read through of participant transcription 123.

Open coding

Following this initial read through I then started the process of open coding the transcript, an example from this study is:

> Clinical engagement is:
> ... process of getting people **on board** to implement practice ... P339
> ... getting everyone **"on board"**... all working together P3310
> ... getting nurses and doctors **on side** ... the same way of thinking on whatever it is we are trying to bring in. P338.
> ... they are **going along with** you aren't they ... with you. P123

Open coding is described by Charmaz as detailed and open analysis of the data, providing the researcher with the opportunity to summarise the data in a descriptive way. I found as I gathered more data the open coding moved from the early descriptive

form to more analytical coding. Charmaz recommends that early codes should be simple, and action orientated with increased abstraction occurring as analysis progresses. This increased abstraction facilitates the progression towards the development of selective coding, the development of selective coding also drives the development of operational definitions for codes essentially to ensure consistency across the life of the analysis process. In some instances, it was through the revisiting of earlier transcripts that helped me develop these operational definitions. Using the example relating to "On board" as the original selective code had been defined. This was revised to "active participation" following the development of Memo 156 and reading literature relating to employee engagement (McLeod and Clarke, 2009) and supported the development of a revised operational definition; refer to Appendix 31 for further detail.

One of the tools I utilised to facilitate the movement back and forth within my data is described by Clarke (2005) as Situational analysis. Situational analysis is defined by Clarke as an approach which can be utilised to analyse complex situations of enquiry. Situational mapping allows the researcher to set out the human, non-human and discursive elements of the research situation as defined and illustrated in the transcriptions, memos and analytical drawings developed through-out the analysis process. The mapping captures and describes the messy nature of the research situation as experienced by the participants and the researcher. Of relevance to this study situational mapping offered the opportunity to consider the data at micro – individual participant level, meso – professional group and unit group level and macro – unit type levels. The maps produced according to Clarke may not represent the final theoretical concept rather they are a stepping stone facilitating the researcher to engage in deeper analytic exercises.

Using this visualisation technique, I began to collect the open codes and early versions of selective codes on Post-it® and displayed them on walls. Figure 9 is an early visualisation of open and selective codes along with theoretical notes relating to "leadership." This diagram resulted from my considerations of leadership being described differently depending on the unit type participants worked in – this will be discussed further in Chapter 4, Findings and in Chapter 5, Discussion section under other reflections.

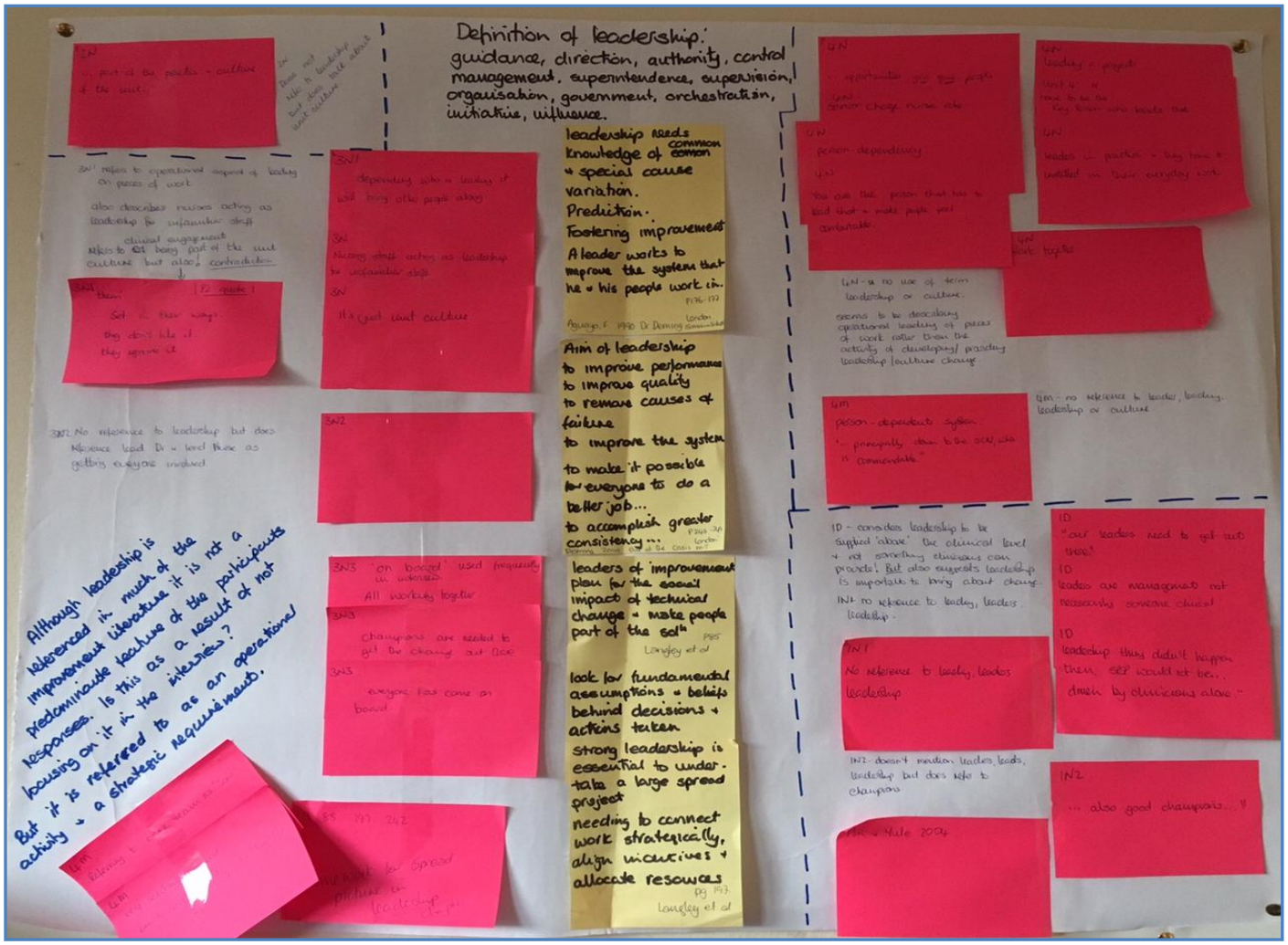


Figure 9

Early development of selective coding (pink) and associated memos (yellow) and linking with available evidence to support theory building.

From the data analysis description provided here it may seem that the selective codes "appear" easily from the data – this was not the case. Figure 10 is an early iteration of developing selective codes: this was created after the completion of eight interviews and I had been able to access all of the study sites at this point in the study.

In Figure10[14] the pink Post-it® represents the open codes identified within individual transcriptions, with the development of selective codes being written directly onto the background paper. Using this process it was possible to begin grouping responses together by professional group as I started to "look" for similarlities / differences in the perceptions described. The yellow Post-it® down the centre of the paper indicates the early development of the selective code for leadership which through further review and iterations became "recognition of leadership" however with data from subsequent interviews and data anlysis these were later distributed between clinical engagement, multi-discilpinary team and enablers. Please refer to section 4.12 for further findings relating specifically to Leadership.

Comparing Figures 10 & 11 with the list of categories in Table 5 it can be seen that there were further revisions as more data were gathered. Data gathering was guided by the analysis process, with questions being shaped to answer specific questions arising from the data, the allows the development of the themes / categories / core categories to be an iterative process. By this process I used the learning from subsequent cycles to help inform the emerging grounded theory. With early selective codes potentially being subsumed into other selective codes or early selective codes being renamed as further data was gathered. This is common within grounded theory where additional data helps guide the operational definitions of codes – refining definitions over time. This I consider is the concept referred to by Charmaz when she advocates that one of the researcher's roles / responsibilities being to look for connections and relationships between the data. Through this iterative process the codes fit the data rather than the data fitting the codes. This is the specific reason why I used the constructivist approach as I wanted the data to guide me in my learning around the topic area.

[14] If reading a black and white version of this text, the darker rectangles are the pink post-its©

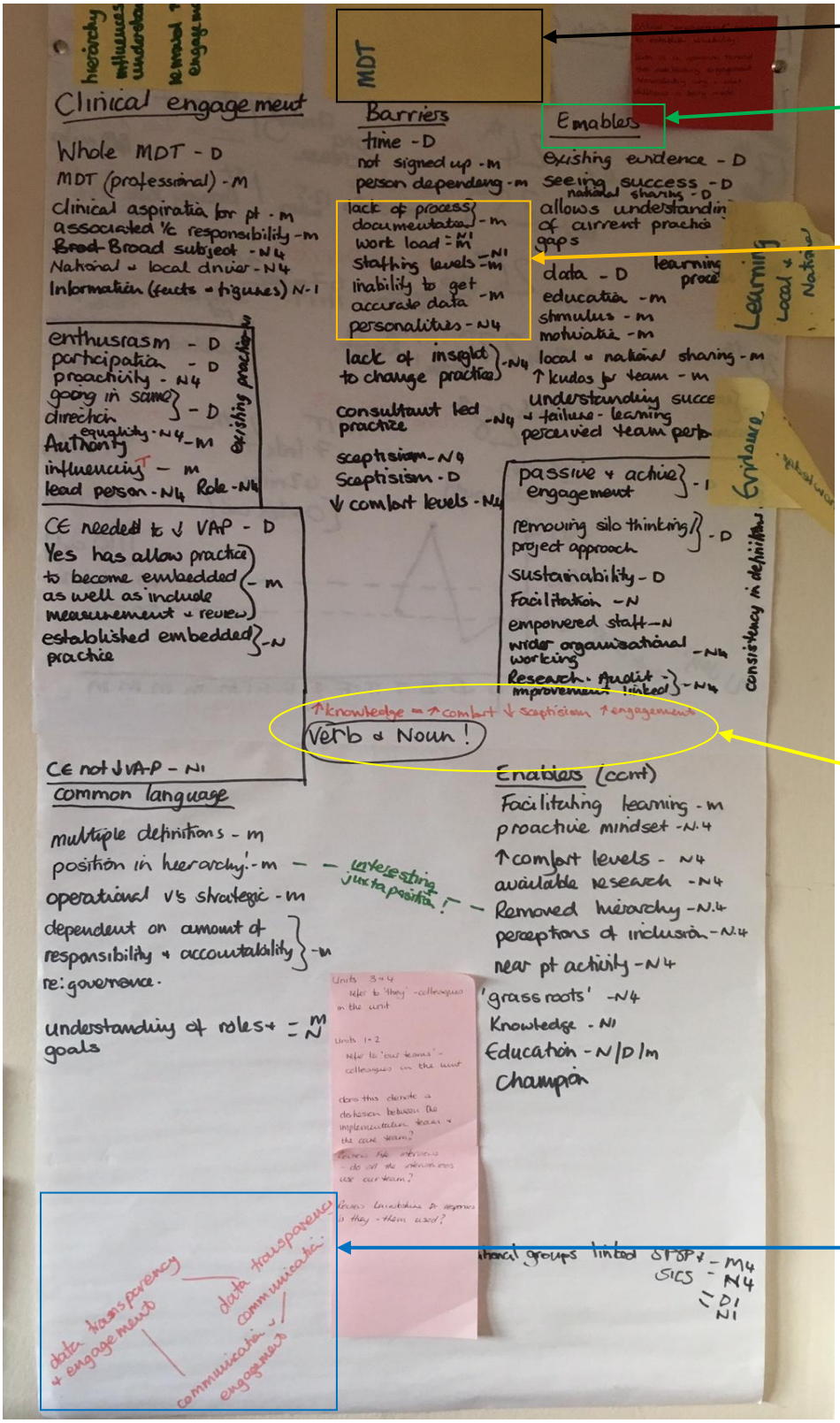


Figure 10
Early situational map illustrating the process to move from open coding to selective coding including theoretical memos and early conceptual diagrams

My Reflection 4 ***Returning to the data***

Having all my data displayed on the wall I consider was a useful way to help me visualise my data all at once. Allowing me the opportunity to quickly refer to other participants responses without having to flick through print outs or scroll through pages on a computer screen. I was able to quickly find excerpts I was thinking about and if required refer to the original transcript as these were readily available when I was working with my data.

On reflection the identification of the language category was facilitated by this as it was while reading through Post-Its© from one participant that the comments from another participant caught my eye. As I was reading through notes from participant 2315 notes from participant 3310 caught my attention and prompted me to investigate further the language used by other participants.

As I was conducting this study on a part time basis, having the facility to return to my data "quickly" and not having to remind myself too much of where I had got to and how I had got there really helped me to re-immerse myself into the data analysis process. This was facilitated using Situational Analysis processes described earlier, with the specific process used being situational mapping. This I achieved by displaying my data on the walls allowing me to make mental connections as I re-read data and importantly it also facilitated me to see all my data at once.

Figure 11 illustrates the first three participant data displayed on the wall. This allowed me to begin using colour for selective codes too. Mini memos provided me with the opportunity to make quick notes which acted as prompts when returning to the data later –representing place holders of a fashion, reminding me where I had progressed to in my analysis as well as affording me the opportunity to remember what my thought processes had been the last time I reviewed the data.

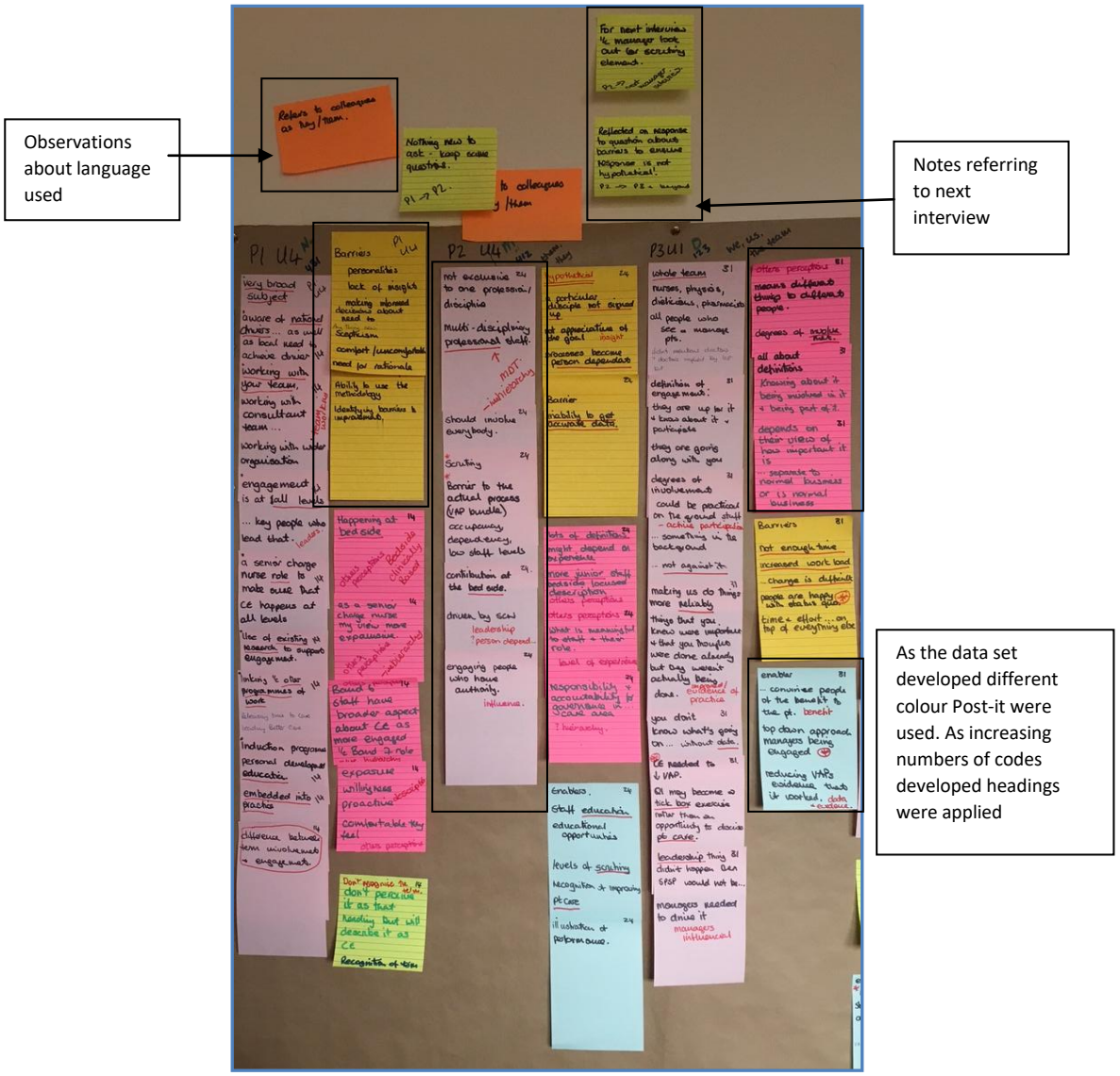


Figure 11
Visual display of the data – an example of how code development progressed as the data set grew.

As previously indicated interviews were the data collection tool utilised for this study, the next sections will set out the rationale and processes utilised to facilitate this.

Interviews

Interviews are a commonly utilised data collection tool in both quantitative and qualitative research, they offer the opportunity to establish and generate a conversation with people on a specific topic (May 2011). For this study I used individual interviews, enabling informed conversation with participants, through the interview process an in-depth exploration was conducted.

In qualitative research approaches there are generally 4 recognised types of interviews these being 1) structured, 2) semi-structured 3) unstructured and 4) group interview / focus groups. Each type of interview meets different data collection and research approach requirements, with structured interviews predominating quantitative research approach and are characterised by fixed questions sets presented in a fixed order and with standardised wording of questions (Robson 2009). Semi-structured and unstructured interviewing offers the researcher more flexibility within the interview, providing as the terminology suggests, some structure within which to guide the interview, with interviewers who use this approach commonly having a checklist of topics to follow, standard wording and question order (Robson 2009). When unstructured interviewing is used the interviewer will have a general area of interest to be explored but the conversation will be allowed to develop as directed by the interviewee (Robson 2009). Group interviews / focus groups involve groups of people exploring a topic of interest, typically these types of interview last an hour or more depending on the number of participants in the group. Typically, in focus groups participants have experience of a specific topic and the group is interviewed in an unstructured way around that topic (Bryman 2016b).

For purposes of this study and following the previously described philosophical position of an interpretive approach it was decided to follow an unstructured interview approach, as this allows the researcher and participant to produce a construction / reconstruction of reality and view point as perceived by the participant (Charmaz 2009). It requires the development of a relationship between the researcher and participant and as with any relationship there may be relative or perceived power differences between the participant and researcher and it may be that the participant

seeks permission from the interviewer to proceed or ask if they have provided sufficient information, this was my experience with several my participants where they asked, *"have I answered you correctly?"* Participant 412 and *"is that what you were looking for?"* Participant 338.

Through the reflective process already described I had been aware that this could be a potential consideration within this study for the following reasons:

1. my role was with a national NHS organisation and closely aligned with the Scottish Patient Safety Programme to which participants and their respective NHS boards were reporting improvement data
2. as well as being a nurse with 10 years clinical experience with NHS Scotland and
3. having previously published articles relating to ventilator associated pneumonia.

I had considered that these points could be perceived as power gradients by potential participants and theoretically deter people from volunteering to participate in the first place or may present a bias in their responses once they have volunteered. Much of the available literature relating to the relationship between researcher(s) and participant(s) assumes that research studies will be approaching patients to participate and makes no reference to approaching staff. Notwithstanding this observation I sought to alleviate the potential for a power gradient to exist between myself and participants, setting the interview as a conversation rather than a "rigid interrogation", having a relaxed and open approach to the sequence of questions and facilitating the participant to guide the direction of the conversation. However as indicted by Karnieli-Miller et al (2009) these activities can all be manipulative and indeed reflective of exploitation and only practiced to an end to secure data for the study. Activities to make the people I am working with as comfortable and relaxed as possible are things I do routinely, and I do not consider myself to be a manipulative person. Feedback from colleagues and peers reflect that this is an activity they recognised as being within my positive skill set and is a skill I used in my interviews.

My reflection 5 ***The Recruitment process and potential biases / influencing factors***
I considered point 1 – my role within the national NHS organisation, closely aligned with SPSP, to be important and potentially influential in both the recruitment for my study and in securing open and honest responses from participants. My experience working within HIS is that all HIS staff are often perceived as full filling a scrutiny role when engaging with boards. This can lead to colleagues in territorial boards thinking that we only want to hear about good things happening within their service and that we will make their lives unpleasant – bringing inspectors in, if outcomes are not being met or standards are not being met. This is not the role of quality improvement practitioners, rather our role is to support teams to develop tools and activities to recognise themselves if care is not as reliable as it could be and to develop improvement activity to address concerns and achieve improved patient / service user outcomes.

Points 2 – being a nurse with 10 years clinical experience and 3 – previous publications relating to ventilator associated pneumonia, I also considered to be relevant in establishing a trusting and open relationship with potential and actual participants. As a nurse I recognised and reflected on the relationships between senior and junior staff where there is an expectation that the senior staff have the greater wealth of knowledge and experience. However, having been involved in quality improvement for several years I am also cognisant of the role fresh eyes can have in questioning "standard practice."

To address these points at the outset of the recruitment phase, during the site visits to introduce the study I took care to be clear that I was not representing HIS and that I was keen to develop my understanding as this was an area of quality improvement I wanted to know more about.

The interview schedule / questions

Four broad, open-ended but focused questions had been developed prior to commencing the interviews; these questions had been developed with the intention to encourage participants to describe their own perspective of establishing clinical engagement in Scottish Intensive care units. Bowling (2014) refers to this as having an interview schedule rather than interview questions. The purpose of using an unstructured interview as a data collection tool is to facilitate the understanding of participants' social world and the meaning of events within that world. Using an unstructured interview allows the researcher to obtain true meanings which participants align with events as well as develop understanding of the complexities associated with their attitudes, behaviours and experiences as a mechanism to capture data which attempts to understand complex behaviour of members within a society; exploring and describing the culture, language and way of life (Fontana and Frey 2005).

As an example of using this approach, I was able to have a conversation with one participant about his perceptions of the role senior management played in facilitating the embedding of quality improvement within the culture of his board (Participant 123.) If I had been using a structured or semi-structured interview approach, I would not have been able to explore this topic as thoroughly. This facilitated the process advocated by Charmaz of looking for connections and relationships within the data. As I had already interviewed two managers and identified that they had perceived a relationship between their role and the embedding of quality improvement which had not been identified prior to the beginning to the interview process, I used the flexibility offered by the unstructured interview process to explore this aspect of the conversation further. As a result, this interview contributed to the development of the selective codes: *"Aware of the need to improve"* and *"Recognised leadership."*

Posing the interview questions

I saw my role as the researcher was to encourage participants to speak freely and spontaneously about their feelings, beliefs, experiences and attitudes towards clinical engagement and quality improvement. I used a mix of questions to encourage the participants to talk about the topic. These were generally opening questions to start the conversation such as *"Can you describe what you perceive clinical engagement to be …"* other question types included probing questions using phrases such as *"Tell me about …", "How do you perceive …"*, and *"Can you describe …"* were used when questions were being posed. I also wanted on occasion to check my understanding of what the participant has said on these occasions I used phrases such as *"What did you mean by …" "Can I explore with you further …" "Do you mean …"* Charmaz (2006) indicates that taking this approach encourages unexpected statements and the participants' stories to emerge; participants often do not expect researchers to encourage them to contribute their reflections. This was demonstrated in this study with the group of nurses from Unit 3 all asking if what they were sharing with me was the "stuff" I wanted to hear about.

For each participant I had developed unique interview schedules, Lofland et al (2006) highlight the importance of having an interview guide or schedule as it provides the interviewer with a list of things to be included in the interview, Appendix 10. The purpose of having the list was for me to be reminded of the avenues of interest

developing from the analysis process. This resulted in a conversation between myself and participant using the topic guides in an effort to keep the interview focussed on the research area but did not restrict the participant to provide answers which would help formulate a theory from his/her conversation. An example of the development of unique questions for individual participants is provided in Figure 5 – this memo resulted in the inclusion of scrutiny as a topic in the interview with participant 3111.

Testing my interview technique

I considered that it was essential for me to test my interviewing techniques and potential interview questions prior to taking them to the field – I considered that it was possible as I became more familiar with the topic area there was the chance that I would to become over familiar with phrases or subject meaning and assume that participants will have the same level of familiarity. This had been highlighted to me during one of the university study days I attended during this study where I frequently use acronyms and had to expand these as I spoke with others less familiar with the topic. With this is in mind, questions were therefore tested prior to entering the field with four critical care nurses with subject matter knowledge; two of the nurses also had knowledge of quality improvement methodology. The purpose of the testing was to reflect on my interview technique as well as potential wording of the questions and the type of data returned during the interviews. Robson (2009) indicates that the testing of questionnaire and surveys is an appropriate activity to ensure that questions are asked in the most appropriate way to encourage responses from participants. Through the testing phase I was also able to practice my interview technique, including the use of the Dictaphone as it had been some time since I had last undertaken this activity.

My reflection 6 ***Testing the Questionnaires***
The testing phase allowed me to test out my technique around the actual interview setting, this turned out to be an important aspect as I was able to share with potential participants that a quiet area away from the clinical area was preferable to reduce the potential for interrupts and background noise. I was also able to explore with my colleagues the form of words I would use to ask some of the early questions.

I didn't analysis this data as it was never intended to be included in the results; I didn't make any notes on this data, I was using it to make sure the wording of the questions was correct rather than the data I was getting back. However, on reflection the information shared by these respondents may have informed my thinking even before setting off into the field and subconsciously informed my first interview. Yet, it would also be argued that my personal experience of participating in quality improvement activity, providing care to critically ill patients diagnosed with ventilator associated pneumonia and extensive knowledge of the literature will also have contributed to and informed not only the first interview but also all subsequent interviews and the data analysis process.

Study population

As previously identified the approach to identifying the study population utilised theoretical sampling. The study is intended to develop an emergent grounded theory describing staff perceptions of clinical engagement related to using quality improvement methodology in Scottish Intensive Care Units. The study population was therefore reflective of this, including all nurses, doctors and managers employed on a permanent basis in any intensive care unit in Scotland. The inclusion of managers in the staff population resulted from the review of *"A systematic narrative review of quality improvement models in health care"* by Powell et al (NHS QIS 2009). Throughout this paper is the explicit reference to the need for senior managers to be involved in quality improvement, Powell et al consider that managers have a key supporting role in the delivery and success of quality improvement activity within any healthcare environment. Managers are considered to have the ability to align the strategic direction of the organisation and the daily operational requirements of patient needs. This was also augmented following a personal conversation with Professor Huw Davies – one of the paper's co-authors, around the topic of study. I was afforded this opportunity at a conference held at St Andrews University in 2012, Professor Davies commented on a poster presentation I gave describing the early iteration of my research proposal suggesting that the inclusion of managers would add valuable dimension to the results.

Nurses and doctors are included in the study population as they are the predominant staff groups within intensive care units.

Inclusion criteria

There are 14 territorial health boards and one special health board in Scotland with 12 of these health boards providing level three patient care also referred to as critical or intensive care.

To answer the question posed for this research study and reflecting on the part-time nature of the study process for me as a doctorate student it was essential to identify a sample of the available units.

> *My reflections 7* ***Clinical Engagement***
>
> *At the outset of this study and because of previous experience, personal development activities and academic reading I had determined that clinical engagement although not well defined in the literature was a recognised context factor essential for the successful delivery of quality improvement. I considered that in units where quality improvement activity had been successful staff would be able to articulate what clinical engagement was. In addition, I considered that where units had not been able to successfully deliver quality improvement staff would not be able to articulate what clinical engagement was.*

Considering My Reflections 7, I determined that utilising one of the outcome measures required by the Scottish Patient Safety Programme would assist with the theoretical sampling process.

Ventilator associated Pneumonia (VAP)

VAP is one of the three nosocomial infections identified within the SPSP Critical Care driver diagram – Appendix 7 - and is the only condition of the three unique to the ICU. The evidence supporting the need to reduce the incidence of VAP in critical care units had been available for a considerable amount of time with Vincent et al reporting in their landmark paper published in 1995; *The prevalence of Nosocomial infections in European intensive care units* (ICU); describing results of a point prevalence study carried out across 17 European countries, including the United Kingdom. An overall ICU acquired infection rate of 21% was observed, with pneumonia being the infection associated in almost half of all cases. The rate of pneumonia identified in UK units was

reported as being 16%; more than 80% of these pneumonias were associated with invasive mechanical ventilation more commonly referred to as ventilator associated pneumonia (VAP). Within this study Vincent et al were also able to demonstrate a direct correlation between prevalence of ICU acquired infection and ICU mortality rate; for UK units the mortality rate was 20%. This paper is frequently referred to in the literature and is commonly used as reference material; however, it is of note that the data analysed by Vincent et al was self-reported by the units taking part and there was no process to validate the rates reported, consequently there may have been inconsistencies in rates reported due to variation in diagnosis definitions; this is identified by the authors as a potential confounder within the data. Irrespective of this is the fact that subsequent studies have also identified VAP acquisition as a major risk to patients in the intensive care unit.

Although the mortality rate of patients acquiring VAP was relatively low at 20%, patients who developed VAP require an additional 14 days mechanical ventilation and prolonged intensive unit admission as well as extended hospital admission. Acquiring a VAP presented a significant personal cost to the patient in prolonged hospital admission as well as considerable financial cost to the hospital in additional bed days and drug requirements. Heyland et al (1999) demonstrated in a prospective case-controlled study that the acquisition of ventilator associated pneumonia (VAP) was associated with increased length of stay in ICU and an increased risk of death.

At the start of this study there were no annually published rates of VAP for Scottish ICUs, each individual unit held their own data as part of their SPSP activity. It is not therefore possible to provide a validated aggregated rate of VAP for Scotland, there were however units where the SPSP aim of 300 days between VAPs had been achieved and units where this had not yet been achieved.

Identifying units to participate

I approached all Scottish ICUs seeking permission to access their VAP rates on the Scottish Patient Safety Programme data management site – IHI extranet[15], 11 of the 12 eligible boards granted this permission. This process will be discussed further in Section 4.1 describing the recruitment process.

[15] The IHI Extranet was a web-based data collection system set up by IHI to facilitate participating teams to collect and display their improvement data, as well as share resources developed through their improvement work and to establish a virtual network for improvers across Scotland.

From these 11 boards 24 critical care units were eligible to be included in the selection process, and the available IHI extranet data was reviewed. A chart was created using the VAP rate per 1000 ventilator days over the previous 12 months and sorted in ascending order showing the units with the lowest VAP rate / 1000 ventilator days to the left. Using the "*Unit selection process flowchart*" in Appendix 11 there was a further filtering of potential study sites. 3 units did not have data available for the preceding 12-month period on the extranet and were therefore removed from the eligible data set - resulting in 21 units being eligible to be included in the selection process.

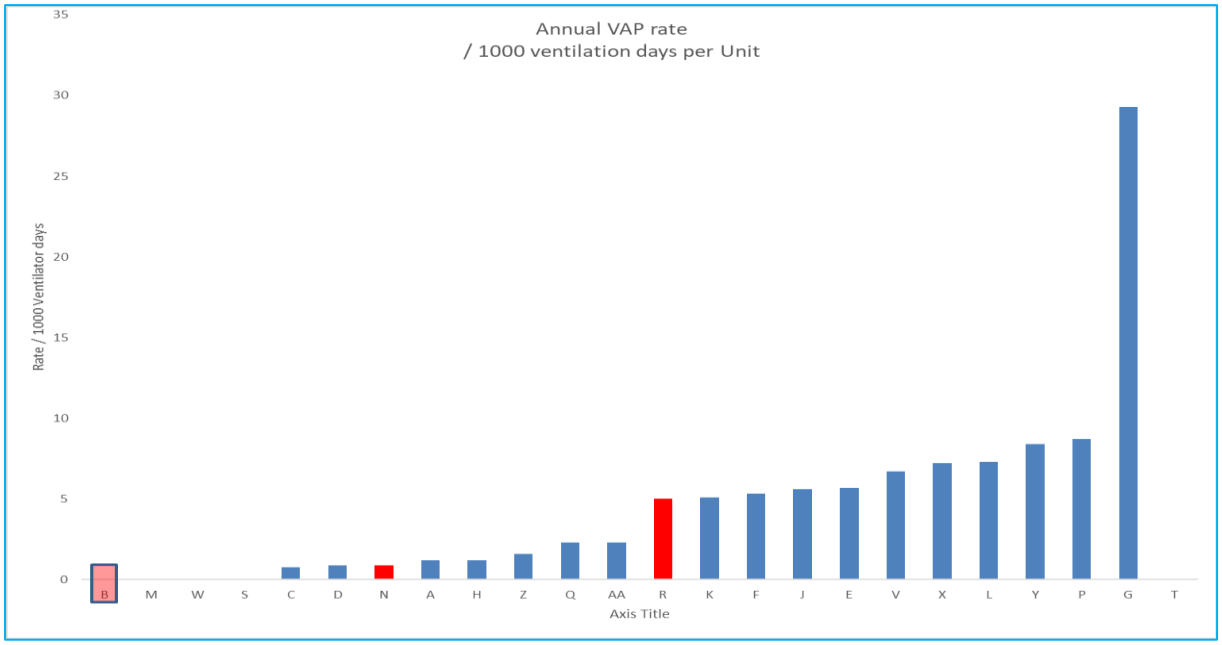


Figure 12
Annual VAP rate /1000 ventilator days for all eligible units in Scotland January 2012 – December 2012.

The graph in Figure 12 illustrates the sorted data. Those units highlighted in Red – units B, N & R were removed from the selection process as they did not have data relating to the previous 12-month period. I therefore approached units M, W, P and G to participate in the study. Although there were three units with no reported VAP in the time-period I approached units as they had been displayed on the graph – therefore units M & W were approached in the first instance as units where there were no VAPs reported in the time-period. I approached units P & G as they were the units with the highest reported VAPs.

Sampling strategy for individual participants.

The premise when using Grounded Theory approach is to let the selection of future participants be determined by the findings from previous data. This was ostensibly the approach I took; however due to delays in being able to meet staff to describe my study[16], the need to reschedule participant appointments and having up to eight week lead in time to meet with participants due to clinical commitments, off duty scheduling and annual leave it was not always possible to be able to do this. Figure 13 details the order that participants were interviewed in with the letter denoting the professional group N=nurse, SM=Service Manager, NM=Nurse Manager and D=Doctor and the number indicates the site number. Those participants who are underlined had to be rescheduled from January and February 2014.

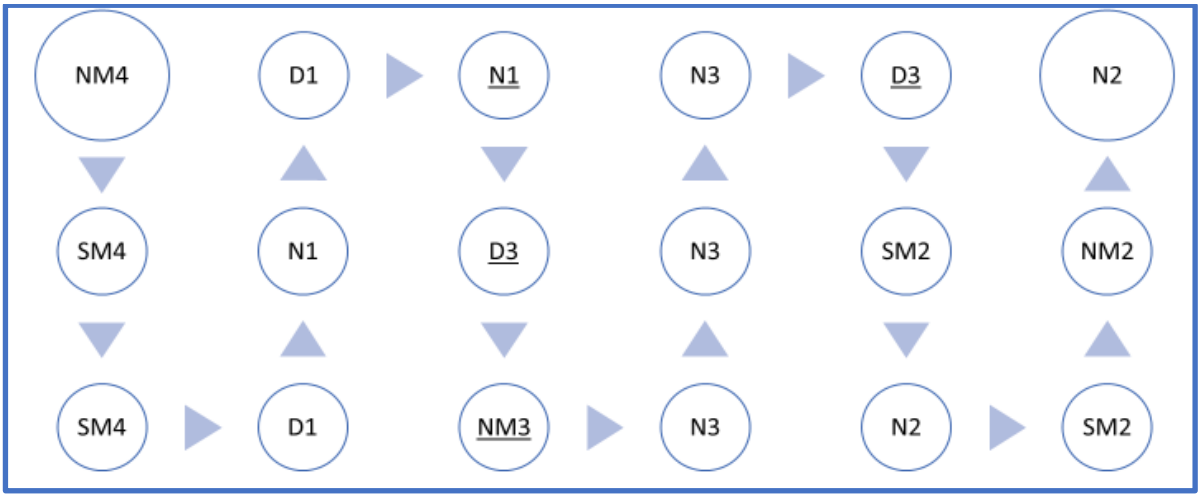


Figure 13
Detail of the order of interviews by professional group and study site

I had also approached on two occasions the medical staff in both Study site 2 and 4 but did not receive response or potential participants from either site.

[16] please referred to the Recruitment Process for more detail

2.4 Ethical Considerations

The purpose of this section is to set out how the study met ethical requirements from a university perspective as well as an NHS Health Research perspective.

There are essentially three ethical issues which should be addressed prior to commencing any research study:

- Maintaining privacy
- Reporting and analysing data honestly
- Taking responsibility for the findings

These requirements are set out in law and are covered by the Data Protection Act (Data Protection Act 1998) and the Declaration of Helsinki (World Medical Association 2014); by undertaking this research study a researcher agreed to abide by them.

Undertaking research with human participants raises several ethical issues and how these were addressed in relation to this study will be explored within this chapter. Ethical approval was sought prior to gathering any data and this process will also be described further later in this chapter.

Recruitment Process

When recruiting participants to take part in any research study there is a risk that coercion may take place (Karnieli-Miller et al 2009). In order that participants can freely participate in any research study they must be provided with clear information about the study purpose, what their participation will involve and how information they share will be used and stored. In addition, participants need to be free to withdraw at any time from the study should they change their minds regarding participation.

To gain access to the critical care units I emailed a template letter to the lead consultant intensivist (Appendix 12), the Senior Charge Nurse for the unit (Appendix 12[17]) and to the service manager of the unit (Appendix 13), this letter introduces myself and seeks permission to meet with staff in the unit ideally via established staff meetings if appropriate, sets out the purpose of the study and anticipated amount of time participants would be interviewed for. Once senior staff agreed for me to approach staff participant information leaflets (Appendix 14) were posted to the unit as well as posters (Appendix 15) advertising the study, two weeks prior to a pre-arranged

[17] Please note the same letter was used with, salutation was adapted to the audience

meeting with staff in the unit by myself. At this meeting I described the study in more detail and answered any questions raised by attendees. To reach as many staff as possible within each participating unit several visits were arranged over approximately three weeks. Contact details were provided on the information leaflets as well as on business cards, these were left with staff in order that they could contact me after the meeting if they did not feel comfortable volunteering at the time.

Informed Consent and Consent forms

People should always be asked in advance if they are prepared to participate in research studies and know what this. Once participants had identified themselves as being interested in participating in the study, I arranged a date to meet with them during their working day to undertake the interview, all interviews were scheduled at least two weeks after volunteering to allow participants time to reconsider if they wanted to take part in the study. Prior to the date of the interview I emailed their work email address the information leaflet again along with a copy of the informed consent form (Appendix 16). On the day of the interview I again discussed the purpose of the study and ensured that all participants understood what participating would involve. The informed consent form was signed by me and the participant and a copy retained by both.

The Researcher's Role

As previously highlighted I was aware that in my role as a member of the Scottish Patient Safety Programme national team my position as researcher could be misconstrued by participants and they may have thought that I was undertaking the study on behalf of Healthcare Improvement Scotland. To build a trusting relationship as required, I made it clear to participants at the outset of the interview that this work was being carried out in my role as a student of University of Stirling and that any data gathered would not be shared with colleagues in HIS.

Patient safety issues

It was acknowledged that there was the potential for staff to disclose issues relating to the standard of care of patients in the unit. It was made clear to participants during the informed consent process that this would be reported to the appropriate channels within their board. For each unit prior to commencing the gathering of data this process was agreed with the senior charge nurse.

Staff safety issues

It was acknowledged that there was the potential for staff to become distressed during the interview. It was discussed during the informed consent process that the interview would be stopped, and assistance sought for the participant.

Confidentiality and Anonymity

Ensuring confidentiality and anonymity of participants and participating environments is standard practice the write up of research studies; being regarded as good practice by ethical committees and being an expectation under the Data Protection Act 1998. When participants provide informed consent to any research study, they expect that their information will be treated respectfully, preserving their anonymity. Confidentially requires that no details will be included in the write up of the study which will allow participants to be identified. To ensure this all participants were allocated a participant number which aggregated three codes for participating unit, staff group and participant number. During the write up of the study participating units and participants were only referred to by their allocated code. The code allocation was known only to me and my research supervisors and was stored separately from the data from the interview. This was discussed with the participants prior to them giving informed consent to participate.

Storage and Protection of Data

All information provided by participants during their participation would be treated in the strictest confidence. Signed consent forms were stored in a locked drawer in a locked room within my dwelling, prior to being transferred to a locked cabinet within the university. Digital recordings of interviews were stored on a Dictaphone until transcription, once I was satisfied that the transcription was accurate recordings were deleted. Transcriptions were saved onto an encrypted password protected memory pen and kept within a locked drawer in a locked drawer in my dwelling; a copy of the transcription was saved onto my password protected university network drive. None of the transcriptions contained person or unit identifiable references. The final write up of the study will include combinations of unit and participant views, with any unit or person identifiable references removed.

Safe Destruction

On completion of the final written report and thesis completion and following granting of the academic award all transcriptions and filed notes will be preserved in a locked

cabinet within the university as per university protocol for 10 years and then destroyed as per university protocol.

Personal Safety

To ensure my personal safety through the participant recruitment and interview phases of this study I carried out all recruitment activity and recruitment within hospital grounds. Recruitment activity as generally within the critical care units participating in the study and were to groups of staff.

Interviews were by necessity undertaken on a 1-1 basis but again within the participating unit environment or within participating manager's offices.

Dissemination of Findings

Having spent almost two years collecting information from 18 participants across four critical care units in Scotland and having committed another four years to the analysis and write up of the findings it would be unethical to not then disseminate the findings. As part of the information provided and informed consent process, I made it clear that the findings would be shared with the critical care community in Scotland as well as the quality improvement community in the wider context.

Obtaining Ethical Approval

NHS IRAS forms were completed and submitted to the School of Nursing, Midwifery and Health Research Ethics Committee, University of Stirling – with approval to progress with the study being granted on 14th June 2013 (Appendix 17).

Following email conversation with NHS Research Scotland Permissions Coordinating Centre (NHS Tayside), as the study did not include patients as subjects' further ethical consent was not required for the study to proceed. Appendix 18 includes the email detailing this decision.

Although NHS Research Ethical consent was not required for this study Letters of access were required from each NHS health board:

Board	Letter of access for research issued	Appendix number	Research & Development Department Certificates	Appendix number
Unit 1	27th September 2013	19	27th September 2013	20
Unit 2	4th October 2013	21	30th September 2013	22
Unit 3	8th October 2013	23	8th October 2013	24
Unit 4[18]	4th October 2013	25	4th October 2013	26

Table 3
Table detailing Letter of Access for Research receipt dates, R&D Dept Certificate issue dates and associated Appendices number for reference for each participating unit.

University Sponsorship & University Insurance

University sponsorship (Appendix 27) and University Insurance confirmation (Appendix 28) were granted 9th September 2013.

[18] Unit 4 also issued a Clinical Governance approval letter 9th August 2013 (Appendix 26a)

Chapter 3 Quality Assurance

The purpose of this chapter is to set out how this study was designed to address issues of quality.

Glaser and Strauss (1967) emphasised two main criteria for judging the adequacy of an emerging grounded theory, these being: it fits the situation and that it works. The emerging theory should help people involved in the situation to make sense of their experiences and manage the situation better. However, this does not address the question relating to the application of the methodology for example *"Is it evident and is there evidence that the researcher applied the constant comparative technique during the data analysis process?"*

I consider that Glasser and Strauss are describing the process of applying the grounded theory methodology reliably and with rigour, and Charmaz attests the quality and credibility of any grounded theory study starts with the data (Charmaz 2006). As already described this study is following a constructionist approach to grounded theory and as with any grounded theory approach currently there is no existing reality to "check" the analysis against. Yet, this does not mean that this study should not include activities to ensure quality and rigor of the resulting theory.

Unlike quantitative methodologies it is not possible to generate grounded theory in an objective unbiased manner as the data produced are obtained from social interactions, therefore they are constructions and interpretations reflecting both the participant and researchers cultural, theoretical and historical positioning (Charmaz 2000). As already referred to in the Reflexivity section, it is essential to achieve transparency of positioning from my perspective and as highlighted these are documented in the personal reflections provided in *"My Reflections"* throughout this thesis. Urquhart (2013) refers to this as reflexivity, which is considered to be a critical process when using a grounded theory approach, it facilitates the researcher's process of critical self-reflection allowing the biases and theoretical predispositions to be made explicit through-out. This is the purpose of me providing *"My Reflections"* within the text – by interspersing these reflective accounts within the text the reader is afforded the opportunity to determine how my thoughts have guided the analysis process.

3.1 Trustworthiness

Establishing trustworthiness of a grounded theory approach according to Sikolia et al (2013) occurs by demonstrating processes which confirm credibility, transferability, dependability and confirmability. The following sections detail the activities I undertook to address each of these individually.

3.2 Credibility

Credibility

Establishing credibility for this study is intended to eliminate obvious mistakes as well as generate richer explanations from the gathered data. There are several options available to ensure credibility of the findings including the use of corroboration, where differing views are obtained. Corroboration was established in this study by approaching four different intensive care units, which were all located within different NHS health boards. Interviewing different professional groups within the critical care professional groups – doctors, nurses and managers, also provided opportunity to establish credibility of findings. However, it is important to recognise that as I am using a constructionist approach it will not be possible to generate one single reality.

Participant credibility

On completion of the analysis a summary of the analysis will be shared with some of the participants as well as experts in the field to see if the account is acceptable, convincing and credible. This mix of practitioner and topic experts' feedback will allow me to ascertain if the developed theory fits with what is currently understood and perceived within the intensive care unit, the quality improvement community as well as contributing in a useful way to the existing body of knowledge. This approach sits well with that advocated by Cooney (2011) in her paper on "*Rigour and grounded theory*", who indicates there are different aspects of credibility which need to be considered to establish the rigour of a study. One aspect is that the interpretive rigour emphasises the trustworthiness of the interpretations made by the researcher and how well these reflect the data gathered.

A summary of the output gathered from participants to assist in the process of establishing and demonstrating credibility will be provided in Appendix 29.

Evidence

Evidence will be provided within the results and discussion sections providing direct quotations from interview transcriptions to supporting findings. Gibbs (2007) suggests that the inclusion of direct quotes provides readers with the opportunity to get closer to the data, I consider that this also allows me to demonstrate how the ideas and theories were constructed.

3.3 Transferability

I undertook activities to ensure analysis was consistent and reliable throughout the life of the study. This I achieved by developing, operational definitions for the selective codes, these were created to ensure that there was a consistency in the terminology used through the analysis process. Similarly, a numbering convention was developed to ensure transparency in the review of transcriptions and the development of associated memos, Appendix 31.

Transcription checking

I completed all transcriptions myself, to ensure all transcriptions were accurate the interview was listened to multiple times following typing up to ensure accuracy. The transcription process was only considered to be complete when no further amendments were required to the transcript. This could result in the interview being listened to four or five times. This had the added benefit of allowing me to immerse myself in the data and I consider this facilitated my ability to recall participant quotes when reviewing other transcripts and during other interviews. I was also familiar with the participant's voices and I consider this also helped with my recall of interview content.

Operational definitions

Definitional drift as described by Gibbs (2007) can be the result of having large datasets which are generated over a considerable amount of time as is common in grounded theory. Codes generated early in the study can be applied differently later in the study due to changes in the thought processes, topic familiarity and knowledge development. To prevent this, I developed operational definitions for codes as they were generated from the data, these were written down and referred to during any data analysis session. The development and recording of operational definitions according to Langley et al (2009) allows users to put communicable meaning to a concept. I created operational definitions for selective codes as well as themes; by generating operational

definitions it ensured I maintained consistency in my analysis and it allowed me to understand if selective codes and themes were becoming too generic and effectively catch all terms. The development of the operational definitions followed the same iterative cycles described earlier within Chapter 2 in my discussion on reflexivity. By having clarity of the operational definitions and having these written down I was able to maintain consistency in the coding process between episodes of analysis. It also allowed me to develop a set of clearly defined terms to review and determine if they still fitted with the data coming out of the interviews. Klein and Myers (1999) describe this type of activity as establishing heuristic cycles, the researcher develops an understanding of complex situations by moving from preconceptions about the meanings of the parts and their relationships. This understanding is developed by progressing from precursory understanding of the part to establishing understanding of the whole as well as moving from an assumed global understanding of the whole context back to an informed understanding of the parts.

3.4 Dependability

Dependability refers to the validation that the data presented reflects the changing conditions being studied. This is achieved by another individual or individuals who evaluate the processes employed to undertake the grounded theory study to ensure consistency with the methodology and that they were applied reliably across time. This role was undertaken by my research supervisors, who explored the methodological processes employed throughout the data collection and analysis phases. This is referred to by Cooney (2011) as establishing methodological rigour, ensuring that the methodological framework is applied reliably and consistently throughout the life of the research project. This was achieved through supervision meetings, peer review, colleague review and participant review – please refer to Appendix 29 for further detail.

Supervision meetings

As this study is being undertaken as part of a clinical doctorate programme, I had regular meetings with my research supervisors. These meetings offered me the opportunity to not only review progress but to also explore the fidelity of my use of the methodology as well as explore and examine my open coding – selective coding and theme, category and core category development. Although this does not exactly reflect code cross-checking as described by Gibbs it has provided me with the opportunity to

explore the concepts and ideas behind codes in a consistent and constructively critical environment – ensuring I have clarity in my definitions and can accurately articulate them. These supervision meetings also contributed to the reflexivity process where my supervisors challenged me to explain my thinking, be clear in my articulation of my theory and the processes I had used to reach the eventual grounded theory, pulling out my assumptions.

One of my supervisors also reviewed two of the earlier interview transcripts to validate the open coding process and to explore with me how I had used these to develop future interview questions and to influence subsequent coding activity.

Peer review

Also built into the study process has been the annual study days run by the university. This has offered me informal opportunities to test my understanding as fellow students and academic staff asked about my study, as the study progressed. Part of this process has included the opportunity to develop my ability to clearly articulate my approach and findings to people less familiar with the topic area. At the student support meeting I attended in 2017, fellow students discussed my findings diagrams, exploring my use of colour in diagrams as well as the terminology used. This was particularly helpful as quality improvement and my area of study was unfamiliar to them. I was offered the opportunity to considered how to make my findings more accessible to the wider nursing and allied healthcare professional communities.

Colleague review

Alongside the university supervision meetings have been regular professional development meetings with my line managers and quality improvement colleagues where I have again had the opportunity to explore my project and emerging theory. These opportunities have afforded me the opportunity to test emerging theory with colleagues with quality improvement background, explore other avenues of theory and are incorporated as appropriate into Appendix 29.

Participant review

As a final dependability check I also sent the findings to one of the participants who I knew had a clear understanding of the quality improvement methodology for his comment and to sense check my findings.

A summary of participant, peer and colleague review has been provided in Appendix 29 "Summary of participant and expert feedback"

3.5 Confirmability

Confirmability according to Morrow (2005) is the process of providing objectivity within a research study while recognising the research cannot be objective. Erikson in 1986 (cited by Morrow 2005) proposed 5 types of evidentiary adequacy these being:

1) Adequate amounts of data to inform the research study.

   This has been achieved within this study by interviewing sufficient participants to achieve theoretical saturation, which has been previously discussed in Chapter 2 within the Data collection methods section.

2) Adequate amounts of variety in data.

   This has been achieved within this study by interviewing participants from four different intensive care units, as well as three different professional groups. In addition, although the interview schedule was available to guide the conversation, participants were asked to share their perceptions. Questions were posed as opened questions facilitating the opportunity to respond positively or negatively.

3) Interpretive status of evidence.

   Throughout the thesis I have shared through "My Reflections" where I am aware that I have potential biases, preconceptions which could have influenced my interpretation of the data. I have sought to check in with other colleagues in both the clinical and quality improvement field to explore my findings with a view to hearing how others would interpret what I was thinking.

4) Adequate disconfirming evidence

   When analysing the data, I was conscious that it would be easy to just look for data that confirmed how I was making assessments. It was also possible through the grounded theory approach to test out theories with participants. Using assessments from previous data analysis to guide the next iteration of questions as well as checking my understanding of the perceptions shared by participants in the moment.

5) Adequate discrepant case analysis

This was achieved by presenting participants with the opposite analysis of previous data and asking if this reflected their experience.

Additional confirmatory activities which research can employ include directly discussing findings with participants; I achieved this by sending the findings to one of the participants and seeking feedback – included in Appendix 29. I also worked with one of my supervisors, who has experience of grounded theory approach to analyse transcripts with a view to observing reliability of coding and there is evidence provided in this thesis of the processes used to develop memos, selective coding and theme development (Sikolia et al 2013).

Chapter 4 Findings

4.1 Introduction

This chapter will set out the demographics of the participants who have contributed to the development of the grounded theory formed by this study. I will then offer a supporting description of the emergent grounded theory within the findings which addresses the research questions posed:

1) How different staff groups working in intensive care units describe clinical engagement and

2) The influence of clinical engagement on implementing quality improvement.

The subsequent sections of this chapter will provide detail of the selection codes and how these link to the system of profound knowledge, how the findings may be related to the different unit type's ability to achieve the Scottish Patient Safety Programme (SPSP) aim and finally other reflections developed from the findings.

Characteristics of the study sites and participants.

Using the selection criteria described in the Study Population section – four units were approached to participate, all units agreed to participate once the locally defined research and development requirements had been met. The participating units were located throughout Scotland and all provided level three patient care[19]. Two of the participating units met the description of "achieving the SPSP[20] VAP[21] reduction aim" and two of the units met the description of "not achieving the SPSP VAP reduction aim," the standard phrases used from here on to describe these two unit types will be "Achieving Units" and "Not Achieving Units" respectively .

Three of the units predominately provided level three patient care in urban populations and one of the units provided critical care to a rural population. The bed count in the units ranged from 5 – 12[22] and all of units provided placement opportunities for nursing students and medical trainees at the time of interviews taking place. All four units

[19] Please refer to Glossary for definition of level three care.
[20] Scottish Patient Safety Programme
[21] Ventilatory Associated Pneumonia
[22] No further detail will be provided relating to the participating units to not inadvertently identify any or all the units.

actively participated in SPSP routinely providing monthly data on process and outcome measures for their workstream.

All 18 interviews took place over a nine-month period October 2013 – June 2014. Time between interviews was determined by two factors, 1) my ability to transcribe and analyse data and 2) the ability to approach and secure time with volunteers. The second point was further impacted by the fact that most volunteers were frontline staff providing direct clinical care and it was not always possible to keep appointment times due to clinical priority – four interviews had to be rescheduled for this reason. Figure 14 provides detail of the interview timescale.

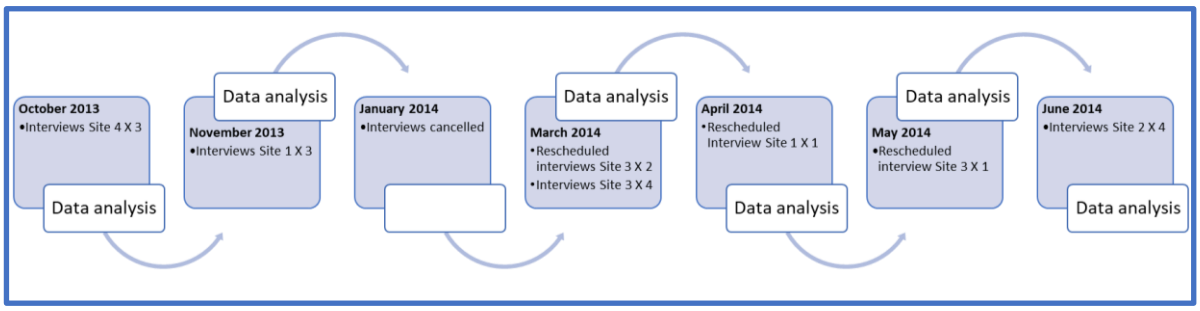


Figure 14
Details the timescale for interviews across the life of the study.

Participant Demographics

From the four units, 18 participants volunteered to take part in individual interviews. Table 4 provides detail of the numbers of participants, which professional groups were represented and within which unit. Units one & two are described as Achieving Units, while units three & four are described as Not Achieving Units.

unit *Staff group*	1	2	3	4	*Totals*
	Achieving units		Not Achieving units		
Manager	1 (Nurse manager)	2 (Service manager Nurse manager)	2 (Service manager Nurse manager)	2 (Service manager Nurse manager)	*7* *(3 service managers* *4 nurse managers)*
Nurse	1	2	3	1	7
Doctor	2	0	2	0	4
Totals	4	4	7	3	

Table 4
Details the number of participants per unit by professional group

There were 11 (61%) female participants and 7 male participants.

7 (39%) of participants identified themselves as either Service Managers (3) or Nurse Managers (4), all the service managers were nurses who had taken roles as managers and no longer provided direct clinical care. While the Nurse Managers all maintained part of their roles to include direct clinical care within the intensive care unit.

7 (39%) of participants identified themselves as nurses providing direct clinical care as the main purpose of their role, one of the participants also had an additional research component to their role.

4 (22%) of participants identified themselves as doctors – all were Consultant Intensivists.

5 (71%) of participants identified as managers were female,

7 (100%) of participants identified as nurses were female and

4 (100%) of participants identified as doctors were male.

All participants had been practicing within the critical care environment for 10 years or more, with 8 (44%) having more than 20 years' experience.

Quality Improvement experience

All the Service Managers / Nurse Managers indicated that they had a responsibility to support the delivery of quality improvement and SPSP aims for their units.

2 of the four Consultant Intensivists had lead roles in quality improvement for their unit and organisation and 1 was an active contributor in SPSP projects within his organisation.

All the nurses described themselves as having experience of and participation in quality improvement activity. The nurses from Unit 3 explicitly identified that the SPSP work was the specific responsibility of a colleague who was identified as the "SPSP Nurse." The SPSP Nurse was described to work directly with the Charge Nurse and Consultant, looking at the data and deciding what improvement activity should take place in the unit.

Developing a grounded theory of clinical engagement

Appendix 31 provides detail of all the open codes, selective codes as well as the operational definitions assigned to the selective codes used during the data analysis process. These operational definitions were developed to ensure consistency in selective code definitions across the life of the project recognising the fact that data collection would take more than 12 months to complete, having operational definitions ensured consistency in data analysis and coding throughout this time.

In Table 5, column one details the 20 selective codes which had been identified in the analysis process; these were further refined to 7 distinct themes / categories:

- Clinical engagement definition
- Perceptions of others
- Multi-disciplinary team
- Barrier
    - To establishing clinical engagement and (theme)
    - bringing about change (theme)
- Enablers
    - To establishing clinical engagement and (theme)
    - bringing about change (theme)
- Person dependency
- Language

As the purpose of using a grounded theory approach is to facilitate constant comparative analysis these themes and categories have changed over time. In particular the labels relating to enablers and barriers have been refined from enablers to establishing clinical engagement and enablers to bringing about change and barriers to establishing clinical engagement and barriers to bringing about change to "enablers" and "barriers" with themes of "establishing clinical engagement" and "bringing about change." The decision to change the category labels to enablers and barriers was a pragmatic one as it could be argued that either label is appropriate – however from the available literature the labels identified reflect current thinking and I considered that the theory may therefore be more accessible to colleagues in the field for whom this study is ultimately intended for.

As previously indicated in the introduction section of this thesis, I consider the links with the system of profound knowledge to be an important and fundamental building

block of any improvement activity undertaken. The consideration of how each of the themes / categories was linked back to the system of profound knowledge will be addressed within the Finding Section 4.9 and within the Discussion Section 5.7 of this paper.

Table 5 provides a summary of the findings from this study. Please refer to Appendix 31 for the full findings – including operational definitions of selective codes, themes and categories. To develop the summary of selective codes, themes, categories and core categories, considerably more data was used and contributed than is presented here, however for ease of illustration much of the data has not been represented here.

Selective codes	Themes	Categories	Core categories
On board	Clinical engagement definition	Clinical engagement	Clinical engagement
Aware of need to improve			
Collective / collaborative			
Ownership			
Perceived by other colleagues	Clinical engagement as perceived by others	Perceptions of others	
Multi-disciplinary team / team / whole team	Multi-disciplinary team	Multi-disciplinary team	
Lack of understanding	Barriers to bringing about change	Barriers	
Not seeing the value			
Increased work load			
Staffing resource			
Tick box exercise			
QI approach			
Hierarchy / authority	Barriers to establishing clinical engagement		
Personal attributes			
Scepticism			
Negative data perspective			
Tick box exercise			
Location of change	Enabler to bringing about change	Enablers	
Knowledge / understanding			
Champions of the change			
Positive data perspective			
Recognised leadership	Enablers to establishing clinical engagement		
Communication			
Knowledge / understanding			
Person dependency	Person dependency	Person dependency	
Them & Us	Language	Language	Cultural indicator
Collective			

Table 5
Table of findings summarising the selective codes, themes, categories and core categories identified from this Grounded theory study.

Appendix 32 provides the findings in full including open coding, operational definitions of selective codes and themes as well as incorporating the links to the System of Profound Knowledge. Appendix 31 provides an example of how memos were developed for each of the steps including a number system to ensure I could identify the audit trail towards memo development, the example provided is for the development of the clinical engagement category.

The following sections will address each of the categories in turn in the order seen in Table 5. The "barriers" and "enablers" were considered to require sub-division as participants seemed to be describing different aspects of barriers and enablers which I named "establishing clinical engagement" and "bringing about change."

Each section will be considered under the identified categories, sections will include descriptions from the participants perspective as an entire group as well as consideration of the findings as related to the different professional groups presented and the different units presented. Each section will also include findings in relation to the identification of selective codes and the links with the system of profound knowledge.

As previously established the purpose of this study was to develop understanding of how staff in Scottish intensive care units perceive clinical engagement. Exploring this was the focus of the interviews, I therefore considered that it was important to discuss this within the first results section. Subsequent topics are the additional categories developed from the iterative analysis process fundamental to grounded theory approach. Section 4.9 describes the findings in relation to the links with the system of profound knowledge and in section 4.10 I present my theoretical illustration of the new knowledge developed from this study. Section 4.11 explores the findings in relation to achieving SPSP VAP aim and the chapter is concluded with other reflections which have arisen from this study.

My Reflection 8 ***Recognising Assumptions!***

Having been immersed in the literature relating to clinical engagement and quality improvement for approximately 5 years by the time I was starting the data collection part of my clinical doctorate I had made the assumptions that the terminology would be familiar to colleagues working in critical care units across Scotland. However, it quickly became apparent even during the recruitment phase that the terminology was not commonly recognised. I was conscious that in all of the units I visited during the recruitment phase that I was asked on more than one occasion what the term clinical engagement meant. This presented me with a problem – did I provide enquirers with my description of clinical engagement and potentially have any participants merely repeat my own definition during the interview or completely ignore the question? In practice I explained that this was the reason I was conducting the study and I would be really interested to hear how others described clinical engagement. I was conscious that ignoring the question could potentially deter participants if they thought that they didn't

Figure 15 provides graphical illustration of the emergent theory resulting from this grounded theory study. It shows that from the data gathered for the 18 participants two core categories were identified: "Clinical Engagement" and "Cultural Indicators." These core categories were developed from seven categories. The findings relating to these categories will be set out in the following sections of the thesis.

An emergent theory of clinical engagement in relation to implementing Quality Improvement methodology

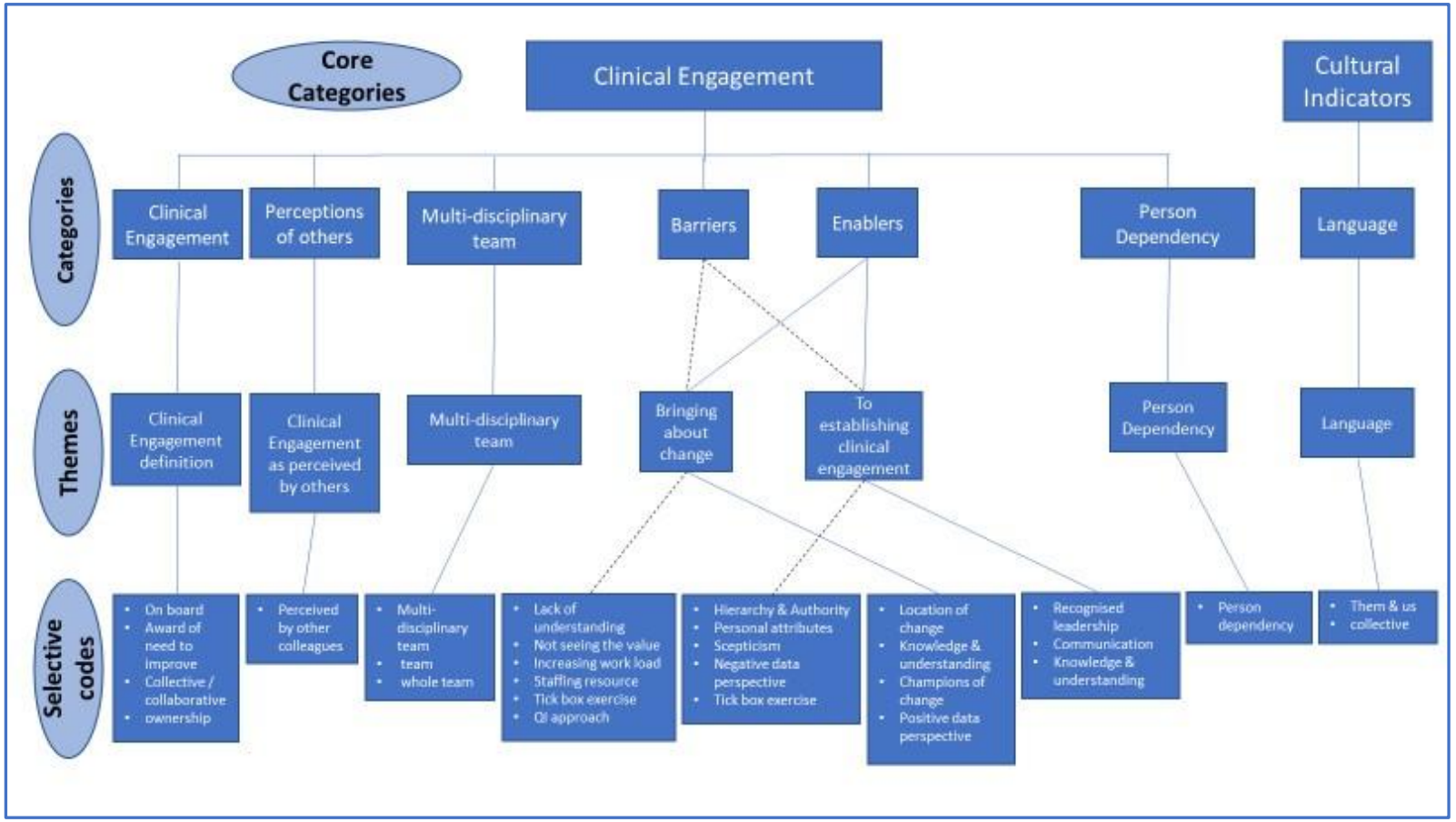


Figure 15
An emergent theory of clinical engagement in relation to implementing Quality improvement methodology.

4.2: Clinical engagement

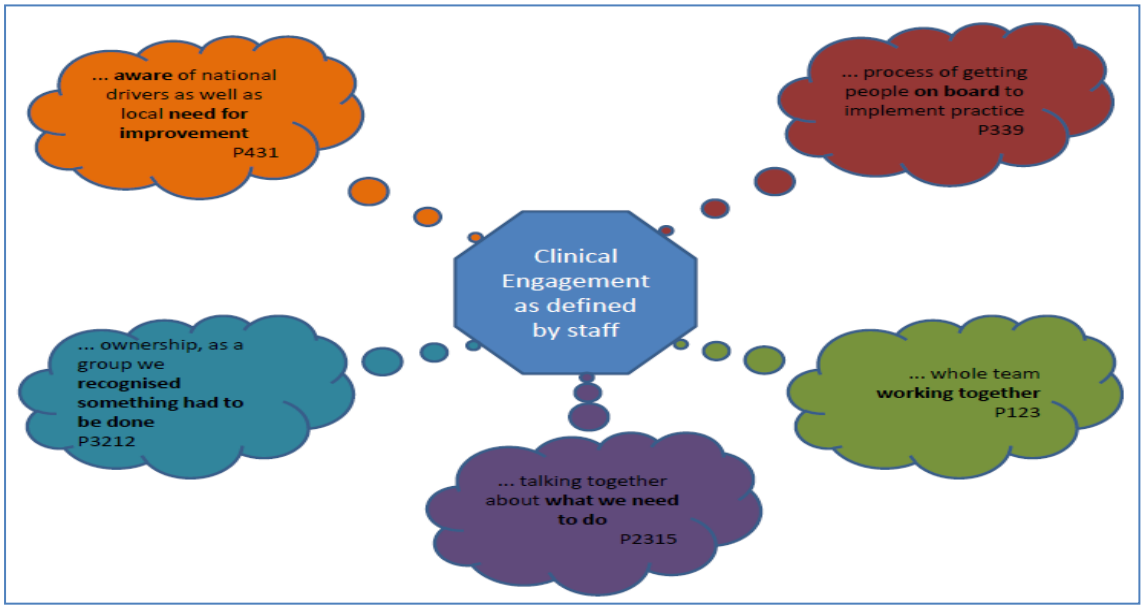


Figure 16
A sample of responses provided by participants describing clinical engagement.

Findings

The perceptions offered by participants, some of which are illustrated in Figure 16, indicated that staff considered clinical engagement to be an interactive activity. Clinical Engagement required the use of mechanisms to encourage staff to become part of the activity to bring about change *"... getting everyone "on board"... all working together"* P3310. Terminology used indicated an interactive and proactive approach this is illustrated in the excerpt from participant P339 who perceived that clinical engagement was *"... process of getting people on board..."* I consider that this is an example of activity and action rather than a passive and reactive process.

Findings by professional groups

Generally, the perceptions shared by the different professional groups - nursing, medical and managerial - were similar, with all staff groups using the same types of words to describe clinical engagement.*" ... getting nurses and doctors on side ..."* (Nurse) *"... as a group we recognised that something had to be done..."* (Doctor) *"... whole team working together ..."* (Manager) with the theme of action again being identified. The nurse manager from Unit 4 stated that *"...it is not exclusive to one discipline or the other."* P412

It is possible to suggest from the data that within the nursing staff group the more senior staff seemed to describe a strategic perception of clinical engagement – with one senior nurse indicating that part of her role was to generate a recognition among more junior staff *"... of the local and national drivers to progress improvement."* This was also a subject observed among the doctors who participated, all 4 doctors referred to the need for participation in the Scottish Patient Safety Programme. P3212 a consultant who was also the SPSP lead for his unit described the need to develop *"... ownership, as a group we recognised something had to be done"* P3212 .

This recognition of the strategic perspective did not appear to be shared by the more junior nursing staff who participated in the interviews. This will be explored further in Section 5.10 of the discussion chapter.

Findings by unit groups

Like the professional groups, there was little difference between the perceptions shared within and between the two-unit types, with "achieving units" and "not achieving units" using similar terminology and words to describe clinical engagement. The following responses were provided across the four units

Achieving units

"... whole team working together ..." P123, *"...there is a multi-disciplinary responsibility..."* P134

"...exploring ways as a group that we can reduce VAPs." P2315 *"...staff have an active interest in pushing through the desired improvement and staff "like" and agree with the idea ..."* P2118

Not achieving Units

"... the same way of thinking on whatever it is we are trying to bring in." P338*"... getting everyone on board... all working together"* P 3310 *"... ownership, as a group we recognised something had to be done..."* P3212 *"... absolute involvement, it's a team approach*." P3113

"... engagement itself is at all levels ..." P431 "It should involve everyone ... and ... we should all understand what the processes are around what we are trying to do." P412

Selective codes

The selective codes identified were 1) on boarding 2) awareness of need for improvement as well as 3) collective / collaborative and 4) ownership.

Collective / collaborative and ownership were expressed in relation to the approach taken within the units to developing clinical engagement required to bring about improvement.

An additional selective code which emerged from the data related to how participants described their colleagues' perceptions of clinical engagement. Participants suggested that colleagues may not have the same definition for clinical engagement as they had. With some participants reflecting that this could create a problem when trying to bring everyone together to achieve a common goal. As this was referred to by almost all participants it was decided to identify it as a separate category described in section 4.3 The four selective codes set out above were aggregated to one single theme of clinical engagement.

Links to the System of Profound Knowledge

Linking participant perceptions to the system of profound knowledge has been identified as an important aspect of this study. Through the process of iterative data review, reflection on available literature and experiential learning I developed a theoretical framework to link the perceptions offered in relation to the selective codes associated with clinical engagement and the four lenses[23]. I considered that it was important to use the selective codes as the link within the framework as using the wider theme of clinical engagement would not allow the level of detail required to identify which lenses were appropriate as it could be argued that all of the lenses relate to all of the themes.

Appendix 32 provides the memos developed to link the lenses and selective codes. For ease of reference Table 6 provides detail of the selective codes and associated lenses.

[23] Through the process of data review and experiential application of the System of Profound Knowledge in my daily work I tested aligning the themes with the lenses. However, I did not consider that this allowed the level of detail I considered to be required to add knowledge to the field and therefore tested aligning with the selective codes. This provided a greater level of granular detail to the findings.

Selective code	Associated lens
"on boarding"	Building knowledge Human side of change
Aware of need to improve	Building knowledge Human side of change
Collective / collaborative	Human side of change
Ownership	Human side of change

Table 6
Detail of the selective codes and associated lenses identified for the category named "Clinical Engagement"

4.3 Perceptions of others' understanding of clinical engagement

Findings

All participants suggested that colleagues would *"probably", "possibly"* or *"were likely to"* describe clinical engagement in a different manner to them, participant 137 said *"... don't know that everyone would know what that phrase meant..."* and also suggested *"... there could be other perceptions within the unit."* Other perceptions held across the four units are include here: *"For clinical engagement to work we need to understand what it means ... I had to read up on the topic ..."* P338 *"...there could be other interpretations in the unit ..."* P137 *"... it's not a term we are familiar with ... it's a new term for something that happens anyway ..."* P2315 "*... differences in understanding is probably a barrier ..."* P3111 *"... as a senior charge nurse my view is more expansive. Junior staff may not know ..."* P431. This demonstrates that generally clinical engagement is not a well-recognised term.

Some participants suggested that this may present a problem, there was a sense that without common understanding of the terminology clinical engagement might not work. Participant 3111 suggested the *"... differences in understanding is probably a barrier ..."* Within unit 3 one participant proposed *"If they don't understand it, they are going to say nothing to do with me."*

Findings by professional groups

There were differences observed in responses across the professional groups with medics and managers perceiving that colleagues would know what the phrase was although they may describe it differently, P2315 said *"... it's not a term we are familiar with."* Among the nurse participants there was a perception that colleagues would probably describe it differently and that some colleagues may not know what the term

referred to, as described by participant 339 *"If they don't understand it they are going to say nothing to do with me."*

Findings by unit group

As it had proved difficult to recruit medical staff in all the units it is not possible to make observations in relation to potential differences between the two types of units.

Selective codes

All open codes were grouped under a single selective code *of "perceptions of others understanding of clinical engagement."*

Links to the system of profound knowledge.

As previously suggested the *"human side of change"* lens relates to the ability to understand how individuals and groups will react to and engage with change. Understanding how colleagues perceive concepts and understanding how their perceptions are different is essential to being able to develop strategies to develop a common goal and direction. It is also important to recognise that Deming highlights the need for any change team to reflect on the values and beliefs held within the team.

By bringing these three concepts together:

1) the ability to understand individual and group reaction to change

2) the ability to understand colleagues' perceptions and how they differ and

3) affording space to reflect on team beliefs and values

I consider the data is indicating the need to developing a collective understanding of the direction of change and activity required to achieve the common goal, I therefore have used this data to support the association of the second lens with this theme – *"building knowledge."*

All participants referred to enablers and barriers during their interviews when discussing perceptions of others, these will be addresses as separate topics.

4.4 Multi-disciplinary team

Findings

The perceptions offered by the participants suggested that staff recognised the need for a multi-disciplinary team as being essential to support quality improvement activity and

to support the development of clinical engagement. This perception was developed as participants all referred to the multi-disciplinary team in response to being asked what they perceive clinical engagement was. I took this to indicate that the establishment of the multidisciplinary team (MDT) was the physical demonstration of clinical engagement. Participants used phrases such as *"... whole team involvement ..."* (P123) and *"... working with your team ... at all levels ..."* (P431). Words frequently used were *"involved"* and *"involvement,"* similarly the word *"team"* was used by all participants.

When asked to describe how the MDT was made up in their unit respondents described a variety of constituent parts; these being depicted in the word cloud illustrated in Figure 17. Using a word cloud[24] allows text data to be quantitatively displayed illustrating for the reader perceived weighting represented by all of the participants individual data sets, the larger the word in the cloud being the most frequently referenced cross the whole group. It can be seen from this that participants referred to the multidisciplinary team as an entity as well as the many constituent parts with nurses and doctors also frequently being cited. Some participants referred to positions within hierarchy as well as professional roles.

Figure 17
Wordle developed from participant responses describing the membership of their multi-disciplinary teams

Findings by professional groups

When reviewing the data there did not appear to be any differences observed between the professional groups and the terminology used.

[24] The word cloud programme uses the frequency of a word appearing in a list of words to assign increased font size for every word appearing. There is no significance to the different text colours.

Findings by unit groups

When looking at this data in relation to the achieving units and not achieving units, it is of interest to note that the participants from the achieving units provided a more detailed description of the multidisciplinary team. For example, the multidisciplinary team was described as more than the traditional nurse / doctor membership – suggesting the inclusion of dietician, physiotherapist and pharmacist in the team. In not achieving units' participants were less likely to be as descriptive of the membership of the multidisciplinary team, although they did describe the need for allied health professionals to be in the MDT. However, it would be inappropriate to propose that this observation represented a relationship, as some participants from Not Achieving units also described the wider multidisciplinary team.

Participants from both types of units indicated that although it was not always possible for the additional professional groups to be physically present during the improvement activity, participants emphasised that the involvement and inclusion of these professional groups in the planning and review of results was something they actively pursued. I consider this also indicates the recognition of the need to include a wider stakeholder group in improvement work as well as clinical activity.

Selective codes

Within this theme there were three selective codes identified, these being "multi-disciplinary team", "team" and "whole team." These were aggregated to a single theme of "multi-disciplinary team"

Links to the system of profound knowledge

Deming refers to the "Human side of change" lens as having knowledge relating to how people as individuals interact with each other and the system within which they work. A fundamental aspect of being able to bring about change requires a group to be able to function as a team, working together towards a common purpose.

4.5 Barriers

Findings

Throughout the interviews with all participants and in all units, it became apparent relatively quickly that participants were able and willing to describe what they perceived to be barriers to securing clinical engagement within their units. In some instances, participants volunteered these reflections unprompted and on other occasions this was a specific question asked during the interview.

Through the iterative process previously described, the open codes were arranged under 11 selective codes which I consider represent participant perceptions of barriers. During analysis it became apparent that these barriers could also be further themed as being 1) "barriers to bringing about change" or 2) "barriers to establishing clinical engagement." These themes will be discussed further.

Barriers to bringing about change

During the analysis phase of this study it became apparent that the barriers and enablers described by participants could be considered as the opposing ends of a continuum. Participants reflected that lack of understanding of the need for change as well as an inability to see the value in improving or in deed understanding the value in the activity as presenting barriers to change. P2315 reflected that colleagues would question why the change was being asked for *"I don't see why, why should we have to start doing that now?"* Perceptions of increased workload were also suggested as a barrier, some participants specifically referred to the quality improvement work being perceived within their units as a *"Tick box exercise."* P137 Specifically in relation to the use of the quality improvement methodology participants perceived that this also presented a barrier for colleagues who did not understand the methodology, P3212 indicating that *"... the Patient Safety Programme itself is a barrier."*

Barriers to establishing clinical engagement

"... inability to get accurate data..." (P412) was offered as a barrier to engagement as well as the perception that *"... you don't know what is going on ... without data."* (P123) Participants also cited "personality" as being a barrier to establishing clinical engagement – with one participant suggested that *"Depending on who is leading it ..."* (P431) will determine the success or otherwise of the improvement / change activity.

Potentially linked to this is the concept of hierarchy with participants suggesting that *"Hierarchy ... preventing success – if senior staff don't like the idea it won't happen"* (P338)

Results relating to professional groups

There were no differences in the barriers described across the professional groups, barriers described by participants can be considered as reflecting strategic and operational level aspects of healthcare delivery. With more senior staff (both nursing and medical) and managers offering reflections at a more strategic level in the units. Junior staff in not achieving units provided a more operational perspective of barriers. Due to the challenge of securing participants in one of the two not achieving units it would be inappropriate to suggest there is a relationship.

Results relating to unit groups

The barriers described by participants were consistent across the two-unit types; there was a rich description of barriers offered by participants in all four units. I consider it is therefore appropriate to suggest staff are aware of barriers no matter irrespective of being in an achieving unit or a not achieving unit.

Selective codes

Participants were able to identify several barriers to both bringing about change as well as establishing clinical engagement. Comparing Table 7 to Table 5 nearly twice as many barriers were identified than enablers.

Selective codes	Themes
Lack of understanding	Barriers to bringing about change
Not seeing the value	
Increased workload	
Staffing resource	
Tick box exercise	
QI approach	
Hierarchy / authority	Barriers to establishing clinical engagement
Personal attributes	
Scepticism	
Negative data perspective	
Tick box exercise	

Table 77

Table detailing the selective codes and themes associated with the category of Barrier.

Links to the system of profound knowledge

During conversation with participants it became apparent that barriers to change and establishing clinical engagement were aspects that were met on a regular basis. Participants were able to articulate these barriers readily; of interest one participant took care to indicate that these were hypothetical suggestions and did not reflect the situation in her unit. Yet, another participant from the same unit described similar barriers as being present in their unit. Table 8 sets out the selective codes and themes aligned with this category and how they relate to the system of profound knowledge.

Selective code	System of Profound knowledge	Themes
Lack of understanding	Building knowledge Understanding variation	Barrier to bringing about change
Not seeing the value	Building knowledge Human side of change	
Increased workload	Human side of change	
Staffing resource		
Tick box exercise	Human side of change	
QI approach	Building knowledge	
Hierarchy / authority	Human side of change	Barrier to establishing clinical engagement
Personal attributes	Human side of change	
Scepticism	Building knowledge Understanding variation Human side of change	
Negative data perspective	Understanding variation	
Tick box exercise	Building knowledge Understanding variation	

Table 8
Table detailing the selective codes, system of profound knowledge and themes aligned with the category of Barriers

4.6 Enablers

Findings

Participants identified enablers across all units, and these were located under two themes – 1) "enablers to bringing about change" and 2) "enablers to establishing clinical engagement".

Enablers to bringing about change

Participants described enablers as being activities which were needed in relation to change; using phrases such as *"... embedded in practice..."* (P431) and *"... now it's done properly and reliably ..."* (P3212) when referring to the implementation of the VAP

prevention bundle in their units[25]. Other participants referred to the team needing *"... to know what the implications are for the patient."* (P134). Participants also indicated that providing and having access to data and measurement to demonstrate improvement was vital to enabling change, referring to having *"...evidence..."* (P123) of improvement as well as allowing others to see *"... the difference it was making..."* (P137) and using the *"... display of data ..."* being *"... really clear and positive reinforcement ..."* (P2315). Another aspect perceived by participants as an enabler to bringing about change is the development or facilitation of "champion" roles – P3310 described how *"Champions are needed to get the change out there ..."*

Enablers to establishing clinical engagement

Through the iterative data analysis process, I began to identify a second aspect of enablers which I have assigned as a theme of enablers to establishing clinical engagement. These activities could be described as enablers to implementing the VAP prevention bundle, however when speaking with participants it became apparent that these were more generic activities being described. Some participants specifically called these out as being required for clinical engagement – P134 indicated *"... that you need to know what you are dealing with."* Other participants referred to *"... leadership required to keep the work moving"* (P3113) and P431 refers to *"... key people who lead the work." "... part of the practice and culture in the unit"* P2315, "*... get it into everyday practice ... get it into medicine kardex, and stuff like that, make a checklist"* P137 *"It's part of the ward round we do every day..."* P134

Finding by professional groups

Again, as with other categories there were not differences in the findings between the professional groups, however all doctors referred to the need for data and the benefit of having *"good quality"* data available to engage colleagues in the improvement activity. Nurses who had a managerial role also referred to data as being an important aspect of establishing engagement with the improvement activity also emphasising the need to provide medical colleagues with the "evidence" to support clinical engagement.

Findings by unit type

As has been previously identified there were no differences between the enablers described by the two different unit types. In achieving units staff perceived that

[25] Introduced in My Reflection 2 and available in Appendix 6

colleagues recognised that improvement was required to improve outcomes for patients in their care. This was not observed in the perceptions offered by participants from the not achieving units.

Selective coding

Under the theme of enablers there were several selective codes identified, Table 9 illustrates how the selective codes have been assigned between the two themes. Of note selective code "knowledge and understanding" was determined to belong under both themes identified with Enablers.

Selective codes	Themes
Location of change	Enablers to bringing about change
Knowledge & understanding	
Champions of the change	
Positive data perspective	
Recognising leadership	Enablers to establishing clinical engagement
Communication	
Knowledge & understanding	

Table 9
Table detailing the selective codes and themes associated with the category of Enablers

Links to the system of profound knowledge

Establishing enablers to change and establishing clinical engagement requires good understanding of the "human side of change"; understanding what drives people and what encourages them to participate in change is a fundamental aspect of change theory. As a result, all the selective codes associated with the category of Enablers are considered to link with the human side of change lens as detailed in Table 10. In addition, the selective code "positive data perspective" has been aligned with the "understanding variation" lens too, as this is a specific aspect of understanding the theory behind the model for improvement. It can also be seen that most of the selective codes have also been aligned with the "building knowledge" lens – this as with other categories reflects the need for teams undertaking improvement and change activity to develop their own knowledge of how to engage people. There is also a need to understand what activities do and don't support change. Deming refers to building knowledge specifically in relation to trying out change within practice, however in his definition he indicates that the more knowledge about a system under consideration the greater the likelihood for success.

Selective codes	Themes	System of profound knowledge
Location of change	Enablers to bringing about change	Building knowledge Human side of change
Knowledge & understanding		Building knowledge Human side of change
Champions of the change		Building knowledge Human side of change
Positive data perspective		Building knowledge Understanding variation Human side of change
Recognising leadership	Enablers to establishing clinical engagement	Human side of change
Communication		Human side of change
Knowledge & understanding		Building knowledge Human side of change

Table 10
Table detailing the selective codes, themes and system of profound knowledge aligned with the category of Enablers

4.7 Person dependency

Findings

Person dependency was described explicitly by some respondents and referred to implicitly by other. There were two types of person dependency described by participants:

1. relating to the improvement work being dependent on an individual or a defined group of individuals and
2. relating to the individual or professional group level of willingness to engage with the improvement activity.

Findings by professional groups

Doctors commonly reflected that the majority of the practical work – clinical activity involved in bringing about the improvement involved the nursing group and that it was commonly the nurses who would prompt their medical colleagues to remember to do specific activities. I consider this to be a form of person dependency as the activity may not be undertaken without the prompt from the nursing staff.

Nurses also reflected that much of the practical activity fell to the nursing group to drive forward as much of the changes to patient care required to implement the VAP prevention bundle were direct nursing care activities (Appendix 8).

Senior manager participants did not reflect the differences in the professional groups and did not refer to the perceived split in activity referred to by the doctor and nurse respondents. However, those managers who had both clinical and managerial responsibilities did make reference to the split in activity between nursing and medical teams: P421 making direct reference to the fact that the *"... work is driven by the SCN[26]..."* and *"... improvement is principally down the SCN ..."* This response highlights both the individual person dependency often inherent in quality improvement as well as the professional group dependency already identified with nurses providing a prompt for the doctor to undertake an activity as described earlier.

Findings by unit group.

Person dependency was referred to explicitly in units 3 & 4 which are not achieving units, with participants using phrases such as *"I lead the work and share with the Band 6 nurses what we are doing..."* (P431) this reference relates to the example above where the senior manager has called out the fact that "... *improvement is principally down the SCN ..."* Similarly, within unit 3 participants reflected that the secondment opportunity offered to nurse A where *"...she devised the work and encouraged others to participate ..."* (P338) suggests that person dependency existed within both units in relation to establishing engagement with the work required as well as bringing about the improvements in patient care.

Participants in unit 3 & 4 also shared observations relating to colleagues' personal attributes, with references made that *" ... individual personalities affect adoption of change."* (P3212) Other phrases shared suggested that the person leading the activity / change / improvement needed to the *"liked"* if it was to be successful. Other examples of person dependency offered by participants:

"The work is driven by the SCN" P412 and yet the same participant suggests that *"... processes become person dependent"* P412. Personal traits are also noted to drive person dependency *"... individual personalities affect adoption of change"* P3212 and again in unit 4 participant P412 offers that the success observed in the unit is *"... principally down to the SCN, who is commendable ..."* P412

[26] Senior charge nurse

For units 1 & 2, which are achieving units, there were no examples of person dependency shared during the interviews although it was a topic explored. Participants from units 1 & 2 did not refer to person dependent nor did they refer to personal traits in relation to improvement activity or change.

Selective codes

For this theme there was a single selective code developed – this being person dependency.

Links to the System of profound knowledge

This theme has been linked with "Building knowledge" and "Human side of change" lens of profound knowledge.

4.8 Language

> *My reflection: 9* ***Category Development***
>
> *This has been a difficult category to define and to even decide if it truly is a category.*
>
> *There have been several iterations of this category name examples of previous category titles are: "language used to refer to each other" and "colleague reference". I have decided to use the single word "Language" as the category name as it feels to me to be the most unambiguous word to use - I perceive that other phrases would require definition and may over complicate the message I am trying to convey through this work.*
>
> *I have also considered if it was a part of the person dependency category already described in the findings. However, on reflection and following conversations with colleagues also working in the field of Quality Improvement I have decided to make Language a category in its own right.*

Findings

This category only became apparent to me after undertaking all of the interviews and during the continued data analysis phase; occurring more as a reflection during a conversation with a colleague on a work-related topic when the idea occurred to me to review the transcripts to see if it was something I had missed in my analysis. Revisiting the transcripts, I noted the following comments made by participants:

Achieving units

"... once we saw the difference it was making ..." P137 *"As a team, we talk about the things we need to do to improve patient care".* P2218

"We work together to implement the improvement work" P2315 and *"... as a group having the opportunity to talk about proposed change"* P 2315 *"Understanding why we are implementing change and agree a way forward"* P2118

Not achieving units

"Depending on who is leading it will bring other people along" P338 *"They don't always do as they are told ..."* P3310 *"It's up to us, the QI team to do the improvement work ..."* P3111 *"I am the SPSP lead clinician so am personally invested in the work"* P 3212 *"I lead the work in the unit and share with the Band 6 nurses what we are going to do ..."* P431 and *"They see it as my role ..."* P431

Findings by professional group

The language used by nursing respondents when referring to their professional peers as well as their clinical peers i.e. medical peers appears to indicate that there was a difference in perception between the professional groups. Some nurses made the distinction between colleagues engaged in improvement activity and those not engaged by using the terms "them" and "us"; where "them" appeared to refer to colleagues who were not participating / engaging in the improvement activity. This observation was not made on reviewing medical or managerial transcriptions.

Findings by unit group

Reviewing the transcripts by unit group identified a difference in the language used in achieving units compared to not achieving units.

In Achieving unit's language was more reflective of collaborative working with participants referring to team working, working together to find solutions to challenges and staff describing being listened to and considered when offering ideas.

In not achieving units the language seemed to indicate high levels of person dependency as well as perceptions of "*them"* and *"us"* as described above.

Selective codes

The selective codes identified for this category are "Them & Us" and "Collective," with collective being used to describe the collaborative culture described by participants.

Links to the system of profound knowledge

The theme of language has been linked with the "human side of change" lens of profound knowledge.

4.9 Selective codes and System of Profound knowledge

To link the data back to the methodology utilised by the Scottish Patient Safety Programme (SPSP) to reduce ventilator associated pneumonia (VAP) and implement the VAP prevention bundle, the results in Appendix 32 also includes a column indicting which of the Lens of Profound Knowledge I consider each of the selective codes are relating to. Table 11 provides this detail in a single table to facilitate reading.

Selective codes	**Links to System of profound knowledge**		
On board	Building knowledge	Human side of change	
Aware of need to improve	Building knowledge	Human side of change	
Collective / collaborative	Human side of change		
Ownership	Human side of change		
Perceived by other colleagues	Building knowledge	Human side of change	
Multi-disciplinary team / team / whole team	Human side of change		
Lack of understanding	Building knowledge Understanding variation	Understanding variation	
Not seeing the value	Building knowledge	Human side of change	
Increased workload	Human side of change		
Staffing resource			
Tick box exercise	Human side of change		
QI approach	Building knowledge		
Location of change	Building knowledge	Human side of change	
Knowledge / understanding	Building knowledge	Human side of change	
Champions of the change	Building knowledge	Human side of change	
Positive data perspective	Building knowledge	Human side of change	Understanding variation
Hierarchy / authority	Human side of change		
Personal attributes	Human side of change		
Scepticism	Building knowledge	Human side of change	Understanding variation
Negative data perspective	Understanding variation		
Tick box exercise	Building knowledge	Understanding variation	
Recognised leadership	Human side of change		
Communication	Human side of change		
Knowledge / understanding	Building knowledge	Human side of change	
Person dependency	Building knowledge	Human side of change	
Them & Us	Human side of change		
Collective	Human side of change		

Table 11

Selective codes and associated System of Profound Knowledge categories

As described in *Chapter 3 Quality Assurance*; I shared Table 11 with two colleagues I work with on a regular basis and a study participant, who I consider have a good working knowledge of the system of profound knowledge. The considerations from these opportunities are included in Appendix 29.
Collating all the selective codes and system of profound knowledge as illustrated in Table 11 reveals that the clear majority of the codes aligned with *"Building knowledge"* (14) and *"Human side of change"* (22) and 5 codes being aligned with *"Understanding variation."* Some of the selective codes have been aligned with single lenses (13) while other codes have been aligned with 2 or 3 codes.
As the selective codes are associated with these three lenses it is not possible from this study to suggest that the absence or representation of any specific lenses can be used as indicators of achieving / not achieving the improved VAP outcome for patients or establishing clinical engagement.

I did not recognise until I was well into the write-up phase and created Appendix 33, that only three of the four lenses were represented by the selective coding and lens alignment, it was only at this point that I realised that I had not aligned the *"Appreciation of the system"* lens with any of the selective codes identified. On recognising this I went back to my data and reviewed all the transcripts to see if there were examples where participants had shared perspectives which could be aligned to this lens. Within the data I was able to identify single examples where four participants had described an understanding of / or reference to the wider systems within which they operated and that this may have an impact on their ability to deliver the reductions in VAP rates sought by SPSP. The participants who had made these observations were from Unit 4, 3 and 2. They were two senior nursing managers, one doctor and one service manager.

From the data analysis carried out there is no difference in the lenses aligned to the selective codes identified across the two-unit types. This may be for several reasons including:

- the lenses themselves being too broad in their descriptions and therefore created a catch all situation where selective codes representing both the relative positive and negative stance could be aligned under all of them,

- the participant group being relatively narrow in nature and
- the proxy measure used to identify the two-unit types not being the correct measure.

These reasons will be explored further within the discussion section of this paper.
As a result of this piece of work it is possible to provide much more context in relation to the lenses when considering staff perceptions of establishing clinical engagement within intensive care settings in Scottish hospital.
Figure 18 has been developed to provide this greater understanding which has been developed from this study[27].

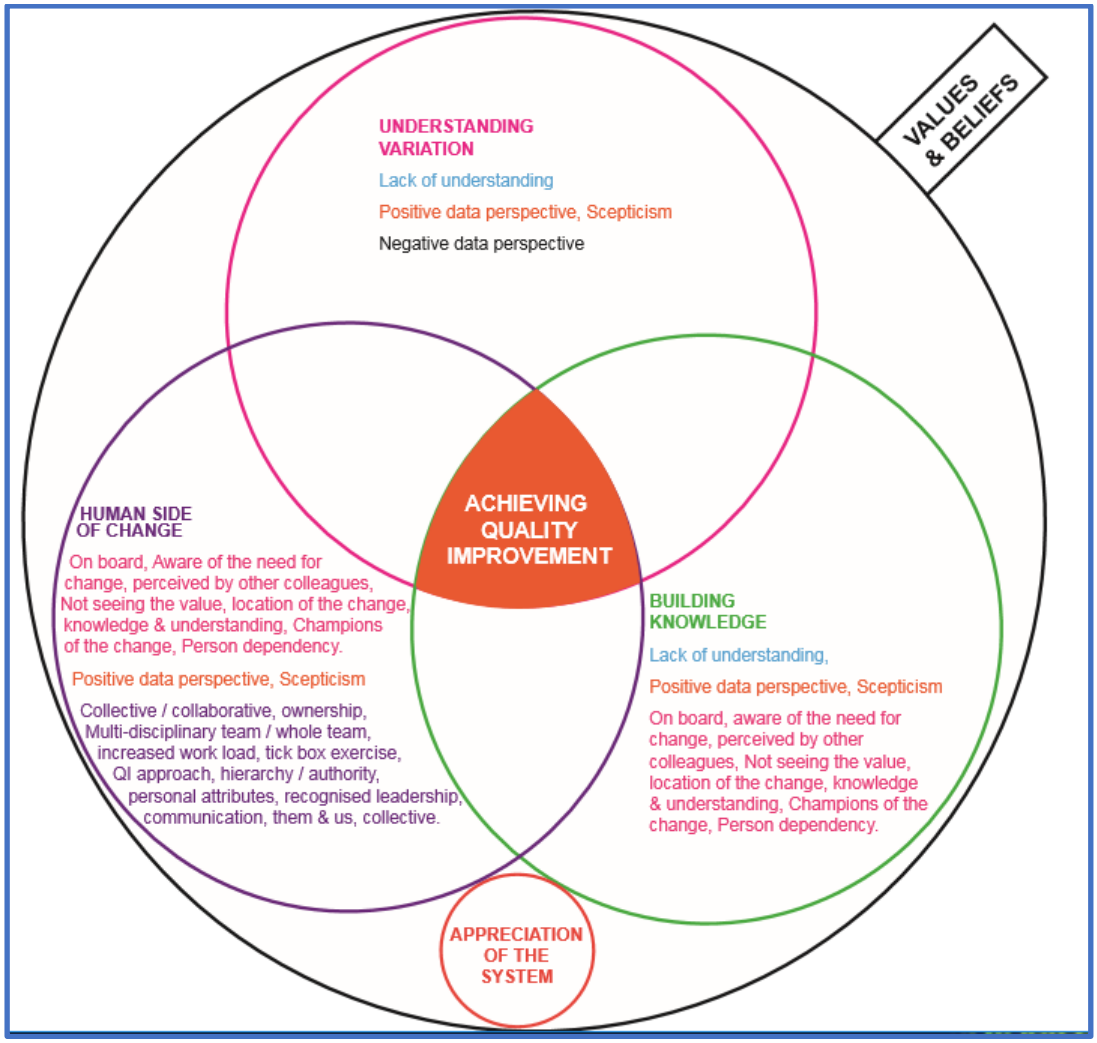


Figure 18
Diagram illustrating the relationship between selective codes and the system of profound knowledge

[27] The colour coding within the diagram has been developed to facilitate the reader to understand which selective codes are located within multiple lenses. For example, the blue text "Lack of understand" appears within both Understanding Variation Lens and Building Knowledge but not the Human side of change lens.

4.10 Categories and core categories

Figure 19
Graphical illustration of the core categories developed from this grounded theory study.

Figure 19 has also been developed to illustrate the relationship of the categories and core categories identified from the interviews undertaken. From the seven categories identified and described in the finding above there were two core categories created. These are:

- Clinical engagement and
- Cultural indicators

The core category named "Clinical engagement" is considered to include perceptions of 1) **clinical engagement**, 2) descriptions of the **multi-disciplinary team**, 3) **perceptions of** how **others** understand clinical engagement, 4) **enablers** and 5) **barriers** to establishing clinical engagement as well as bringing about change and 7) evidence of **person dependency** within improvement activity. These aspects of establishing clinical engagement were perceived and described across both achieving and not achieving units. However, there were differences in the descriptions relating to 1) enablers and 2) barriers, 3) person dependency and the 4) language used to refer to colleagues between the two-unit types. Enablers were more likely to be referred to in achieving units and barriers were more likely to be referred to in not achieving units. Person dependency was explicitly referenced in not achieving units, while participants in achieving units did not refer to person dependency.

It is important to note that although Figure 19 currently illustrates the arrows of equal weight, from these findings it is not possible, and it would be inappropriate to suggest this is the case. Further study would be required to explore the weighting of the arrows and the potential influence of each core category.

While the core category named "Cultural indicator" has a single category of language, with language specifically referring to the terms used by participants to describe colleagues within their units. Participants from achieving units used collective and inclusive terminology when referring to colleagues. While participants in not achieving units used terminology which suggested a less cohesive team.

As an explicit output of this study I have developed a definition of clinical engagement, using the selective codes identified in this study to guide this definition:

> **Clinical engagement is the need for the multi-disciplinary team to develop a shared understanding and have ownership of the need for improvement. To be working together to enhance enablers and address barriers in relation to implementing quality improvement methodology.**

I would propose that this definition be tested with the critical care community to establish whether it is appropriate and has meaning for them to be able use in practice.

To support this combining Figure 18 and Figure 19 it is possible to provide examples from participant responses of activities and understanding of quality improvement within the context of the system of profound knowledge as well as the relationship with the identified categories and core categories needed to establish clinical engagement. The development of the combined diagram illustrated in Diagram 20[28] provides detail of the context within which staff in Scottish Intensive care units understand and perceive clinical engagement. This detail has been incorporated into the system of profound knowledge to offer more healthcare related context for practitioners working with the model for improvement generally and the system of profound knowledge specifically.

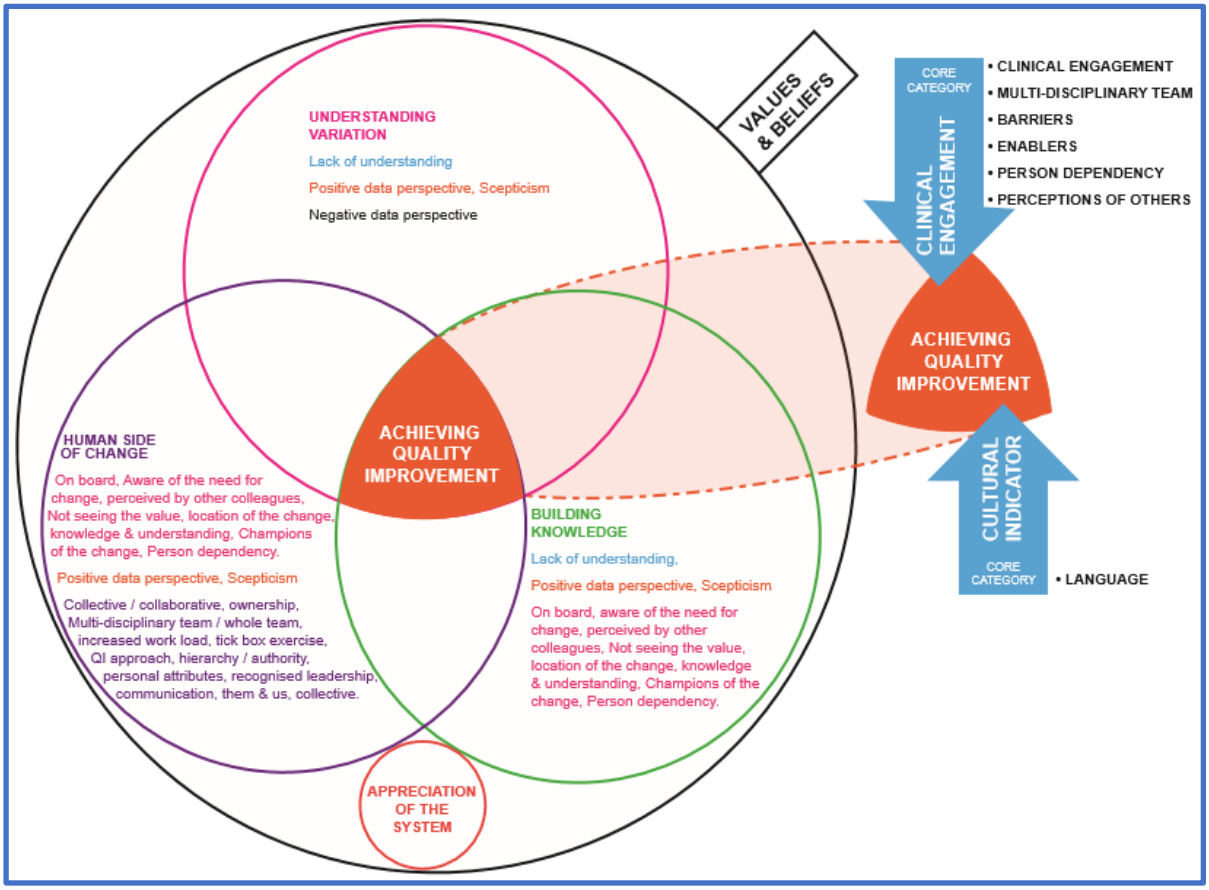


Figure 20
Illustration of the system of profound knowledge, the relationship with the selective codes identified and the connection with the identified categories and core categories related to achieving quality improvement.

[28] Colour has been used in the same way in this diagram as in Figure 18

4.11 Achieving the Ventilator Associated Pneumonia (VAP) aim

Ventilator associated pneumonia (VAP) rates were used to support theoretical sampling for this study, using the VAP rates reported by units via the IHI Extranet. When considering the categories identified and their relation to the two-unit types as represented in the Figure 21 it is possible to begin to develop understanding of the differences between the units.

Participants from both unit types perceived clinical engagement, the multi-disciplinary team and how other perceived clinical engagement in similar terms. The differences between the two-unit types were observed in the responses relating to person dependency, enablers and barriers to establishing clinical engagement and enablers and barriers to bringing about change as well as the language used when referring to colleagues. In the achieving units' participants did not refer to person dependency and they were more likely to describe enablers to establishing clinical engagement and bringing about change. In addition, participants in achieving units referred to colleagues in collegiate terms referring to "we" and "the team," while nursing participants in not achieving units referred to colleagues as "them."

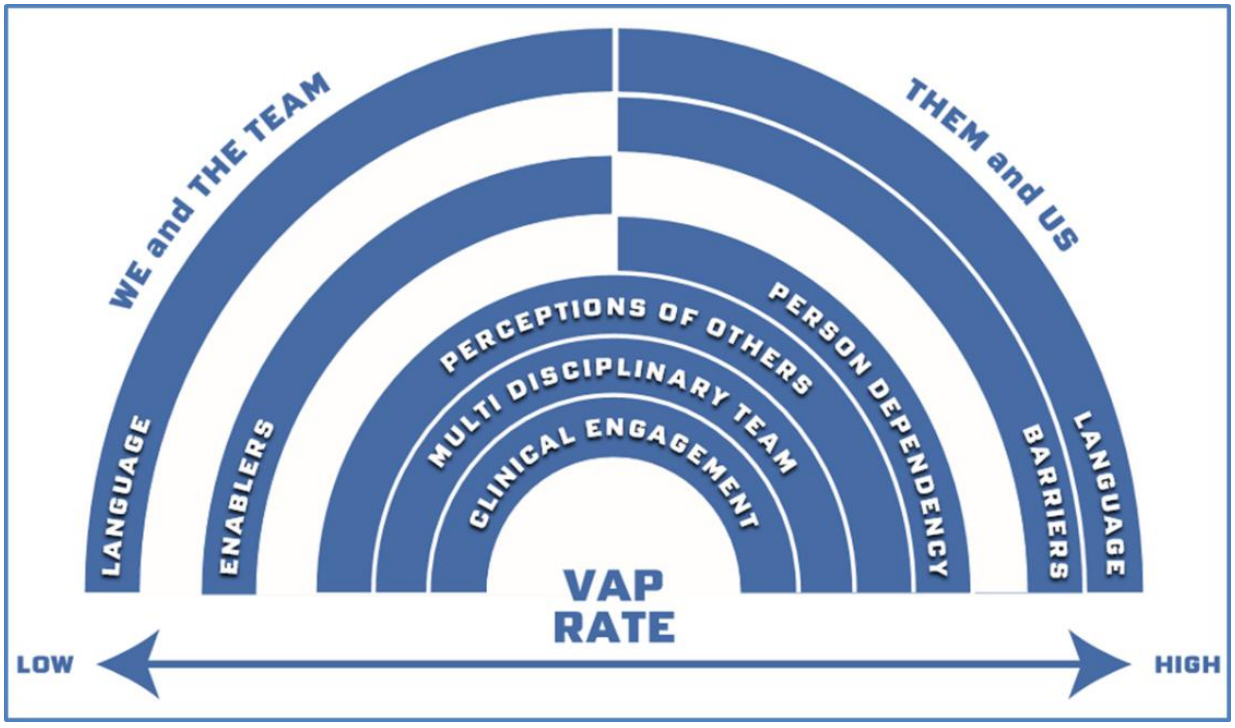


Figure 21
Diagram of the relationship between categories and the unit VAP rates

4.12 Other reflections from the findings.

Leadership

Although leadership was an aspect explored during the interviews this was not, as previously indicated in the introduction of this section, a selective code explicitly identified in the data analysis, although it was referred to by several participants. As leadership was an aspect which had been identified during early reading round the topic of quality improvement, I do consider it to be prudent to include the topic in the findings of this study. Figure 9 has already been included in this findings section as an example of "early selective code development."

This will be explored further in the discussion section as a separate section exploring the concept of leadership in relation to the wider topic of improvement and change.

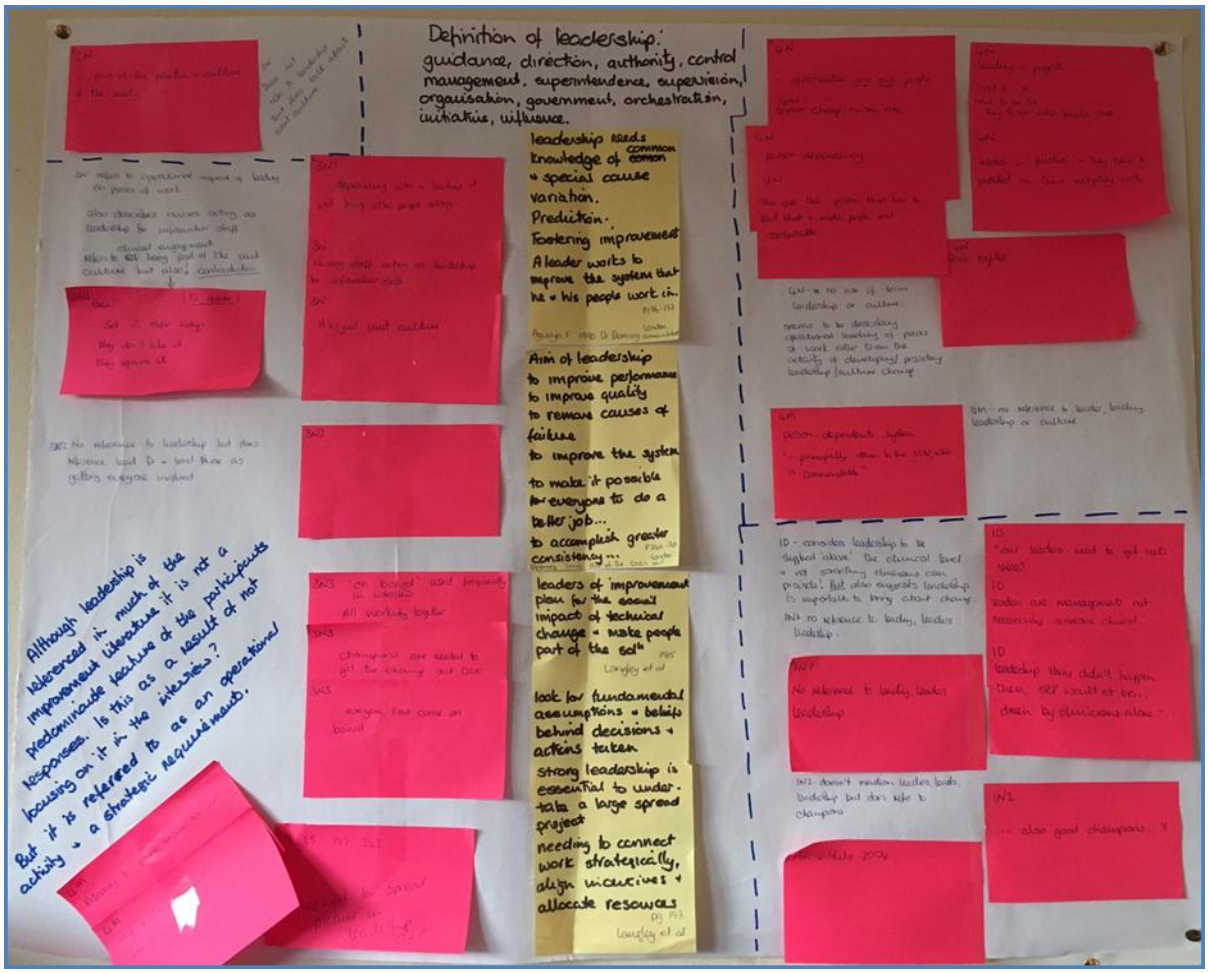


Figure 9
Early development of selective coding (pink) and associated memos (yellow) and linking with available evidence to support theory building.

Participants who did refer to leadership in their interviews used the term interchangeably when referring to culture. The roles assumed to be encompassed by leadership included the induction of unfamiliar staff into the unit practices and getting everyone on board with the improvement activity. However, there were different perceptions of what leadership constituted from acting as a champion for the improvement work to providing senior management leadership. I consider Leadership to therefore represent both a noun and verb for participants, by this I mean that it was a label for a role within hierarchy but also an activity which anyone within the team could assume.

4.13 Summary

From the evidence provided has it been possible to answering the research questions posed in this study?

In relation to question one: *How different staff groups working in intensive care units describe clinical engagement?* Staff across the four units used the same terms and phrases to describe clinical engagement. All three staff groups, nursing, medical and managerial, used the same terminology when referring to clinical engagement. There was consensus that clinical engagement related to all staff groups providing care in the intensive care units. Where participants were familiar with the term "clinical engagement" they recognised that the literature often relating to engaging medical staff only. Participants in units 1, 3 & 4 referred to the importance of getting medical engagement to progress quality improvement activity, and participants in units 3 & 4 perceived that this was important to achieve the SPSP VAP aim. Participants in Unit 1, 2 & 3 described establishing clinical engagement as an active process, while participants in Unit 4 suggested that having staff participate in improvement activity was sufficient.

Research question 2 posed the question: what is "*The influence of clinical engagement on implementing quality improvement*?" As described above, staff from all four units described clinical engagement in similar terms. The differences between the achieving and non-achieving units related to the enablers and barriers described. Participants from non-achieving units described barriers rather than enablers to establishing clinical engagement, this group of staff also used less inclusive language when referring to colleagues and identified person-dependencies within the quality improvement teams.

Chapter 5 Discussion

The purpose of this study is to explore the perceptions of staff working in Scottish intensive care units in relation to establishing clinical engagement supporting the implementation of quality improvement methodology. This next chapter will discuss the findings and how they relate to existing knowledge and understanding of the topic areas.

5.1 Selective codes, Categories and Core Categories and the System of Profound Knowledge

It could be argued that the categories and core categories identified in the findings section do not present any further knowledge to the field of quality improvement in relation to achieving improved patient care in critical care settings. However, I would claim that there has been new knowledge generated here, particularly when considering Table 5 representing the *"Table of findings, summarising the selective codes, themes, categories and core categories."* Reflecting on the conclusions from the context factors literature review I would propose that the selective codes are how the participants describe the context / context factors they are encountering. I have also assigned context factor labels to the aggregated selective codes, following this line of thinking the categories would then be considered as high-level context factors. As a result, it is now possible to begin to articulate how clinical engagement as a context factor is perceived by practicing clinicians and managers within the Scottish critical care setting and how important clinicians perceive clinical engagement is to achieving improvement.

Deming's system of profound knowledge is cited as one of the fundamental blocks on which the model for improvement is built, indeed much of the teaching for quality improvement capacity and capability building in Scotland is based around model for improvement and in some course the four lenses. The detail in "*The Improvement Guide*" (Langley et al 2009) provides some guidance on the system of profound knowledge but provides little details for quality improvement practitioners or clinical staff to help them understand the context(s) relating to the individual lenses. It is also not evident from *"The Improvement Guide"* or texts describing the model for improvement, if the four lenses are equally weighted, or which order they should be addressed when commencing quality improvement activity. Langley et al (2009) do refer to there being a

synergistic effect between the lenses and that they must all be addressed at some point during improvement activity to secure reliable and sustained improvement. In addition, there is no reference in the literature presented relating to context / context factors and the link to the system of profound knowledge. Although Kringos et al (2015) do link the context literature to the MUSIQ tool, there is again no explicit link to the system of profound knowledge in their paper.

So; what has this study added to the existing knowledge?

From the findings presented in this study I have reconstructed the traditional illustration of the system of profound knowledge – Figure 20 - using the selective codes identified in the data analysis phase to provide representation of staff perceptions in Scottish intensive care units of their understanding and contextualisation of clinical engagement in relation to quality improvement. It is now possible to provide practical healthcare related examples of how clinical engagement supports improvement activity. Perhaps most importantly from this study it is also possible to articulate the importance of cultural indicators to understanding why teams may not be achieving the result they would like.

The cultural indicator identified in this study is the use of language among the clinical team members. With collegiate language being observed in the achieving units and terms suggesting less cohesion observed in the non-achieving units. Culture is frequently cited in change management and quality improvement literature, Kotter (1978), Senge (2006) and Heskett (2012) being just three for examples, as being an important predictor of successful improvement activity. Kaplan et al (2010) and Kaplan et al (2012) in their MUSIQ tool assessing readiness for engagement with quality improvement activity also highlight the importance of understanding team culture. However, as with many other aspects of quality improvement there is not concrete examples of what to measure and determine the quality of the culture within the team. What has been highlighted in this study is the possibility of determining team culture by listening to the words used among the team members.

5.2 Clinical engagement

Within the clinical engagement literature there has been recognition that establishing engagement is essential for driving improvement in any aspect of healthcare improvement (Dixon-Wood et al 2013). With the literature commonly focused on the need to establish engagement within the medical profession, citing clinical engagement

as one of the most important aspects of quality improvement. The literature neglects to reflect or consider the need to engage with other professional groups who are involved in improvement activity. This focus was commonly explained in the literature by stating that without having doctors engaged then quality improvement activity would not happen. For example, Reinertsen et al (2007) encourage the use of a "*Physician engagement difficulty assessment"* tool with the sole purpose of determining how difficult it will be to engage physicians in improvement activities. This was in relation to multi-professional improvement projects and proposed that without medical engagement there was reduced likelihood of change being achieved. This influential role played by medical staff in the success or otherwise of improvement was also reflected in responses from participants in Unit 3 of this study.

Yet, the questions posed in the Reinertsen assessment tool reflect the questions any improvement team should be considering and asking in relation to the theoretic concepts posed by the system of profound knowledge and in particular when thinking about the "human side of change" lens. I would propose therefore despite the previous focus being solely on medical engagement this study suggests similar issues are consistently identified across the wider multi-professional group – thus one of the contributions of this study is the wider application of assessment tools to evaluate engagement levels. Lyndon and Cape (2017) are clear that developing a sense of ownership and inclusion across all professional groups involved in improvement and specifically highlight clinical engagement as a mechanism to achieve this.

Participants reflected that achieving reduced VAP rates is only possible if clinical engagement was established in their units across the multi-disciplinary team. From the findings drawn from this study I would propose that focusing only on engaging medical staff at the expense and potential exclusion of other professional groups could be creating or reinforcing barriers to establishing clinical engagement. Parand et al (2010) allude to this in their review of medical engagement in the Safer Patient Initiative but do not expand. All participants in this study irrespective of their professional group referred to the need to get colleagues and members of other professional groups on board with the required improvement work and that this is best achieved by generating a shared purpose and ownership of the work. This is frequently referred to in change management text as creating a shared vision, Kotter (2012) in his writing about

developing a guiding coalition to lead change emphasises the important of a shared vision to ensure the group knows collectively where they are going.
When talking about clinical engagement and activities which helped to establish it, participants referred to the concept of "*onboarding"* – this was a specific phrase used by participants in three of the four participating units. *"Onboarding"* is described as activities specifically intended to induct or assimilate new employees into the organisation (HIS 2015). Participants in this study referred to *"onboarding"* as an activity undertaken by improvement *"champions"* or people involved in the improvement work to encourage other members of staff in all staff groups to participate and engage in the improvement work. *On-boarding* is also an explicit activity undertaken by the Clinical Directorate within HIS and when working with partner organisations both in healthcare settings and beyond into social care settings. The explicit purpose of *on-boarding* for HIS is to develop a sustainable infrastructure to ensure the effective use of improvement methodology (HIS 2015).
Although, not all participants used the specific term "onboarding" in their descriptions of activities intended to engage people in the improvement work, participants did make references to / described / reflected actions to actively engage others in the improvement work. These actions and activities were considered as important to establishing clinical engagement especially among staff who appeared to be less inclined to participate in the improvement activity. Kringo et al (2010) highlight this in relation to the use of the MUSIQ tool to understand context and readiness for change. While Weiner (2009) although not specifically using the term "on boarding" does acknowledge the importance of engaging everyone in the preparatory stages of change. This would suggest that establishing clinical engagement requires a pro-active approach with the team making decisions about how to and perhaps more importantly who to "target" in their engagement activity.

Other definitions of *"onboarding"* include reference to organisational socialisation of individuals, often referred to as inducting new members to the team or organisation. The literature relating to this topic however, suggests that rather than merely being the induction of new members of staff this is in fact an on-going activity involving the reinforcement of values, beliefs and patterns of behaviours for the entire staff group. Chao et al (1994) reflect that organisational socialisation offers the individual the

opportunity to appreciate the values, abilities and expected behaviours essential in assuming the role with the team. This thinking also fits well into the concept of organisational culture. Schein in 1985 suggested that organisational culture was developed and maintained by the leadership and it is the unique talent of the leader to work with the culture. However, this reliance on the leader to establish and maintain the organisational culture is not recognised by Priola and Hurrell (2011) who indicate that culture is associated with the beliefs, values, meanings and expectations shared and developed by the members of the team or organisation. The development of the organisational culture although a social construct is a result of both formal processes related to structure and rule as well as informal ways of acting and behaving (Hester et al 2013). The structures and rules are utilised to define and orientate the members of the organisation to understand where the power and influence lies and are commonly defined by the executive / strategic team within the organisation or sub-unit of the organisation. Individual members of the organisation contribute to the development of the culture within the organisations and are observable in the actions and behaviours displayed within the organisation. From their research, Chao et al (1994) found that existing employees are more likely to demonstrate organisational cultures and values, they are therefore providing role model examples for new members of staff to understand what is expected of them and to become socialised into the organisational culture. However, if the organisational culture, values and beliefs are not made explicit and shared; this role modelling may be counterproductive in socialising staff. Scammell (2018) indicates that there can be a mismatch between what individuals and organisation says they do and what is observed in practice. A further influencer in establishing staff commitment to a task, particularly if it requires a change in existing practice is related to the perception of staff that the task / change reflects their own personal values and beliefs. Staff must perceive a vested interest and understand what is in it for them to commit to the task in hand (Kotter, 2012).

The question I am left with having reviewed literature relating to context, context factors and clinical engagement is where does one concept end and the other start? I am struck by the similarities in the evidence presented in the literature and the perceptions of participating staff that clinical engagement should be considered an influential context factor.

5.3 Multi-disciplinary team and Teamwork

When considering the multidisciplinary team and clinical engagement "team working", "team work" and "the team" were regularly referred to by all participants, and this is reflected in the healthcare literature with multidisciplinary team and team work[29] being frequently cited keyword when considering change within health care environments and beyond. Shared vision and participant willingness and confidence in change were all aspects highlighted within the literature relating to context (Wiener 2009: Powell et al, 2009: Parand et al 2010: Taylor et al 2011) as well as the clinical engagement literature (Neale et al 2007: Detwiller and Petillion 2014: Jeffs et al 2018). Change cannot be achieved by one individual; Kotter (2012) suggests that it is not possible for one person to be able to generate the ideal conditions to support transformational change. It is not likely that they can develop the vision and communicate it to large numbers of people, as well as remove the obstacles, generate short-term wins and embed the new way of working within the organisation culture. Kotter advocates that building a team with the correct multi-disciplinary composition, adequate levels of trust and a shared goal are essential to bring about transformational change. Taylor et al (2011) in their reporting from the expert panel highlighted the importance of leadership and teamwork specifically as important context in relation to quality improvement although they are unable to causally relate this to outcomes of improvement work.

The concept of effective team working is regularly cited within change management and organisational culture literature as being the fundamental component to support successful and sustained improvement no matter where and what improvement is required. Lancaster (1999) describes the requirements for organisational change; stating that effective teams are the fundamental learning unit of the organisation; with effective teams being linked to the development of high performing organisations. This anecdotal description offered by Lancaster is shared and expanded by Vincent (2010) in his *"Patient Safety"* textbook. Vincent describes the healthcare teams required for the delivery of safe high-quality care, proposing that the group of individuals considered as a team not only have to have a shared common goal but also defined tasks within the

[29] For this paper "teamwork" will be used to represent team working, teamwork and the team within this chapter.

team and that they will only achieve their goal through interdependent and co-operative working.

Lee (2004) refers to the need for an effective team to drive change and improvement more than 100 times in his text: *"If Disney ran your hospital."* Lee refers to the dispiriting effect of poor team performance, negativity and uninspiring leadership being related to levels of low morale. Similarly, Kornacki and Silverskin (2012) include the effective team as being one of five levers required to lead physicians through change.

The concept of team working and multidisciplinary team working is not new to healthcare delivery and I have developed an illustration of the typical geographic reach of each team within a typical hospital setting, provided in Figure 22. Increasing circle size inferring increased geographic reach across the hospital system but not necessarily patient related workload for each profession.

- the nursing teams, which incorporate the nurses designated for the ward or unit
- the medical team again designated usually for a department incorporating several wards and
- the allied health professional (AHP) teams who can work at department level or at hospital team level.

Figure 22
Illustration of the geographic clinical dispersion of the different teams providing care within an acute hospital setting.

Due to this difference in professional groups reach and the need to provide 24-hour patient care seven days a week it is not possible to have the same people working

together daily. Vincent (2010) suggests therefore it may be that some healthcare delivery teams are no more than a group of individuals brought together by chance; with the off duty acting as the selection process – potentially resulting in ineffective teams. Indeed, this was an aspect to establishing the effective team referred to by participants. One participant described how they found it challenging to have a dietician included in the ward round due to their reduced numbers within the board. Still, the team had developed mechanisms to ensure that the dietician team were involved in the patient ward round as well as the improvement activity required to implement the VAP prevention bundle. Similarly, two participants reflected that engaging physiotherapy colleagues represented a similar challenge in their board. These professional groups are not as well represented on the word cloud and this geographic reach described by Lancaster and illustrated in Figure 22 may go some way to explain why this is.

Within the nursing and medical literature there is a considerable volume of evidence relating to the need for effective teams and indeed the use of multidisciplinary teams to facilitate quality improvement activity and bring about effective and sustained change. Pingleton et al (2013) used the concept of the multidisciplinary team to drive an increase in venous thrombo-embolus (VTE) prophylaxis prescribing and associated reduction in VTE, citing the need for the interprofessional healthcare team for positive results. This quality improvement report from Pingleton et al describes two levels of team development – 1) the multidisciplinary committee team who developed the improvement approach and 2) the clinically based team who were involved in the delivery of the change in patient care. It is not clear from the article if the two teams had discreet membership or if members where in both teams[30]. The paper does not provide detail of any evaluation of the efficacy of either team – it is therefore not possible to determine if it is the committee or the clinical team or both that made the

[30] It is interesting to note from the statistical process chart provided in the report that the rate of VTE at the end of the reported study period is higher than before they started and that in the two month period immediately before the introduction of the VTE committee meetings and for 10 months after there was an adverse effect on the VTE rate for the hospital, however the data would suggest that 14 months after the introduction of the project there was a VTE rate was reverting to previously observed rates, but by the end of the study the data does not suggest a statically significant improvement in VTE rates as the control lines should not have been adjusted in November 2010.

improvements although Pingleton et al suggest that the teams developed were influential in the projects improvement. Pingleton et al's findings may be reflective of my study findings in relation to the cultural indicator where the team have consciously or unconsciously established a "them" & "us" perspective of the team rather than an inclusive "we, the team" perspective.

Hampe (2015) in her review of physician-led sepsis quality improvement teams indicates that the purpose of the quality improvement team is to have a commonly shared goal and that this goal must be shaped by the team rather than others external to the clinical team. This is also reflected in the development of the TeamSTEPPS model, which is an evidenced-based patient safety programme developed in the USA. TeamSTEPPS is an acronym for team strategies and tools to enhance performance and patient safety. Epps and Levin (2015) describe the central component of the model to be the development of an effective team around the patient, describing four components of the effective team – 1) leadership, 2) communication, 3) situation monitoring and 4) mutual support.

Within the model for improvement and the MUSIQ tool for there are similar emphases on the development of effective teams and understanding the barriers and enablers for the effective team (Langley et al, 2009 and Kaplan et al 2010). Several papers from the critical care literature also highlight this need for effective team working to support improvement in patient care (Pronovost et al 2008: Hawe et al 2009: Morris et al 2011) citing effective multidisciplinary teams as being essential to achieve improvement in patient care. It is also important to recognise the impact of hierarchy on the efficacy of teamworking. Considering the context factors literature again reminds us that not only the operational structure but also the organisational structure can have either facilitative or barrier effects on teamwork. Taylor et al (2011), Weiner (2009) and Lekka (2011) indicate the influence of hierarchical structure, both formal and informal and the influence on teamworking, while Aveling et al (2015) highlight the importance of ensuring staff have clarity in their role, conduct and practice. Lyndon and Cape (2016) articulate this as understanding the degree of hierarchy existing within a team; increased degree of hierarchy adversely affects outcomes. McLeod and Clarke (2009) recognise this in more general employee engagement; indicating that organisation with

increased autonomy and reduced hierarchy are associated with increased outcome from a business perspective.

Teamworking, and the multi-disciplinary team can therefore be considered important aspects in delivering change in practice and this was supported by the responses from the participants in this study. Across all four units and all professional groups participants cited team working and the development of the multidisciplinary team as being essential in achieving clinical engagement in their units.

This reflects a theory developed by Lancaster (1999) in relation to effective improvement teams. Lancaster proposes that there are two "levels" of teams within healthcare: multidisciplinary and interdisciplinary teams. Lancaster proposes that multidisciplinary teams should be considered as working groups made up of different professional groups involved in the assessment of and treatment of one patient, each group works independently of the other. While in interdisciplinary teams the professionals making up the team have developed a strong shared goal and discuss opposing views in a constructive manner to reach solutions for complex problems.

The definition of clinical engagement developed from this study; with participants identifying the need to develop a shared understanding of the need for improvement suggests that in actual fact participants are describing the elements of an interdisciplinary team by Lancaster's definition rather than a multi-disciplinary team.

5.4 Perceptions of others' understanding of clinical engagement

Having a shared understand of a definition / topic is regularly cited as an enabling factor in achieving improvement or change. Knowing that everyone is referring to the same thing in the same way is a fundamental requirement for moving forward as a group. This is another aspect which was identified in the context factors literature review, with Aveling et al (2016) and Gilhooly et al (2019) highlighting the importance of stakeholder engagement and development of shared understanding of purpose. Similarly, McLeod and Clarke (2009) also emphasise the importance of shared understanding towards a common goal.

One of the recurring themes evident from the interviews in this study, related to participants assuming that colleagues would refer to clinical engagement in a different way to the way they described it. It became obvious that participants were talking about

the same thing but using different terminology. In addition, several nursing participants indicated that they had looked the term up / "googled it" before the interview. Alvesson and Berg (1992) described this as establishing a social constructivist view of reality which only exists as a common construct depending on what is observed, interpreted and acted on by the membership of the group to which it applies. To bring about successful change it is required that there be a shared understanding and meaning developed, but also that these are actively re-examined over time. I consider this is also related to the need for quality improvement participants to have a shared understanding of their purpose and goal of activity, Parand et al (2010) specifically call this out as *"… shared perception of the purpose …"*

However, none of the participants indicated that this was an aspect of their improvement work which they had spent time considering either individually or as a group. Is it therefore fair to assume that there has not been a conscious decision to establish and build on existing clinical engagement despite participants indicating that it is an important factor required to achieve the improvement aims?

Gordon et al (2013) has established that staff require to be able to align meaning to their work for them to engage in a meaningful and effective way. By being able to align meaning, staff are more effective as individuals and create a more cohesive unit / team; this reflects evidence provided by McLeod and Clarke (2009) on employee engagement and establishing meaning and purpose. Feeley and Swensen (2016) in their *Restoring Joy in Work for the healthcare workforce* paper make direct reference to the work of Deming (2000) suggesting that having shared meaning facilitates staff to engage in change activity. Semkowski (2014) indicates that for groups to be effective there needs to be a shared or common goal as well as open communicates and interactions among the group members. It is only through this that the team will be able to operate effectively and achieve the intended goals. By establishing a strong, shared culture Hester et al (2013) propose that the organisation can develop a flourishing and successful community while a weak or divided culture undermines the collective aims.

Weiner (2009) identifies all these aspects in his debate paper describing *"A Theory of Organisational Readiness for Change"*, without consideration of these context, teams cannot be sure they have favourable conditions to achieve improvement. And without

conversations to establish a shared understanding teams may not be moving in a similar direction.

5.5 Enablers & Barriers

Enablers and barriers are well recognised topics in relation to establishing change. Most literature / texts refer to the need to identify both to bring about effective and sustained change. Within context literature enablers and barriers are specifically identified by Parand et al (2010) who refer to seven different factors which are considered as both enablers and barriers, while Canaway et al (2017) make reference to *"… facilitators and barriers …"* citing these specifically as context to be considered in relation to quality improvement activity.

Participants of this study were able to identify both and they were consistently described across both unit type. It was possible to identify and specify from participant responses two different of enablers and barriers:

1) in relation to bringing about change and

2) in relation to establishing clinical engagement.

However, it was also interesting to note that in achieving units, participants were less likely to refer to barriers to bringing about change and establishing clinical engagement, they were more likely to describe and discuss the enablers. In non-achieving units, the opposite was the case, where participants provided examples of barriers more readily. This can be seen in Figure 21 which illustrates the relationship between the unit's VAP rate and the participant responses.

There was similarity in the topics described across all of the units from the perspective of change or improvement management, recognising what these barriers and enablers are allow teams to be able to consider what particular activities to introduce to support improvements. Through the recognition of enablers and barriers teams start to develop *appreciation of the system* they are working in as well as developing understanding of the *human side of change.* Understanding these two lenses relating to the culture within the team would facilitate the establishment of clinical engagement and enable improvement in patient care and improved outcome measures.

It was observed that junior nursing staff did not reference a strategic perspective in relation to enablers and barriers – rather this group of nurses reflected in the interviews a more operational perspective on enablers and barriers. Their reflections focused much more on the practical activities of implementing quality improvement methodology, this may be related to their junior position within the team and potentially not being involved in strategic development or it may reflect their inability to see how they fit into the wider strategic picture within their organisation. This observation may indicate that there are therefore "levels" within the team's ability to appreciate their system and potentially illustrates a disaggregation of the team. This observation may also be related to the findings from Lyndon and Cape (2011) who referring to the degree of hierarchy having an impact on programme outcome – with increased levels of hierarchy adversely impacting outcome. Although it was not possible to test this in this study due to junior nurses were not being recruited in all units it would not be appropriate to suggest this may also be an illustrative factor pointing to reasons for not achieving the reduction in VAP rates.

5.6 Person dependency

Person dependency in not a specific aspect of context identified in the literature review. However, several authors (Weiner 2009: Krein et al 2010: Parand et al 2010: Speroff et al 2010: Kringos et al 2015: Aveling et al 2016: Canaway et al 2017) make reference to staffing resources as being influential to positive quality improvement outcomes. It could be considered that due to low staffing resources quality improvement activities become a person dependent process as it is not possible to commit the time for all members of staff to become involved in training and meetings required to deliver the methodology. Similarly, in some organisations staff with an interest in the approach become the de facto quality improvement person. From my personal experience this is how I became the quality improvement nurse lead for my intensive care unit in the early days of SPSP.[31]

Person dependency described by participants in this study referred to:

1. the improvement work being dependent on an individual or a defined group of individuals and

[31] Scottish Patient Safety Programme

2. the individual or professional group level of willingness to engage with the improvement activity.

Again, as with enablers and barriers, person dependency within any system is well recognised as a detrimental factor when trying to bring about change. Person dependency increases the potential for other team members to perceive that they are somehow not involved or are not required to be involved in change activity. Person dependency although potentially ensuring short-term reliability in activity and processes, in the long term can lead to more than one way of working or in the event of the person leaving the team a complete breakdown of activity as others do not know how to do their role.

Within the quality improvement literature person dependency is often referred to in terms of establishing sustainability. The Health Foundation (2012) paper "*Quality improvement training for healthcare professionals. Evidence Scan"* note findings from previous studies which have identified *"over-reliance on certain individuals" as* being a common theme identified; initially improvement has been secured but then regressed to previous levels if the individual leaves or moves onto another project. Again, I recognise this description as I experienced this within the intensive care unit where I initially lead the surveillance work to reduce the ventilator associated pneumonias without using an effective change methodology and then not being able to sustain reduction in our VAP rates. And, during the interviews for this study, participants in the non-achieving units made direct reference to person-dependent processes, indicating that patient safety activity was a specific person's job and as a result the participants perceived they had nothing to do with it. This was not referred to by participants in the achieving units.

The *Engaging with Quality Initiative* paper published by the Health Foundation (Ling et al 2007) identifies the concept of person dependency and lack of sustainability due to changing staff as an adverse context factor, and is influential in identifying where improvement has been sustained and change embedded into practice. However, where a stable staffing group and person dependent systems are in place there is some degree of benefit observed in outcomes. Similarly, this was a theme frequently referred to throughout the *"Learning Report: The Safer Patient Initiative"* (Health Foundation 2011a).

A potentially counterintuitive observation was offered by participants in the study, who identified that champions within units supported staff engagement, increased reliability in processes and improved outcomes. Champions are identified in the literature relating to context factors (Powell et al 2009: Lyndon and Cape 2016) as being a positive resource utilised to engage staff and acting as role models for changes in practice however there is no reference to the potential for champions supporting person dependency in either paper.

As identified in the finding section *"Leadership"* was an aspect discussed and explored by participants in the study – however it was not linked explicitly with the development of clinical engagement, rather it was introduced as a concept in relation to quality improvement in the wider sense. Leadership is also a recurring theme identified in literature relating to clinical engagement and employee engagement generally. The importance of leadership to the topic of context factors and clinical engagement has become apparent over the lifetime of this study and has relevance to the aspect of the model illustrated in Figure 21 where the arcs are incomplete.

Colville (2009) indicates that effective leadership is central to organisational sense-making; this I consider relates to the concept highlighted within the sections referring to person-dependency and perceptions of others of clinical engagement. Without a leader who can grab the attention of the group and to convey a relevance of the improvement work others in the team may not become engaged in the work. However, Collinson (2009) indicates that leadership is a two-way relationship between the leader and followers, which requires endorsement from the followers within the group / organisation towards the leader. Effectively the followers have the power to endorse the leader's positions and without that endorsement the leader would not hold that position. This endorsement only occurs if the followers consider that the leader embodies the values of the group; leaders are considered to act as role models, encouraging value internalisation and psychological identification of the group.

Revisiting the concept of the sense-making role attributed to the leader by Colville, Collinson proposes that this is part of the power relationship inherent in the leadership role. However, in recognition of the interdependent relationship between leader and followers it is important to reflect that the followers exert power in their operationalisation of the managed meanings developed by the leader. And, followers

are in the position to participate in disguised dissent which is most likely to occur where followers don't perceive that they have been listened to and where performance controls in the form of monitoring and targets have been introduced. This is, according to Collinson, characterised by "foot-dragging" and "disengagement," is this disengagement reflected in the category identified as person dependency and the differences in languages used to refer to colleagues?

5.7 Cultural Indicator

> *"Culture cannot be managed; it emerges. Leaders don't create culture; members of the culture do. Culture is ..., a means of endowing their [peoples] experiences with meaning."*
>
> (Dekker 2011 pg. 78)

Often when failures are encountered in processes and service root cause analysis indicates that the problem at the heart of the problem is ineffective culture. This impacts the ability of individuals to engage in continuous quality improvement and deliver an effective, quality service (Kieffer 2015). In 2011 the Health Foundation published an evidence scan focusing on the effect of improving safety culture on patient and staff outcomes. It is noted that there is an assumption within the quality improvement community that improving safety culture will both directly and indirectly affect patient outcomes – interestingly it is not explicitly indicated whether this is a positive or negative correlation. As with most topics related to quality improvement the outcomes of studies are often mixed and of variable quality, making it difficult to understand causal links between culture and outcomes. Often it is possible to establish links between staff behaviour and effective safety culture but the link with patient outcomes is less evident (Health Foundation 2011c).

The following two sections attempts to understand the derivative of the term cultural indicator, exploring the meaning of both words and how this term may relate to the findings from this study.

The meaning of culture

The Cambridge English dictionary indicates that when the word culture is used as a noun it means *"the way of life, especially the general customs and beliefs of a particular group of people at a particular time."*

Cambridge Dictionary (accessed 16th October 2017)

A paper produced for the Columbia Basin RDI (2013) describes culture as the *"totality of the experience that provide a coherent identity and sense of common destiny to a people."* Again, as in the dictionary definition there is reference to the way of living and a shared understanding or a social cohesion within the group. Much of the literature available on cultural indicators references back to the UNESCO *Universal Declaration on Cultural Diversity* (2001) which states that the process of developing culture forms new ways of knowing and meaning which creates new norms of behaviour and being. It encompasses the values systems, traditions and beliefs held within the group. However, there may be many ways of understanding the culture within the group and it may be perceived and described differently by different members of the identified culture. This is also reflective of the differences in describing clinical engagement by participants in the study.

Culture is recognised in the literature review of both context factors and clinical engagement. For example Minkman et al (2007) in their systematic review identify *"... participative, flexible and risk-taking organisational culture ..."* as a context factor which may have an impact on quality improvement outcomes. Similarly Knight (2018) reporting on student engagement with clinical learning identify three socio-cultural influences including culture which need to be considered. Aveling et al (2016) in their ethnographic study of accountability in patient safety identify six different types of culture which need to be considered, including institutional, economic and social.

The meaning of indicators

Indicators are tools which help understand and place value on a phenomenon or system. Indicators are well recognised within the healthcare setting, with indicators being commonly utilised to determine the quality or safety within healthcare settings. It is suggested that indicators allow people to make sense of, monitor or evaluate any aspect of a system they wish to measure. The outcome measures of SPSP could be

considered as indicators of the quality and safety of the healthcare systems within Scotland.

During the data collection, analysis phases and in the write up of the findings that it had become apparent that it could be possible to explore the idea of a cultural indicator in relation to establishing clinical engagement and achieving the SPSP aims. I determined that it was the language used by participants which could be a possible indicator of the culture within the teams. A blog post by Jaques exploring *"The power of language for improving organisational culture,"* suggest that language can be the catalyst for improving not only culture but also the performance of the business. This concept is raised by Hester et al (2013) when they propose that the language and terminology used by people within an organisation is an overt expression of the organisational culture.

Cultural Indicators

Cultural indicators therefore could be considered as a mechanism to measure the culture within a group of peoples or a specific society. Cultural indicators are often developed to facilitate programme evaluation or quality of life for society members (Columbia Basin RDI 2013). Hawkes (2001) recognises the fact that evaluating progress requires the inclusion of a cultural indicator, however it is also recognised that this is an area which has been understudied, lacks co-ordination among existing studies and available data is of questionable quality (Columbia Basin RDI 2013). Hawkes suggests that the word culture is a complex and highly contested word in the English language; yet the dictionary definitions provided earlier indicate that culture refers to both the values held within a group as well as the social expression of those ways of being within a group. If culture is the way of being within the group / society, does it therefore describe the value system held within that group / society?

As identified in the findings section of this paper it became apparent that the language used by participants may be an indicator of the culture which existed within their teams. Heskett (2012) indicates that the culture of an organisation reflects the behaviours observed in the people of the organisation – these behaviours reflect their assumptions, how they think and act as well as their beliefs and values. The culture displayed helps establish expectations, fosters trust and can facilitate communications and it is suggested can contribute to more productive outcomes. Kouzes and Posner

(2002) refer to the culture observed within an organisation as a reflection of the values held by the individuals within the team(s) and that people cannot fully commit to an organisation that does not fit with their beliefs. When there are shared beliefs and values within a work force there is also a common language used. These shared values help to promote strong norms within the team as well as increased organisational effectiveness. Edmondson (2012) proposes that by developing a shared set of beliefs and values within a team facilitates the development of respect and trust which the team can then use during times of challenge and debate. Challenge and debate are normal within teams where people with different backgrounds are brought together to solve problems, come up with new ideas as well as deliver innovation. Kotter (2012) refers to culture in the same way as those cited above but he goes further to suggest that shared values are less apparent yet more deeply embedded in the culture and are more difficult to change than norms of behaviour. The culture of a group of people according to Kotter is exerted through their actions and not as a result to explicit description of a cultural expectation. Similarly, Kotter indicates that cultural change is only possible after the change in actions and behaviours asked of people have been able to demonstrate improvement in performance.

Does this explain the difference in results between the two-unit types in this study? Although both units have been able to reduce their incidence of VAPs, is it only because achieving units, have been able to achieve the programme aim of 300 days between VAPs that they also demonstrate a culture of shared values and beliefs while not achieving units had yet to achieve the aim and at the time of the interviews did not appear to demonstrate a culture of shared values and beliefs. This could suggest that achieving the desired improvement drives the change in culture, yet much of the change management literature would suggest the opposite relationship.

The concept of organisational culture has already been introduced within the clinical engagement sections where reference was made to organisational socialisation, this is also important to consider in relation to cultural indicators. Kotter (1978) referring to the development of “organisational dynamics” cites the social system which exists within the organisation as influential in determining the aspects of the work which are considered as important and that this is determined by the members of the system and where they place high value. Interestingly the example offered by Kotter in 1978 refers

to the value placed on safety by the organisation – if safety is not considered to be of high value this will not be where employees invest their efforts. Kotter also identified that two organisations can have the same intended outcome yet depending on the employees' norms, outcomes can be different. This is also reflected by Hawkes (2001) who cites Kotter and Heskett (1992) describing research studies which found that strong culture based on shared values outperformed other firms by a huge margin. Kotter and Heskett are clearly referring to commercial industry, while Hawkes is exploring the culture relating to environmental organisations. The question I am then left asking of the findings: *"is it appropriate to assume this would be the same within health care? Is the difference in achieving the VAP aims observed between the two units related to the organisational dynamics?"* Considering Hester et al (2013) it could be possible to make this connection and hypothesis that yes potentially Kotter and Heskett theory is transferrable to health care. Similarly, Semkowski's writing on theory of group dynamics would again suggest that it is possible to make tentative links that the units' outcomes in relation to achieving the VAP rate is associated with the culture within the units.

The reliance on individuals to lead and drive improvement as described in the person dependency section previously could also be a cultural indicator. As described in the findings section, this was an aspect more evident within the units where the SPSP aim had not been achieved and relates to the aspect of person dependency described earlier.

5.8 Other reflections

Strategic overview.

One area of difference identified within the nursing participant group was that more junior staff did not refer to the strategic perspective associated with achieving the reduction in VAP rate. However, it would be inappropriate to consider this as a general finding due to the small number of junior nursing staff participating in the study. This would be an area which could be further explored in future studies.

- Linking the concept of understanding the wider strategic picture to being able to see the wider picture.

5.9 Achieving the Ventilator Associated Pneumonia (VAP) aim

Much has been written in relation to the VAP diagnosis definition (Dellinger et al 2004 and Rea-Neto et al 2008) and whether the definitions are applied consistently within units never mind across the country. This was not an aspect which was explored during the interviews and this, it could be reasoned, calls into question the results. However, irrespective of the VAP results for the units the differences in the perceptions between the two units are valid findings as they reflect the perceptions of staff in these units and point to a difference in the cultures particularly in relation to person dependency, reflections of barriers and enablers and perhaps most importantly in relation to how the specifically nursing teams refer to each other.

5.10 Study limitations

The limited number of units participating in this study could be cited as a weakness of this study, with the criticism relating to the perceptions gathered representing a small percentage of the total Scottish critical care clinical population. However as this is a grounded theory approach and it has been highlighted throughout this report that the purpose of the study is to begin to understand staff perceptions it would be inappropriate and not the intention of this study to propose that the findings represent a generalisable way of thinking about clinical engagement and quality improvement. Glaser and Strauss (1967) indicate that it is not possible to develop provisional tests from a grounded theory approach rather the researcher is developing a theory which can be tested at a later stage. During the construction of categories I achieved Charmaz's definition of theoretical saturation *"... when gathering fresh data no longer sparks new theoretical insights..."* and that conducting more interviews would have been a waste of participant time as well as my own with not benefit to the study outcome.

Another potential weakness of this study is that there was no mechanism to provide observable behaviours relating to the emergent grounded theory. I think that it would be helpful to be able to describe and define through observation of interactions between staff within the different unit types. This would provide observable and measurable behaviour of teams who want to be able to describe whether they have achieved the desired culture change during the implementation of quality improvement methodology. There is often reference in quality improvement literature where authors have described culture change within the team or organisation but the lack of

understanding of the social construct of clinical engagement means that there was not a description of measurable and / or observable behaviours. I consider that this could have been achieved by observing staff interactions, including the language used during interactions within the participating units. In addition, using triangulation of findings through observations of practice could have offered the opportunity to understand if there is indeed a difference between the responses participants shared in the interview setting and what they demonstrate in practice. It may have been that the linguistic differences observed in unit three and four were unique to those individuals and not pervasive throughout the units. And it is unlikely that staff would have overtly referred to colleagues in the terms of "them & us" in practice, the observed practice may rather be "foot-dragging" as described by Collinson (2009). It is recognised that observation as a data collection tool has challenges which would need to be addressed if such a study were to be undertaken.

I had recognised in the development of my study that the use of the VAP rate as a mechanism to theoretically sample units would represent a challenge in relation to differentiating between unit types. This was due to there has been much debate in Scotland around the diagnosis definition used for VAP, with units taking different approaches to data collection and using different diagnosis definitions for VAP. These differences in diagnosis definitions could potentially have had an impact on reported infection rates. An example of this can be demonstrated for the unit I worked in, we had been using a surveillance methodology for about 3 years before the introduction of SPSP and we had recognised that some patients with VAP met the diagnostic definitions agreed for our surveillance progress but were not clinically treated and vice versa. Within our unit it was determined that VAP which met the HELICS[32] definition would be counted and those which did not were excluded – this remained the process on introduction of data reported to SPSP, this was a pragmatic decision agreed by the consultants, infection control team and the internal SPSP team. It is my understanding that this was not the approach taken in all other units, this was mainly due to there being only one other unit in Scotland using the HELICS data collection methodology. I had also debated with my supervisor during the early phase of my study how I was going to have a mechanism to differentiate between the different units. I had also

[32] Hospitals in Europe Linked for Infection Control through Surveillance https://www.sicsag.scot.nhs.uk/hai/helics_protocol.pdf

explored the option of using central venous catheter related blood stream infections (CRBSI) as a mechanism to theoretically sample units, however due to the very low prevalence of this nosocomial infection within units it was not possible to identify two distinct unit types.

5.11 Summary

Clinical engagement was considered by participants in all units to be important in relation to achieving the SPSP ventilator associated pneumonia (VAP) reduction aim. Participants were clear that this engagement applied to all staff groups involved in the delivery of care in the intensive care unit. This is clearly illustrated in the descriptions provided of the multidisciplinary teams represented in Wordle (Figure 17). The two main professional groups specifically identified as being important to get "on board" to positively impact unit outcomes by participants are nurses and doctors. This is consistent with both the context / context factors and clinical engagement literature.

In the two non-achieving units' participants identified challenges securing engagement with colleagues both from their professional group and from medical colleagues. In one of the non-achieving units, it was not possible to recruit medical staff to participate. Participants all identified the fact that colleagues were likely to describe clinical engagement different, it was suggested that this was potentially due to there being no standard definition which everyone could refer to.

A lack of shared understanding of a definition / topic has also been highlighted in the literature relating to context / context factors. Is this because clinical engagement is a context related to quality improvement and due to a lack of clarity in the definition of context this also contributes to a lack of clarity when describing clinical engagement?

Person-dependency was also identified as a specific category within the data relating to non-achieving units. Although it was not identified within the context / context factors literature, the literature relating to engagement (McLeod and Clarke 2009), general change management (Pettigrew et al 1992) and quality improvement (Health Foundation 2012) all makes reference to the challenges observed in achieving improvement where there is person-dependency.

During interviews, participants found it relatively easy to identify enablers and barriers to achieving the VAP aim. Some of the literature reviewed relating to context / context

factors suggested that enablers and barriers should be considered as context / context factors. Where the literature referred to enablers and barrier it was common that the same topic could be considered as both, this is highlighted by Parand et al (2010) in relation to establishing clinical engagement with medical staff. In the interviews for this study it was noted that staff from not achieving units were more likely to discuss and describe barriers than enablers.

It could therefore be questioned how the enabler and barriers identified by participants were exerting their greatest influence?

In summary, using a grounded theory approach has allowed me to begin to put detail to the system of profound knowledge framework used by quality improvement teams across Scotland. This detail relates to establishing clinical engagement in intensive care units as teams work to achieve one of the SPSP aims, reducing Ventilator Associated Pneumonia.

Using this approach has facilitated the processes of both identifying context / context factors as perceived by clinical staff as well as the operational definitions used by staff daily. By developing this detail, I believe it is possible to move towards greater understanding of what context and clinical engagement means for critical care staff. Having a shared understanding is a common theme identified in the literature relating to context / context factors, clinical engagement and change management.

Aligning these definitions of context / context factors with the system of profound knowledge also facilitates quality improvement practitioners who may be supporting teams to have a shared understanding. This is particularly important where the quality improvement practitioner does not have a shared subject matter background. Understanding how the descriptions fit into the system of profound knowledge lenses can facilitate conversations to develop greater understanding of the enablers and barriers to progressing improvement.

Chapter 6 Strengths and quality of the research study.

Strengths

As identified in the introduction section of this thesis the Scottish Government has recommended and supported the use of the model for improvement as the change

methodology for the public sector in Scotland. With the strategic aim being the improvement in outcomes for the people of Scotland using public services. A large resource, both financial and personnel, has been invested in this approach across a wide variety of settings within healthcare as well as the wider public service arena. Many healthcare practitioners are aware of the methodology with many able to describe the PDSA cycle, from a strategic perspective it is important that as practitioners we can articulate how to use the methodology to bring about the identified improvement in care, using language which is familiar and relevant. Yet for some aspects of the methodology, i.e. the system of profound knowledge there is often no empiric evidence to support staff understand what is being referred to aid implementation. Similarly, for terminology extensively used in association with quality improvement activity i.e. context / context factors and clinical engagement, there is often a lack of agreed operational definitions. As the purpose of this study is to develop an emergent grounded theory to support this knowledge development, I therefore consider this to be a strength of both the topic area and the research approach taken. Using grounded theory, I have been able to gather examples of language used by practitioners in the critical care community and begin to articulate a theory of the meaning of context factors and clinical engagement used in the reality of quality improvement methodology in clinical practice.

Quality

Ensuring the quality of this study has been an essential component of activity throughout. I have taken opportunities to check findings with colleagues within the qi community as well as within the participant group. The feedback from these different sources has already been discussed within the reflexivity section in Chapter 3 and within the Chapter 4 findings section.

Chapter 7 Next Steps

Having conducted this study utilising a grounded theory approach I would recommend that next steps from a research perspective would be undertake a study with a wider audience to understand if the perceptions of the participants elicited in this study are representative of the wider clinical community working in critical care in Scottish Intensive care units and other care settings. The link between organisational culture and socialisation introduced in Section 5.1 *"Clinical Engagement"* is an interesting

concept which it has not been possible to fully explore within this study due to the data collection tool used being interviews. As a further recommendation I would propose that future studies incorporate observation of relationships and linguistic interactions between different units for example carrying out further interviews and incorporating observational studies within the same participating units. By utilising a triangulated approach, it could be possible to clarify if / how the language differences drawn from the interview transcripts impacts daily relationships between staff in the units and if these can be correlated with the outcomes for improvement activity within the care settings.

I would propose an additional next step to be the use of a Delphi method to gather known experts in the field of qi and the theory of the system of profound knowledge to explore the theory proposed from this study and its addition to existing knowledge. Given the importance placed on the methodology to improve public service delivery in Scotland to explore the potential implications for Policy and practice development in relation to the health and social care integration agenda in Scotland.

Chapter 8 Conclusion

Providing high quality safe care for patients in Scottish hospitals including intensive care units has been identified by the Scottish Government, who introduced a country wide quality improvement programme in 2008.

Quality improvement to improve care and reduce adverse outcomes for patients has been reported in the healthcare literature since the early 1990's and has been supported by several national reports from both Unites States of America and the United Kingdom. As a result, there is a growing body of evidence describing the context factors required to support effective quality improvement. However, there is often a lack of clear definitions in the literature facilitating the reader to understand what is being described and how it may relate to their area of practice. This is true in relation to the definitions relating to context /context factors, which are thought important influences on successful change and quality improvement. From personal experience working in clinical practice and supporting quality improvement I recognise clinical engagement as one context factor that can have an influence on success.

Having used the model for improvement and the system of profound knowledge framework as the quality improvement tools to support change in an intensive care unit, I am aware from personal experience of the challenges presented by a lack of shared understanding and proceeding with a quality improvement project when it is assumed that everyone shares the same common goals and willingness to be engaged in said project.

Undertaking a grounded theory approach in four intensive care units in Scotland has allowed me to; explore with staff their perceptions of clinical engagement, how they perceive it influences their ability to achieve improvement and to develop an emergent theory of clinical engagement in relation to implementing quality improvement methodology.

Using the descriptions provided by staff, I have been able to provide a working definition of clinical engagement. It has also been possible to begin to describe context / context factors as well as perceive this context in practice. Having this information has also in turn facilitated the population of the four lenses of the System of Profound Knowledge, which is a fundamental framework supporting all quality improvement activity, with further understanding of clinical engagement as a key context factor to consider in quality improvement methodology. This provides practitioners, both clinical and quality improvement, with valuable understanding of clinical engagement aspect of context factors required to progress effective change.

The perceptions of participants reflected the literature relating to context and clinical engagement but also highlighted the need to better understand the link between context, clinical engagement specifically and the outcomes of quality improvement programmes. This is explicitly emphasised in relation to enablers and barriers, for example: in non-achieving units were the barriers identified preventing clinical engagement and therefore reducing the teams' ability to achieve the VAP aim. While achieving units discussed the enablers that facilitated clinical engagement and thus helped the team achieve the aim of improving VAP rates. Cultural indicators, such as the use of language within teams, may also be reflective of active clinical engagement. Participants discussed the importance of the causal links between active clinical engagement and programme outcomes – a findings in keeping with those from a relatively small evidence base in the literature.

The emergent theory developed from this study is, intensive care staff – nursing, medical and managerial all perceive clinical engagement in a similar way irrespective of the units' ability to deliver quality improvement aims – reductions in ventilator associated pneumonia (VAP) rates. However, where there is difference between the achieving and non-achieving units is in the way staff refer to each other. In achieving units the language observed was collegiate in nature – we, us, the team, together. In non-achieving units the language observed suggested a team demonstrating less cohesion in their way of being – them and us, that's someone else's job, I'm not involved in that work.

Further research should be undertaken to test this emergent theory, this could be achieved with the use of an ethnographic study within the units who have participated in this study to determine if the perceptions offered by staff in interviews was also their observed practice when interacting in daily practice. In addition incorporating linguistic analysis into the ethnographic study design would offer researchers the opportunity to better understand the importance of team language in the development of effective teams and their ability to achieve quality improvement aims.

An additional avenue of study would be in relation to the exploring the difference between multi-disciplinary teams and interdisciplinary teams. If it was possible to clearly articulate what staff mean when they are referring to their teams, it could be possible to utilise this as an additional context factor when describing the conditions required for effective quality improvement. I would recommend the use of an action research approach to this research working across teams who have implemented quality improvement methodology and those who are early in their journey.

Appendices

Appendix 1 Model for Improvement & Scottish context

The Model for Improvement as a change management model

It was not the purpose of this study to evaluate the efficacy of the Model for Improvement as a change model rather the following section will provide a high-level overview of the approach. Providing this overview offers the reader the opportunity to understand the strategic and frontline context which existed at the outset of the introduction of the methodology to the healthcare setting in Scotland. Scotland is the first country in the world which has adopted this as a country-wide approach to improvement.

The methodology was trialled in UK through the Safer Patient Initiative and evaluated by the Health Foundation (2011a & 2011b) and as a result it was determined that the methodology should be used as the change model supporting SPSP. The *"3 step improvement framework for Scotland's Public Services"* document has since been developed by the Scottish Government (2013), on the strength of the output from SPSP. The *"3 step improvement framework"* document supports and advocates the use of the Model for Improvement (MfI) as a change model for all areas of public service delivery. In addition, several nationally funded improvement programmes have been developed using this as the preferred improvement and change model – these include the *Early Years Collaborative* and the *Raising Attainment for All Programme*[1].

The MfI, illustrated in Figure 1 below is made up of three fundamental questions intended to drive improvement and incorporates plan-do-study-act (PDSA) cycles. Langley et al (2009) state that answering the three questions is necessary to guide any improvement effort, while utilisation of the PDSA cycle is essential to effect implementation and sustained improvement.

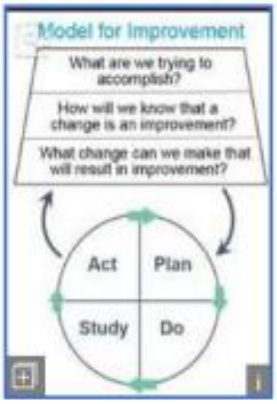


Figure 1

The Model for Improvement (Langley et al, 2009. Pg. 24)

[1] These have recently been combined and are now referred to as the Children and Young Peoples Improvement Collaborative (CYPIC)

Users are required to consider and answer the following three questions when undertaking improvement:

1. **What are we trying to accomplish?** Teams are encouraged to set out in a clear and unambiguous manner what they are trying to accomplish, using a measurable aim or outcome measure which is time limited. This aim should have been developed in collaboration with the whole team to encourage ownership of the piece of work.
2. **How will we know that a change is an improvement?** By using prospective dynamic time series quantitative measurement and qualitative learning teams can determine if the things they are putting in place to improve patient care are making a difference and leading to the expected improvement. This is a move away from the usual mechanism of using interrupted time series data analysis which is common in healthcare. In the past teams may have decided that a project / piece of work will last for a specific period and would measure at the beginning and at the end. It would only be on the completion of the period that it would be possible to see if there had been any improvement or not, this is not an ideal situation. As well as using prospective dynamic time series data, teams link the outcome measure(s) as defined in question one with process and balancing measures. By using process measures it is possible to determine if the change is happening as intended i.e. are all patients receiving the new assessment for their condition or not. While balancing measures allow the teams to evaluate if their improvement work is having advantageous or adverse effects elsewhere in the care delivery system. Balancing measures are also referred to as the measure of unintended consequences. Teams are also able to determine as they are progressing what is preventing the new activity being embedded in practice. Linking process and outcome measures, collecting and displaying data prospectively and reviewing the data over time will allow evaluation in real- time of the impact of change. This impact can be advantageous or adverse, but teams do not have to wait until the end of the time to discover this.
3. **What change can you make that will result in improvement?** Using available evidence, teams identify practices / activities which are thought to lead to improved outcomes for patients. These practices / activities are often evidence-based practices / interventions which are known to improve patient outcomes. The piece of work / project is therefore guided by the best available evidence; through trial and data review teams can adapt interventions into practice which fit into their own local context.

Having addressed the three questions, teams then use the PDSA cycle, illustrated in the lower section of Figure 1 as a circle to try out small tests of change. These small tests are used to

determine if it is possible to change practice and ensure it is delivered reliably. This part of the model allows teams to be able to identify what things within existing local care delivery systems are preventing reliability.

Most clinical teams involved in SPSP throughout Scotland will have received training in the components of the MfI and will have attended national, regional or local learning sessions to encourage sharing of their experiences in implementing the approach. Clinicians will have received either local training in the use of the methodology from colleagues who have attended learning sessions or have access to colleagues who have attended one of the two training opportunities described below or they may have attended national training events - Improvement Science in Action (ISIA) delivered by IHI staff or Scottish Improvement Skills (SIS) delivered by SPSP staff. In addition, as part of the infrastructure to support the use of the methodology, SPSP offered individuals within territorial boards the opportunity to attend training events which were run over 6 – 12 months. In addition, local senior sponsorship was required for candidates to be able to secure places on any of the training courses offered.

The purpose of offering the SPSP Fellowship and Improvement Advisor (IA) courses was the recognition that being able to use the MfI as a change model is not the only requirement to bring about successful and sustained change therefore improvement teams within territorial health boards would require access to colleagues with additional knowledge of the methodology.

Appendix 2 Deming's "System of Profound Knowledge"

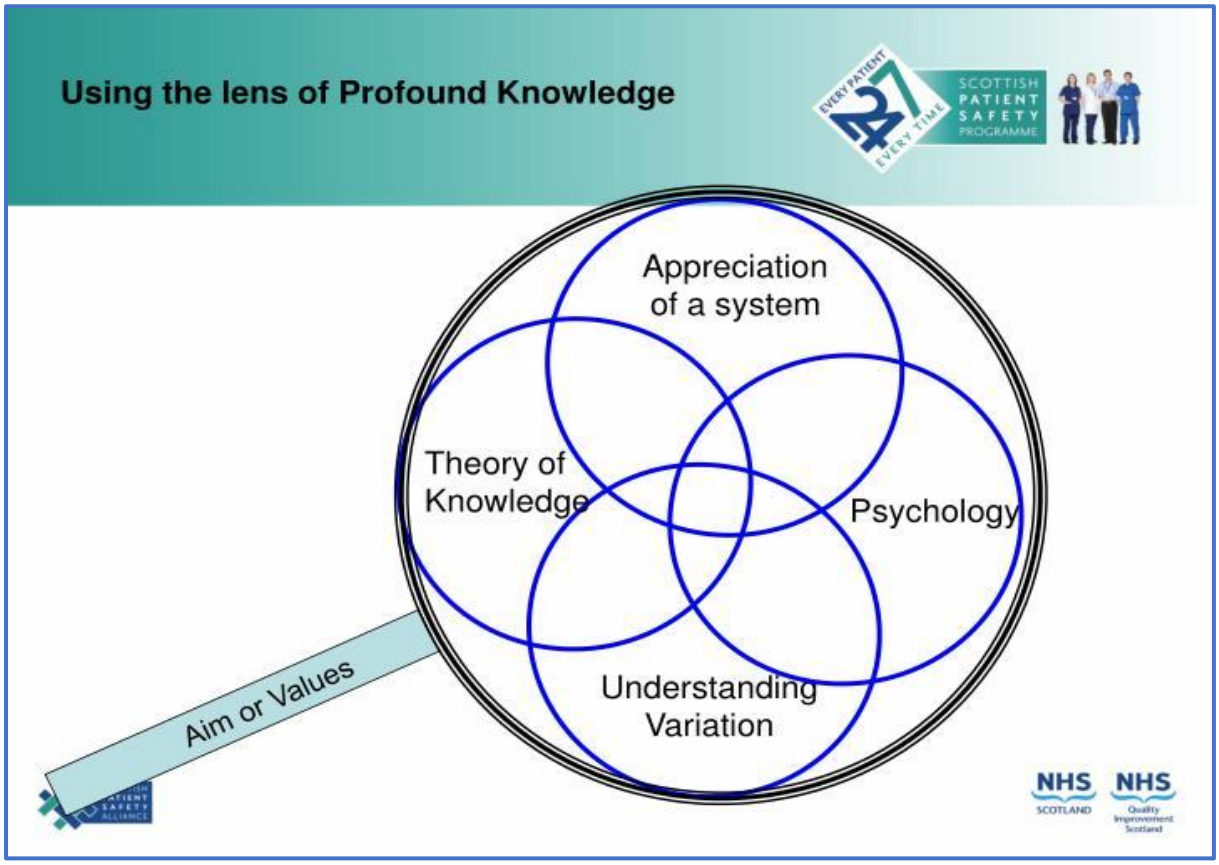


Illustration of the System[33] of Profound Knowledge.

[33] Also referred to as the Lens of Profound Knowledge

Appendix 3 Operational definitions for consistency in literature review (context)

ID	**Authors**	**Date**	**Title**
operational Definition	Name of authors as detailed on article	Date of Publication	As detailed in publication
Journal details	**Volume / pages**	**Context - setting**	
		Location of study	
Study design / QI method	**Population**	**Aim**	
Approach to carrying out the study as described by authors	Description of study population / literature reviewed as defined by authors	Aim of paper where detailed by authors	
Methodology	**Main findings**	**Context described**	
Methodological approach as described in paper by authors.	Summary of findings section reported by authors	Detail provided by authors where they have directly identified context. (Indicate if there are no context described. Note of not described in findings)	
other comments	**Author identified limitations**	**Review identified limitation**	
Additional comments provided by authors in their paper	Summary of limitations where identified by authors.	Summary of limitations or general observations of the entire paper as noted by reviewer.	

Appendix 4 Tabular collation of Literature review data (context)

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
1	Alexander, Weiner, Baker, Shortell & Becker	2006	Community Hospitals	Cross sectional analysis of community hospital administration data	To: 1) examine the association between the intensity of care management implementation in hospitals and hospital performance on 4 selected indicators of patient safety 2) assess the extent to which relationships are moderated by hospital organisation and environmental context	quality of care data, use of statistical and process management tools, focus on process and system improvement, guideline use years involved in quality improvement
2	Minkman, Ahaus & Huijsman	2007	Chronic care provision	Systematic Literature Review 1996 - 2006	To understand the empirical evidence for improved performance by the implementation of interventions based on Malcolm Baldrige Quality Award criteria, European Foundation Quality Management, Excellence model and the Chronic Care Model	characteristics of health care system social values, history of quality assurance, skills in decision making, adoption of quality information system, Participative, flexible and risk-taking organisational culture, positive association with self-management and clinical information systems, healthcare setting patient population, quality improvement culture, strong physician leadership.
3	Halbesleben, Wakefield & Wakefield	2008	Healthcare settings	Systematic Literature ReviewTime period not defined	Literature review	Context factors are not specifically discussed, the term **"blocks"** is used instead. Policies / Laws / RegulationProtocols / Guidelines, Work process, design, technology, people
4	Weiner	2009			Defining organisational readiness for change and develop a theory of its determinants and outcomes	Participant willingness and confidence to change is high, Organisational culture, Polices & procedures, Past experience, Organisational resources, Organisational structure

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
5	Masso & McCarthy	2009	Residential aged care facilities, Australia	Literature review 2002 - 2008	To use evidence from available literature to develop evaluation of up-take and continued use of evidence in residential aged care	No detail in results section but further description from the wider literature in the discussion section Receptive context appears to have been identified from one systematic review paper in 2004
6	Powell, Rushmer & Davies	2009	International healthcare literature	Systematic narrative review of literature	To understand what approaches exist to manage change, their relative strengths and weaknesses and their potential application in the organisations that make up NHSScotland	Complexity of care, Multiple existing standards, guidelines and protocols which are often poorly integrated, multiple stakeholders, strong inter and intra professional boundaries, continued dominance of the medical profession, reluctance of many health professionals to engage in QI activities, limitations in the abilities of managers to direct or control health professionals, varying standards of data and infrastructure support for data collection and analysis contest variation around what counts as quality in health care and the nature of evidence, traditional patterns of education and socialisation that have focused on individual expertise and have not encouraged a team or system-wide approach the on-going impact of successive, on-going NHS re-organisation together with a history of top-down changes approaches.

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
7	Krein, Damschroder, Kowalski, Forman, Hofer & Saint	2010	United States Healthcare setting	Qualitative methodology incorporating surveys and qualitative interviews.	To understand the infection prevention practices used by U.S. hospitals and the associated local context, in relation to preventing central-line associated blood stream infections, ventilator-associated pneumonia and catheter-associated urinary tract infections.	Leadership, culture & resources
8	Parand, Burnett, Benn, Iskander, Pinto & Vincent	2010	Nursing, medical, pharmacy staff.Patient safety / governance leadsChief Executive	Qualitative interviews with staff members involved in the programme – Part of a larger series of studies.	To identify factors affecting doctor's engagement with the Safer Patients Initiative (SPI)	Barriers and Enables were identified as the 7 factors. 1) quality improvement track record 2) resource allocation 3) perceptions of the purpose of SPI 4) Evidence of efficacy 5) External expertise 6) local programme champions 7) managerial involvement Also, Barriers and Enablers were provided which had been identified within the interview data. "
9	Speroff, Nwosu, Greevy, Weinger, Talbot, Wall, Deshpande, France, Ely, Burgess, Englebright, Williams & Dittus.	2010	North American Intensive Care Unit staff	Cross sectional analysis of multi-survey data from 1406 staff - nurses, ancillary staff, allied staff & physicians	To determine if an organisational group (teamwork) culture show better alignment with patient safety climate	<u>Not specifically called out as context factors</u> Organisational structure is a context factor incorporating team functioning, staff morale, patient satisfaction and safety climate. As well as job satisfaction, perceptions of management and working conditions

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
10	Øvretveit, Shekelle, Dy, McDonald, Hempel, Pronovost, Rubenstein, Taylor, Foy & Wachter	2011	American Healthcare settings	Research Review and Expert Panel	Literature Review	Definition of context provided but not what they might be. Context is discussed in relation to "readiness for change"
11	Taylor, Dy, Foy, Hempel, McDonald, Øvretveit, Pronovost, Rubenstein, Wachter & Shekelle.	2011	American Healthcare settings	Expert Panel leading to framework development and consensus	Two Surveys were conducted to determine the context likely to influence Patient Safety Practice implementation	Safety Culture, teamwork & leadership involvement structural organisational characteristics external factors availability of implementation & management tools
12	DY, Taylor, Carr, Foy, Pronovost, Øvretveit, Wachter, Rubenstein, Hempel, McDonald & Shekelle	2011	American Healthcare settings	Expert Panel leading to framework development and consensus	To develop a framework allowing classification and comparison of Patient Safety Practices	Leadership, culture or institutional financial status or quality improvement infrastructure
13	Lekka	2011		Literature review	To carry out a review of the literature on high reliability organisations to identify the characteristics and processes that account for these organisations' high safety and reliability levels.	Context factors required in a High Reliability Organisation are: Deference to expertise during emergencies management by exception, climate of continuous training, several channels are used to communicate safety critical information, in-built redundancies

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
14	Piscotty & Kalisch	2014	All literature relating to nursing use of clinical decision support systems	Literature review 1900 - 2013	Literature Review of available relevant data	Referenced but not explicitly described or named
15	Ijkema, Langelaan, Van de Steeg & Wagner	2014	Physicians, nurses & members of policy team	Qualitative methodology based on semi-structured interviews	To gain insight into which factors impede and which facilitate the implementation of a complex multi-component improvement initiative in hospitalised older patients	Insight into effects, Knowledge, Guidance
16	Burston, Chaboyer, Gillespie & Carroll	2014	Discharges surgical patients from 2 wards in an acute care hospital	Cohort study using historical control and time series data	To examine the relationship between the implementation of a transforming care initiative and patient outcomes related to inpatient falls and hospital acquired pressure ulcers	Not specifically called out as context factors

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
17	Kringos, Sunol, Wagner, Mannion, Michel, Klazinga & Groene	2015	International Health care literature	Systematic literature review	To describe the reporting of context factors in the literature on the effectiveness of QI strategies. To assess the relationship between the context factors and the effectiveness of QI strategies. To analyse the importance of contextual factors	External environment, organisation, QI support & capacity Micro-system QI team, Organisational level of programme implementation, patient turnover & bed occupancy, staffing levels, quality of evidence & guidelines, maturity of systems supporting decision support , trust in & quality of information, education outreach
18	Aveling, Parker & Dixon-Wood	2016	Healthcare staff in hospitals providing acute care	Ethnographic study	Not specifically called out in the text.	Institutional, symbolic, economic, social, historical and external
19	Lyndon & Cape	2016	Nurses and physicians	Descriptive Qualitative study	The purpose of this study was to describe user experience with implementation of an obstetric haemorrhage toolkit and determine the degree of implementation of recommended practices that occurred during a 31-hospital quality improvement learning collaborative	local organisational culture, local structures and experience of the implementation team, degree of administrative support including project support - equipment, people and data, clinician engagement, inter-departmental relationships, quality of communications, degree of hierarchy

ID	Authors	Year	Population	Study design / QI method	Aim	Context described
20	Canaway, Bismark, Dunt & Kelaher	2017	Chief Medical Officers and Directors of Medical Services in Victoria, Australia in 2016	Qualitative study using thematic analysis of interviews	To understand the concerns and factors that impact on hospital quality and safety.	Organisational culture and perceptions, Governance, Resources, Education & training, Reporting systems & technologies
21	Gilhooly, Green, McCann, Black & Moonesinghe	2019	International Health care literature	a scoping review	To describe the available data relating to care bundle development, implementation and evaluation in acute care hospital	ChampionsMulti-disciplinary teamsanalysis of resultsdevelopment of stakeholder relationshipseducation & trainingpostersprinted algorithmsscreen saversreduced number of bundle components

Appendix 5 List of raw data extracted from context literature review

Context described

quality of care data

use of statistical and process management tools

focus on process and system improvement

guideline use

years involved in quality improvement

characteristics of health care system

social values

history of quality assurance

skills in decision making

adoption of quality information system

Participative, flexible and risk-taking organisational culture

positive association with self-management and clinical information systems

healthcare setting

patient population

quality improvement culture

strong physician leadership

Policies / Laws / Regulation

Protocols / Guidelines

Work process design

Technology

People

Participant willingness and confidence to change is high.

Organisational culture

Polices & procedures

Past experience

organisational resources

organisational structure

Complexity of care

Multiple existing standards, guidelines and protocols which are often poorly integrated

multiple stakeholders

strong inter and intra professional boundaries and the continued dominance of the medical profession

reluctance of many health professionals to engage in QI activities

limitations in the abilities of managers to direct or control health professionals

varying standards of data and infrastructure support for data collection and analysis

contest and negotiation around what counts as quality in health care and around the nature of evidence

traditional patterns of education and socialisation that have focused on individual expertise and have not encouraged a team or system-wide approach

the on-going impact of successive NHS re-organisation together with a history of top-down changes approaches.

leadership, culture & resources

Barriers and Enables were identified as the 7 factors.

Not specifically called out as context factors

Definition of context provided but not what they might be.

Safety Culture, teamwork & leadership involvement

structural organisational characteristics

external factors

availability of implementation & management tools

leadership, culture or institutional financial status or quality improvement infrastructure

Context factors required in a High Reliability Organisation are:

- Deference to expertise during emergencies
- management by exception
- climate of continuous training
- several channels are used to communicate safety critical information
- there are in-built redundancies

Referenced but not explicitly described or named

Insight into effects

Knowledge

Guidance

External environment

organisation

QI support & capacity

micro-system

QI team

Organisational level of programme implementation

patient turnover & bed occupancy

staffing levels

quality of evidence & guidelines

maturity of systems supporting decision support

trust in & quality of information

education outreach

Institutional, symbolic, economic, social, historical and external

local organisational culture

local structures and experience of the implementation team

degree of administrative support

project support - equipment, people and data

clinician engagement

inter-departmental relationships

quality of communications

degree of hierarchy

Organisational culture and perceptions

Governance

Resources

Education & training

Reporting systems & technologies

Champions

Multi-disciplinary teams

analysis of results

development of stakeholder relationships

education & training

posters

printed algorithms

screen savers

reduced number of bundle components

Appendix 6 Characteristics of health care Organisations (Powell et al 2009)

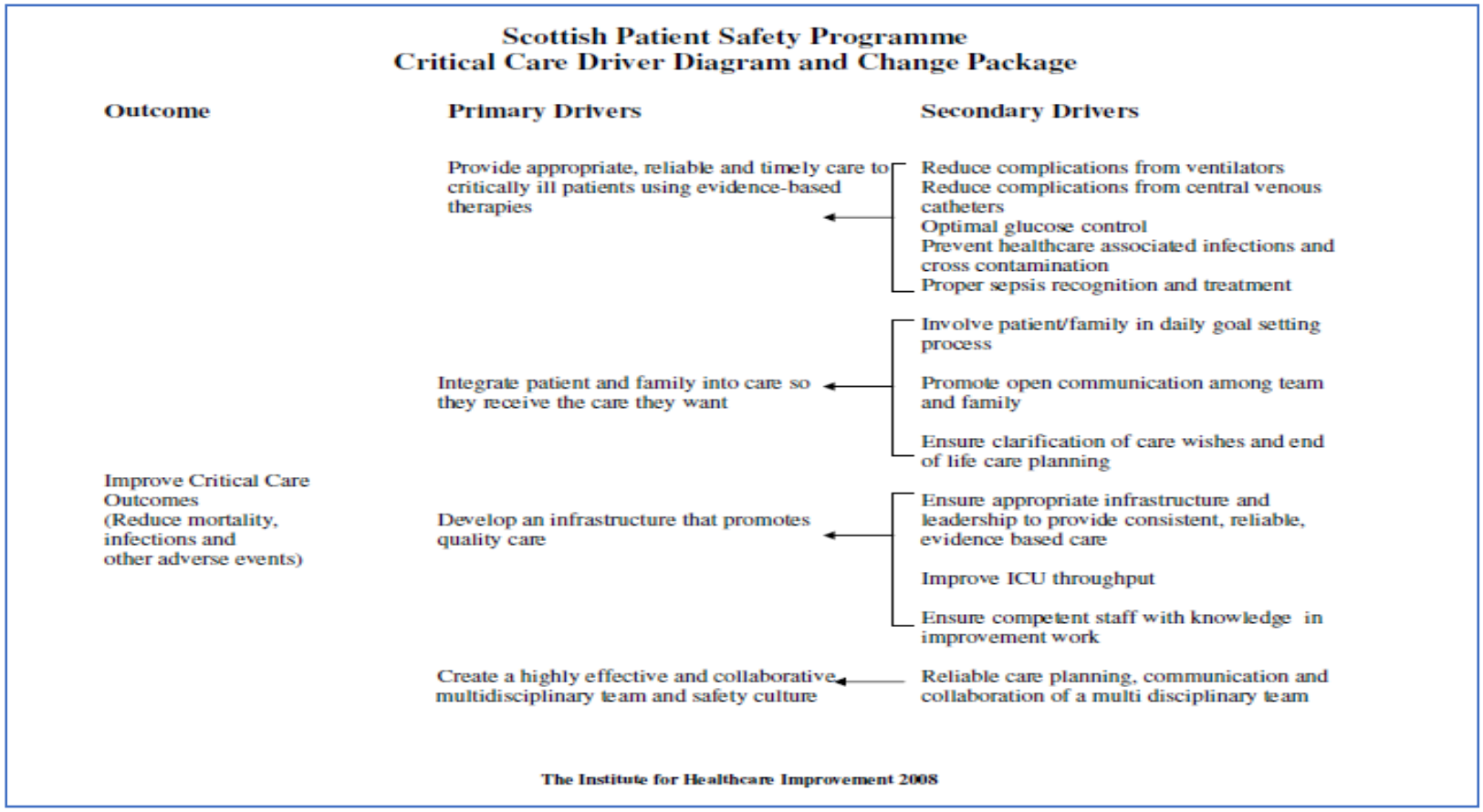
Box H: Characteristics of health care organisations

- Complexity of care processes
- Multiple existing standards, guidelines and protocols which are often poorly integrated
- Multiple stakeholders (e.g. patients, communities, staff, media, politicians)
- Strong inter- and intra-professional boundaries, and the continued dominance of the medical profession (and unless their involvement is secured – which is challenging – quality improvement initiatives will remain peripheral and their impact will be limited)
- Reluctance of many health professionals to engage in quality improvement activities
- Limitations on the ability of managers to direct or control health professionals;
- Varying standards of data and infrastructure support for data collection and analysis
- Contest and negotiation around what counts as 'quality' in health care and around the nature of 'evidence'
- Traditional patterns of education and socialisation that have focused on individual expertise and have not encouraged a team or system-wide approach
- The ongoing impact (on staff, on structures, and on processes) of successive NHS reorganisations together with a history of top-down change approaches.

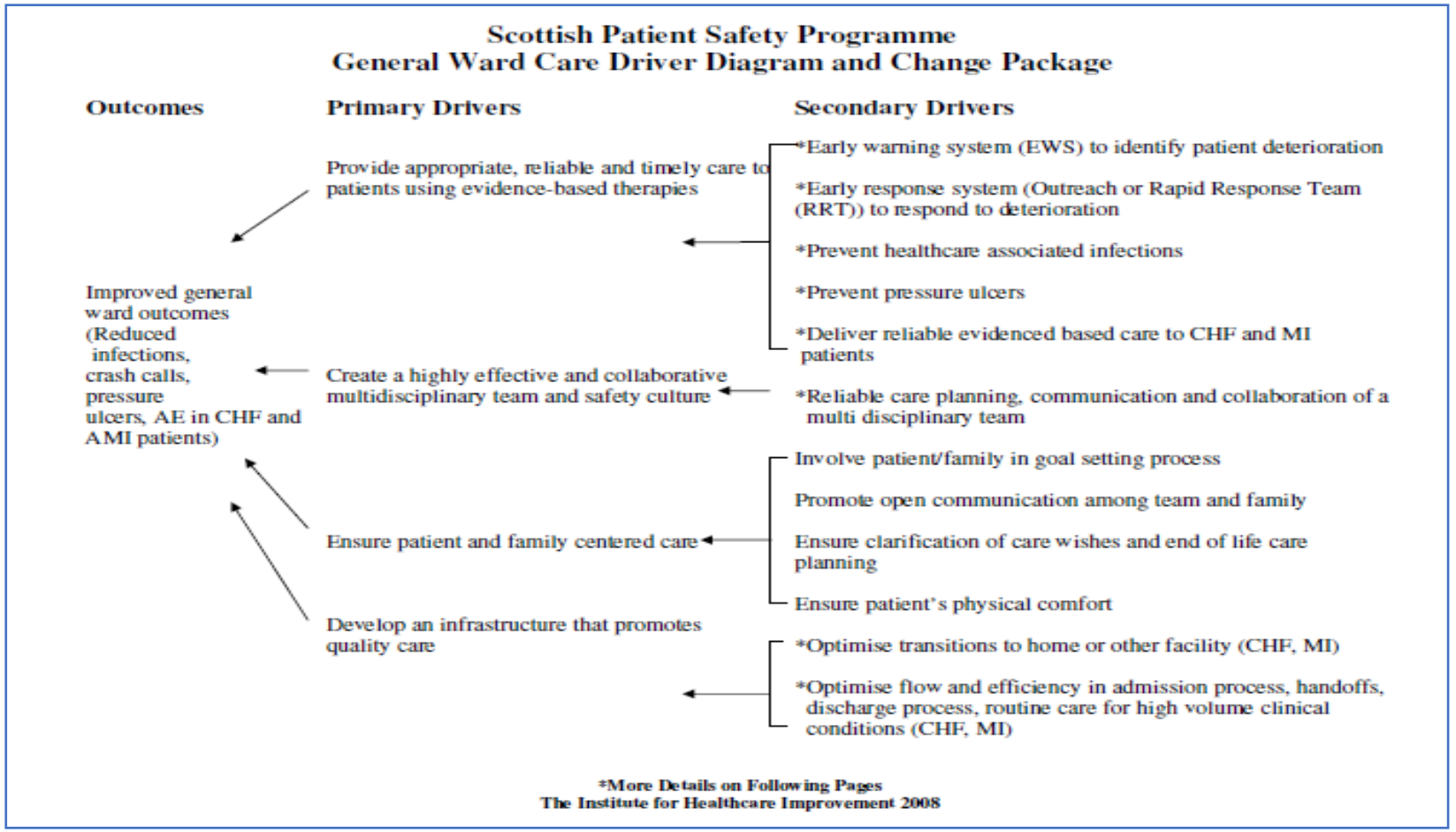
Sources: Ovretveit 1996; Pollitt 1996; Koeck 1998; Buetow and Roland 1999; Bate 2000; Batalden 2001; Ferlie and Shortell 2001; Fitzgerald et al. 2002; Ham et al. 2003; Leatherman and Sutherland 2003; McNulty 2003; Sheaff et al. 2003; Fulop et al 2005; Davies et al. 2006.

Appendix 7 Driver diagrams

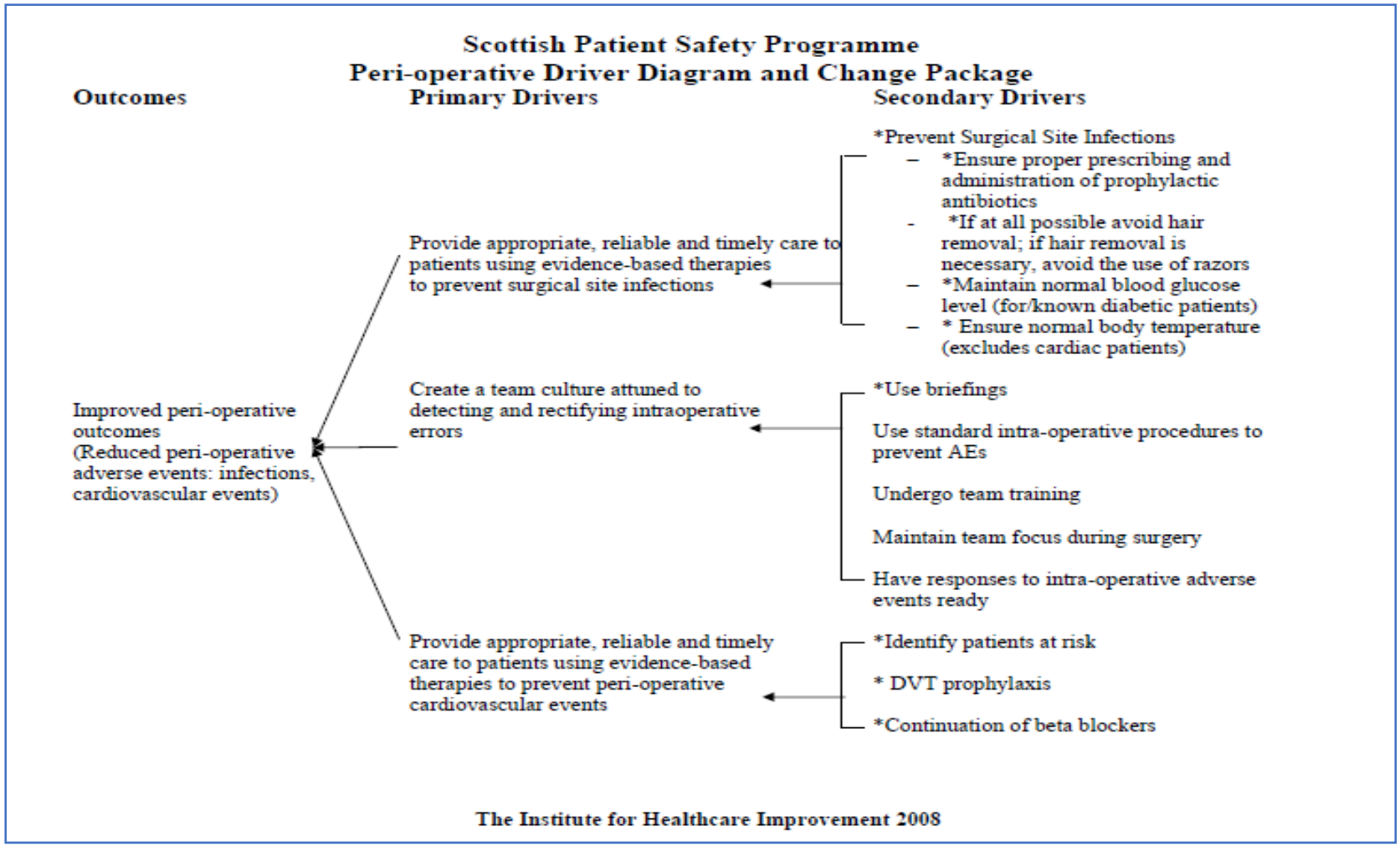
Critical care Driver Diagram



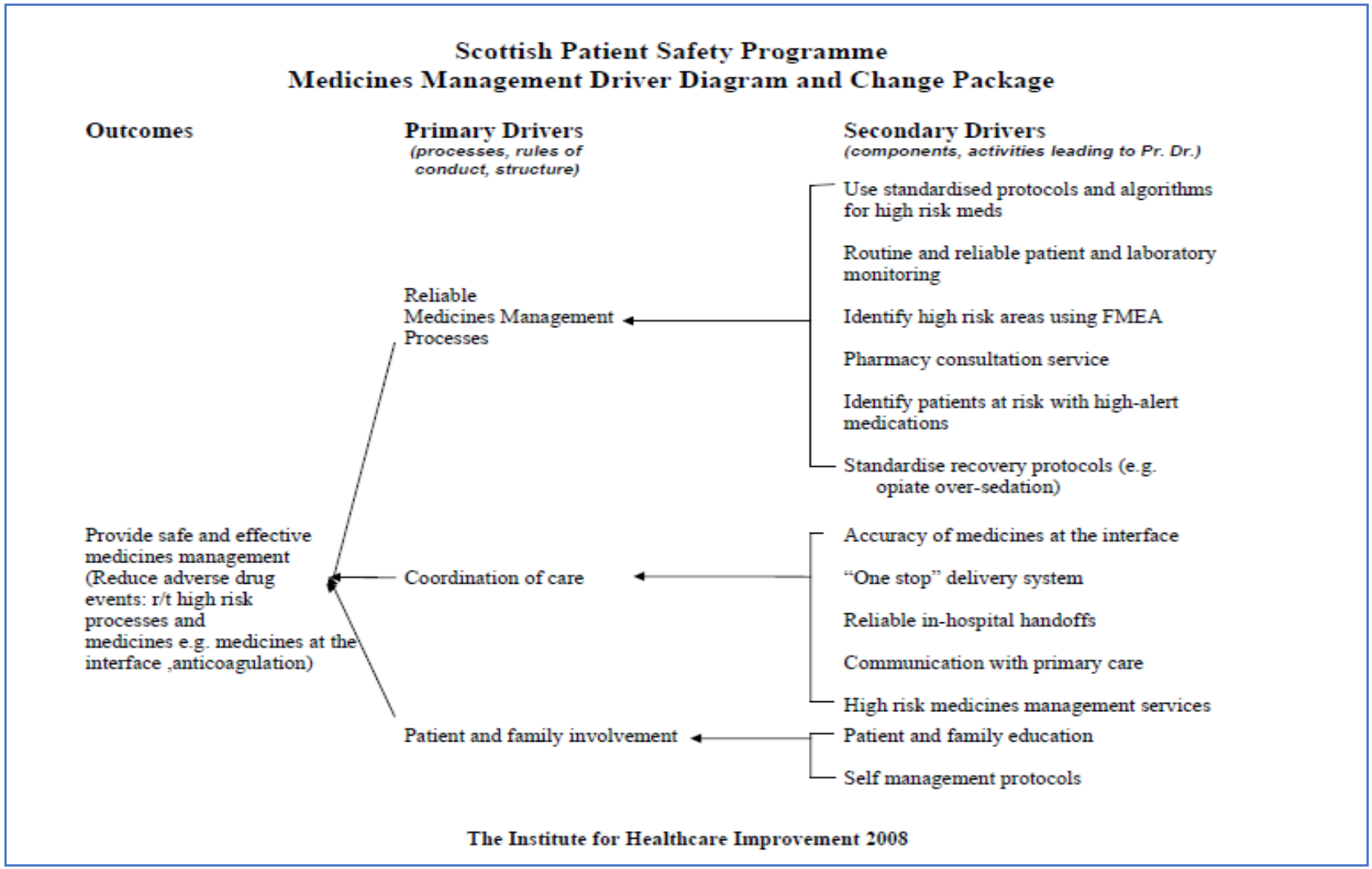
General Ward driver diagram



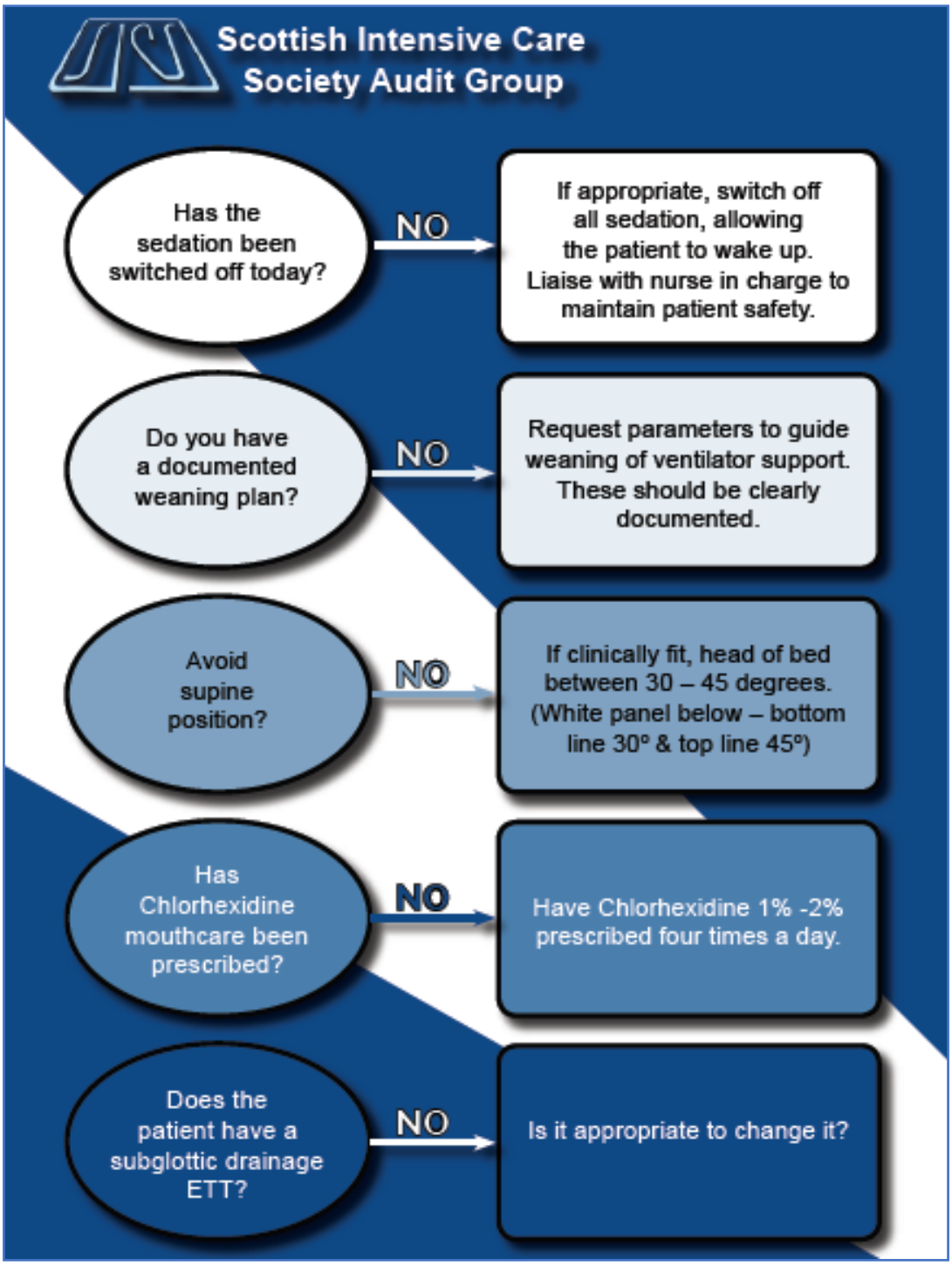
Peri-operative Care Driver diagram



Medicines Management Driver Diagram



Appendix 8 VAP prevention bundle



Appendix 9 Tabular collation of literature review data (clinical engagement)

ID	Authors	Date	Title	Journal details	Volume / pages	Context - setting	Study design / QI method	Main findings
1	Benn, Burnett, Parand et al	2009	Studying large-scale programmes to improve patient safety in whole care systems: Challenges for research	Social Science & Medicine	69 Pg. 1767 - 1776	International Literature	Literature review	The efficacy of large-scale improvement programmes is dependent on a multitude of factors including the engagement of frontline staff as well as management engagement. It was demonstrated that management engagement was increased all participating site however it is not described explicitly how this was achieved.
2	Kirkpatrick, Jesperson, Dent et al	2009	Medicine and Management in a Comparative Perspective: The Case of Denmark and England.	Sociology of Health and Illness	31(5) Pg. 642 - 658		Literature review	Relating to the effective relationships established when medical staff engage with managers within the organisation, comparing Denmark and England.
3	McLeod & Clarke	2009	Engaging for Success	Office of Public Sector Information		International literature	Literature review	Engagement is a two-way relationship between the individual and organisation. Effective active engagement correlates with positive outcome for the organisation and the individual. There is a difference between active engagement and passive participation – passive participation is related to low morale, poor organisational outcomes and low retention rates while active engagement has the reverse correlation.
4	Wilkinson, Powell & Davies	2011	Are clinicians engaged in quality improvement?	Health Foundation Evidence:		International Literature	Literature review	Active involvement is an essential requirement for quality improvement in any organisational setting. However, HS organisations struggle to secure clinical engagement. Lack of engagement is commonly associated with conflict in perspective of how quality is defined and who has the responsibility to deliver. Patient engagement in quality improvement is also highlighted.
5	Best et al	2012	Large-System Transformation in Health Care: A Realist Review	The Milbank Quarterly	90(3) Pg. 421 - 456		Literature review	Five "simple rules" of Large-system transformation which are likely to enhance the success of initiatives – blending designated leadership with distributed leadership, establishing feedback loops, attendance to history, engaging physicians and including patients & families. Engagement and leadership are closely aligned and have a synergistic effect but are also impacted by local context. Specifically call out physician engagement but also talk about multi-professional engagement too. Physicians are not necessarily required to achieve improvement but have the power over initiatives and can veto progress.
6	Braithwaite et al	2014	Harnessing implementation science to improve care quality and patient safety: a systematic review of targeted literature	International journal for Quality in Health Care	26(3) Pg. 321 - 329	Targeted International literature	Literature review	Do not refer specifically to engagement of staff, but report that staff co-operation influences the uptake of an implementation initiative.

ID	Authors	Date	Title	Journal details	Volume / pages	Context - setting	Study design / QI method	Main findings
7	Pannick, Sevdalis, Anthanasiou	2016	Beyond clinical engagement: a pragmatic model for quality improvement interventions, aligning clinical and managerial priorities.	BMJ Quality & Safety	25 Pg. 716 - 725		Literature review	Clinical Engagement is not well defined. Recognition of the link between clinical engagement and context factors. Clinical engagement involves staff actively contributing to quality improvement within their normal job role, to maintain and enhance organisational goals. Without organisational commitment or contribution to the active engagement there I not improvement in patient care. Clinical engagement should involve and encompass the wider health care professional groups not just medical staff
8	Knight	2018	How Clinical Instructor Behavior Affects Student Clinical Engagement from a Motivational Perspective	Journal of Nuclear Medicine Technology	46(2) Pg. 99 - 106	University Hospitals in United States of America	Literature review	Paper related to student doctor engagement with tutors. Introduces the concept of self-determination theory and its relationship to engagement and participation.
9	Melder, Robinson, McLoughlin, Iedema, Teede	2020	An Overview of Healthcare Improvement: Unpacking the Complexity for Clinicians and Managers in a Learning Health System	Internal Medicine Journal		International Literature. Systematic and narrative reviews and meta-analysis	Literature review	Engagement required at all levels with healthcare settings including within the Board. There is a strong relationship between effective medical engagement and improved patient outcomes. Meaningful engagement is achieved by ensuring clinicians perceives that their focus is on individual patient care
10	Croft, Williams, Mann, Cohen & Phillips	2007	Can hospital episode statistics support appraisal and revalidation? Randomised study of physician attitudes	Clinical Medicine	7(4) Pg. 332 - 338	NHS England and NHS Wales Consultant physicians	Quantitative: Randomised Controlled Trial	Aim of the study was to promote data quality improvement through clinical engagement. Where consultants were engaged in data collection processes, they reported increased confidence in using and trusting the data reported. Where consultants were not engaged in the data collection processes there was considerable reservation about the data and its validity. Those consultants who were not engaged in the process perceived the data to be inaccurate and unfit for purpose.
11	Detwiller & Petillion	2014	Change Management and Clinical Engagement	CIN: Computer, Informatics, Nursing	32(6) Pg. 267 - 273	A local health authority in British Columbia, Canada	Quantitative study	Reflecting on a project lead by local nursing team. Multiple skills and interventions required to establish change including consensus building, systems thinking approach, understanding of theory of change. Improvement team provided leadership and facilitated the group to move towards common standards of practice. Involvement of the clinical staff was instrumental in creating the new standards of care. Devolved responsibility fundamental. It is not clear in the early part of the paper that physician engagement was not included in clinical engagement. Physician engagement was challenging to establish and should have been sought sooner in the project as it delayed progress, while the team worked to engage the medical team.

ID	Authors	Date	Title	Journal details	Volume / pages	Context - setting	Study design / QI method	Main findings
12	Da Silva	2015	What's getting in the way? Barriers to improvement in the NHS	Health Foundation	24	Evidence scan	Quantitative	The characteristics of the individual can adversely impact their ability to lead or engage in improvement. Clinicians limited understanding of improvement tools can lead to reduced engagement. Organisational constructs such as silo working can lead to lack of staff engagement. Enablers of engagement identified as dissemination of data from improvement activity related to increased engagement with change.
13	Spurgeon, Mazelan & Barwell	2011	Medical engagement: a crucial underpinning to organizational performance	Health Services Management Research	24 Pg. 114 - 120	United Kingdom	Quantitative	Although engagement does correlate with performance it is not always clear the direct causality. Engagement is a multi-faceted construct and therefore complex, which leads to the lack of clarity in establishing links between performance and engagement. Medical engagement is critical to ensuring service changes are carefully planned and effectively implemented, although there is not comparator group of alternative professionals to confirm this. The Medical engagement scale used measures ability and willingness to participate. Medial engagement is associated with improved patient mortality, reduction in severe harm reports and increased stability in levels of service delivery. Statistical relationships exist for the three points above.
14	Burnett et al	2010	Organisational Readiness: Exploring the preconditions for success in organisation-wide patient safety improvement programmes.	Quality & Safety in Health Care	19 Pg. 313 - 317	United Kingdom, NHS	Qualitative	Medical engagement is essential for the success of improvement programmes. The process of developing active engagement among medical staff rather than passive acceptance is not understood.
15	Parand, Burnett, Benn, Iskander, Pinto and Vincent	2010	Medical engagement in organisation-wide safety and quality-improvement programmes: experience in the UK Safer Patients Initiative	Quality & Safety in Health Care	19	Acute care in United Kingdom	Qualitative	7 factors which are considered enablers and barriers: QI track record, Resource allocation, Perceptions of purpose, evidence of efficacy, external expertise, local champions, managerial involvement. Each factor can contribute positively or negatively. Medical engagement is considered a complex socio-political and motivational issue underpinned by a series of inter-related factors associated with organisational context.
16	Jeffs, McShane, Indar et al	2018	Using Local Data to Improve Care and Collaborative Practice	Journal of Nursing Care Quarterly	33(3) Pg. E1 – E7	Acute care setting, Canada	Qualitative	Introducing change to care in an acute care setting is dependent on using data to understand local context and the ability to progress and staff are looking to improve care and engage in collaborative practices. Early engagement with medical staff would have supported quicker progress.

ID	Authors	Date	Title	Journal details	Volume / pages	Context - setting	Study design / QI method	Main findings
17	Donaldson et al	2015	Bridging the Gap Between Content and Context: Establishing Expert Consensus on the Content of an Exercise Training Program to Prevent Lower-Limb Injuries	Clinical Journal of Sports Medicine	25(3) Pg. 221 - 229	Australian Football League Medical Officers	Delphi Study	Primary outcome was the level of agreement on the appropriateness of proposed exercises and progressions for inclusion in FootyFirst. Engaging clinicals and sports scientists was essential to achieve consensus. Agreement was reached using a Delphi approach across three rounds of discussion. Exercises were only included where there was "strong" or "very strong" agreement from the group. It is not detailed in the paper how consensus was reached within each round nor how engagement was determined in the process.
18	Guthrie	2004	Engaging Physicians in Performance Improvement	American Journal of Medical Quality	20(5) Pg. 235 - 238	United States of America	Discussion Paper	There is a direct relationship between the ability of those in management positions to effectively communicate the case for improvement with key physicians. The ensure the improvement achieves the intended outcome managers and physicians need to work together to create a sense of purpose for the change required.
19	Alimo-Metcalfe & Bradley	2008	Cast in a new light	People Management		United Kingdom healthcare	Discussion Paper	Successful engaged leadership is achieved by 1) engaging stakeholders from the outset, 2) establishing a collective vision of good-quality service, 3) establishing non-hierarchical teams, 4) developing supportive culture where staff receive informal support from colleagues and team leads and 5) a collective team response to top-down changes and the development of joint actions plans
20	Patel, Spilsbury & Shulka	2010	Clinical contributions to addressing the social determinants of health	Clinical Medicine	10(2) Pg. 130 - 133	International perspective	Discussion Paper	Clinical engagement through out the organisation is essential to improvement outcomes for patients. It is essential that clinicians engage across the health and social care setting to promote and embed prevention services for all. Utilising appropriate data to influence strategy, programmes and partnerships. It is only with effective clinical engagement that it will be possible to both improve quality and ensure value for money in care services.
21	Maybin & Thorlby	2008					National Report	Facilitated clinical engagement with community and specialist practitioners to ensure a "partner" approach to commissioning. Clinical leadership and work force planning to ensure improved services for patients and service users

Appendix 10 Interview Schedule

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SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Interview schedule

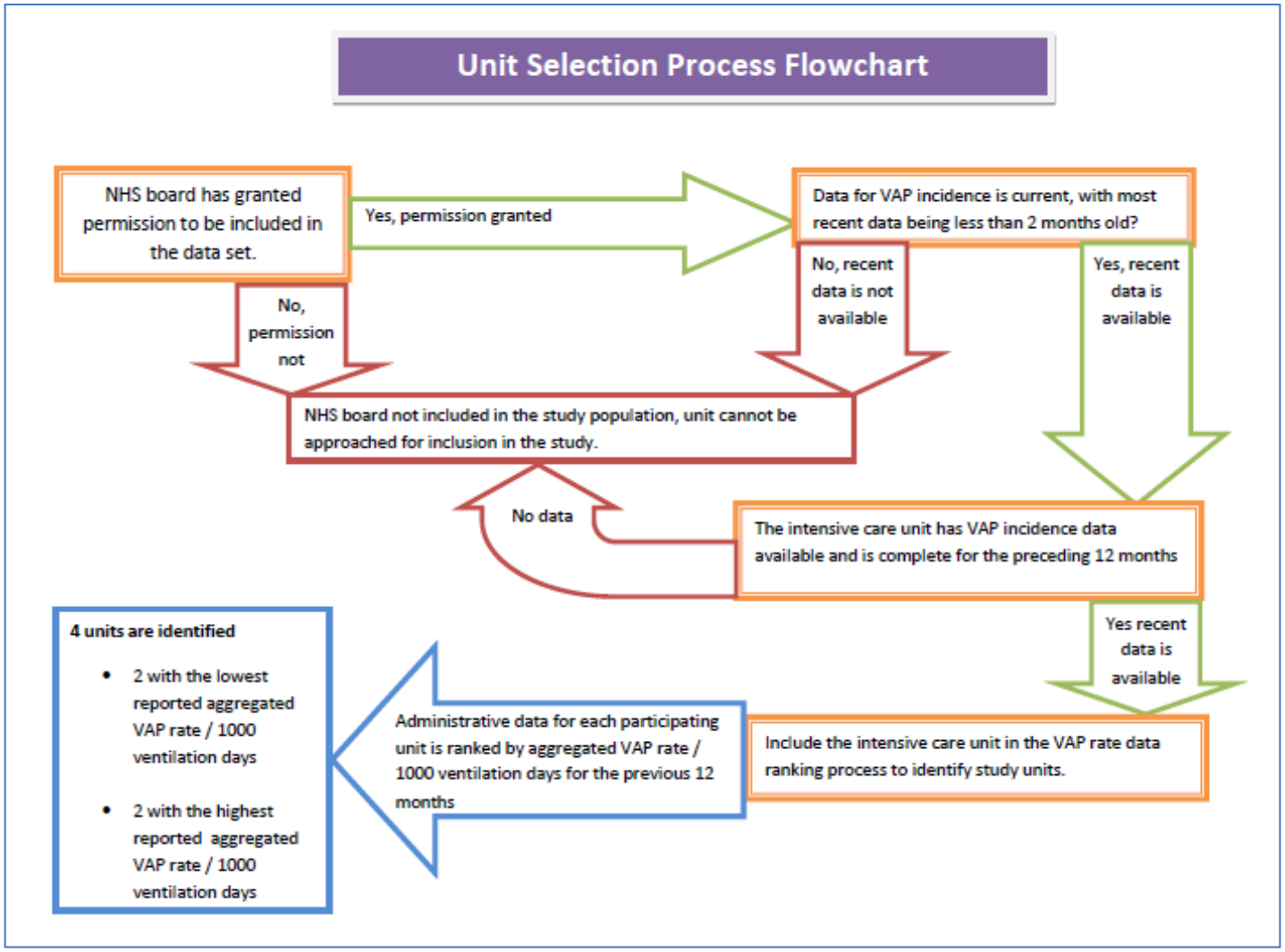
Opening question

"Please tell me in your own words what clinical engagement means to you in relation to reducing VAP incidence in your ICU."

Subsequent questions to be asked.

- If you perceive there are barriers to establishing clinical engagement in the unit, can you describe these for me?
- If you perceive there are enablers to establishing clinical engagement in the unit, can you describe these for me?
- Do you perceive that all members of staff perceive clinical engagement in the same within the unit?
- Do you perceive that clinical engagement is influential in the unit's ability reduce VAP incidence?

Appendix 11 - Unit selection process flowchart



Appendix 12 Template letter to the lead consultant intensivist and senior charge nurse (2-page letter)

KE

DD/ MMM /2013

UNIVERSITY OF STIRLING

SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Kirsteen Ellis
Clinical Doctorate Student
School of Nursing, Midwifery and Health
University of Stirling
Stirling FK9 4LA

Tel: 07974 155 242

Email: k.s.ellis@stir.ac.uk

Lead Consultant / Senior Charge Nurse Intensive Care Unit
NHS Board
Scotland

Dear
I am a clinical doctorate student in the School of Nursing, Midwifery and Health at the University of Stirling, I am undertaking a study to investigate the meaning of Clinical Engagement for hospital managers, doctors and nurses who have been involved in the implementation of quality improvement methodology.

As you will know from the literature on the subject of clinical engagement, establishing clinical engagement is central to successful implementation of quality improvement methodology but it is also identified in the literature that it is not always clear what is meant by clinical engagement, for instance does it refer to only the medical profession or is this all frontline healthcare providers? How do frontline staff themselves perceive clinical engagement?

The purpose of my study is to seek clarity on how staff describe clinical engagement and to investigate if there is a relationship between the words and phrases used by staff to describe clinical engagement and unit ventilator associated pneumonia (VAP).

I would like to approach the staff in your unit seeking volunteers to take part in 30 minute individual interviews to explore this further. Ideally I would like to interview 3 doctors of any grade and 3 nurses of any band who have been involved in the implementation of quality improvement methodology in your unit. I will also be interviewing three hospital managers who have responsibility for critical care services in your board.

I would like to attend your unit and present my proposed study at a staff meeting, providing further detail on the rationale for the study and how you and your staff would be able to contribute to my study. Please find attached a generic information leaflet which I would distribute to staff prior to me presenting my study.

Please do not hesitate to contact me or my study supervisors if you have any questions or would like to discuss my study further

Kind regards

Kirsty Ellis

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Centre for Health Science
Old Perth Road
Inverness IV2 3JH

Tel: +44 (0) 1463 255655
Fax: +44 (0) 1463 255654

Stirling Campus:
Stirling
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Tel: +44 (0) 1786 466340
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Western Isles Campus:
Western Isles Hospital
MacAulay Road
Stornoway Isle of Lewis HS1 2AF

Tel: +44 (0) 1851 708243
Fax: +44 (0) 1851 706070

CC: Research & Development Department NHS board
Dr Ashley Shepherd, University of Stirling – study supervisor ashley.shepherd@stir.ac.uk
Dr Iain Atherton, University of Stirling – study supervisor iain.atherton@stir.ac.uk

Appendix 13 Template letter to Senior Manager / Service Manager of the Unit

KE

DD/ MMM /2013

UNIVERSITY OF STIRLING

SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Kirsteen Ellis
Clinical Doctorate Student
School of Nursing, Midwifery and Health
University of Stirling
Stirling FK9 4LA

Tel: 07974 155 242

Email: k.a.ellis@stir.ac.uk

General Manager / Service Manager / Nurse Manager Intensive Care Unit
NHS Board
Scotland

Dear
I am a clinical doctorate student in the School of Nursing, Midwifery and Health at the University of Stirling, I am undertaking a study to investigate the meaning of Clinical Engagement for hospital managers, doctors and nurses who have been involved in the implementation of quality improvement methodology.

As you will know from the literature on the subject of clinical engagement, establishing clinical engagement is central to successful implementation of quality improvement methodology but it is also identified in the literature that it is not always clear what is meant by clinical engagement, for instance does it refer to only the medical profession or is this all frontline healthcare providers? How do frontline staff themselves perceive clinical engagement?

The purpose of my study is to seek clarity on how staff describe clinical engagement and to investigate if there is a relationship between the words and phrases used by staff to describe clinical engagement and unit ventilator associated pneumonia (VAP).

I would like to invite you to take part in a 30 minute individual interview to explore your perceptions of the topic. I will also be interviewing three doctors and three nurses who have been involved in implementing quality improvement methodology in your unit.

I have also written to the lead intensivist and senior charge nurse requesting permission to attend your unit and present my proposed study at a staff meeting, providing further detail on the rationale for the study and how you and your staff would be able to contribute to my study. If you were unable to join this meeting I would like to meet with you to discuss the study further. Please find attached a generic information leaflet which I provides some more detail of my study.

Please do not hesitate to contact me or my study supervisors if you have any questions or would like to discuss my study further

Kind regards

Kirsty Ellis

Highland Campus:
Centre for Health Science
Old Perth Road
Inverness IV2 3JH

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Western Isles Campus:
Western Isles Hospital
MacAulay Road
Stornoway Isle of Lewis HS1 2AF

Tel: +44 (0) 1851 706243
Fax: +44 (0) 1851 706070

CC: Research & Development Department NHS board
Dr Ashley Shepherd, University of Stirling – study supervisor ashley.shepherd@stir.ac.uk
Dr Iain Atherton, University of Stirling – study supervisor iain.atherton@stir.ac.uk

Appendix 14 Participant Information Leaflets

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Who has designed and reviewed the study?

The study has been designed by me under the supervision of my research supervisors Dr Ashley Shepherd and Dr Iain Atherton from the School of Nursing, Midwifery and Health, University of Stirling. The study is not being funded by any external sponsors.

Further information
If you have any questions or would like further information about the study, please contact Kirsteen Ellis Clinical Doctorate student, School of Nursing, Midwifery and Health, University of Stirling k.s.ellis@stir.ac.uk or phone: _____ who will be happy to discuss any queries you may have.

Alternatively please feel free to contact Dr Ashley Shepherd, Senior Lecturer and Research Supervisor, ashley.shepherd@stir.ac.uk or Dr Iain Atherton, Lecturer and Research Supervisor, iain.atherton@stir.ac.uk .

If you wish to speak to an independent advisor about the study or if you have any complaints, please contact Professor Billy Lauder at the School of Nursing, Midwifery and Health, University of Stirling
(Tel: _____)

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Version: V0_2	

UNIVERSITY OF STIRLING

SCHOOL OF NURSING, MIDWIFERY AND HEALTH

How do Staff in Scottish Intensive Care Units describe Clinical Engagement?

Information Leaflet

I would like to invite you to take part in a study to understand the perceptions which doctors and nurses working in ICUs have of clinical engagement. For you to decide whether or not you would like to participate, it is important that you understand why we are carrying out this study and what exactly it involves if you agree. This leaflet should help explain what we are doing so please take time to read it carefully and discuss it with others if you wish. If there is anything you are unsure about or you want to find out more please ask me for more information.

Who am I?
My name is Kirsteen Ellis and I am a registered nurse, with clinical experience in critical care nursing. I am also a Clinical Doctorate Student from the School of Nursing, Midwifery and Health, University of Stirling. The study is being run as part of my Clinical Doctorate training.

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SCHOOL OF NURSING, MIDWIFERY AND HEALTH

What is the purpose of the study?
I am interested in understanding how doctors and nurses in Scottish ICUs who have been involved in implementing quality improvement methodology perceive clinical engagement.

Why have I been approached?
I am inviting doctors and nurses in four ICUs selected from across Scotland to take part and share their individual perceptions of clinical engagement.

Do I have to take part?
You do not have to take part, participation is voluntary. You have been given this Information Leaflet prior to attending a presentation of the study by me, Kirsteen Ellis. If you are interested in taking part after reading this leaflet, please contact me on the mobile number _____ or by email k.s.ellis@stir.ac.uk
Alternatively please speak with me when I visits your unit to discuss the study further on .....

What will I have to do?
If you are interested in taking part, I will organise a time for you to undertake an in-depth interview with me at a time which is convenient to you. The discussion will be to explore your perceptions of clinical engagement relating to your work to reduce ventilator associated pneumonia in your unit. The discussion will be audio-recorded. If you do decide to come along, you will be asked to sign a consent form. Participation in the interview is entirely voluntary and you may leave the interview at any time without having to give a reason.

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Version: V0_2	

Will I be paid for participating?
No

Confidentiality
Nothing that you say in the interview will be linked to you as an identifiable individual. I will be the only person who will be listening to recordings of the interview and all the recordings will be securely stored.

Ethical issues
The Ethics Research Committee of the School of Nursing, Midwifery and Health, University of Stirling, has no ethical objections to this study and has given permission for this study to be carried out.

What will happen to the results of the research study?
The findings from this study will used during my study to gain a clinical doctorate and the findings will written up in my thesis. Also, the overall findings of the study will be published in a scientific journal but you will not be identified in any way in the report. A summary of the findings of the study will also be sent to you.

Appendix 15 Recruitment Poster

Have you been involved in implementing quality improvement methodology in your units?

And

Would you like to share your views on clinical engagement?

Volunteers Required

I am looking for volunteers to take part in 30 minute interviews.

Why not come along to hear more on: .....

At .....

If you are interested:

Contact Kirsteen Ellis

Clinical Doctorate Student

University of Stirling, School of Nursing, Midwifery & Health

07XXXXXXXX

k.s.ellis@stir.ac.uk

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SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Appendix 16 Participant Consent Form

UNIVERSITY OF STIRLING

SCHOOL OF NURSING, MIDWIFERY AND HEALTH

Centre Number:

Study Number:

Participant Identification Number:

CONSENT FORM

Title of Project: How do Staff in Scottish Intensive Care Units Describe Clinical Engagement?

Name of Researcher: Kirsty Ellis

	Participant initials
I confirm that I have read and understand the information sheet dated 28/04/2013 (versionV0_2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
I understand that the interview will be recorded on a digital recording machine prior to transfer to an electronic document	
I understand that confidentiality will be respected and no information that discloses my identity will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities.	
I give consent that during the write-up of this study and in any future publications my responses can be used but that the researcher will ensure that it will not be possible to identify me or my unit from the text or quotes used	
I agree to take part in the above study.	

.....

Name of Participant Signature Date

.....

Name of Person taking consent Signature Date

When completed: 1 for participant; 1 for researcher site file, 1 scanned copy for researcher

File: 20120310_Consentformv0_3		Date:28/04/13
Produced by: KEllis	Page 1 of 1	Review date / status: draft

Appendix 17 School Ethical Consent

JP/SG

18 June 2013

UNIVERSITY OF STIRLING

SCHOOL OF
NURSING, MIDWIFERY
AND HEALTH

Email: nursingmidwifery@stir.ac.uk
Web: www.nm.stir.ac.uk

John Paley
Chair
School Research Ethics Committee

School of Nursing, Midwifery and Health
University of Stirling
Stirling FK9 4LA

Tel: +44 (0) 1786 466399
Fax: +44 (0) 1786 466333
Email: john.paley@stir.ac.uk

Kirsteen Ellis
Clinical Doctorate Student
School of Nursing, Midwifery and Health
University of Stirling
Stirling
FK9 4LA

Dear Kirsteen

How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

Thank you for submitting this application, which was discussed by SREC members on 14 June 2013.

I'm happy to confirm that the Committee has approved the application.

May I take this opportunity to remind you that a site-file of *all* documents related to the research should be maintained throughout the life of the project, and kept up to date at all times. The site file template can be found on the SREC page of the School's website. Please bear in mind that your study could be audited for adherence to research governance and research ethics protocols.

Yours sincerely

John Paley
(Chair)
School of Nursing, Midwifery and Health Research Ethics Committee

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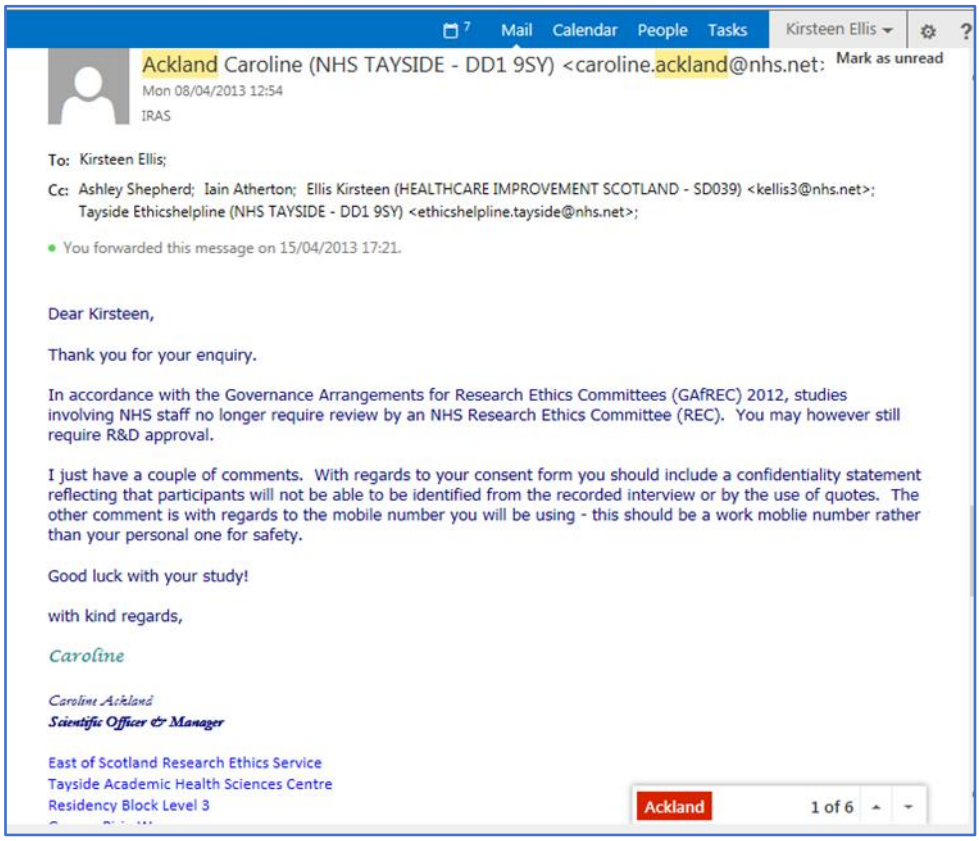
Tel: +44 (0) 1851 708243
Fax: +44 (0) 1851 706070

Appendix 18 Email response from Caroline Ackland – Tayside Ethics



7 Mail Calendar People Tasks Kirsteen Ellis

Ackland Caroline (NHS TAYSIDE - DD1 9SY) <caroline.ackland@nhs.net: Mark as unread

Mon 08/04/2013 12:54

IRAS

To: Kirsteen Ellis;

Cc: Ashley Shepherd; Iain Atherton; Ellis Kirsteen (HEALTHCARE IMPROVEMENT SCOTLAND - SD039) <kellis3@nhs.net>; Tayside Ethicshelpline (NHS TAYSIDE - DD1 9SY) <ethicshelpline.tayside@nhs.net>;

You forwarded this message on 15/04/2013 17:21.

Dear Kirsteen,

Thank you for your enquiry.

In accordance with the Governance Arrangements for Research Ethics Committees (GAfREC) 2012, studies involving NHS staff no longer require review by an NHS Research Ethics Committee (REC). You may however still require R&D approval.

I just have a couple of comments. With regards to your consent form you should include a confidentiality statement reflecting that participants will not be able to be identified from the recorded interview or by the use of quotes. The other comment is with regards to the mobile number you will be using - this should be a work moblie number rather than your personal one for safety.

Good luck with your study!

with kind regards,

Caroline

Caroline Ackland
Scientific Officer & Manager

East of Scotland Research Ethics Service
Tayside Academic Health Sciences Centre
Residency Block Level 3

Ackland 1 of 6

Appendix 19 Letter of Access Unit 1

NHS to NHS letter of access: proforma confirmation of pre-engagement checks
Version 1

For NHS researchers who have a substantive NHS contract of employment or clinical academics with an honorary clinical contract with an NHS organisation, and who need an NHS to NHS letter of access from an NHS organisation hosting their research

CONFIRMATION OF PRE-ENGAGEMENT CHECKS

To: R&D Office
C/O

Job title: Associate Improvement Advisor

Contract end-date: Permanent post

Workplace and postal address: Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Electronic Staff Record number: 1053599

As the representative of the NHS employer[1] of the above-named person, I can confirm that s/he is employed by this organisation. I understand that the responsibility for ensuring that the appropriate pre-engagement checks have been undertaken rests with us as the individual's substantive employer. I can confirm that the appropriate pre-engagement checks have been completed, commensurate with her/his job description and proposed research role in your NHS organisation, and in line with NHS employment checks standards

Name of employer's representative: Jenny Davidson-Boyd

Job Title: HR Advisor

[1] For clinical academics, this would be a representative from their HEI employer

Workplace address: Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB
Tel: 0131 623 4711
Email: jenny.davidson-boyd@nhs.net

Appendix 20 Research & Development Certificate Unit 1

Research and Development Support Unit
Ground Floor

Mrs Kirsteen Ellis
Healthcare Improvement Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Date: 27th September 2013
Our ref 13/[ ]032
Study title: How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

Dear Ms Ellis

Thank you for sending me details of your study with a request for management approval. I can confirm that the study review team has reviewed the documentation and on this basis I am pleased to inform you that your study has management approval for commencement within NHS [ ]

It is a condition of this approval that everyone involved in this study abides by the guidelines/protocols laid down by this Health Board in respect of confidentiality and Research Governance. It is your responsibility to ensure you are familiar with these; please do not hesitate to seek advice if you are unsure. (Copies of Research Governance Framework document available via the website www.sehd.scot.nhs.uk/cso and then use the publications link).

We also note that it is the sponsor's responsibility to ensure that appropriate training is in place for all local investigators. It is important that all research must be carried out in compliance with the Research Governance Framework for Health and Community Care and the new EU Clinical Trials Directive (for clinical trials involving investigational medicinal products).

As part of the Health Board's responsibilities under Research Governance we will be monitoring studies at least on an annual basis. It is therefore important that all records in connection with the study are kept up to date and available for review. We are also required to inform you that details of your study will be entered onto our R&D database. As custodian of the information collated during this research project, you are responsible for ensuring the security of all personal information collected, in line with NHS Scotland IT Security Policies, until the destruction of this data.

If your study is adopted by UKCRN into a portfolio then please advise this department of recruitment figures by adding accrual data to that database on a monthly basis.

Please notify the R&D office immediately you become aware of any serious adverse events associated with this research.

You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary. I understand that performance of this study will not infringe on NHS [redacted]ability to deliver our usual level of service.

May I take this opportunity to wish you every success with your project. Please do not hesitate to seek help and advice from the R&D Support Unit [redacted] if there is anything which you feel you would like assistance with. I look forward to hearing about your work as it progresses and would appreciate a short annual report and a final report when the study is complete.

Yours Sincerely,

[redacted]
R&D Director

Cc
NRS

Appendix 21 Letter of Access Unit 2

Mrs Kirsteen Ellis
University of Stirling
Gyle Square
1 South Gyle Crescent
EDINBURGH
EH12 9EB

Date: 4 October 2013

Dear Mrs Ellis

Letter of access for research
Project Title : Clinical Engagement in ICU – R&D Ref 13-059 NRS13/GA85

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through [redacted] for the purpose and on the terms and conditions set out below. This right of access commences on 4 October 2013 and ends on 28 February 2014 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation.

You are considered to be a legal visitor to [redacted] premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through [redacted] you will remain accountable to your employer University of Stirling, but you are required to follow the reasonable instructions of your nominated manager [redacted] Clinical Nurse Manager, ICU or [redacted] R&D Manager in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with [redacted] policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with [redacted] in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on [redacted] premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

[redacted] will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

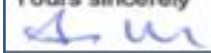
You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Where applicable, your substantive employer will initiate your Independent Safeguarding Authority (ISA) registration in-line with the phasing strategy adopted within the NHS (as from 26th July 2010 at the earliest). Once you are ISA-registered, your employer will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your substantive employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity.

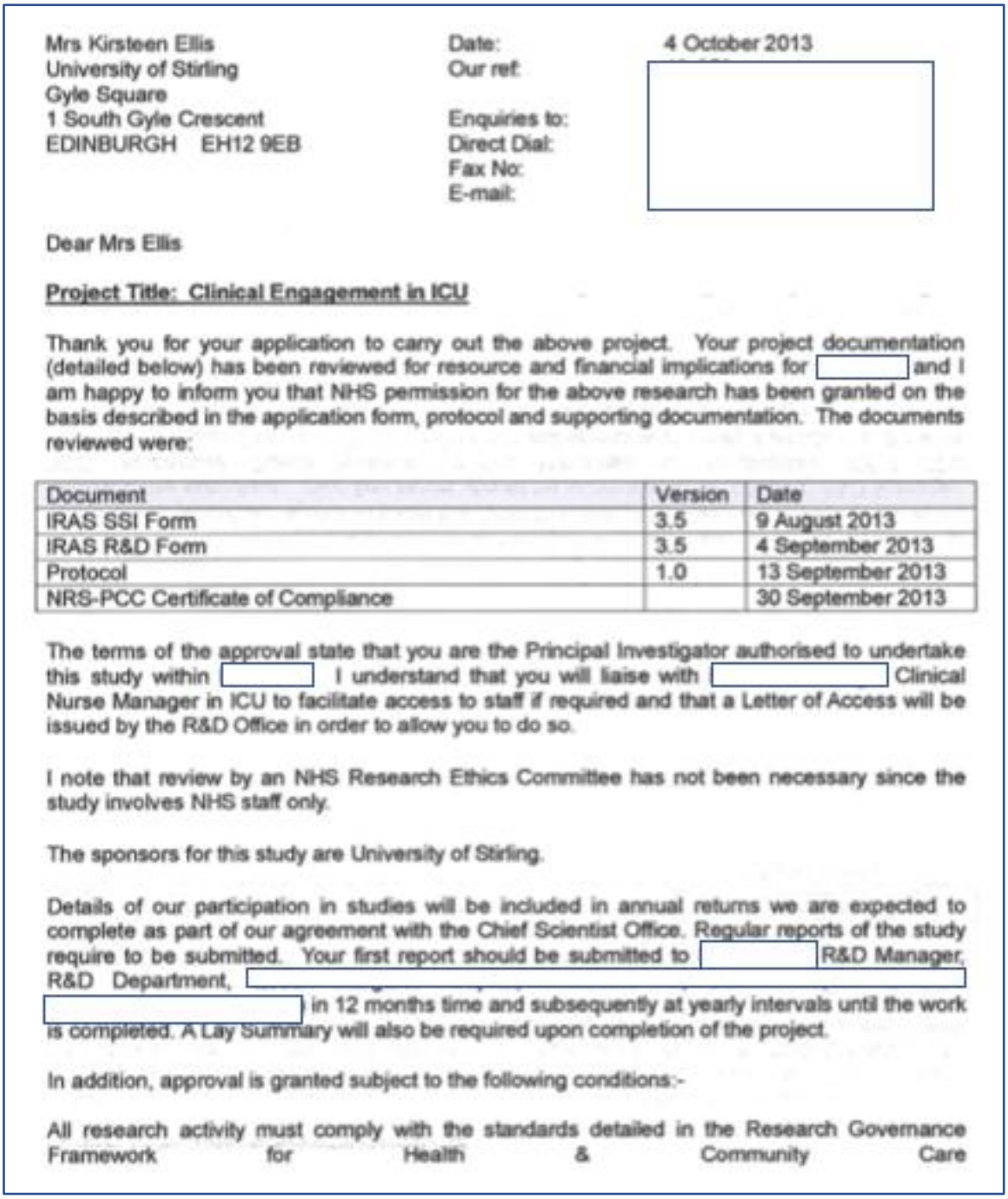
Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or ISA registration, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely



Appendix 22 Research & Development Certificate Unit 2



Mrs Kirsteen Ellis
University of Stirling
Gyle Square
1 South Gyle Crescent
EDINBURGH EH12 9EB

Date: 4 October 2013
Our ref:

Enquiries to:
Direct Dial:
Fax No:
E-mail:

Dear Mrs Ellis

Project Title: Clinical Engagement in ICU

Thank you for your application to carry out the above project. Your project documentation (detailed below) has been reviewed for resource and financial implications for [redacted] and I am happy to inform you that NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation. The documents reviewed were:

Document	Version	Date
IRAS SSI Form	3.5	9 August 2013
IRAS R&D Form	3.5	4 September 2013
Protocol	1.0	13 September 2013
NRS-PCC Certificate of Compliance		30 September 2013

The terms of the approval state that you are the Principal Investigator authorised to undertake this study within [redacted] I understand that you will liaise with [redacted] Clinical Nurse Manager in ICU to facilitate access to staff if required and that a Letter of Access will be issued by the R&D Office in order to allow you to do so.

I note that review by an NHS Research Ethics Committee has not been necessary since the study involves NHS staff only.

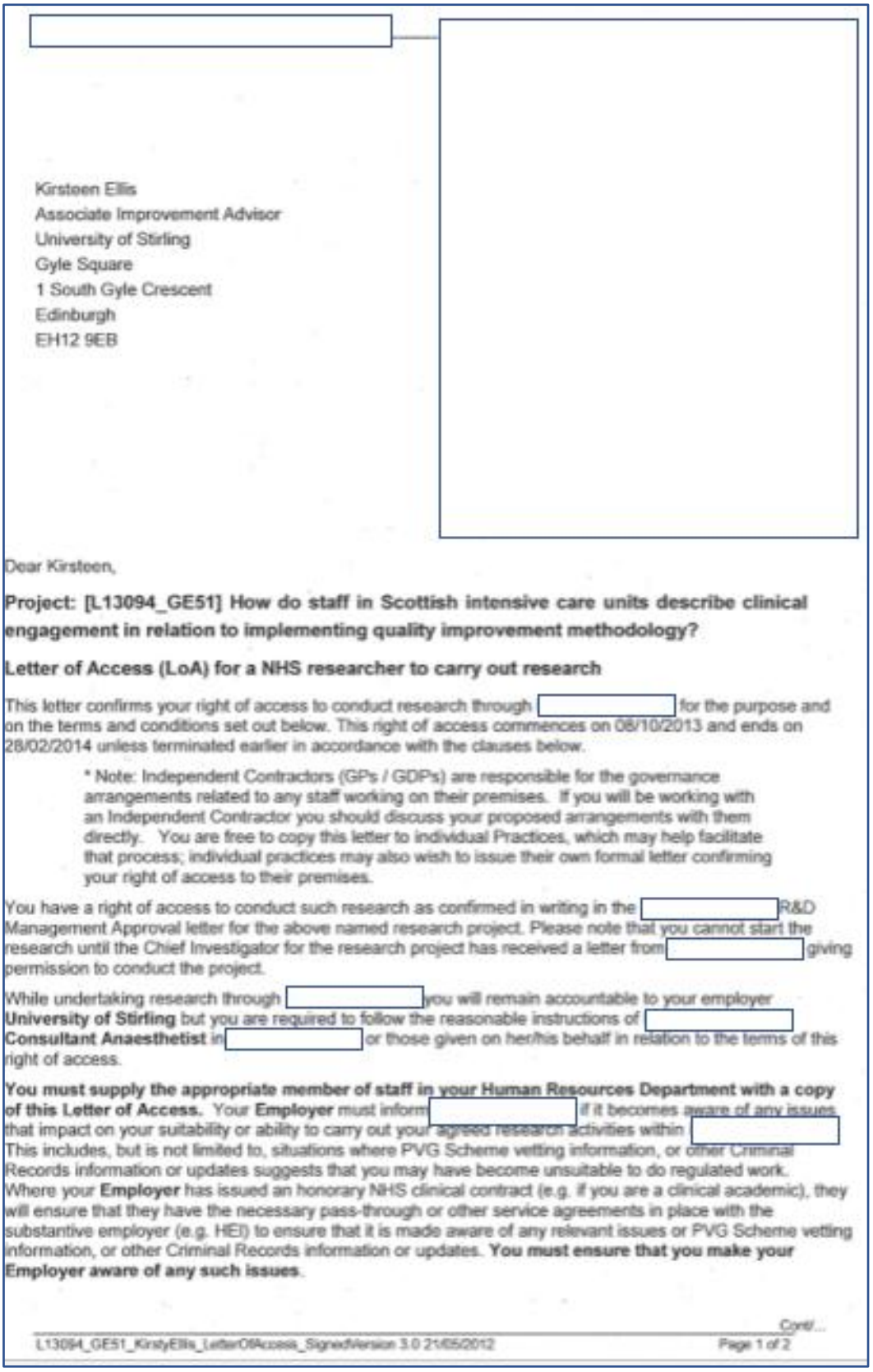
The sponsors for this study are University of Stirling.

Details of our participation in studies will be included in annual returns we are expected to complete as part of our agreement with the Chief Scientist Office. Regular reports of the study require to be submitted. Your first report should be submitted to [redacted] R&D Manager, R&D Department, [redacted] in 12 months time and subsequently at yearly intervals until the work is completed. A Lay Summary will also be required upon completion of the project.

In addition, approval is granted subject to the following conditions:-

All research activity must comply with the standards detailed in the Research Governance Framework for Health & Community Care

Appendix 23 Letter of Access Unit 3



Kirsteen Ellis
Associate Improvement Advisor
University of Stirling
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Dear Kirsteen,

Project: [L13094_GE51] How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

Letter of Access (LoA) for a NHS researcher to carry out research

This letter confirms your right of access to conduct research through [redacted] for the purpose and on the terms and conditions set out below. This right of access commences on 08/10/2013 and ends on 28/02/2014 unless terminated earlier in accordance with the clauses below.

* Note: Independent Contractors (GPs / GDPs) are responsible for the governance arrangements related to any staff working on their premises. If you will be working with an Independent Contractor you should discuss your proposed arrangements with them directly. You are free to copy this letter to individual Practices, which may help facilitate that process; individual practices may also wish to issue their own formal letter confirming your right of access to their premises.

You have a right of access to conduct such research as confirmed in writing in the [redacted] R&D Management Approval letter for the above named research project. Please note that you cannot start the research until the Chief Investigator for the research project has received a letter from [redacted] giving permission to conduct the project.

While undertaking research through [redacted] you will remain accountable to your employer **University of Stirling** but you are required to follow the reasonable instructions of [redacted] **Consultant Anaesthetist** in [redacted] or those given on her/his behalf in relation to the terms of this right of access.

You must supply the appropriate member of staff in your Human Resources Department with a copy of this Letter of Access. Your **Employer** must inform [redacted] if it becomes aware of any issues that impact on your suitability or ability to carry out your agreed research activities within [redacted] This includes, but is not limited to, situations where PVG Scheme vetting information, or other Criminal Records information or updates suggests that you may have become unsuitable to do regulated work. Where your **Employer** has issued an honorary NHS clinical contract (e.g. if you are a clinical academic), they will ensure that they have the necessary pass-through or other service agreements in place with the substantive employer (e.g. HEI) to ensure that it is made aware of any relevant issues or PVG Scheme vetting information, or other Criminal Records information or updates. **You must ensure that you make your Employer aware of any such issues.**

Cont/...

It remains the Employer's responsibility to inform [redacted] of any relevant issues irrespective of whether you hold a substantive or honorary NHS clinical contract.

You are considered to be a legal visitor t[redacted] premises. You are not entitled to any form of payment or access to other benefits provided by [redacted] to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by NHS [redacted] in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with [redacted] policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Lanarkshire in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on [redacted] premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that [redacted] accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Lanarkshire will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

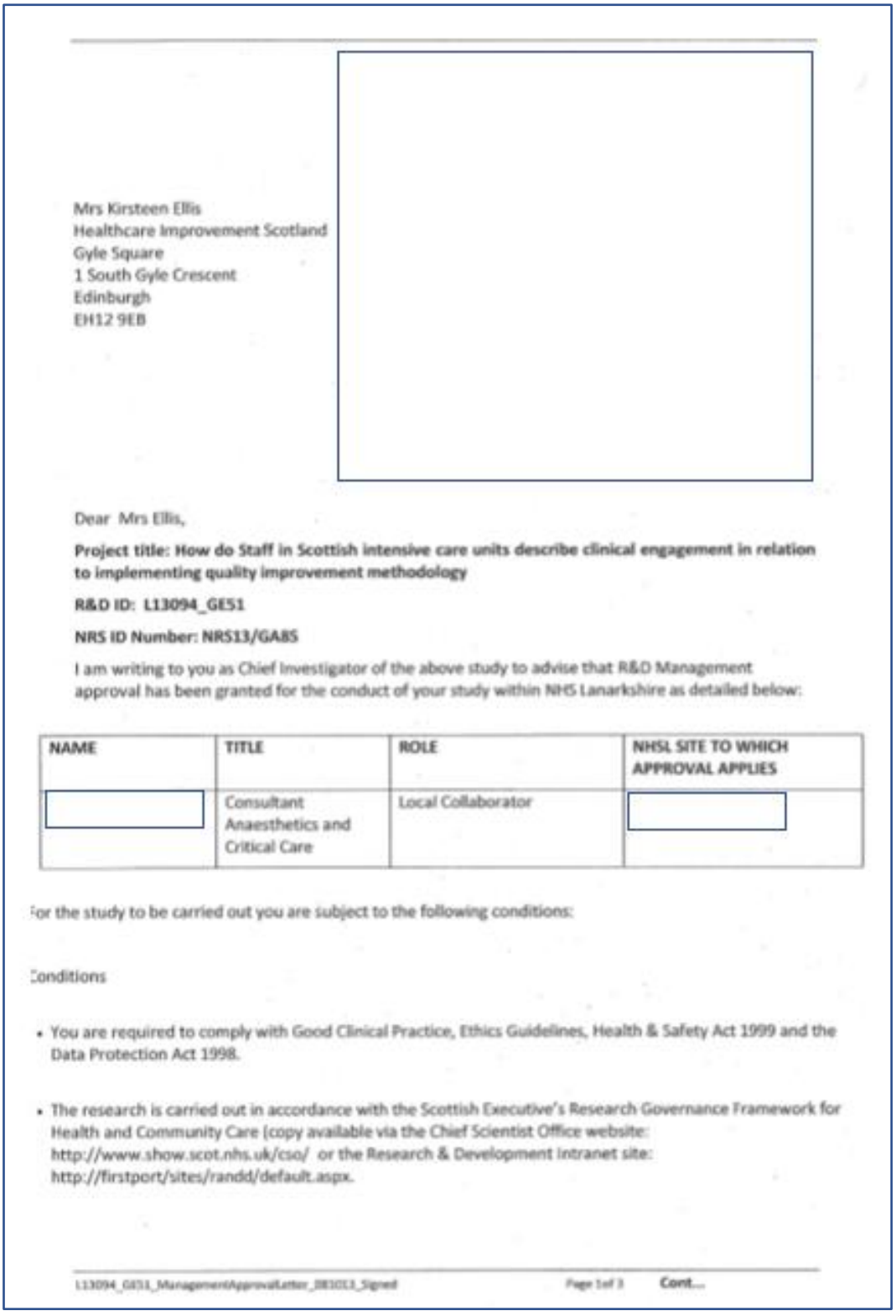
If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in [redacted]

Yours sincerely

[redacted]

Corporate Research & Development Manager

Appendix 24 Research & Development Certificate Unit 3



Mrs Kirsteen Ellis
Healthcare Improvement Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Dear Mrs Ellis,

Project title: How do Staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology

R&D ID: L13094_GE51

NRS ID Number: NRS13/GA85

I am writing to you as Chief Investigator of the above study to advise that R&D Management approval has been granted for the conduct of your study within NHS Lanarkshire as detailed below:

NAME	TITLE	ROLE	NHSL SITE TO WHICH APPROVAL APPLIES
	Consultant Anaesthetics and Critical Care	Local Collaborator	

For the study to be carried out you are subject to the following conditions:

Conditions

- You are required to comply with Good Clinical Practice, Ethics Guidelines, Health & Safety Act 1999 and the Data Protection Act 1998.

- The research is carried out in accordance with the Scottish Executive's Research Governance Framework for Health and Community Care (copy available via the Chief Scientist Office website: http://www.show.scot.nhs.uk/cso/ or the Research & Development Intranet site: http://firstport/sites/randd/default.aspx.

L13094_GE51_ManagementApprovalLetter_081013_Signed Page 1of 3 Cont...

- You must ensure that all confidential information is maintained in secure storage. You are further obligated under this agreement to report to the [redacted] Data Protection Office and the Research & Development Office infringements, either by accident or otherwise, which constitutes a breach of confidentiality.

- Clinical trial agreements (if applicable), or any other agreements in relation to the study, have been signed off by all relevant signatories.

- You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary.

- You notify the R&D Department if any additional researchers become involved in the project within NHS Lanarkshire

- You notify the R&D Department when you have completed your research, or if you decide to terminate it prematurely.

- You must send brief annual reports followed by a final report and summary to the R&D office in hard copy and electronic formats as well as any publications.

- If the research involves any investigators who are not employed by [redacted] but who will be dealing with [redacted] patients, there may be a requirement for an SCRO check and occupational health assessment. If this is the case then please contact the R&D Department to make arrangements for this to be undertaken and an honorary contract issued.

I trust these conditions are acceptable to you.

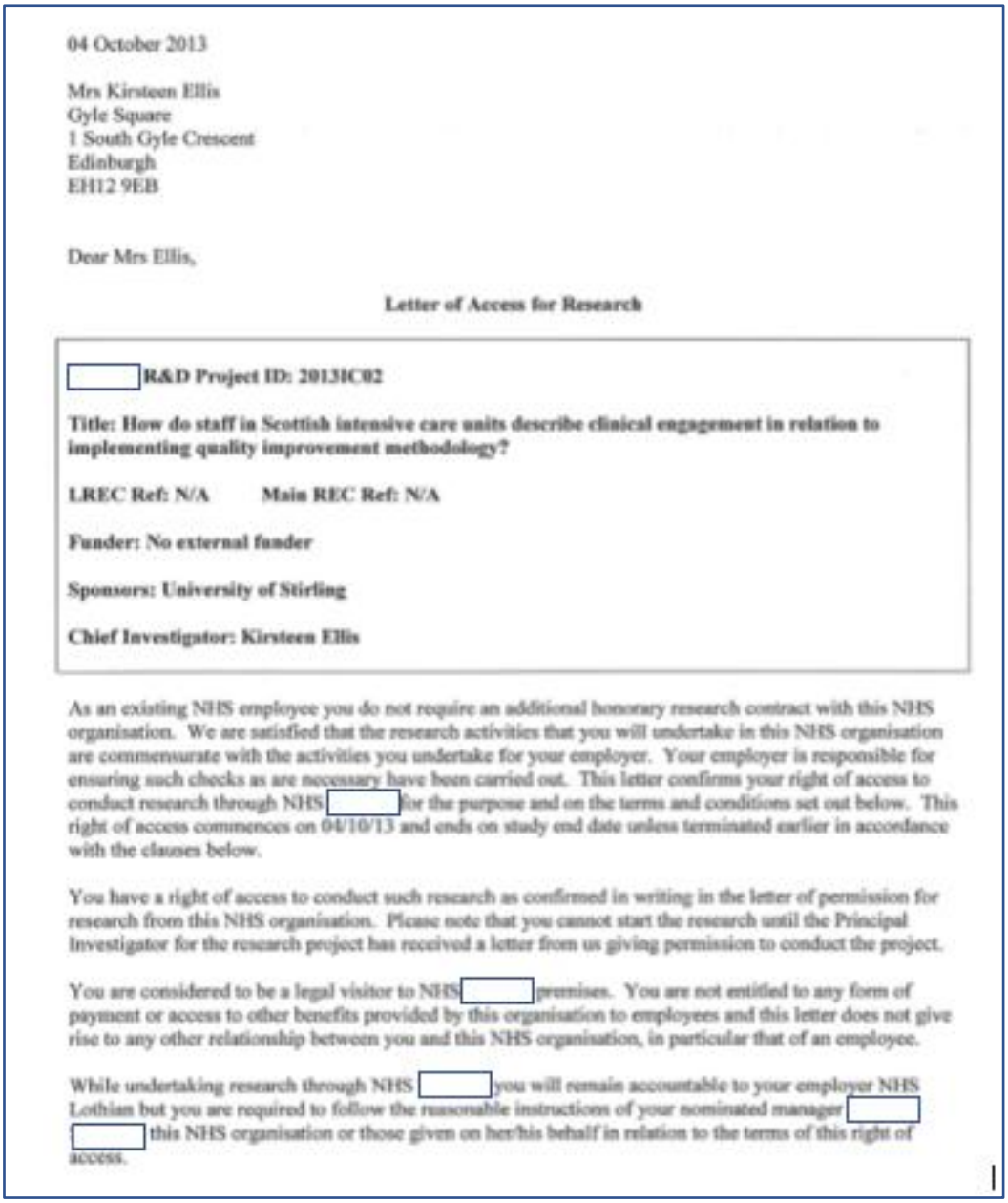
Yours sincerely,

[redacted]

NAME	TITLE	CONTACT ADDRESS	ROLE
[redacted]	Consultant Anaesthetics & Critical Care	Anaesthetics Department, [redacted]	Local Collaborator
Carol Johnstone		University of Stirling 3B1 Cottrell Building Stirling Campus Stirling FK9 4LA	Sponsor Contact

c.c – (email)
nhsg.nrscc@nhs.net

Appendix 25 Letter of Access Unit 4



04 October 2013

Mrs Kirsteen Ellis
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Dear Mrs Ellis,

Letter of Access for Research

[redacted] **R&D Project ID: 2013IC02**

Title: How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

LREC Ref: N/A **Main REC Ref: N/A**

Funder: No external funder

Sponsors: University of Stirling

Chief Investigator: Kirsteen Ellis

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is responsible for ensuring such checks as are necessary have been carried out. This letter confirms your right of access to conduct research through NHS [redacted] for the purpose and on the terms and conditions set out below. This right of access commences on 04/10/13 and ends on study end date unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to NHS [redacted] premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through NHS [redacted] you will remain accountable to your employer NHS Lothian but you are required to follow the reasonable instructions of your nominated manager [redacted] [redacted] this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS [redacted] policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS [redacted] in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS [redacted] premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

NHS [redacted] will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager and R&D Office in this NHS organisation.

Yours sincerely

[redacted]

Appendix 26 Research & Development Certificate Unit 4

04 October 2013

Mrs Kirsteen Ellis
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Dear Mrs Ellis,

R & D MANAGEMENT APPROVAL -

Title: How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

Chief Investigator: Kirsteen Ellis

Principal Investigator: Kirsteen Ellis

Ref: 2013IC02 **NRS Ref: NRS13/GA85**

REC Ref: N/A

EudraCT Ref: N/A **CTA Ref: N/A**

Sponsor(s): University of Stirling

Funder(s): No external funder

Many thanks for your application to carry out the above project here in NHS . I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in .

Approval is granted on the following conditions:-

- ALL Research must be carried out in compliance with the Research Governance Framework for Health & Community Care, Health & Safety Regulations, data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).
- All amendments to be notified to R & D Office.
- All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS where required (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx).
- R & D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally.
- Notification to R & D Office of any change in funding.

Version 3 – 15/03/2012

- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.

- All eligible studies will be added to the UKCRN Portfolio http://public.ukcrn.org.uk/. Recruitment figures for eligible studies must be recorded onto the Portfolio every month. This is the responsibility of the lead UK site. If you are the lead, or only, UK site, we can provide help or advice with this. For information, contact Charles Weller – (01382) 383822 – charles.weller@nhs.net or Liz Livingstone – (01382) 383872 – elivingstone@nhs.net.

- Annual reports are required to be submitted to [redacted] R & D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.

- Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to [redacted] R & D Office.

- You may be required to assist with and provide information in regard to audit and monitoring of study.

Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.

Approved Documents

Document	Version	Date
Protocol	1.0	13/09/13
IRAS R & D Form		
SSI Form		
Information leaflet	2.0	28/04/13
Consent form	1.0	05/09/13
Letter of invite to general manager/service manager/nurse manager ICU		
Letter of invite to lead consultant/senior charge nurse ICU		
Interview schedule		28/04/13
Poster		
Executive sponsor letter		
Unit selection process flowchart		
VAP care bundle		
Interview schedule		
Insurance		09/09/13
CV – Ashley Shepherd		05/08/13
CV – Iain Atherton		07/08/13
CV – Kirsteen Ellis		
Confirmation of pre-engagement checks		
University of Stirling REC approval		18/06/13
Email confirming no Ethics review necessary – Caroline Ackland		08/04/13

May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact [redacted] R & D Office should you require further assistance.

Yours sincerely,

Appendix 26a Clinical Governance Approval Unit 4

Clinical Governance Checklist for approval of external Quality Improvement Work

Name of Chief Investigator/ Applicant: **Kirsteen Ellis**

Title of project: **How do staff in Scottish Intensive care units describe clinical engagement in relation to implementing quality improvement methodology?**

Project Reference number

Ethics Reference number (where relevant)
Ethical consent not required, as advised by
NHS Ethics Committee, Tayside

Date of receipt:

1. **Purpose of the project**
   To understand the words and phrases used by clinical staff in Scottish Intensive care units to describe implementing quality improvement methodology and to determine if the words and phrases used differ depending on units VAP rate.

2. **Sponsor of the project**

   University of Stirling, School of nursing, midwifery and health

3. **Funder(s) of project:**

   Not applicable

4. **External Contact details**

   Kirsteen Ellis, Clinical Doctorate Student, School of Nursing, midwifery & health
   07568179960
   Dr Ashley Shepherd, University of Stirling
   Dr Iain Atherton, University if Stirling

5. **Lead contact(s) for NHS**

6. **Financial Implications**

No financial implications to NHS [redacted] other than releasing staff for 30 minute interviews.

7. Timetable of work

Volunteer staff being sought for 30 minute interviews, a maximum of 9 members of the clinical team

8. Ethical Issues *(including; ensuring privacy, confidentiality and data protection; possible role conflict, ethical issues relating to topic and how these have been addressed, approval from Ethics Committee)*

MAIN ETHICAL ISSUES

1. **Avoiding Coercion**
   Participants will be recruited for interviews using fliers and information letters. These will be made freely available and visible prior to the presentation meeting. The information letters will not be personalised. It will be made clear that participation is entirely voluntary. The wording in the invitation letters is not intended to be coercive. Participants will return expressions of interest to the researcher via email, phone call or at the presentation meeting.

2. **Confidentiality**
   Members of staff may have concerns that their views can be attributable in the raw data used to write up the study. However, the researcher will make it clear that any views expressed will not be linked to any individual in a manner to allow them to be identified and no unit will be directly identified in the study findings.

3. **Interviews**
   The researcher will make it clear to all participants that they are free to stop or leave the interview at any point if they feel uncomfortable or upset for any reason. The researcher will have an established mechanism to deal with any difficult situations which may rise which will have been agreed with participating units prior to commencing interviews. This process may differ depending on the staff group being interviewed and the NHS board in which the interview is taking place – prior to commencing any interviews the researcher will source details of local processes as well as contact details for local board counselling services.

DATA HANDLING

All data will be handled as per the Data Protection Act Scotland (1998)[10].

Data used to identify study sites will be retained on a password protected computer only accessed by the researcher. This data will be retained until data analysis is completed. This data will not be used in paper format.

All study sites and participants will be assigned a random identifier known only to the researcher and her supervisors. Data will be handled by the researcher only with the support of her supervisors.

All research documents, interviews, field notes, etc will be saved on a password protected computer. A document naming convention will be used to ensure the most recent document is accessed and developed.

The researcher will preserve one copy of all transcripts and field notes as a mastercopy – this will be saved on a password protected computer and an encrypted hard drive to ensure that data can't be lost. A data management repository will be created to ensure that all transcripts and field notes remain linked – this will use the random identifier assigned to participants.

As well as being stored on the researcher's laptop, all data will be saved on the University network at

the end of any day it has been worked on – the researcher has the facility on her laptop to access the network remotely.

All audio-recording transcriptions will be undertaken by the researcher. The digital recorder will be assessable by the researcher alone; no interviews will be saved on the digital recorded after transcription. Between the recording of the interview and the typing up of the interview the digital recorder will be kept in a locked drawer and only accessible by the researcher.

All data will be stored as described above until the completion of the research study and the researcher's success completion of her clinical doctorate studies at this time all electronic data used for analysis will be deleted.

Any paper copies with participant identifiable data will be disposed of as per University of Stirling "Confidential Disposal of Documents and Records Advisory Note" (2006)

9. Caldicott Guardian Issues

As there will be no patient identifiable data included in this study, Caldicott Permission is not required[7]

10. Consent Issues *(including: consent form and information given to participants)*

INFORMED CONSENT

Prior to the commencement of the study permission from all NHS boards will be secured to access the administrative data required to identify the study sites. For any unit where permission has not been granted they will not be included in the study population. Informed consent will have been obtained in the form of a response to an email letter (Appendix 1).

Prior to participating in the recorded semi-structured in-depth interviews all participants will be required to complete and sign an informed consent document (Appendix 9). Each participant will retain a copy and the researcher will also keep a paper copy and an electronic scanned version.

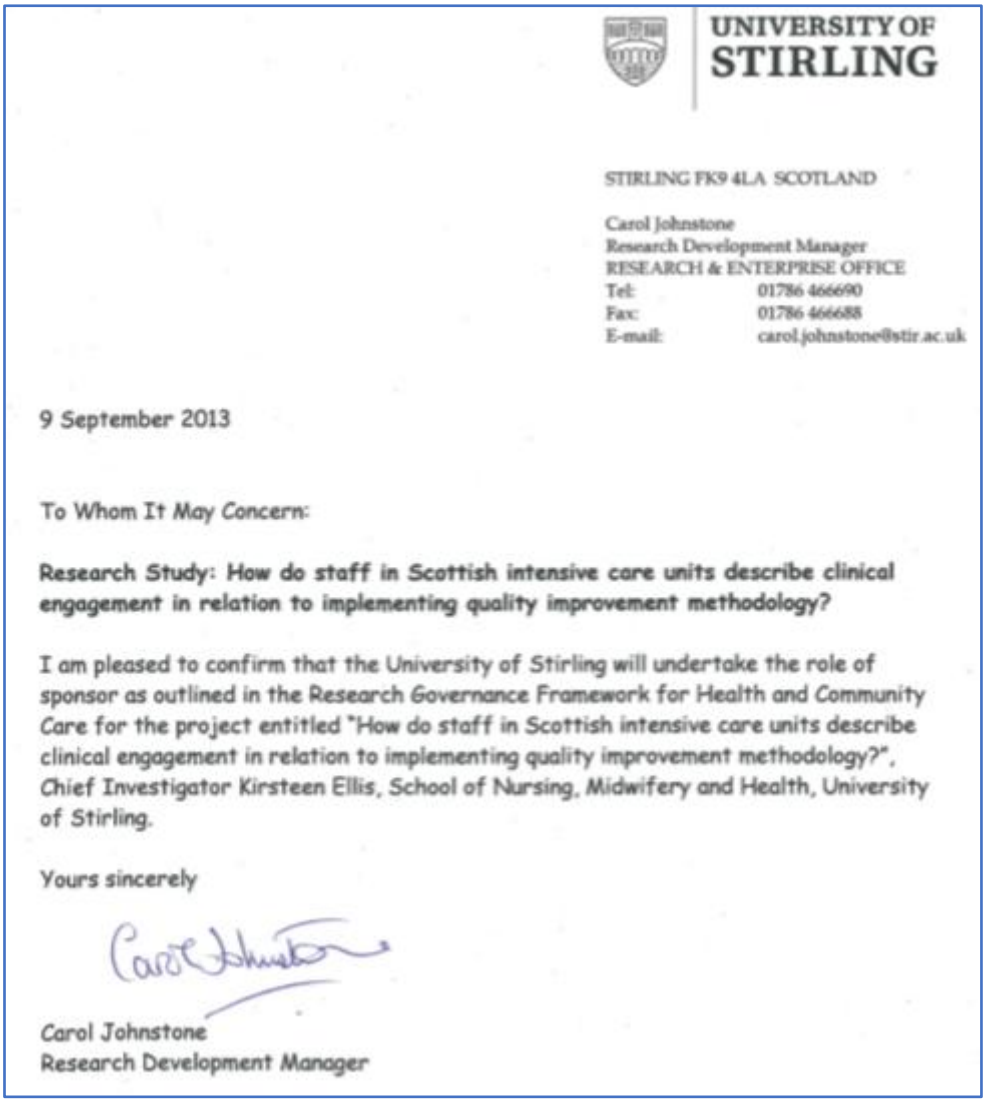
11. Is there a project overview containing the following? *(Please attach the information)*

Background	Yes [X]	No [ ]
Aims and Objectives	Yes [X]	No [ ]
Where is the work being carried out	Yes [X]	No [ ]
Proposed time schedule	Yes [X]	No [ ]
Methodology	Yes [X]	No [ ]
Population, sampling & enrolment procedures	Yes [X]	No [ ]
Data collection (including data collection tool)	Yes [X]	No [ ]
Data input	Yes [X]	No [ ]
Storage of data	Yes [X]	No [ ]
Interpretation of data	Yes [X]	No [ ]
Dissemination of results	Yes [X]	No [ ]

12. Further comments *(including reasons if ticked No above)*

Please refer to accompanying document appendices for all letters of introduction, participant leaflets, informed consent, etc

Appendix 27 University Sponsorship Letter



UNIVERSITY OF STIRLING

STIRLING FK9 4LA SCOTLAND

Carol Johnstone
Research Development Manager
RESEARCH & ENTERPRISE OFFICE
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9 September 2013

To Whom It May Concern:

Research Study: How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

I am pleased to confirm that the University of Stirling will undertake the role of sponsor as outlined in the Research Governance Framework for Health and Community Care for the project entitled "How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?", Chief Investigator Kirsteen Ellis, School of Nursing, Midwifery and Health, University of Stirling.

Yours sincerely

Carol Johnstone
Research Development Manager

Appendix 28 University Insurance Certificate

UNIVERSITY OF STIRLING

STIRLING FK9 4LA SCOTLAND

Carol Johnstone
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09 September 2013

To Whom It May Concern:

Research Study: How do staff in Scottish intensive care units describe clinical engagement in relation to implementing quality improvement methodology?

This study is included in the following cover put in place by Aon Ltd. These policies are renewed annually and the current period of insurance is 1 August 2013 – 31 July 2014.

I confirm that the following cover is in place:

Professional Indemnity policy provides indemnity for legal liability to third parties arising from breach of professional duty, neglect, error or omission in the course of the business of the University of Stirling. The limit of the Professional Indemnity cover is £5,000,000 for any one event and in aggregate in any one period of insurance.

Combined Liability Insurance - Employers Liability cover is provided for legal liability to employers for death, injury, illness and disease arising out of the business of the University of Stirling. Public/Products Liability is provided for legal liability for accidental loss of or damage to Third Party property or for death, injury, illness or disease arising out of the business of The University of Stirling including liability arising from goods sold or supplied. Indemnity Limit for each is £10,000,000.

Combined Excess Liability Insurance for Employers Liability & Public/Products Liability. Cover limit is £10,000,000 in excess of £10,000,000 with a total limit of indemnity in respect of Employers Liability of £20,000,000.

I trust that this is sufficient for your requirements. Please however do not hesitate to get in touch with me should you have any queries.

Yours sincerely

Carol Johnstone
Research Development Manager

Appendix 29 Summary of participant and expert review feedback

- Grounded Theory Diagram
    - The diagram is a useful account of the different components that need to be considered when considering clinical engagement. The cultural indicator of language is an interesting theory, and its potential to identify an area for appropriate intervention has positive implications for leaders at organisational as well as ward level i.e. a senior charge being able to assess the level of clinical engagement of her staff or an organisation being able to determine organisational culture / readiness to change. Developing and validating a language-based tool for utility at ward level based upon the themes could be a logical progression which offers a practical and evidence-based tool to establish clinical engagement.
    - The diagrams are all helpful and it is good to see context added to the System of Profound Knowledge.
- It is essential to highlight that the apparently "balanced" relationship illustrated in Figure 16 (Graphical illustration of the core categories developed from this Grounded Theory Study) at this time cannot be determined. From this work it has not been possible to determine the weighting of each of the side of the "see saw."
- In relation to the lack of reference to the "Appreciation of the System" lens:
    - There may be unique aspects associated with conducting a study within the intensive care community. It is a closed system with ownership and control held firmly by the players within that environment – this may be what lead to the limited connections with the "Appreciation of the system" lens.
    - The group interviewed may have unspoken assumptions about the ITU system, these were not explored in this study.
- A reflection which it would have been good to explore would have been environmental changes which participants may have undertaken to facilitate the establishment of clinical engagement.
- What was the influence of role modelling in establishing consistent behaviours? Exploration with the community and how this supports the development of

"rituals" where activities are undertaken because that's the way it's done here. In contrast to the group establishing a practice because it is recognised to be the "correct" activity to undertake.

- In relation to application to other clinical environments it is important to consider the links between social engagement and clinical engagement. What is the impact of this within intensive care staff communities? Anecdotal evidence and personal experience would suggest that Intensive care units commonly have an integrated facilitate for coffee and meal break i.e. a room within the unit for staff to have breaks. This is commonly used by both medical and nursing staff, facilitating the opportunity to establish "social" relationships as well as professional relationships.
- How does the point above impact the perceptions of tribes within the intensive care clinical community? The where the perception is that the hierarchy within some intensive care units is relatively flat and the lines between professional tribes are less distinct than in other clinical environments.

- Findings Diagram[34]
    - The diagrams offer a progressive thought process whereby, it appears that the selective codes established in the concept of clinical engagement have been mapped onto Deming's Improvement Model. The interaction/integration of the themes and emergent theory of 'language' is demonstrated. And this is later displayed as a novel finding which could modify/enhance Deming's Improvement model. The findings in terms of the research question is included in a clever and easily understood diagram which associate low VAP rates with 'we and the team language' and enablers, and high VAP rates with 'them and us' language, barriers and person dependency.

- The theory and findings diagrams are clear and from an outsider I understand your findings and the thought process along the way.

[34] Provided by a researcher familiar with grounded theory approach and quality improvement.

- A particularly useful theory for practitioners (and researchers) to begin further exploratory work around clinical engagement and a novel contribution to the field of improvement/implementation science.

Appendix 30 Memo coding convention

In order to maintain a clear memo audit trail, I developed a two numbering schemes which allowed me to track the order in which memos were written and whether they were specific to a participant response or as a general observation made during the study. General observation may have been made during the review of transcriptions, journal articles, reading of text or during conversation with colleagues.

General observations were merely in number order with each subsequent memo being one number higher than the previous memo for example:

Memo	Content of memo
33	made from interview with 3310 *"... describes barriers as resistance and being not so receptive to change."* This prompted my memo to consider how resistance is different to scepticism.
34	made for interview with 3310 refers to education being required to bring others on board. This prompted my memo to look out for other references to education in subsequent interviews and to review previous transcriptions for this topic and consider including in subsequent interviews.

An example of general memos made during the data analysis process

As can be seen from although the topics were unrelated but acted as a prompt to me to remember to look something up or to consider including in subsequent interviews. These memos were often but not exclusively developed during the initial post interview review commonly in my car after the interview and were "spur of the moment" considerations.

When memos were developed during the transcription review phase commonly in a more considered and analytic way, I used a more structured numbering convention to allow clarity of the thought processes. I wanted to be able to understand in the future how I had reached the conclusion I had made in the memo.

When a memo relates to only one transcription it will be denoted Memo number.number – the first number refers to the participant number and the number after the dot refers to the number of previous memos made from that particular transcription for example Memo 9.1 is the first memo developed for the transcription of participant number 9 as illustrated below.

Memo number	Content of the memo
Memo 9.1	"getting people on board" – this terminology reminded me of language used by Dr Brian Robson when he referred to getting clinical leads engaged with quality improvement work in Healthcare Improvement Scotland. Look out for this in other transcripts.

An example of a memo relating to one participant

When a memo was developed and referred to two different transcriptions the numbering convention used allowed me to understand the process of developing the memo for example Memo 1_9_12_15.1 indicates that the memo was developed having

reviewed transcriptions 1, 9, 12 & 15 and that the memo was the first one developed from this combination. Memo1_9_12_15.1 provides this example.

Memo number	Content of the memo
Memo 1_9_12_15.1	Participants use different examples to support their perceptions of how people understand the need for improvement / change.

Example of a memo developed from review of multiple transcriptions – numbering convention indicated the order of transcription review

The sequence of the numbers in the memo number also indicated the order of the transcription review which lead to this memo for example below illustrates Memo 12_3.1 was developed after reading transcription from participant 12 which jogged a recollection from participant 3

Memo number	Content of memo
Memo 12_3.1	Participant refers to the need to develop ownership of the improvement activity – does this reflect recognition of need to improve / change – yes as this is qualified by the follow up comment about the recognition that something needs to be done.

Example of a transcription where memo was developed following retrospective review of earlier transcription.

Through the development of this memo number convention it is possible to clearly illustrate that the data analysis process was not merely a linear progression through the transcriptions – these examples of the numbering convention affirm the continual looping back to re-review transcriptions throughout the analysis phase which is a central component of using the grounded theory approach.

Appendix 31 Clinical Engagement findings complete table including operational definitions and memo audit trail examples

The table below illustrates for the Clinical Engagement theme the complete process of developing open codes, selective codes, themes, categories and core categories and incorporates examples of memos used during the development of each. Please refer to Appendix 30 for the memo coding convention.

Participant quotes *open coding in bold	**Open coding Memo audit trail**	**Selective coding**	**Operational Definition of selective coding**	**Theme**	**Operational definitions of themes**	**Category**	**Core category**	**Lens of profound knowledge Memo audit trail**	**Link to Lens of profound knowledge**
Clinical engagement is: ... process of getting people **on board** to implement practice ... P339 ... getting everyone "**on board**"... all working together P 3310 ... getting nurses and doctors **on side** ... the same way of thinking on whatever it is	**Memo 9.1** "getting people on board" – this terminology reminded me of language used by Dr Brian Robson when he referred to getting clinical leads engaged with quality improvement work in Healthcare Improvement Scotland. Look out for this in other transcripts.	"On board " Revised to active participation following the development of Memo 156	Participants use the term "on board" or "on side" to describe clinical engagement, This was revised to "active participation" following the development of Memo 156	**Clinical engagement definition**	Participant descriptions of clinical engagement			**Memo 9_10. 10** Reflecting on the use of the terminology "on board makes me think of this as an active process*, someone or some people have to take a conscious decision to facilitate getting people on board and this won't happen without intervention.	Building knowledge Human side of change

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
we are trying to bring in. P338 ... they are going **along with you** aren't they ... with you. P123	**Memo 10.1** again, the reference to getting "everyone on board". This is the second reference using the terminology "on board" to describe clinical engagement. **Memo 156** Review of terminology in P123, P125, P338, P339 & P3310 getting staff on side or on boards seems to be an activity							Considering this in relation to Deming's' Lens of profound knowledge – understanding what encourages people to become activity engaged in change is an essential component of success or failure. Teams will also develop the knowledge surrounding the effective and ineffective activity required to get people engaged.	

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
								* This memo contributed to memo 156 thinking about activity participation.	
Clinical engagement is: ... **aware** of national drivers as well as local **need for improvement** ... P431 ... they know what we do and **why we do it** – to improve. P339 ... ownership, as a group we **recognised something had to be done** P3212 ... understanding	**Memo 1.2** Recognition of the need to change and what potentially drives that. **Memo 9.15** There is recognition of the need to change among the team – this reflects P431 comment about national drivers and their influence on local recognition to improve. **Memo 12_3.1**	Aware of need to improve **Memo 1_9_12_15.1** Participants use different examples to support their perceptions of how people understand the need for improvement / change.	Participants describe that colleagues recognise / identify the need to improve current practice					Memo 148 Relates to Memo 1_9_12_15.1, facilitating peoples understanding of the need to improve / make changes relate directly with the "Human side of change" lens, where Langley et al (2009) suggest that by understanding motivation and behaviour	Building knowledge Human side of change

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
why we are implementing change P2315	Participant refers to the need to develop ownership of the improvement activity – does this reflect recognition of need to improve / change – yes as this is qualified by the follow up comment about the recognition that something needs to be done. Memo 15. 4 Understanding why improvement is required – this made me reflect if this							of people results in achieving the desired change. Specifically, recognition of the behaviours driving an individual's motivations from both an intrinsic and extrinsic perspective as well as attracting people to the change. Through different approaches potentially reflected in the different terminology and language used the	

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
	indicated recognition of the need for change – participant subsequently refers to providing reasons / research / evidence to support the need for change as being part of clinical engagement.							teams within the four units may have developed understanding of what is required to hook into the motivations of others. However, as some teams have achieved different levels of success in relation to reducing VAPs perhaps the building of knowledge for this aspect of clinical engagement is an indicator of a team's ability to achieve the VAP	

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
								reduction?	
Clinical engagement is: ... getting everyone on board... all **working together** P 3310 ... whole team **working together** ... P123 ... absolute involvement, it's a **team approach**. P3113 ...exploring ways **as a group** that we can reduce VAPs. P2315 ... ownership, **as a group** we recognised something had to be done P3212	**Memo 10.2** This makes me think about a collective / collaborative approach. Review prior transcripts for similar wording. **Memo 10_3.1** Reviewing the transcripts of earlier interviews, the term "working together" / "team approach" was cited by several participants including P123 Memo 13.1 This participant offered a description of	Collective / collaborative **Memo 173** There appears to be a links between selective codes: "Aware of the need to improve" and "Collective / collaboration." Is it that successful units have been more effective at addressing these and using them as enablers, therefore overcoming their potential to act as barriers?	Words used imply a collaborative or collective approach					**Memo 176** Again, as with the other selective codes within this theme there are direct links to the human side of change and the requirement to work as a collaborative entity – reaching solutions to the recognised problem through team working and cooperation.	Human side of change

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
... the **same way of thinking** on whatever it is we are trying to bring in. P338	clinical engagement which again included reference to a team approach. Looking for this link was prompted by the Memo 10_3.1. There are multiple references within this interview and others, where working in a collaborative manner within and across professional groups are provided. **Memo 15.1** Exploring ways as a group suggests	**Memo 175** This refers to the approach to solving the need to make improvement to practice for improved patient care.							

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
	a conscious collaborative and inclusive approach to solving a recognised problem – this is supported by Heskett (2012).								
Clinical engagement is: ... generating **ownership** by the clinical team. P 3113 ... **ownership,** as a group we recognised something had to be done P3212 ... gives people a bit of **ownership** P2315 ... they can bring things forward on	**Memo 13.4** I don't think the concept of ownership has been referred to previously – revisit previous transcripts for this term. **Memo 13_12.1** The concept of ownership was introduced by participant 12 when referring to	Ownership	Participants expressed a need for teams to develop ownership of the activity					**Memo 177** The selective code called "ownership" again fits well with the important contributions described by Langley et al (2009, pp, 84, 85), where they describe the need to attract people to the proposed change. Resistance to	Human side of change

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
their own. P431	activity the team had undertaken to encourage participation in the improvement work. Memo 1. **Memo 12.3** Participant refers to the need to develop ownership of the improvement activity. **Memo 15.5** References to ownership were highlighted following interview with participant 12. This is a references participant 15							implementing change may be observed when people don't feel included or don't understand the need for change.	

Participant quotes *open coding in bold	Open coding Memo audit trail	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Lens of profound knowledge Memo audit trail	Link to Lens of profound knowledge
	has made in another unit – so it's not a term bespoke to unit 3.								

Appendix 32 Full findings

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
Clinical engagement is: ... getting everyone "**on board**"... all working together P 3310 ... process of getting people **on board** to implement practice ... P339 ... getting nurses and doctors **on side** ... the same way of thinking on whatever it is we are trying to bring in. P338	"On board "	Participants use the term "on board" or "on side" to describe clinical engagement	**Clinical engagement definition**	Participant descriptions of clinical engagement	**Clinical engagement**	**Clinical engagement**	Building knowledge Human side of change
Clinical engagement is: ... **aware** of national drivers as well as local **need for improvement** ... P431 ... people **recognise the need** to change practice P339 ... ownership, as a group we **recognised something had to be done** P3212 ... talking together	Aware of need to improve	Participants describe that colleagues recognise / identify the need to improve current practice			**Clinical engagement**		Building knowledge Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
about **what we need to do** ... P2315							
Clinical engagement is: ... getting everyone on board... all **working together** P 3310 ... whole team **working together** ... P123 ... absolute involvement, it's a **team approach**. P3113 ...exploring ways **as a group** that we can reduce VAPs. P2315 ... ownership, **as a group** we recognised something had to be done P3212 ... the **same way of thinking** on whatever it is we are trying to bring in. P338	Collective / collaborative	Words used imply a collective approach			**Clinical engagement**		Human side of change
Clinical engagement is: ... generating **ownership** by the clinical team. P 3133 ... **ownership,** as a	Ownership	Participants expressed a need for teams to develop			**Clinical engagement**		Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
group we recognised something had to be done P3212		ownership of the activity					
Perceptions of how others understand clinical engagement: ...**don't know** that everyone would know what the phrase meant P137 For clinical engagement to work we **need to understand what it means** ... I had to read up on the topic ... P338 ...there could be **other interpretations** in the unit ... P137 ... it's **not a term we are familiar with** ... it's a **new term** for something that happens anyway ... P2315 I studied it. **If they don't understand it, they are going to say nothing to do with me**. P339	Clinical engagement as perceived by other colleagues	Participants describing how other colleagues may perceive the term clinical engagement	**Clinical engagement as perceived by others**	Participants' perceptions of how others perceive clinical engagement.	**Perceptions of others understanding of clinical engagement**	**Clinical engagement**	Building knowledge Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
... as a senior charge nurse my view is more expansive. Junior staff **may not know** ... P431 ... **differences in understanding** is probably a barrier ... P3111							

Participant quotes *open coding in bold	**Selective coding**	**Operational Definition of selective coding**	**Theme**	**Operational definitions of themes**	**Category**	**Core category**	**Link to Lens of profound knowledge**
Clinical engagement is: ... working with your **team** ... at all levels ... P431 **multidisciplinary** professional staff P412 ... whole **team** ... P123 You need a **multi-disciplinary team** P 137 ... everyone's involvement in reducing VAPs ... the **multi-disciplinary team** P3111 ... involving all members of the **team** P3212 ... absolute involvement, it's a **team** approach P3113 ... introducing changes as a team ... the **whole team** not just medics P2315 ... **multi-disciplinary** responsibility P134	Multi-disciplinary team / team / whole team	Participants refer to team, whole team or multi-disciplinary team when describing clinical engagement	**Multi-disciplinary team**	Participant descriptions of clinical engagement referring specifically to team or multidisciplinary teams	**Multi-disciplinary team**	**Clinical engagement**	Human side of change
Not having enough **insight** P431 Staff **don't see the**	Lack of understanding	Perceptions of participants	**Barrier** to bringing about	Barriers as described by participants	**Barriers**	**Clinical engagement**	Building knowledge Understanding

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
need for change		is that colleagues cannot see the purpose / value in the activity	change	which will stop change happening within the intensive care unit			variation
People **not signing up** to work P123 **We have done this before, and it didn't work** P2315 We have never had to do it that way before, so **I don't see why we should have to start doing that now** P2315	Not seeing the value	Participants perceived colleagues were unable to understand the value in activity	**Barrier** to bringing about change		**Barriers**		Building knowledge Human side of change
Perception that the change will **require more work** P123 Existing **workload** P134 ... it's **extra paperwork** ... is that necessary P2315 ... **not enough time** ... P 123	Increased workload	Participants describing activities which are considered as additional to existing activity	**Barrier** to bringing about change		**Barriers**		Human side of change
Availability of staff (don't have the	Staffing resource	Participants referring to	**Barrier** to bringing		**Barriers**		

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
numbers)P134		lack of staffing resources	about change				
Tick box exercise P137 Quality improvement may become a **tick box exercise** P123	Tick box exercise	Participants indicated that colleagues are not fully engaged with the activity	**Barrier** to bringing about change		**Barriers**	**Clinical engagement**	Human side of change
People are not comfortable with the **methodology** {QI} P123 ... the **Patient Safety Programme** ... P3212	QI approach	Participant reference to the improvement methodology	**Barrier** to bringing about change		**Barriers**		Building knowledge
Happening at the bedside ...it's **embedded in practice**... P431 ... it's so **embedded in practice** P 339 ...perception that it was being done ... but **now it's being done properly and reliably** P 3212 ... part of the **practice and culture in the unit** P2315	Location of change	Participants describe change as being embedded in practice	**Enabler** to bringing about change	Enablers as described by participants which will allow change to happen within the unit	**Enablers**	**Clinical engagement**	Building knowledge Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
... get it into **everyday practice** ... get it into medicine kardex, and stuff like that, make a checklist P137 **It's part of the ward round we do every day** P134							
For clinical engagement you need: ... to have a **knowledge base** ... to know what you are dealing with P134 ... to **know** what the **implications are for the patient** P134 **Understanding** why we are implementing change P2315 **Evidence & research** that something will work ... P2315	knowledge / understanding		**Enabler** to bringing about change		**Enablers**	**Clinical engagement**	Building knowledge Human side of change
Champions are needed to get the change out there P 3310 ... identifying an	Champions of the change	Participants refer to the term champion, or imply	**Enabler** to bringing about change		**Enablers**	**Clinical engagement**	Building knowledge Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
interested party P3113 ... also, a good **champion** P137 ... **there are people I know I can call on & say help me with this** ... P3310		motivational person					
Need facts and figures in front of you P134 Levels of "**scrutiny**" ... recognising the improvement in patient care P412 Reducing VAPs ... **evidence** that it {QI} works P123 ... once they **saw the difference** it was making ... P137 ... **display of data**... really clear and positive reinforcement ... P2315 ... **measurement** is important in all this, **measurement** for improvement P3212	Positive data perspective	Participants refer to the use of data or information to support change or engagement implying a positive effect	**Enabler** to bringing about change		**Enablers**	**Clinical engagement**	Building knowledge Understanding variation Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
Hierarchy within the team prevents progress – if senior staff don't like the idea it won't happen P338 Staff feel they have lost their **position of power** P416 ... levels of **scrutiny** and illustration of **performance** ... P412	Hierarchy / authority	Participants refer to power / authority / position within the care delivery team in a negative way	**Barrier** to establishing clinical engagement		**Enablers**	**Clinical engagement**	Human side of change
Barriers can be very much about **personalities** P431 **Depending on who is leading** it will bring other people along P338 ... levels of staff comfort with proposed change P431 ... it's **personalities** P2315 ... individual **personalities** affect the adoption of change ... P3212 ... **dynamics** in the unit ... P2315	Personal attributes	Participants indicated perceived negative personal values & beliefs of colleagues	**Barriers** to establishing clinical engagement	Barriers as described by participants which will prevent the establishment of clinical engagement	**Barriers**	**Clinical engagement**	Human side of change
Anything new, people	Scepticism	Participants	**Barrier** to		**Barriers**	**Clinical**	Building

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
are always very **sceptical** P431 **Scepticism** P137 ...people ... **thought well we do that anyway** ... which I suspect probably wasn't the case P137 ... **perception that it was being done** ... P3212		used the word scepticism or referred to colleagues thinking there was no need to change current activity	establishing clinical engagement			**engagement**	knowledge Understanding variation Human side of change
Inability to get accurate data P412 ... you don't know what's going on ... **without data** P123	Negative data perspective	Lack of data perceived as being detrimental to establishing clinical engagement	**Barrier** to establishing clinical engagement		**Barriers**	**Clinical engagement**	Understanding variation
Tick box exercise P137 Quality improvement may become a **tick box exercise** P123	Tick box exercise	Participants indicated that colleagues are not fully engaged with the activity	**Barrier** to establishing clinical engagement		**Barriers**	**Clinical engagement**	Building knowledge Understanding variation
Doctor C and SCN A provide the **leadership** required to	Recognised leadership	Participants describing leadership,	**Enabler** to establishing clinical	Enablers as described by participants	**Enablers**	**Clinical engagement**	Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
keep the work moving P3113 The **work is driven** by the SCN P412 ... identifying **leadership** P3113 ... key people who **lead the work** P431		terms or phrases which imply leadership i.e. driven by, led by	engagement	which will facilitate the establishment of clinical engagement			
... **listen** to their ideas ... P3111 ... **giving** information and **running** sessions ... P3111 ... **having** "buzz"[35] session P3111 & P3310 ... having the **opportunity to talk** about proposed change P 2315 ... **sit & discuss** ... to bring forward their ideas ... volunteering to take something forward ... P3111	Communication	Participants describe activity which involved listening to and informing colleague of the change activity taking place.	**Enabler** to establishing clinical engagement		**Enablers**	**Clinical engagement**	Human side of change

[35] Term redacted as unit identifiable

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
For clinical engagement you need: ... to have a **knowledge base** ... to know what you are dealing with P134 **Understanding** why we are implementing change P2315 **Evidence & research** that something will work ... P2315	knowledge / understanding		**Enabler** to establishing clinical engagement		**Enablers**	**Clinical engagement**	Building knowledge Human side of change
Nurse A in her secondment devised the work and **encouraged others** to participate P338 I **lead the work** in the unit and share with the Band 6 nurses what we are going to do ... P431 I am the SPSP lead clinician so am **personally invested** in the work P 3212 The **work is driven** by the SCN P412 ... processes become **person dependent**	Person dependency	Participants describing one person or individuals who have assumed a role to ensure activity is undertaken.	**Person dependency created within the unit**	Participant descriptions of person dependency within their units.	**Person dependency**	**Clinical engagement**	Building knowledge Human side of change

Participant quotes *open coding in bold	Selective coding	Operational Definition of selective coding	Theme	Operational definitions of themes	Category	Core category	Link to Lens of profound knowledge
P412 ... individual **personalities** affect adoption of change P3212 ... **principally down to the SCN**, who is commendable ... P412							
They don't always do as **they** are told ... P3310 **They** see it as my role ... P431 It's up to **us** to do the improvement work ... P3111	Them Us	Words used by participants which appear to refer to other members of the team	**Language**	Language used to refer to other members of the team	**Language**	**Cultural indicator**	Human side of change
As a **team, we** talk about the things **we** need to do to improve patient care. P2218 **We** work together to implement the improvement work P2315	We The team						

Appendix 33 selective codes and associated Lenses

Selective codes	Links to System of profound knowledge			
	Building Knowledge	Human Side of Change	Understanding Variation	Appreciation of the System
On board	Y	Y	N	N
Aware of need to improve	Y	Y	N	N
Collective / collaborative	N	Y	N	N
Ownership	N	Y	N	N
Perceived by other colleagues	Y	Y	N	N
Multi-disciplinary team / team / whole team	N	Y	N	N
Lack of understanding	Y	N	Y	N
Not seeing the value	Y	Y	N	N
Increased workload	N	Y	N	N
Staffing resource				
Tick box exercise	N	Y	N	N
QI approach	Y	N	N	N
Location of change	Y	Y	N	N
Knowledge / understanding	Y	Y	N	N
Champions of the change	Y	Y	N	N
Positive data perspective	Y	Y	Y	N
Hierarchy / authority	N	Y	N	N
Personal attributes	N	Y	N	N
Scepticism	Y	Y	Y	N
Negative data perspective	N	N	Y	N
Tick box exercise	Y	N	Y	N
Recognised leadership	N	Y	N	N
Communication	N	Y	N	N
Knowledge / understanding	Y	Y	N	N
Person dependency	Y	Y	N	N
Them & Us	N	Y	N	N
Collective	N	Y	N	N

References

Alemu, G., Stevens, B., Ross, P and Chandler, J. (2015) The Use of a Constructivist Grounded Theory Method to Explore the Role of Socially-Constructed Metadata (Web 2.0) Approaches *Qualitative and Quantitative Methods in Libraries* 4, pp. 517–540

Alexander, G., Weiner, B. J., Baker, L.C., Shortell, S. M and Becker, M. (2006) Care Management Implementation and Patient Safety *Journal of Patient Safety* 2(2), pp. 83 – 96

Alimo-Metcalfe, B and Bradley, M. (2008) Cast in a new light *People Management*

Alvesson, M and Berg, P. O. (1992) *Corporate Culture and Organisational Symbolism* Berlin: Walter de Gruyter Chapter 6, pp, 106 – 109

Aveling, E. L, Parker, M and Dixon-Woods, M. (2014) What is the role of the individual accountability in patient safety? A multi-site ethnographic study. *Sociology of Health & Illness* 38(2), pp, 216 – 232

Bates, P. (2014) Context is Everything: In *Perspectives of Context* London: Health Foundation

Benn, J., Burnett, S., Parand, A., Pinot, A., Iskander, S and Vincent, C. (2009) Studying large-scale programmes to improve patient safety in whole care systems: Challenges for research. *Social Science & Medicine* 69, pp, 1767 - 1776

Berry, B. (2016) *There is a relationship between systems thinking and W. Edward Deming's Theory of Profound Knowledge*. Accessed via: http://www.berrywood.com/wp-content/uploads/2011/08/DemingPaper.pdf

Bertalanffy, L. (1969) *General System Theory* Revised Edition New York: George Braziller Chapter 1

Best, A., Greenhalgh, T., Lewis, S., Saul, J. E., Carroll, S and Bitz, J. (2012) Large-System Transformation in Health Care: A Realist Review *The Milbank Quarterly* 90(3), pp, 421 – 456

Best, M and Nuehauser, D. 2006 Walter A Shewhart, 1924, and the Hawthorne factory *Quality and Safety in Health Care* 15, pp, 142–143. doi: 10.1136/qshc.2006.018093

Birt, L., Scott, S., Cavers, D., Campbell, C and Walter, F.(2016) Member checking: A tool to enhance trustworthiness or Merely a nod to validation? *Qualitative Health Research* 26(13), pp, 1802 – 1811

Bodenheimer, T, Wagner, E, H and Grumbach, K. (2000) Improving primary care for patients with chronic illness *Journal of American Medical association* 288, pp, 1175 - 1179

Bowling, A. (2014) *Research Methods in health. Investigating health and health services* 4th Edition England: McGraw-Hill, pp, 1 – 2, 200, 391

Braithwaite, J, Marks, D and Taylor, N. (2014) Harnessing implementation science to improve care quality and patient safety: a systematic review of targeted literature International *journal for Quality in Health Care,* 26(3), pp, 321 – 329

Bryman, A. (2016a) *Social Research Methods* 4th Edition Oxford: Oxford University Press Chapter 18, pp, 408 – 409, 411

Bryman, A. (2016b) *Social Research Methods* 4th Edition Oxford: Oxford University Press, pp, 501

Burnett, J., Fan, C., Motowidlo, S. J and Degroot, T. (1998) Interview notes and validity *Personal Psychology*, 51, pp, 375 - 396

Burnett, S., Benn, J., Pinto, A., Parand, A., Iskander, S and Vincent, C. (2010) Organisational Readiness: Exploring the preconditions for success in organisation-wide patient safety improvement programmes. *Quality & Safety in Health Care,* 19

Burston, S., Chaboyer, W., Gillespie, B and Carroll, R. (2014) The effect of a transforming care initiative on patient outcomes in acute surgical units: a time series study *Journal of Advanced Nursing,* 71(2), pp, 417 – 429

Cambridge Dictionary http://dictionary.cambridge.org/dictionary/english/culture accessed 16th October 2017

Canaway, R., Bismark, M., Dunt, D and Kelaher, M. (2017) Medical Directors' perspectives on strengthening hospital quality and safety. *Journal of Health Organisation and Management,* 31(7/8), pp, 696 – 712

Chao, G.T., O'Leary-Kelly, A. M., Wolf, S and Klein, H. (1994) Organisational Socialisation. Its content and consequences. *Journal of Applied Psychology,* 79(5), pp, 730 – 743

Charmaz, K. (2000) In Denzin, N, K. and Lincoln, Y.S. *The SAGE handbook of qualitative research* 2nd Edition London: SAGE Publishing Chapter 19

Charmaz, K. (2006) *Constructing Grounded Theory A practical guide through qualitative analysis* London: SAGE Publications

Charmaz, K. (2014) *Constructing Grounded Theory* 2nd Edition London: SAGE, pp, 27, 155-156, 168

Chassin, M. R. and O'Kane, M. E. (2010) *History of quality improvement. Towards improving the Outcome of Pregnancy III* Accessed via www.marchofdimes.com

Clarke, A.E. (2005) *Situational Analysis. Grounded Theory after the postmodern turn.* Electronic Resource accessed 30/12/2016 via http://dx.doi.org.ezproxy.stir.ac.uk/10.4135/9781412985833.n3

Collins Dictionary Accessed via: https://www.collinsdictionary.com/dictionary/english/onboarding

Collinson, D. (2009) In: Clegg, S, R. and Cooper, C, L. (Editors) *The SAGE handbook of Organizational Behavior* Vol 2: Macro Approaches London: SAGE Publications Chapter 15

Colton, D. (2000) Quality Improvement in Health Care. Conceptual and Historical Foundations. *Evaluation & the Health Professions*, 23(1), pp, 7-42

Columbia Basin RDI. (2013) *Cultural Indicators Literature Review. Developing the Columbia Basin Rural Development Institute's Cultural Research Pillar* accessed via http://www.cbrdi.ca/wp-content/uploads/Cultural-Literature-Review.pdf

Colville, L. (2009) In: Clegg, S, R. and Cooper, C, L. (Editors) *The SAGE handbook of Organizational Behavior* Vol 2: Macro Approaches London: SAGE Publications Chapter 9

Cooney, A. (2011) Rigour & grounded theory. *Nurse Researcher*, 18(4), pp, 17 – 22

Corbin, J and Holt, N. L. (2005) In: Somekh, B and Lewis (Editors) Grounded Theory *Research Methods in the social sciences.* Thousand Oaks, CA: SAGE, pp, 49 - 55

Creswell, J. W. (2009) *Research Design Qualitative, Quantitative and Mixed Methods Approaches*. 3rd Edition London: SAGE, pp, 4

Croft, G. P., Williams, J. G., Mann, R. Y., Cohen, S and Philips, C. J. (2007) Can hospital episode statistics support appraisal and revalidation? Randomised study of physician attitudes *Clinical Medicine,* 7(4), pp, 332 - 338

Data Protection Act. (1998) Schedule 1 Accessed via: http://www.legislation.gov.uk/ukpga/1998/29/pdfs/ukpga_19980029_en.pdf

Davidoff, F. (2019) Understanding context: how explanatory theories can help *Implementation Science,* 14 doi:org/10.1186/s13012-019-0872-8

Davies, H, Nutley, S. M and Mannion, R. (2000) Organisational Culture and quality of health care. *Quality in health care,* 9(2), pp, 111 -119

De Silva D. (2015) *What's getting in the way? Barriers to improvement in the NHS*. Health Foundation. No. 24.

Dekker, S. (2011) *Drift into Failure. From hunting broken components to understanding complex systems* Surrey: Ashgate, Chapter 4,

Dellinger, R. P., Carlet, J. M., Gerlach, H., Calandra, T., Cohen, J., Gea-Banacloche, J., Keh, D., Marshall, J., Parker, M., Ramsay, G., Zimmerman, J., Vinvent, J-L and Levy, M. (2004) Surviving Sepsis Campaign guidelines for management of severe sepsis and septic shock. *Critical Care Medicine,* 34, pp, 858 – 873, doi: 10.1097/01.CCM.0000117317.18092.E4

Deming, W. E. (1994) *The New Economics* London: MIT Press, pp, 92 and 93

Deming, W. E. (2000) *Out of the Crisis* London: MIT Press

Department of Health. (2000) *An organisation with a memory. Report of an expert group on learning from adverse events in the NHS* London: Department of Health

Detwiller, M. and Petillion, W. (2014) Change Management and Clinical Engagement *Computer, Informatics, Nursing* 32(6), pp, 267 - 273

Dixon-Woods, M and Martin, G. P. (2016) Does Quality Improvement improve quality? *Future Hospital Journal,* 3(3), pp, 191 – 4

Dixon-Woods, M. (2014) The problem of context in quality improvement In: *Perspectives of Context* London: Health Foundation

Dixon-Woods, M., Leslie, M., Tarrant, C and Bion, J. (2013) Explaining Michigan: an ethnographic study of patient safety programme. Implementation Science 8 http://www.implementationscience.com/content/8/1/70

Dixon-Woods, M., Baker, R., Charles, K., Dawson, J., Jerzembek, G., Martin, G., McCarthy, I., McKee, L., Minion, J., Ozieranski, P., Willars, J., Wilkie, P and West, M (2014) Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study. *BMJ Quality and Safety,* 23, pp, 106–115. doi:10.1136/bmjqs-2013-001947

Dixon-Woods, M., Bosk, C. L., Aveling, E. L., Goeschel, C. A and Pronovost, P. J. (2011) Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program. *The Milbank Quarterly*, 89(2), pp, 167–205

Donaldson, A., Cook, J., Gabbe, B., Lloyd, D. G., Young, W and Finch, C. F. (2015) Bridging the Gap Between Content and Context: Establishing Expert Consensus on the Content of an Exercise Training Program to Prevent Lower-Limb Injuries *Clinical Journal of Sports Medicine,* 25(3), pp, 221 – 229

Doody, O. and Noonan, M. (2013) Preparing and conducting interviews to collect data. *Nurse Researcher*, 20(5), pp, 28-32 doi:10.7748/nr2013.05.20.5.28.e327

DY, S. M., Taylor, S. L., Carr, L. H., Foy, R., Pronovost, P.J., Øvretveit, J., Wachter, R. M., Rubenstein, L. V., Hempel, S., McDonald, K. M and Shekell, P.G. (2011) A framework for classifying patient safety practices: results from an expert consensus process *BMJ Quality & Safety* doi:10.1136/bmjqs.2010.049296

Edmondson, A. C. (2012) *Teaming How organisations learn, innovate and compete in the knowledge economy.* San Francisco: Jossey-Bass, Chapter 2

Eppe, H. R and Levin, P. E. (2015) The TeamSTEPPS Approach to Safety and Quality. *Journal of Pediatric Orthopaedics*, 35(5), Supplement 1, pp, S30 – S33

Feeley, D and Swensen, S.J. (2016) Restoring joy at work. It's more than just reducing burnout. *Health Executive,* 31(5), pp, 70 - 71

Fontana, A and Frey, J. (2005) In: Denzin, N, K. and Lincoln, Y.S. *The SAGE handbook of Qualitative Research* 3rd Edition, London: SAGE publishing

Frances, R. (2010) *Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust Volume I,* London: The Stationary Office

Gabbay, J and Le May, A. (2010) *Practice-Based Evidence Healthcare. Clinical Mindlines* 1st Edition, Oxon: Routledge, Chapter 5

Gibbs, G. R. (2007) *Analyzing Qualitative Data*. London: SAGE Publications

Gilhooly, D., Gree, S. A., McCann, C and Moonesighe, S. R. (2019) Barriers and facilitators to the successful development, implementation and evaluation of care bundles in acute care hospital: a scoping review *Implementation Science,* http://doi.org/10.1186/s13012-019-0894-2

Glaser, B. (1992) *Basics of Grounded Theory Analysis Emergence vs Forcing* CA: Sociology Press, Chapter 6

Glaser, B. G. and Strauss, A. (1967) *The Discovery of Grounded theory, Strategies for Qualitative Research*. Saint Louis: Mosby Co, pp, 1

Goeschel and Pronovost (No date) ….
https://www.ahrq.gov/downloads/pub/advances2/vol2/Advances-goeschel_24.pdf

Goldman, A. (1999) *Knowledge in a social world*. Oxford: Clarendon Press, Part 1

Gordon, S, Hayes, L and Reeves, S. (2013) *Bedside Manners. Play and workbook*. London: Cornell University Press

Guthrie, M. (2004) Engaging Physicians in Performance Improvement. *American Journal of Medical Quality*, 20(5). Pp, 235 - 238

Hampe, H. (2015) Physician Led Sepsis Quality Improvement Team. *Critical Care Nursing Quarterly,* 38(2), pp. 188 – 199

Hasbesleben, J. R. B, Wakefield, D. S and Wakefield, B. J. (2008) Work-arounds in healthcare settings: Literature review and research agenda *Health Care Management Review,* 33(1), pp, 2 – 12

Haskett, J. (2012) *The Culture Cycle. How to shape the unseen force that transforms performance*. New Jersey: FT Press

Hawe, C., Ellis, K., Cairns, C and Longmate, A. (2009) Reduction in ventilator-associated pneumonia: active versus passive guideline implementation *Intensive Care Medicine,* 35 pp, 1180 – 1186

Hawkes, J. (2001) *The Fourth Pillar of Sustainability Culture's essential role in public planning*. Australia: Common Ground Publishing

Health Foundation. (2011a) *Learning Report: Safer Patient Initiative. Lessons from the first major improvement programme addressing patient safety in the UK*. London: Health foundation

Health Foundation. (2011b) *Safer Patient Initiative phase two A controlled evaluation of the second phase of a complex patient safety intervention implemented in English hospitals*. London: Health Foundation, pp, 12

Health Foundation. (2011c) *Does improving safety culture affect patient outcomes*? London: Health Foundation

Health Foundation. (2012) *Quality improvement training for healthcare professionals. Evidence Scan*. London: Health Foundation

Healthcare Improvement Scotland (2015) – *Improving Healthcare Together Clinical Engagement Strategy 2014-2017* Scotland: Healthcare Improvement Scotland Accessed via: http://www.healthcareimprovementscotland.org/our_work/clinical_engagement/clinical_engagement_resources/clinical_engagement_strategy.aspx

Heskett, J. (2012) *The Culture Cycle*. *How to shape the unseen force that transforms performance.* New Jersey: FT Press

Hester, R. Roger, A and Robb, M. (2013) In: MacKian, S. and Simons, J. *Leading managing and caring: understanding leadership and management in health and social care*. Oxford: Routledge, Chapter 12

Heyland, D., Cook, D., Griffith, L., Keenan, S. P and Brun-Boisson, C. (1999) The Attributable Morbidity and Mortality of Ventilator Associated Pneumonia in the Critically Ill Patient. *American Journal of Respiratory and Critical Care Medicine,* 159, pp, 1249 – 1256

Hunter, A., Murphy, K., Grealish, A., Casey, D and Keady, J. (2011) Navigating the grounded theory terrain. *Nurse Researcher*, 18(4), pp, 6 - 10

Ijkema, R., Langelaan, M., Van de Steeg, L Wagner, C. (2014) What impedes and what facilitates a quality improvement project for older hospitalised patients? *International Journal for Quality in Health Care,* 26(1), pp, 41 – 48

Institute of Medicine. (2001) *Crossing the Quality Chasm.* Washington: National Academy Press

James, W. (1909) *The Pluralistic Universe* London: Longmans, Green & Co pp, 250 – 260

Jaques, R. (Blog post) *What's in a word – The power of language for improving organisational culture*. Accessed via: http://sapartners.com/language-improving-organisational-culture

Jeffs, L., McShane, J., Indar, A and Maria, M. (2018) Using local data to improve care and Collaborative Practice. *Journal of Nursing Care Quarterly,* 33(3) pp, E1 – E7

Kaplan, H., Brady, P. W., Dritz, M. C., Hooper, D. K and Linam, W. M. (2010) The influence of context on Quality Improvement Success in Health Care: A systematic review of the Literature *Milbank Quarterly,* 88(4), pp, 500 – 559

Kaplan, H., Provost, L. P., Froehle, C. M and Margolis, P.A. (2012) The Model for Understanding Success in quality (MUSIQ): building a theory of context in healthcare quality improvement *BMJ Quality & Safety,* 21, pp, 13 – 20 doi:10.1136/bmjqs-2011-000010

Karnieli-Miller, O Strier, R and Pessach, L. (2009) Power relations in Qualitative Research. *Qualitative Health Research*, 19(2), pp, 279 - 289

Kieffer, R. Quality culture and its measurement Parenteral Drug Association https://www.pda.org/pda-europe/news-archive/full-story/2015/01/30/quality-culture-and-its-measurement

Kirkpatrick, I., Jesperson, P. K., Dent, M and Neogy, I. (2009) Medicine and Management in a Comparative Perspective: The Case of Denmark and England. *Sociology of Health and Illness,* 31(5), pp, 642 -658

Klein, H, K. and Myers, M. (1999) A Set of Principles for Conducting and Evaluating Interpretive Field Studies in Information Systems. *MIS Quarterly,* 23 (1), pp, 67–94

Knight, A, W. (2018) How Clinical Instructor Behavior Affects Student Clinical Engagement from a Motivational Perspective *Journal of Nuclear Medicine Technology, 46*(2)

Kohn, L.T, Corrigan, J. M. and Donaldson, M. S. (2000) *To Err is Human.* Washington D.C.: National Academy Press

Kornacki, J. and Silversin, J. (2012) *Leading Physicians Through Change: How to Achieve and Sustain Results*. USA: American College of Physician Executives (ACPE)

Kotter, J. P. and Hester, R. (1992) *Corporate Culture and Performance*, New York: The Free Press

Kotter, J. P. (1978) *organizational dynamics diagnostics and intervention,* London: Addison-Wesley Publishing Company, Chapter 2

Kotter, J. P. (2012) *Leading Change,* Boston: Harvard Business Review Press, Chapter 10

Kouzes, J. M. and Posner, B. Z. (2002) *Leadership the Challenge,* 3rd Edition, San Francisco: Jossey-Bass, Chapter 3

Krein, S. L., Damschroder, L. J., Kowalski, C. P and Forman, J. (2010) The influence of organisational culture on quality improvement and patient safety efforts: a multi-centre qualitative study. *Social Science and Medicine,* 71 pp, 1692 – 1701

Kringos, D. S., Sunol, R., Wagner, C., Mannion, R., Michel, P., Klazinga, N. S and Groene, O. (2015) The influence of context on the effectiveness of hospital quality improvement strategies: a review of systematic reviews. *BMC Health Services Research,* 15, doi:10.1186/s12913-015-0906-0

Lancaster, J (1999) In: Lancaster, J. *Nursing Issues in Leading and Managing Change,* London: Mosby, Chapter 6

Landis, S. E., Schwarz, M and Curran, D. R. (2006) North Carolina Family Medicine Respiratory Residency Program's Diabetes Learning Collaborative. *Family Medicine,* 38, pp, 190 - 195

Langley, G. J., Moen, R. D., Nolan, K. M., Nolan, T. W., Norman, C. L and Provost, L. P. (2009) *The Improvement Guide A practical approach to enhancing organizational performance,* 2nd Edition, San Francisco: Jossey-Bass, pp, 24, 119

Lee, F. (2004) *If Disney Ran Your Hospital 9 ½ things you would do differently*. USA: Second River Healthcare

Lee, R. I. and Jones, L. W. (1933) *The foundations of good medical care*. Chicago: University of Chicago Press, pp, 3

Lee, S., Choi, K., Kang, H., Cho, W and Chae, Y. M. (2002) Assessing the factors influencing continuous quality improvement implementation: experience in Korean hospitals, *International Journal of Quality in Health Care,* 14(5), pp, 383 – 391

Lekka, C. (2011) High *Reliability Organisations. A review of the literature,* London: Health & Safety Executive

Leung, L. (2015) Validity, reliability and generalisability in qualitative research *Journal of Family Medicine and Primary Care,* 4(3), pp, 324 – 327

Ling, T, Soper, B, Buxton, M., Hanney, S., Oortwijn, W., Scoggins, A and Steel, N. (2007) *An Evaluation of The Health Foundation's Engaging with Quality Initiative Second Annual Report,* London: Health foundation

Lipitz-Snyderman, A., Steinwachs, D., Needham, D. M., Colantuoni, E., Morlock, L. L and Pronovost, P. J. (2011) Impact of a state-wide intensive care unit quality improvement initiative on hospital mortality and length of stay: retrospective comparative analysis *British Medical Journal online,* accessed via: https://www.bmj.com/content/bmj/342/bmj.d219.full.pdf

Lofland, J. and Lofland, L.H. (1999) In Bryman, A and Burgess, R. G. *Qualitative Research,* Vol III, London: SAGE, pp, 3 - 12

Lofland, J., Snow, D., Anderson, L and Lofland, L. (2006) *Analysing Social Settings: A guide to qualitative observation and analysis*. 4th Edition, CA: Windsworth

Longmate, A., Ellis, K., Boyle, L., Maher, S., Cairns, C. J. S and Lloyd, S. M. (2011) Elimination of central-venous-catheter related bloodstream infections from the intensive care unit *BMJ Quality and Safety,* 20, pp, 174 - 180. doi:10.1136/bmjqs.2009.037200

Lucas, B. and Nacer, H. (2015) *The habits of an improver,* London: Health Foundation

Lyndon, A. and Cape, V. (2016) Maternal Haemorrhage Quality Improvement Collaborative Lessons *Journal of Maternal & Child Nursing,* 41 (6), pp, 363 – 371

Majoura, Y and Bozic, K. J. (2012) Brief History of Quality Improvement in US Healthcare. *Current Reviews in Musculoskeletal Medicine,* 5(4), pp, 265 - 273

Mason, J. (2002) *Qualitative Researching,* 2nd Edition, London: SAGE, pp, 1

Masso, M. and McCarthy, G. (2009) Literature review to identify factors that support implementation of evidence-based practice in residential aged care, *International Journal of Evidence Based Healthcare,* 7, pp, 145 - 156

Matar, D.S., Julius C., Thomas A. L and Berenholtz, S. M. (2013) Achieving and Sustaining Ventilator Associated Pneumonia–Free Time among Intensive Care Units (ICUs): Evidence from the Keystone ICU Quality Improvement Collaborative *Infection Control and Hospital Epidemiology,* 34(7), pp, 740 -743

May, T. (2011) *Social Research. Issues, methods and process*. 4th Edition, England: McGraw-Hill Open University Press

Maybin, J. and Thorlby, R. (2008) *High Quality Care for All,* London: Kind fund

McLeod, D. and Clarke, N. (2009) *Engaging for success: enhancing performance through employee engagement.* Surrey: Office of Public Sector Information

Melder, A., Robinson, T., McLoughlin, I., Iedema, R and Teede, H. (2020) An overview of healthcare improvement: unpacking the complexity for clinicians and managers in a learning health system. *Internal Medicine Journal,* pp, 1 – 11
https://onlinelibrary.wiley.com/doi/epdf/10.1111/imj.14876

Miller and Crabtree (2005) In: Denzin, N, K. and Lincoln, Y.S. *The SAGE handbook of qualitative research,* 3rd Edition, London: SAGE publishing pp, 624

Minkman, M. Ahaus, K. And Huijsman, R. (2007) Performance Improvement based on integrated quality management models: what evidence do we have? A systematic review, *International Journal of Quality in Health Care,* 19(2), pp, 90 - 104

Montgomery, P. and Bailey, P. H. (2007) Field notes and Theoretical Memos in Grounded Theory. *Western Journal of Nursing Research,* 29(1), pp, 65-79

Morrell, C. and Harvey, G. (1999) *The Clinical Audit Handbook*. London: Baillière Tindall

Morris, A. C., Hay, A. W., Swann, D. G., Everingham, K., McCulloch, C., McNulty., Brooks., Laurenson, I. F., Cook, B and Walsh, T. S. (2011) Reducing ventilator associated pneumonia in intensive care: impact of implementing a care bundle. *Critical Care Medicine,* 39(10), pp, 2218 - 2224

Morrow, S. (2005) Quality and Trustworthiness in Qualitative Research in Counselling Psychology, *Journal of Counselling Psychology,* 52(2), pp, 250 – 260

Mosaic Project: http://mosaicprojects.com.au/WhitePapers/WP1044_Systems_Thinking.pdf

Nelson, E.C., Batalden, P.B., Mohr, J.J and Plume, S. K. (1998) Building a quality future*. Frontiers of Health Service Management,* 15(1), pp, 3 – 32

O'Reilly, K. A. and Parker, N. (2013) Unsatisfactory Saturation: A critical exploration of the notion of saturated sample sizes in qualitative research. *Qualitative Research,* 13, pp, 190-7

Ogrinc, G., Davies, L., Goodman, D., Batalden, P., Davidoff, F and Stevens, D. (2016) SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence); revised publication guidelines from a detailed consensus process, *BMJ Quality and Safety,* 25 (12), pp, 986 - 92

Oh, T. E. (2003) In: Bersten, A. D and Soni, N *Oh's Intensive Care Manual*. 5th Edition, Edinburgh: Butterworth Heinemann, Chapter 1

Øvretveit, J. (2004) A framework for Quality Improvement Translation: understanding the conditionality of interventions, *Joint Commission Journal on Quality and Safety,* pp, 15 – 24

Øvretveit, J. (2011) Understanding the conditions for improvement research to discover which context influences affect improvement success. *BMJ Quality and Safety,* 20 (supplement 1), i18 – i23,doi:10.1136/bmjqs.2010.045955

Øvretveit, J. (2014) How does context affect quality improvement? In: *Perspectives of Context,* London: Health Foundation

Øvretveit, J., Shekelle, P. G., Dy, S. M., McDonald, K. M., Hempel, S., Pronovost, P. J., Rubenstein, L., Taylor, S. L., Foy, R and Wachter, R. M. (2011) How does context affect interventions to improve patient safety? An assessment of evidence from studies of five patient safety practices and proposals for research, *BMJ Quality and Safety,* doi:10.1136/bmjqs.2010.047035

Pannick, S, Sevdalis, N and Anthanasiou, T. (2016) Beyond clinical engagement: a pragmatic model for quality improvement interventions, aligning clinical and managerial priorities. *BMJ Quality & Safety,* 25

Parand, A., Burnett, S., Benn, J., Iskander, S., Pinto, A and Vincent, C. (2010) Medical engagement in organisation-wide safety and quality improvement programmes: experience in the UK Safer Patients Initiative, *Quality and Safety in Healthcare,* 19, e44, doi:10.1136/bmjqs.2010.047035

Patel, K. C. R., Spilsbury, P. and Shulka, R. (2010) Clinical contributions to addressing the social determinants of health, *Clinical Medicine,* 10(2), pp, 130 - 133

Perry, B. (2011) In: May, T *Social Research. Issues, Methods and Process,* 4th Edition, England: McGraw-Hill, pp, 228

Pettigrew, A. and Whipp, R. (1993) *Managing Change for Competitive Success,* Oxford: Blackwell Publishers, Chapter 1

Pettigrew, A., Ferlie, E. and McKee, L. (1992) *Shaping Strategic Change,* London: Sage Publishing, pp, 313 - 317

Pingleton, S. K., Carlton, E., Wilkinson, S., Beasley, J., King, T., Wittkopp, C., Moncure, M and Williamson, T. (2013) Reduction of Venous Thromboembolism (VTE) in Hospitalized Patients: Aligning Continuing Education with Interprofessional Team-Based Quality Improvement in an Academic Medical Center. *Academic Medicine*, 88(10), pp, 1454 - 1459

Pinto, A Benn, J Burnett, S., Parand, A and Vincent, C. (2011) Predictors of the perceived impact of a patient safety collaborative: an exploratory study. *International Journal for Quality in Health Care,* 23(2), pp, 173–181

Piolat, A., Olive, T And Kellogg, R. T. (2005) Cognitive Effort during Note Taking. *Applied Cognitive Psychology,* 19, pp, 291 - 312

Pitscotty, R. and Kalisch, B. (2014) Nurses' use of clinical decision support, *Computers, Informatics, Nursing,* 32(12), pp, 562 – 568

Powell, A., Rushmer, K and Davies, H. (2009) *"A systematic narrative review of quality improvement models in health care,"* Edinburgh: NHS QIS

Priola, V. and Hurrell, S. A. (2011) In: Butler, M and Rose, E. (Editors) *Introduction to Organisational Behaviour,* London: Chartered Institute of Personnel and Development, Chapter 15

Pronovost, P., Berenholtz, S. and Needham, D. (2008) Translating evidence into practice: a model for large scale knowledge translation changes that can improve patients' health are often difficult to get into practice, even when backed by good evidence. *British Medical Journal,* 337, pp, 963 - 965

Pronovost, P., Holzmueller, C. G. Needham, D., Sexton, J. B., Miller, M., Berenholtz, S., Wu, A. W., Perl, T. M., Davis, R., Baker, D., Winner, L and Morlock. (2006) How will we know patients are safer? An organization-wide approach to measuring and improving safety. *Critical Care Medicine,* 34(7), pp, 1988 - 1995

Provost, L. P. and Murray, S. K. (2011) *The Healthcare Data Guide,* San Francisco: Jossey-Bass, Chapter 4

Quinn, J. B. (1992) *Intelligent Enterprise: A knowledge and service base paradigm,* New York: Free Press

Randall, R et al (2010): In Arnold, J., Randall, R., Patterson F. et al Work Psychology, 5th Edition Canada: Pearson Education, Chapter 3

Rea-Neto, A., Youseff, N. C. M., Tuche, F., Brunkhorst and Ranieri V. M. (2008) Diagnosis of ventilator-associated pneumonia: a systematic review of the literature. *Critical Care*, 12, R56 https://doi.org/10.1186/cc6877

Reinertsen, J.L., Gosfield, A.G., Rupp, W and Whittington, J. W. (2007) *Engaging Physicians in a Shared Quality Agenda. IHI Innovation Series white paper*. Cambridge, Massachusetts: Institute for Healthcare Improvement.

Resar, R., Pronovost, P., Haraden, C., Simmonds, T., Rainey, T and Nolan, T. (2005) Using a bundle approach to improve ventilator care processes and reduce ventilator associated pneumonia. *Journal on Quality and Patient Safety,* 31(5), pp, 243 - 248

Roberts, G. and Fulop, N. (2014) The role of context in successful improvement In: *Perspectives of Context,* London: Health Foundation

Robson, C. (2009) *Real World Research,* 3rd Edition, Chichester: Wiley pp, 18, 270

Rogers, E. M. (2003) *Diffusion of Innovation,* London: Free Press, pp, 370

Ryan, R, M. and Deci, E. L. (2000) Self-Determination Theory and the Facilitation of Intrinsic Motivation, Social Development, and Well-Being. *American Psychologist,* 55(1), pp, 68 – 78, DOI: 10.1037/0003-066X.55.1.68

Scammell, J. (2018) *Creating a Customer Service Mindset*. Brighton Victoria: Major Street Publishing

Schwandt, T. (2007) *The SAGE Dictionary of qualitative enquiry*. 3rd Edition, Electronic Resource accessed on 30/12/2016 via: http://dw.doi.org.ezproxy.stir.ac.uk/10.4135/97814129862681.n298

Scotland Act in 1998 http://www.legislation.gov.uk/ukpga/1998/46/pdfs/ukpga_19980046_en.pdf

Scottish Executive Health Department. (1999) *Towards a Healthier Scotland: a white paper*. Edinburgh: Scottish Executive

Scottish Executive Health Department. (2000) *Our National Health A plan for action, a plan for change,* Edinburgh: Scottish Executive

Scottish Executive Health Directorate. (2005) *A guide to service improvement,* Accessed via: http://www.gov.scot/resource/doc/76169/0019037.pdf

Scottish Government. (2007) *Better Health, Better Care Action Plan,* Edinburgh: Scottish Government, Accessed via: http://www.gov.scot/Resource/Doc/206458/0054871.pdf

Scottish Government. (2013) *3 step Improvement framework for Scotland's Public Services,* Edinburgh: Crown Copyright 2013

Scottish Intensive care Society Audit Group (SICSAG). (2007) *Audit of critical care in Scotland in 2005 / 2006,* Accessed via http://www.sicsag.scot.nhs.uk/Publications/SICSAG_Report2005_06.pdf

Scottish Intensive Care Society: *VAP Prevention bundle* http://www.sicsag.scot.nhs.uk/hai/VAP-Prevention-Bundle-web.pdf

Seale, C. (2012) Generating Grounded Theory. In: Seale, C *Researching Society and Culture* 3rd Edition, London: SAGE publishing, Chapter 22, pp, 395 – 396, 398

Semkowski, J. (2014) *Theory of Group Dynamics*. Accessed via: https://prezi.com/ras-pp3vq-nk/theories-of-group-dynamics/

Senge, P. (2006) *The Fifth Discipline. The Art and Science of the Learning Organisation,* Revised Edition, London: Random House Business Books

Sexton, J. B., Berenholtz, S. M., Goeschel, C. A., Watson, S. R., Holzmueller, C. G., Thompson, D. A., Hyzy, R. C., Marsteller, J. A., Schumacher, K and Pronovost, P. J. (2011) Assessing and improving safety climate in a large cohort of intensive care units. *Critical Care Medicine,* 39(5), pp, 934 - 939

Shewhart, W. A. (1931) *Economic Control of Quality of Manufactured Product,* London: John Wiley & Sons

Shortell, S. M., O'Brien, J. L., Carmen, J. M., Foster, R. W., Hughes, E. F., Boerstler, H and O'Connor, E. J. (1995) Assessing the impact of continuous quality improvement / Total Quality Management: Concept versus Implementation, *Health Services Research,* 30(2), pp, 377 – 401

Sikolia, D., Biros, D., Mason, M and Weiser, M. (2013) Trustworthiness of Grounded Theory Methodology Research in Information Systems. *MWAIS 2013 Proceedings 16*

Speroff, T., Nwosu, S., Greevy, R., Weinger, M. B., Talbot, T. R., Wall, R. J., Deshpande, J. K., France, D. J., Ely, E. W., Burgess, H., Englebright, J., Williams, M. V and Dittus, R. S. (2010) Organisational Culture: variation across hospitals and connections to patient safety climate, *Quality and Safety in Health Care,* 19, pp, 592 – 596, doi:10.1136/qshc.2009039511

Spurgeon, P., Mazelan, P. M. and Barwell, F. (2011) Medicine engagement: a crucial underpinning to organisational performance. *Health Services Management Research,* 24, pp, 114 – 120, DOI: 10.1258/hsmr.2011.011006

Stetler, C., Ritchie, J., Rycroft-Malone, J., Schultz, A and Charns, M. (2007) Improving quality of care through routine, successful implementation of evidence-based practice at the bedside: an organisational case study protocol using Pettigrew and Whipp model of strategic change, *Implementation Science,* 2(3), doi:10.1186/1748-5908-2-3

Strauss, A. and Corbin, J. M. (1990) *Basics of Qualitative Research: Techniques and procedures for developing grounded theory*. Newbury Park, CA: SAGE

Strauss, A. and Corbin, J. M. (1998) *Basics of Qualitative Research: Techniques and procedures for developing grounded theory*. Thousand Oaks, CA: SAGE, pp, 212

Taylor, S, L., Dy, S., Foy, R., Hempel, S., McDonald, K., Øvretveit, J., Pronovost, P. J., Rubenstein, L. V., Wachter, R. W and Shekelle, P. G. (2011) What context features might be important determinants of the effectiveness of patient safety practice interventions? *BMJ Quality and Safety,* 20, pp, 611 – 617, doi:10.1136/bmjqs.2010.049379

Tong, A,, Sainsbury, P and Craig, J. (2007) Consolidated criteria for reporting qualitative research (COREQ): a 32-item Checklist for interviews and focus groups, *International Journal of Quality in Health Care,* 19, pp, 349 – 357

Touskas, H and Chia, R. (2002) On Organizational Becoming: Rethinking Organizational Change. *Organization Science,* 13(5), pp, 567–82

UNESCO (2001) Universal *Declaration on Cultural Diversity* http://portal.unescor.org/en/ev.php-URL_ID=13179&URL_DO=DO_TOPIC&URL_SECTION=201.html, Accessed on 16th October 2017

Urquhart, C. (2013) *Grounded Theory for Qualitative Research A Practical Guide,* London: SAGE

Van de Voorde, C and Leonard, C. (2007) *Search for Evidence and Critical Appraisal: Health Service Research KCE Process Notes,* (D2007/10.273/39)

Vincent, C. (2010) *Patient Safety,* 2nd Edition, West Chichester: Wiley-Blackwell

Vincent, J., Bihari, D., Suter, P., Bruining, H. A., White, J., Nicolas-Chanoin, M. H., Wolff, M., Spencer, R. C and Hemmer, M. (1995) The Prevalence of Nosocomial Infection in Intensive care units in Europe: Results of the European Prevalence of Infection in Intensive care (EPIC) Study. *The Journal of American Medicine Association,* 274(8), pp, 639 – 644

Weiner, B. J. (2009) A theory of organisational readiness for change, *Implementation Science*, 4, doi:10.1186/1748-5908-4-67

Wideman, M., Whittler, M and Anderson, T. (2005) Barcode medication administration: Lessons learned from an intensive care unit implementation. In: Henriksen, K., Battles, J. B., Marks, E, S. et al. *Advances in patient safety: from research to implementation Vol 3. Implementation Issues,* (AHRQ Publication No. 05-0021-3)

Wilkinson, J., Powell, A and Davies, H. (2011) *Are clinicians engaged in quality improvement*. Health Foundation

Wilson, D. C. (2009) In: Clegg, S. R. and Cooper, C. L. (Editors) *The SAGE handbook of Organizational Behavior* Vol 2: Macro Approaches, London: SAGE Publications, Chapter 24

World Medical Association. (2014) *Declaration of Helsinki* Accessed via: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/