RESEARCH PAPER

THE HEALTHCARE SYSTEM: WILL WE EVER LEARN?

REVIEW OF THE COMMON THEMES ARISING FROM UK AND IRELAND HEALTHCARE INQUIRIES

TABLE OF CONTENTS

1.0 Abstract 5

2.0 Introduction 5

3.0 Literature Review 6

4.0 Objective 6

5.0 Methodology 6

6.0 Summation of High-Profile Organisational Inquiries in the UK 7

6.1 The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

6.1.1 Background Surrounding the Mid Staffordshire NHS Trust Public Inquiry 7
6.1.2 Summary of Findings of the Mid Staffordshire NHS Trust Public Inquiry 7
6.1.3 Recommendations Surrounding the Mid Staffordshire NHS Trust Public Inquiry 10

6.2 The Liverpool Community Health Independent Review (2018)

6.2.1 Background surrounding the Liverpool Community Health Independent Review 11
6.2.2 Summary of Findings Surrounding the Liverpool Community Health Independent Review 11
6.2.3 Recommendations Surrounding the Liverpool Community Health Independent Review 13

6.3 The Report of the Morecambe Bay Investigation (2015)

6.3.1 Background Surrounding the Morecambe Bay Investigation 13
6.3.2 Summary of Findings Surrounding the Morecambe Bay Investigation 14
6.3.3 Recommendations Surrounding the Morecambe Bay Investigation 16

6.4 The Bristol Royal Infirmary Inquiry (2001)

6.4.1 Background of the Bristol Royal Infirmary Inquiry 16
6.4.2 Summary of Findings from the Bristol Royal Infirmary Inquiry 16
6.4.3 Recommendations from the Bristol Royal Infirmary Inquiry 17

7.0 Summation of High Profile Organisational Inquires in Ireland 19

7.1 Savita Halappanavar Patient Safety Investigations

7.1.1 Background to the Savita Halappanavar Investigations 19
7.1.2 Summary of Findings from the Savita Halappanavar Investigations 19
7.1.3 Recommendations arising from the Savita Halappanavar Investigations 20

7.2 Scoping Inquiry into the Cervical Check Screening Programme (2018)

7.2.1 Summary of Findings from the Scoping Inquiry into the Cervical Check Screening Programme 21
7.2.2 Recommendations from the Scoping Inquiry into the Cervical Check Screening Programme 21

7.3 Portlaoise Perinatal Deaths Investigation Report (2015)

7.3.1 Background to the Portlaoise Perinatal Deaths Report 23
7.3.2 Summary of Findings from the Portlaoise Perinatal Investigations Report 23
7.3.3 Recommendations from the Portlaoise Perinatal Investigations Report 24

7.4 Investigation into the quality, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (2012)

7.4.1 Background to the Investigation into the quality, safety and governance of the care provided by Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH)...... 25

7.4.2 Summary of Findings from the Investigation into the quality, safety and governance of the care provided by AMNCH for patients who require acute admission.. 25

7.4.3 Recommendations from the Investigation into the quality, safety and governance of the care provided by AMNCH for patients who require acute admission.. 27

7.5 Clinical Review of the Maternity Services at Portiuncula Hospital (2018)

7.5.1 Background to the Clinical Review of the Maternity Services at Portiuncula Hospital.................... 27

7.5.2 Summary of Findings from the Clinical Review of the Maternity Services at Portiuncula Hospital.. 27

7.5.3 Recommendations from the Clinical Review of the Maternity Services at Portiuncula Hospital...... 28

8.0 Common Themes arising between the Inquiries of the UK and Ireland........................ 30

8.1 Governance........ 30

8.2 Organisational Culture........ 30

8.3 Person Centred Care........ 31

8.4 Risk Management........ 32

8.5 Incident Management........ 32

8.6 Complaints Management........ 33

8.7 Audit........ 33

9.0 Driving Improvements........ 34

9.1 Governance........ 34

9.2 Organisational Culture........ 35

9.3 Person Centred Care........ 36

9.4 Risk Management........ 36

9.5 Incident Management........ 37

9.6 Complaints Management........ 38

9.7 Audit........ 39

10.0 Conclusion........ 40

11.0 Bibliography........ 41

12.0 List of Abbreviations........ 47

1.0 ABSTRACT

Tragedies should be powerful motivators for learning and improvement, indeed, the only honourable response to the victims is to try to ensure that similar tragedies are not repeated in the future (McCrea & Vincent, 2014). This paper takes the learnings from a number of seminal reports into catastrophic failings in healthcare within Ireland and in the UK, draws together the themes and patterns that are repeated time and again and draws on these findings to identify core processes that are central to ensuring the quality and safety of patient care provided.

2.0 INTRODUCTION

Following the publication of the HIQA Patient Safety Investigation Report arising from the death of 31 year old Savita Halappanavar in 2012 from septic miscarriage, HIQA's then Director of Regulation, Phelim Quinn, commented "*The findings of this investigation clearly show that where responsibility for implementation of learning is not clearly owned, then learning does not happen.*" Quinn's comment reflected the investigation finding that the case of Savita Halappanavar shared striking similarities with the case of Tania McCabe and her son Zach in 2007, a catastrophic maternal and neonatal death. The McCabe investigation had identified 27 key recommendations to address failings in the maternal care provided to Tania, however, 5 years later, the Halappanavar investigation had found that these recommendations were, in general, ignored or forgotten, with the lessons unlearnt.

The lack of learning arising from healthcare inquiries has not gone unnoticed. Goodwin (2019) poses the question "*if inquiries are about learning the lessons of the past, why do they appear to find the same failings time and again?*"

Almost 20 years ago the prevalent themes that arose within catastrophic failings in health and social care were considered by Higgins (2001) and she posits that five key factors are generally present in some combination, those being:

- **Isolation** in organisational or geographic terms, which leaves clinicians and others left behind by developments elsewhere, unaware of new ideas or suspicious of them, and unexposed to constructive critical exchange and peer review.
- **Inadequate leadership** by managers or clinicians, characterised by a lack of vision, an inability to develop shared or common objectives, a management style which can be weak or bullying, and a reluctance to tackle problems even in the face of extensive evidence.
- **System and process failure** in which a series of organisational systems and processes are either not present or not working properly, and the absence of these checks and balances allows problems to occur or develop. Systems involved may include those for clinical audit, appraisal, personal development, business planning, performance review, budgeting and so on.
- **Poor communication** affecting both communication in the healthcare organisation and between healthcare professionals and service users, such as staff and patients. It is common to find that many stakeholders knew something of the problems subsequently investigated by an inquiry, but no-one was able to see the full picture in a way that would prompt action.
- **Disempowerment of staff and service users** in which those who might have raised problems or concerns were discouraged from doing so either because of a learned sense of helplessness in the face of organisational dysfunction or because the cultural norms of the organisation precluded such actions.

More recently, Goodwin (2019) considered the recurrence of the same themes over the last 20 years, but she asserts that the theme of culture has now become the preeminent concern. The last two decades of inquiries

have identified culture to be the primary cause of healthcare failures, suggesting that despite considerable investment of time, money and expertise, effectively tackling the problem of culture within the healthcare environment has yet to be solved.

3.0 LITERATURE REVIEW

The UK inquiries reviewed to support this paper's findings include:

- The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)
- The Liverpool Community Health Independent Review (2018)
- The Report of the Morecambe Bay Investigation (2015)
- The Bristol Royal Infirmary Inquiry (2001)

The Irish inquiries reviewed include:

- Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar (2013)
- The Scoping Inquiry into the CervicalCheck Screening Programme – Scally Report (2018)
- Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise (2015)
- Report on the investigation into the quality, safety and governance by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) for patients who required acute admission (2012)
- External Independent Clinical Review of the Maternity Services at Portiuncula Hospital, Ballinasloe (PUH) and of 18 perinatal events which occurred between March 2008 and November 2014 (2018)

4.0 OBJECTIVE

The objective of this paper is to present and examine some of the common systemic weaknesses that have underpinned healthcare tragedies that occurred within the UK and Ireland and identify key learnings to drive improvements within the healthcare sector.

5.0 METHODOLOGY

Formal inquires and reports into adverse healthcare events throughout Ireland and the UK are numerous and a body of knowledge is now available to support a comparative analysis of failings and deficits within healthcare. In this paper, each inquiry, investigation or review is presented under the following headings:

- Background: This provides a brief summary of the scale of the investigation, including the facts which brought it about.
- Summary of findings: A discussion of the main themes and central characteristics of the organisation at the centre of the investigation.
- Recommendations: A summary of the principal recommendations from the relevant report.
- The findings arising from each investigation is then assessed to identify reoccurring themes that were factors in the failures that arose.

6.0 SUMMATION OF HIGH-PROFILE ORGANISATIONAL INQUIRIES IN THE UK

6.1 The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

6.1.1 Background Surrounding the Mid Staffordshire NHS Trust Public Inquiry

In a small district hospital in Staffordshire in the UK, at least 400 people died as a result of receiving poor care over a 50 month period, from January 2005 to March 2009 (BBC, 2019). In all, Stafford Hospital gave rise to 5 official reports culminating in the Francis Report in 2013 which followed a 31-month public inquiry. "*Mid-Staffs*" has since become a byword for NHS care at its most negligent (Campbell, 2013). The Mid Staffordshire NHS Foundation Trust Inquiry reflects, in the words of Sir Ian Kennedy "*a shocking story of appalling standards and chaotic systems for looking after patients and governors who ignored the warning signs of poor care and put cost control ahead of patients and their safety*" (Campbell, 2013) .

Mid Staffordshire reflected an insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities, with an overwhelming emphasis on finances and achieving Foundation Trust status, and inadequate staffing (particularly of nurses) arising from workforce reductions employed to meet financial targets (Goodwin, 2019).

6.1.2 Summary of Findings of the Mid Staffordshire NHS Trust Public Inquiry

6.1.2.1 Governance

The Mid-Staffordshire NHS Foundation Trust was operating in an environment in which its leadership was focused on financial issues and paid insufficient attention to the risk indicators in relation to the quality of service delivery. The Board failed to get a grip on their accountability and governance structure during the period under review (Francis, 2010).

The governing Trust's reports identified numerous governance and clinical issues including, but not limited to (Francis, 2013):

- The staff at the Trust perceived the governance as weak.
- The committees and reporting arrangements were continually changing and the structure for governance did not report to the Board.
- For close to six months in 2006, the Trust did not have a substantive Medical Director or Director of Nursing.
- Many Doctors felt marginalised and disengaged from the governance system.
- A number of Consultants felt they were not listened to, and that the Trust did not welcome constructive criticism or heed concerns about the care of patients.
- There was a lack of urgency in the Board's approach to problems.
- Statistics and reports were preferred to patient experience data, with a focus on systems, not outcomes.
- There was a lack of internal and external transparency regarding the problems that existed at the Trust.

6.1.2.2 Culture

The Trust's culture was one of self-promotion, rather than critical analysis and openness. Several witnesses involved in the Mid Staffordshire Foundations Trust Inquiry made reference to a negative and uncaring culture that was detrimental to patient care (Francis, 2013).

A recurrent criticism of clinical engagement from Consultants was a perception of a top-down approach by management at the Trust. The managerial approach was described as an attempt to "*dictate and impose*". Consultants were critical of the decisions made by management, especially when they were not consulted prior to implementation. It was reported that this contributed to a sense of professional disempowerment (Francis, 2013).

The cultural themes that emerge in respect of the Mid-Staffordshire NHS Foundation Trust included: (Nursing Times, 2013):

- *Attitudes to patients and staff:* The patients reported a reluctance to insist on basic care or medication for fear of upsetting staff.
- *Bullying:* An atmosphere of fear of adverse repercussions in relation to a variety of events was described by many staff witnesses. The staff described a forceful style of management (reported by some as bullying).
- *Target-driven priorities:* A high priority was placed on the achievement of targets, in particular, A&E waiting time targets. The pressure to meet targets generated fear that failure to meet goals could lead to dismissal.
- *Disengagement from management:* The Consultant body largely disassociated themselves from management and often adopted a fatalistic approach to management issues and plans.
- *Low staff morale*: The constant strain of financial difficulties, staff cuts and difficulties in delivering an acceptable standard of care took its toll on morale and was reflected by absence and sickness rates.
- *Isolation*: There is a sense that the Trust and its staff carried on much of its work in isolation from the wider NHS community. It was not as open to outside influences and changes in practice as would have been the case in other places and lacked strong associations with neighbouring organisations.
- *Lack of openness:* The Board conducted a significant amount of business in private when it was questionable whether privacy was really required.
- *Acceptance of poor standards of conduct*: Evidence suggested that there was an unwillingness to use governance and disciplinary procedures to tackle poor performance.
- *Reliance on external assessments:* The evidence indicated that the Trust was more willing to rely on favourable external assessment of its performance rather than on internal assessment.
- *Denial:* In spite of the criticisms the Trust had received, there was a tendency for some staff and management to discount these criticisms by relying on their view that there was much good practice and that the reports were unfair.

6.1.2.3 Person Centred Care

The Mid Staffordshire NHS Foundation Trust patients were not treated in an environment that was patient centred, with staff numbers reduced to a diluted skill mix that provided no assessment of the risks posed to patients. The Francis Report attributed the "*relentless drive to reach foundation trust status*" as being the cause for the Board playing down safety concerns, continuing to run services known to be deficient, with no priority being given to confidentiality or support of colleagues and organisations over the duty to warn others of safety risks (Nursing Times, 2013).

The Healthcare Commission found deficiencies at virtually every stage of the pathway in emergency care. The Trust did not have clear protocols or pathways for the management of patients admitted as emergencies and the care and assessment of patients fell well below acceptable standards (Healthcare Commission, 2009).
Across the Trust there were shortcomings in resuscitation and arrangements to avoid potentially fatal blood

clots. There were shortages of critical care beds and concerns about access to medical advice from critical care specialists. All of these factors contributed to a poor outcome for patients (Healthcare Commission, 2009).

6.1.2.4 Risk Management

Since 2005, the Trust had experienced considerable change in the structure and responsibilities relating to governance and management of risk (Healthcare Commission, 2009). Between 2005 and 2009 auditors' reports identified and reported to the Board serious concerns about deficiencies in the Trust's Risk Management and Assurance System. The auditors called into question the accuracy and reliability of the Trust's compliance with standards. The findings of the report should have been sufficient to question the competence of senior management and leadership of the Trust (Francis, 2013).

The Trust performed poorly on clinical audits. When audits were carried out, there was no robust mechanism in place to ensure changes were implemented, nor did Mid Staffordshire NHS Trust participate in many of the national audits run by the specialist societies (Healthcare Commission, 2009) (Francis, 2010).

The Trust also failed to learn from inquests and from cases which were litigated against them. The Trust paid for litigation investigations, but the reports had not been considered as part of risk management process (Healthcare Commission, 2009).

6.1.2.5 Incidents and Complaint Management

The Mid Staffordshire NHS Foundation Trust had inadequate processes in place for dealing with complaints (Healthcare Commission, 2009).

The Francis inquiry detailed distressing complaints from patients and their families in relation to the care they received (Healthcare Commission, 2009). The Trust management had no culture of listening to patients and basic elements of care and quality of the patient experience within the Hospital were not met. Examples of distressing cases included (Francis, 2010):

- Patients left in excrement in soiled bed clothes for lengthy periods.
- Family members felt they had to launder the patients soiled clothes and bed sheets.
- Patients were left on commodes for long periods of time.
- Patients, who required help during mealtimes, were not assisted.
- Water was not within reach for patients.
- Patients were not assisted when they required the toilet, despite requests for help.
- Wards and toilets were in a filthy condition.
- Untrained staff performed triage in the A&E department.
- Patients and those close to them were treated with callous indifference by staff.

The Trust's Board appeared to be unaware of the extent of the complaints. In the reports submitted to the Board, the complaints got lost in categories, such as "*communication*" or "*quality of care*". Complaints were not given sufficient priority in identifying issues and learning lessons (Francis, 2010).

In theory, the Trust had an appropriate incident reporting system but in practice it was ineffective. The staff had no confidence in the system, they were discouraged from using it, no feedback was provided to staff and there was evidence that the reports were not used to identify areas of systematic concern. This was compounded by the fact that the Trust had inadequate processes in place for dealing with Serious Untoward Incidents (SUIs) (Francis, 2010).

Findings on incident reporting and SUI's (Healthcare Commission, 2009):

- The Trust was in the top (worst) 20% for staff witnessing mistakes and near misses.
- Staff, including senior staff, had little confidence that the Trust learned from incidents.
- Some serious incidents were not reported as serious incidents. These included many cases that went to inquest.
- There was repetition of certain types of serious incidents.
- There was delay in reporting the serious incident to the Trust's board and there was little evidence of discussion of serious incidents by the Board.

6.1.3 Recommendations Surrounding the Mid Staffordshire NHS Trust Public Inquiry

The following are some of the key recommendations arising from the Francis Report (Francis, 2010) (Francis, 2013):

- The introduction of a programme aimed at improving audit in all clinical departments and participation in audit as a requirement for all relevant staff. The Board should review audit processes and outcomes regularly.
- The management of complaints and incident reporting must be reviewed to ensure that it:
    - provides responses and resolutions;
    - ensures staff are engaged in the process, from the investigation of a complaint or an incident, to the implementation of any lessons to be learned.
- The organisation should give priority to ensuring that any member of staff who raises an honestly held concern about the standard or safety of the provision of services to patients is supported and protected from any adverse consequences and should foster a culture of openness and insight.
- Reporting of incidents of concern relevant to patient safety must be insisted upon. Staff are entitled to receive full feedback in relation to any report they make.
- The organisation should review the management structure to ensure that clinical staff and their views are fully represented at all levels of the Trust and that they are aware of concerns raised by Clinicians on matters relating to the standard and safety of the service provided to patients.
- The organisation should review its record-keeping procedures in consultation with staff.
- The organisation should have an adequate programme for the training and continued development of Directors.
- Following the death of a patient, both the bereaved family and the certifying doctor should be asked whether they have any concerns about the death or the circumstances surrounding the death, and guidance should be given to hospital staff encouraging them to raise any concerns they may have with the independent medical examiner.
- The organisation should initiate an arms-length independent investigation of a complaint where any one of the following apply:
    - A complaint amounts to an allegation of a serious untoward incident;
    - Subject matter involving clinically related issues is not capable of resolution without an expert clinical opinion;
    - A complaint raises substantive issues of professional misconduct or the performance of senior managers;
    - A complaint involves issues about the nature and extent of the services commissioned.

6.2 The Liverpool Community Health Independent Review (2018)

6.2.1 Background surrounding the Liverpool Community Health Independent Review

Liverpool Community Health Trust was formed in 2010 and it provided services for about 750,000 people on Merseyside until 2018. The review examined "*historic incidents of serious harm*" and 17,000 cases relating to patient safety.

Goodwin asserts that although similar in nature, the problems at Liverpool Community Health Trust come across as even more extreme than at Mid Staffordshire: the cost improvement programmes even more ambitious, the willingness of the leadership to intimidate more overt, denial that the cause of the problems had anything to do with cuts in resources and shortage of appropriately trained staff more absolute, and the deleterious effects this had on staff well-being more palpable (Goodwin, 2019).

6.2.2 Summary of Findings Surrounding the Liverpool Community Health Independent Review

An independent review into the widespread failings by a community health trust was carried out by Dr Bill Kirkup CBE. The report outlines how cost improvement programmes imposed by the Trust in a bid to gain Foundation Trust status put the safety of patients at risk and that a culture of bullying meant that staff were scared to speak up or that incidents were ignored or not escalated. The review found that overview of the Trust by external parties failed to identify the services problems for at least four years and concluded that earlier intervention would have reduced the avoidable harm that occurred to patients and staff across the Trust (Kirkup, 2018).

6.2.2.1 Governance

Liverpool Community Health Trust had a desire to demonstrate a robust financial position in pursuit of their application to become a Foundation Trust, but this strategy had very serious adverse impacts on patient safety.

The Liverpool Community Health NHS Trust Review Report identified that the organisation was dysfunctional from the outset, resulting in unnecessary harm to patients consequential to the following key areas of concern (Kirkup, 2018). Findings illustrated:

- A lack of leadership at senior and middle management levels.
- The Chair and Non-Executive Directors were relatively inexperienced and offered insufficient challenge to the management team.
- Inappropriate pursuit of Foundation Trust status, setting unfeasible financial targets and failure to recognise the significant harm that was being inflicted as a result.
- Management of services that the Trust was ill-equipped to deal with, particularly prison healthcare in HM Prison Liverpool.
- Senior leaders, and the Board, failed to realise the Trust was out of its depth.
- Staff were overstretched, demoralised and, in some instances bullied.
- The failure of nursing management and human resource procedures in the management of staff grievances and suspensions.
- The discouragement of reporting incidents and reducing the severity ratings of incidents reported.
- The failure of incident investigations and lessons not being learned.
- Significant unnecessary harm occurring to patients.

6.2.2.2 Culture

The culture of the Trust hampered the ability of staff to provide services to a required standard and impaired their willingness to declare incidents and learn from them. There was a culture of intolerance, disbelief and fear, with a clear lack of care for the workforce. The HR Managers failed to follow procedures and documents showed evidence of staff being suspended for prolonged periods with no rationale or process for resolution (Kirkup, 2018).

The organisation was top-heavy with a blame culture that spread down from the senior leaders. Addressing staff inappropriately by shouting and finger pointing had been the norm within the Trust, which was replicated throughout the organisation (Kirkup, 2018).

6.2.2.3 Person Centred Care

The review found evidence that the clinical capability to deliver the patient care required was compromised by inadequate staffing levels, training, supervision and skills mix within the Trust. Staff were working in a reactive environment, and prevention work was not introduced in a timely manner. Clinical competence and training were found to be lacking in some staff, with evidence-based standards not uniformly applied and learning from incidents and serious incidents was not shared for wider learning. The staff had little time to undertake clinical and management supervision, preventing reflective practice and learning (Kirkup, 2018).

6.2.2.4 Risk Management

The review found that Trust had no clear and effective system to manage risk, in particular, the additional clinical risk arising from cost improvement measures. The Nurse Director was also the Trust's Chief Operating Officer, and therefore was also responsible for achieving the cost improvement programme while at the same time being responsible for the quality of care (Kirkup, 2018).

6.2.2.5 Incident Management

Over the period 2011 to 2014, there were 103 SUI's and there was no evidence that effective action had taken place to improve practice. The Kirkup Report found that incident responses were significantly hampered due to:

- A lack of identification of root causes.
- A lack of time-trend and thematic analysis.
- Plans based on process actions unrelated to patient outcome.
- Failure to review whether actions had been undertaken and completed.
- Lack of evaluation to ascertain whether actions had been successful.
  (Kirkup, 2018).

6.2.2.6 Audit

In 2013 a review of clinical audit was carried out by Trust's internal auditors that identified major issues. However, recommendations from this review were not implemented as the Trust's Management Team as they argued that it should not be their responsibility.

A clinical audit into patient falls (April 2012-March 2013) identified that 15% to 20% of patients who had fallen had no care plan in place to proactively manage their falls risk or improve their confidence and mobility status. It also identified four patients who had fractured their hips had not had incidents reported appropriately or categorised as a serious incident by the Intermediate Care Service (Kirkup, 2018).

A clinical audit of patient pressure ulcers was presented to the Trust Board by the Director of Nursing in February 2013. It outlined the occurrence of 26 grade 3 pressure ulcer incidents of the year to date. The same issues were

identified again in November 2013, January 2014, and between March 2014 and March 2015, without prompting any definitive analysis or corrective actions (Kirkup, 2018).

6.2.3 Recommendations Surrounding the Liverpool Community Health Independent Review

The Liverpool Community Health NHS Trust inquiry report offers a number of recommendations and these include (Kirkup, 2018) :

- Review of the handling of previous serious incidents to ensure they have been properly investigated and lessons learned.
- Review of the handling of disciplinary and whistleblowing cases urgently.
- Staff are not to be placed back into working relationships previously the subject of bullying and harassment.
- The Regulators and oversight organisation must ensure the requisite level of experience of senior management appointees and ensure a system of support and mentorship for Board members where indicated.
- In assessing the level of risk facing an organisation, Regulators and oversight organisations must take into account the cumulative impact of relevant factors, including a newly established organisation, an inexperienced Board, cost improvement targets and service acquisitions.
- Regulators and oversight organisations must review how health care organisations work together jointly at regional and national level and implement mechanisms to improve the use of information and soft intelligence more effectively.
- Regulators and oversight organisations must ensure that, during both local and national reorganisations and reconfigurations, performance and other service information is properly recorded and communicated to successor organisations.

6.3 The Report of the Morecambe Bay Investigation (2015)

6.3.1 Background Surrounding the Morecambe Bay Investigation

The Morecambe Bay Investigation was established by the Secretary of State for Health in the UK to examine concerns raised by the occurrence of serious incidents in maternity services provided by what became the University Hospitals of Morecambe Bay NHS Foundation Trust. Dr. Bill Kirkup carried out this investigation and three years later carried out the Liverpool Community Health Trust Independent Review. The serious incidents related to the deaths of mothers and babies from 1st January 2004 to 30th June 2013 in the Maternity Unit in Furness General Hospital (FGH) (Kirkup, 2015).

The investigation reviewed 233 pregnancies. Of these, 63 showed features of concern prompting a full clinical review, as a result of which found 20 instances of significant or major failures of care associated with 3 maternal deaths, 10 still-births and 6 neonatal deaths between 2004 and 2012. In 13 cases the investigation found that there was "*suboptimal care in which different management would reasonably have been expected to make a difference to the outcome*" (Kirkup, 2015).

In 2017, the Professional Standards Authority (PSA) carried out a lessons learned review of the Nursing and Midwifery Council's (NMC) handling of concerns regarding midwives at the University Hospitals of Morecambe Bay NHS Foundation Trust. The PSA found that the NMC did not take credible information, that it received about the midwives at the FGH, seriously or take action to satisfy itself that the midwives were fit to practise (Professional Standards Authority for Health and Social Care, 2018).

6.3.2 Summary of Findings Surrounding the Morecambe Bay Investigation

The origin of the problems were found to lay in the dysfunctional nature of the maternity service at FGH. The following were identified as having led to the unnecessary deaths of mothers and babies within FGH:

- Clinical competence was substandard, with deficient skills and knowledge.
- Working relationships were poor, particularly between staff groups, such as obstetricians, paediatricians and midwives.
- There was a desire amongst midwives to pursue normal childbirth.
- There were failures of risk assessment and care planning that resulted in inappropriate and unsafe care.
- The response to adverse incidents was grossly deficient, with repeated failure to investigate properly and learn lessons.
- There was an overreliance on inadequate internal investigations.

6.3.2.1 Governance

The Trust had poorly developed clinical governance that meant there was no formal oversight of safety or other quality matters in clinical services, with even high perinatal mortality rates failing to signal problems (Kirkup, 2015).

The maternity and neonatal services had their management arrangements changed six times during the period covered in the review (2004 to 2013). As a result of this managerial instability, there was evidence that lines of responsibility and accountability were blurred, many posts were combined, individuals were given management posts in maternity and neonatal services without any knowledge or experience of those services, and the focus was on operational objectives such as finance and waiting times rather than on governance and quality of services (Kirkup, 2015).

There was a dysfunctional nature to the professional relationships within the Maternity Unit. This was compounded when roles were inappropriately combined, resulting in insufficient checks and balances (Professional Standards Authority for Health and Social Care, 2018).

6.3.2.2 Culture

The investigation found that midwives sought to avoid the involvement of the Obstetricians in the care of their patients. The working of the Maternity Unit rested on one or two influential midwives, who pursued normal childbirth "*at any cost*", and this approach became deeply embedded in the Unit's practice (Kirkup, 2015).

The midwives had developed a defensive culture that tended to support each other rather than identifying and acting on lessons from incidents (Professional Standards Authority for Health and Social Care, 2018).

The investigation found the reaction of staff in the Maternity Unit was shaped by a denial that there was a problem. For example, during staff interviews the panel were told there were "*no specific practice issues*" on review of one maternal death and the other maternal death had been "*unpredictable, unavoidable and we did not highlight any practice issues in that case*". Kirkup (Kirkup, 2015) however detailed significant failings in both cases.

There were strong views amongst staff who felt they were being unfairly criticised. The most notable example of which was an email from one midwife to another concerning a Nursing and Midwifery Council (NMC) investigation titled '*NMC Shit*'.

At Morecambe Bay, it was found that there was a significant degree of tribalism between different staff groups, with the working relationships between the midwives, obstetricians and paediatricians being insular, disengaged,

and characterised by an unwillingness to collaborate (Goodwin, 2019) .

6.3.2.3 Person Centred Care

The two maternal deaths, an intrapartum stillbirth, the death of a baby from sepsis and a baby damaged by shortage of oxygen in labour revealed underlying failures with the patterns in the care provided to the patients, these included:

- Failure to monitor the condition of the mothers and babies properly;
- Failure to recognise signs of clinical deterioration;
- Failure to take effective action in response to developing clinical problems; and
- Failure to communicate effectively within and between clinical teams.

The senior staff in the Maternity Unit did not communicate concerns about the failing clinical standards in the Unit to those whom they reported at Board level, such as the Medical Director or the Chief Executive (Kirkup, 2015) (Professional Standards Authority for Health and Social Care, 2018).

The 2015 Morecambe Bay Investigation found that improvements in knowledge, skills, clinical assessment, investigation and management would have a significant impact on clinical outcomes (Kirkup, 2015). Examples were identified of first contact with patients being inappropriate and, in some cases, having serious consequences, where high risk patients were reviewed by junior staff, with no effective escalation policy. The lack of knowledge and experience contributed to the '*wait and see*' approach and often the consequence of this inaction was further deterioration of the patient's condition (Kirkup, 2015).

6.3.2.4 Risk Management

Kirkup recognised that clinical risk assessment and effective planning were crucial if patient harm was to be avoided, however, the Investigation uncovered many examples of the presumption of normality, with failure to recognise or acknowledge high-risk obstetric patients or to recognise when risk status changed; failure to monitor, review and update clinical management plans for high-risk obstetric patients; failure to transfer high-risk mothers to tertiary-level units for delivery; and failure to transfer high-risk neonates to a regional intensive care unit before further clinical deterioration (Kirkup, 2015).

6.3.2.5 Incident and Complaint Management

Some stillbirths in late pregnancy are neither predictable nor preventable, however, those that occur in labour (intrapartum) to previously normal babies are serious incidents that require investigation. An intrapartum stillbirth that occurred in FGH in 2004 was not reported as a SUI. Five more serious incidents, including deaths, that occurred between 2006 and 2007 also illustrated similar elements of concern but were not reported as SUI's and instead were investigated internally. The investigation of these cases failed to recognise root causes and their underlying causes were not recognised. The investigations followed a pattern of superficiality and protectiveness. All incidents were examined separately and there was an excessive reliance on the superficial differences in outcome, with no consideration given to the human and behavioural factors that may have led to the outcomes (Kirkup, 2015).

In relation to complaint management, the Investigation found that the Trust's governance committees and, ultimately, the Board, were not interested in the lessons learnt or the issues arising from the complaints, but predominantly on how long it took to process an investigation. The information that may have been valuable in the identification of trends, clinical issues or consistent service failures were not considered in any meaningful way (Kirkup, 2015).

6.3.3 Recommendations Surrounding the Morecambe Bay Investigation

The following are some of the key recommendations arising from the Morecambe Bay NHS Trust inquiry report (Kirkup, 2015):

- The organisation must review competencies, skills and knowledge of all clinical staff and must document plans to delivery training and development for staff.
- Multi-disciplinary working must be implemented effectively.
- A protocol for risk assessment must be developed and applied in maternity services.
- The organisation must implement ongoing audit.
- The organisation must identify an approach to better joined up working regarding policies, systems and standards.
- The organisation must identify a programme to raise awareness of incident reporting.
- The organisation must implement a culture that supports openness and honesty with all staff carrying a duty of candour to patients.
- The organisation must implement effective structures to investigate incidents and complaints, carry out Root Cause Analysis, report and communicate results to all relevant stakeholders.
- Review governance arrangements for clinical leadership in obstetrics, paediatrics and midwifery and ensure the appropriateness of the roles and responsibilities allocated to staff.
- Middle and senior managers must have the requisite clarity over roles and responsibilities in relation to the quality and safety of the care being provided.

6.4 The Bristol Royal Infirmary Inquiry (2001)

6.4.1 Background of the Bristol Royal Infirmary Inquiry

The Bristol Royal Infirmary Inquiry was established in 1998 to examine the '*excess deaths*' in paediatric cardiac surgery at the Bristol Royal Infirmary (BRI) between 1984 and 1995. Professor Sir Ian Kennedy chaired the inquiry and it reported in 2001.

In 1984, there was a designated service for babies under the age of one, which involved open-heart surgery at BRI and closed-heart surgery at the Bristol Royal Hospital for Sick Children (BRHSC), both of which were, and continue to be, teaching hospitals associated with Bristol University's Medical School. There was also a service funded from local sources for children over 1 year old, similarly divided between the two hospitals. However, BRI never achieved the critical mass to become a Supra Regional Services (SRS) centre. Over time, adverse events arose and, by the late 1980s, concerns were expressed by healthcare professionals working in the Hospital (Kennedy, 2001).

In 1986, Professor Andrew Henderson distributed a letter at a meeting of the South Glamorgan Health Authority. The letter stated the following "*it is no secret that their [United Bristol Hospital's paediatric cardiac] surgical service is regarded as being at the bottom of the UK league for quality*" (Kennedy, 2001). In 1987, BBC Wales broadcast a programme entitled "*Heart Surgery – The Second Class Service*". Kennedy (2001) detailed that in 1991, a table prepared in United Bristol Hospital Trust disclosed a mortality rate of 30% for open heart surgery in children under the age of one at that time, in comparison to the UK Cardiac Surgical Register (UKCSR) mortality figure at 15.8% for 1990.

6.4.2 Summary of Findings from the Bristol Royal Infirmary Inquiry

6.4.2.1 Governance

Kennedy (2001) found that the overall strategic vision or direction within BRI was lacking at Board level. Clinicians, who were taking up managerial duties, lacked sufficient training, experience and time to recognise

and respond to problems that may have existed in their area of responsibility. These clinicians were not equipped to identify the need to develop lines of communication nor how to introduce good managerial practices. As a result of the lack of managerial training, effective teamwork within the Hospital Directorates did not develop.

6.4.2.2 Culture

The investigators noted the culture of management at BRI was characterised by a clinician-management divide; an oral culture devoid of process and where questions were turned back on the questioner.

It was noted by Kennedy (2001) that some senior management held a position of influence for a long time and there was a '*club culture*' in place that lead to a power imbalance with a few people having all of the control. Informal evening meetings about clinical matters were held in the homes of consultants, with these meetings referred to as the '*paediatric club*'.

Goodwin notes that this '*club culture*' operated largely at the managerial/board levels and entry to the club was dependent on length of service and '*fit*' with the Executive Team (Goodwin, 2019). The Chief Executive made the final decision on who became a Clinical Director from among the senior clinicians with whom he had worked with many years. Challenges to this policy were perceived as disloyalty. This resulted in a concentration of power and a fragmentation of responsibility.

6.4.2.3 Person Centred Care

The Kennedy Inquiry (2001) identified that there was no system in place to establish and outline who was responsible for the management of care of the children undergoing surgery in BRI. The lack of concern for the needs of this group of highly vulnerable patients meant that the quality of care for children who received open-heart surgery at BRI was not what it should have been. There was a lack of effective planning or service frameworks for children's acute healthcare and these deficits were compounded by poor communication and a lack of empathy for families. Kennedy (2001) found that when a child died, the family of the child were not informed appropriately, no counselling was provided and some parents felt that they were being hurried out of the way.

6.4.2.4 Incident Management and Audit

There was an absence of a culture of safety and openness that lead to concerns and incidents not being routinely or systematically discussed and addressed. Unsafe practices continued within the Hospital and were not checked (Kennedy, 2001).

In 1991, a Medical Audit Committee (MAC) was established with the remit of following regional strategy and promoting, facilitating and co-ordinating audit. In 1992/93 and 1993/94 MAC reports noted that clinicians in BRI kept separate logs of their clinical activity and the paediatric cardiologists maintained their own computerised information systems. Dr Roylance took the view that "*the actual audit findings were to remain confidential to those providing the service, i.e. the clinicians*" (Kennedy, 2001).

6.4.3 Recommendations from the Bristol Royal Infirmary Inquiry

The following details some of the key recommendations arising from the Bristol Infirmary Inquiry Report (Kennedy, 2001):

- There should be partnership between healthcare professionals and the patients, whereby the patient and the professional meet as equals with different expertise.
- Information relating to treatment and care should be given in a variety of forms, be provided in stages and be reinforced over time.
- The process of informing the patient, and obtaining consent to a course of treatment, should be regarded as a process and not a one-off event.

- Patients must be given the opportunity to pass on views on the service which they have received.
- A duty of candour, meaning a duty to tell a patient if adverse events have occurred, must be recognised as owed by all those working in the NHS to patients.
- Complaints should be dealt with swiftly and thoroughly, keeping the patient (and carer) informed.
- The criteria and process for selection of the executive directors of a Board must be open and transparent.
- Greater priority should be given to non-clinical aspects of care in six key areas in the education, training and continuing professional development of healthcare professionals:
    - skills in communicating with patients and with colleagues;
    - education about the principles and organisation of the NHS, and about how care is managed, and the skills required for management;
    - the development of teamwork;
    - shared learning across professional boundaries;
    - clinical audit and reflective practice; and
    - leadership.
- Periodic appraisal should be compulsory for all healthcare professionals.
- Periodic revalidation, whereby healthcare professionals demonstrate that they remain fit to practise in their chosen profession, should be compulsory for all healthcare professionals.
- Where clinicians hold managerial roles that extend beyond their immediate clinical practice, sufficient protected time in the form of allocated sessions must be made available for them to carry out that managerial role.
- Any clinician, before appointment to a managerial role, must demonstrate the managerial competence to undertake what is required in that role.
- Any clinician carrying out any clinical procedure for the first time must be directly supervised by colleagues who have the necessary skill, competence and experience until such time as the relevant degree of expertise has been acquired.
- The reporting of sentinel events must be made as easy as possible, using all available means of communication.
- The process of clinical audit should be at the core of a system of local monitoring of performance. Clinical audit should be multidisciplinary.
- A single approach to collecting data should be adopted, that clinicians can trust and use and from which information about both clinical and administrative performance can be derived.
- All surgeons who operate on children, including those who also operate on adults, must undergo training in the care of children and obtain a recognised professional qualification in the care of children.

7.0 SUMMATION OF HIGH PROFILE ORGANISATIONAL INQUIRES IN IRELAND

This section considers a number of high-profile inquiries into health and social care that have occurred in Ireland. Similar themes emerge as to those already seen in the review of the UK reviews.

7.1 Savita Halappanavar Patient Safety Investigations

7.1.1 Background to the Savita Halappanavar Investigations

On 21st October 2012, Savita Halappanavar who was pregnant with her first child, self-referred to the gynaecology ward in University Hospital Galway, part of the Saolta University Health Care Group. She was seventeen weeks pregnant and had been complaining of lower backache for the previous 12 hours. Her medical records noted "*an inevitable/impending pregnancy loss*". Mrs. Halappanavar was admitted for the management of the inevitable miscarriage on the 21st October 2012 (HSE, 2013) (HIQA, 2013).

On the 22nd October 2012 at 00:30 hours, Mrs. Halappanavar's membranes spontaneously ruptured. On the 24th October 2012, Mrs. Halappanavar's condition deteriorated and she was diagnosed with sepsis secondary to chorioamnionitis. Following this, she was admitted to the High Dependency Unit (HDU) at 16:45 hours and, while in the HDU, Mrs. Halappanavar suffered a clinical deterioration. As a result of this deterioration, Mrs. Halappanavar was transferred to the ICU at 03:00 hours on 25th October 2012. While in ICU, she was intubated and mechanically ventilated at 03:30 hours. On 28th October 2012 at 01:09 hours, Mrs. Halappanavar died (HIQA, 2013).

The Hospital's Clinical Director commissioned an investigation into the incident which was overseen by the National Incident Management Team (NIMT) and was chaired by an external independent chair. The investigation focused on the factual circumstances leading up to the incident to identify key causal factors and contributory factors. The final report was published on 13th June 2013. Also, a coroner's inquest took place on the 8th April 2013. On the 19th April 2013, a verdict of medical misadventure was returned.

HIQA carried out an investigation to consider the safety, quality and standards provided by the HSE to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar (HIQA, 2013).

7.1.2 Summary of Findings from the Savita Halappanavar Investigations

7.1.2.1 Governance

The HIQA report communicated the Authority's concern at the complexity of the governance structure and the large numbers of committees in place within the Hospital, with a number of these involving the same members, many of whom also had full-time clinical responsibilities (HIQA, 2013).

The report also identified there were no formal multidisciplinary arrangements or associated governance structure for the prioritisation, development, dissemination and monitoring of usage of policies, guidelines, protocols and care pathways based on best available evidence.

Overall, the Authority found that the clinical governance arrangements were not effective in the context of patient safety and quality systems, the development and implementation of hospital guidelines and the robustness of multidisciplinary working arrangements (HIQA, 2013).

7.1.2.2 Culture

The HIQA investigation found deficits in how learning, particularly in the areas of maternity services and clinically deteriorating patients, has been adopted and implemented following previous investigations and inquiries. These deficits included an inability to apply system–wide learning from adverse findings in one part of the system to minimise clinical risk for all patients (HIQA, 2013).

7.1.2.3 Person Centred Care

The HIQA investigation identified that there was a lack of basic, fundamental care, a failure to recognise risks of clinical deterioration and a failure to act or escalate concerns within the Hospital. At various stages, when observations were carried out, by either the Consultant Obstetrician, Non-Consultant Hospital Doctors (NCHDs) and midwives/nurses, the relevant parties did not appear to act in a timely way in response to the indications of Savita Halappanavar's clinical deterioration. It was noted that consultants on call for the labour ward were not present on the labour ward but rather engaged in other clinical activities. (HIQA, 2013).

The HIQA investigation also identified, through a review of Savita Halappanavar's healthcare record, a number of missed opportunities which, had they been identified and acted upon, may have potentially changed the outcome of her care. For example, following the rupture of her membranes, four-hourly observations including temperature, heart rate, respiration and blood pressure did not appear to have been carried out at the required intervals. At the various stages when these observations were carried out, the consultant obstetrician, NCHD's and midwives/nurses caring for Savita Halappanavar did not appear to act in a timely way in response to the indications of her clinical deterioration (HIQA, 2013).

7.1.2.3 Workforce

The HIQA investigation found there was no evidence that the Hospital facilitated, or had in place, arrangements to ensure that medical and nursing staff had the necessary competencies and skills to provide care to patients at risk of clinical deterioration or to provide training on the recognition and management of sepsis and the clinically deteriorating obstetric patient.

The report identified that there was no formal multidisciplinary skills training or simulation programmes in place to assess the clinical, communications, and team skills competencies (HIQA, 2013).

7.1.2.4 Risk Management

HIQA identified within their investigation that there was no formal clinical pathway to refer high risk obstetric patients to the obstetric anaesthetist antenatal high risk service and that the physical layout of relevant ward was not designed to meet the needs of those patients at risk of clinical deterioration and the complexity and diversity of the patient casemix. The report specified that there was no formal structured process in place to assist in the dissemination of findings and learning from the monthly mortality and morbidity meeting and there was no arrangements to gather, analyse and implement learning from national and international information (HIQA, 2013).

7.1.3 Recommendations arising from the Savita Halappanavar Investigations

The local recommendations for the Hospital Group provided within the HIQA report (2013) included (HIQA, 2013) (HSE, 2013):

- The Group should review its current governance structures and arrangements, including cross committee membership, in order to ensure that these are in line with the principles of good governance and the recommendations of previous HIQA investigations.
- The Group should review its clinical governance arrangements to ensure that all clinical areas are appropriately implementing local and national policies, procedures and protocols and put in place an assurance mechanism to monitor their effective implementation.
- The Group should ensure that all medical and midwifery staff involved in the care of antenatal and post-natal women regularly maintain their professional knowledge, skills and competence in line with best practice and the needs of the patient group being cared for while fulfilling the requirements of professional regulation.
- The Group must put in place arrangements to ensure that the clinical directors have the necessary competencies, as well as adequate time and support, to effectively meet the leadership and managerial requirements of the role.
- The Group must ensure that arrangements are put in place to support and train all staff responsible for

managing risk, adverse incidents, near misses, claims and complaints. The Group should ensure that the review, implementation and monitoring of actions, trend analysis and implementation of learning from such incidents are disseminated to staff and incorporated within the clinical governance arrangements in the Group.

7.2 Scoping Inquiry into the Cervical Check Screening Programme (2018)

7.2.1 Background to the Scoping Inquiry into the Cervical Check Screening Programme

A scoping inquiry into the CervicalCheck Screening Programme arose due to the failure to disclose results of a retrospective audit to a large group of women who had developed cervical cancer in Ireland. The failure to disclose the results came to the public's attention through the case of Ms Vicky Phelan in 2018 (Scally, 2018).

The Terms of Reference for the Scally Scoping Inquiry included an examination of the facts including details of:
i. The non-disclosure of information to Ms. Phelan relating to a CervicalCheck standard case clinical audit carried out following her diagnosis of cervical cancer in July 2014;

ii. The apparent widespread practice of non-disclosure to patients relating to CervicalCheck standard case clinical audits;

iii. The management and level of knowledge of various parties including, but not limited to the HSE, the Department of Health or other public authorities and any relevant service provider of:
1) the Vicky Phelan case
2) any other cases concerning CervicalCheck
3) issues related to the non-disclosure of the clinical audit results

iv. The manner and means through which the relevant facts were shared, escalated, reported and communicated.

After Vicky Phelan's case came to court in April 2018, an unstructured approach to informing the women and the families of the deceased women was adopted. The focus was to achieve disclosure in an extremely short timeframe and with the media closely observing. This time, however, disclosure was not optional, and instructions were issued by the Health Service Executive's (HSE's) Serious Incident Management Team. The Chief Executive Officers of hospitals involved were asked that, at a minimum, the woman or her next of kin were to be informed the following (Scally, 2018):

1. That their cytology was reviewed as part of an audit conducted by CervicalCheck.
2. The date on which the audit was complete.
3. How the review details may relate to their subsequent cancer diagnosis.

Scally (2018) reports that many of the women involved in the scandal found the disclosure appointments stressful and traumatic. Women and the families of deceased women wanted to know why they had not been told previously and they recounted the attitudes and responses of consultants which they deemed to be negative and defensive. An example of an interaction between the consultant and the close relatives of one woman who was deceased is recorded in the report whereby the consultant mentioned several times that the deceased woman was a smoker and the family were also informed by the consultant that '*nuns don't get cervical cancer*' (Scally, 2018).

7.2.2 Summary of Findings from the Scoping Inquiry into the Cervical Check Screening Programme

7.2.2.1 Governance

The Scally Report (2018) identified that a significant portion of the CervicalCheck staff did not have job descriptions, including those in senior management positions. Where job descriptions were in place, they were found not to reflect the role as it was constituted and were inaccurate. CervicalCheck was subject to a reduction in resources and struggled to replace departing staff, which had an impact on the scheme.

7.2.2.2 Culture

The Scally report (2018) found the HSE policies and procedures and the joint HSE/State Claims Agency (SCA) guidelines for implementation of open disclosure left the decision on whether to disclose or not to the judgement of the clinicians involved. This meant that where the doctor decided not to disclose the occurrence and details of an adverse event to a patient, that decision was not subject to further scrutiny. In the guidelines, there was a clause stating that non-disclosure may be appropriate where there is no evidence that the patient would benefit from the disclosure. Scally (2018) concluded that "*The overall message is contradictory. On the one hand, HSE policies support open disclosure and say it 'must' happen; on the other it makes non-disclosure a distinct option*".

The Scally report detailed that the issue of non-disclosure was felt very intensely, and often angrily, by many women and that it wasn't just the nondisclosure, but the rushed nature of the disclosure that did take place that affected them adversely. Women clarified that the characterisation at the meetings of the manner in which women and families were told of their situation varied from unsatisfactory, to inappropriate, to damaging, hurtful and offensive (Scally, 2018).

7.2.2.3 Person Centred

The Scally report makes note of the difficulties many women encountered accessing their medical records. The Inquiry found entirely unreasonable delays in providing a woman with their medical records without good reason (Scally, 2018).

7.2.2.4 Risk Management

The Scally report recommended that CervicalCheck should adopt a formal risk management approach. A key weakness identified was the poor governance by the HSE and weak oversight of CervicalCheck and the National Screening Service (NSS) (Scally, 2018). A particular deficit was the process by which serious risks should be communicated to the appropriate Senior HSE Management levels, and, if necessary, to the Department of Health.

7.2.2.5 Audit

The Scally report found that a CervicalCheck audit was carried out with commendable aims, however, planning, governance and documentation were inadequate (Scally, 2018). The report found that there was very little anticipation of the challenges that would arise when cytology (or other) results were reviewed.

Insufficient data of acceptable quality was generated by the CervicalCheck audit to enable the Scoping Inquiry to form an opinion on the overall outcome of the audit, nor to enable comparisons to be made with other audits, such as those in England and Wales.

7.2.3 Recommendations from the Scoping Inquiry into the Cervical Check Screening Programme

The following are some of the key recommendations arising from the Scally report (Scally, 2018):

- The implementation of new governance arrangements for the HSE should include a substantial revision to the organisational approach to risk management and its reporting.
- CervicalCheck should revise its programme standards to clarify what is mandatory, and to clarify the level of reliance on external accreditation processes.
- CervicalCheck should adopt a formal risk management approach to parameters which do not reach acceptable standards despite full intervention and monitoring.
- Assurances should be sought with respect to the capability to deliver the service as specified and without material change. Where change is possible, robust change management procedures, which include approval by the procuring authority, should be defined.

- Audits should continue to be an important component of cervical screening as this complies with all good clinical practice. Common, robust and externally validated approaches to the design, conduct, evaluation and oversight of audits should be developed across the screening services.
- The HSE's open disclosure policy guidelines should be revised as a matter of urgency. The decision not to disclose an error or mishap to a patient must only be available in a very limited number of well-defined and explicit circumstances.
- Medical staff must be required, as a condition of employment, to complete training in open disclosure and a governance framework for open disclosure must be put in place that includes evaluation and audit.
- NSS needs to advance its thinking on cross programme learning, external QA, and governance oversight of the QA programmes.
- The composition and duration of appointments for all QA Committees should be reviewed.

7.3 Portlaoise Perinatal Deaths Investigation Report (2015)

7.3.1 Background to the Portlaoise Perinatal Deaths Report

In Ireland, an RTÉ Investigation broadcast by a Prime Time programme revealed the tragic deaths of four new born babies over six years at Portlaoise Hospital and the subsequent management of patients and their families by the Hospital and the HSE following the babies deaths (HIQA, 2015). This resulted in the Minister for Health ordering a preliminary assessment of the perinatal deaths in Portlaoise Hospital from 2006 up to that point in 2014, to be followed by an independent investigation as a result of the very negative experiences of a number of patients and their families in receipt of maternity services. The findings of the investigation were documented in the '*Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise*' (HIQA, 2015).

7.3.2 Summary of Findings from the Portlaoise Perinatal Investigations Report

7.3.2.1 Governance

Major deficiencies in corporate and clinical governance were identified in the HIQA report (HIQA, 2015).

At a national level, the investigators found no evidence of meaningful oversight by the HSE of the Hospital. This investigation concluded that there were a number of substantial governance and management issues at Portlaoise Hospital and that sufficient action was not taken by the HSE at a national, regional or local level to address these issues.

At a local level, a Senior Hospital Management Committee was responsible for providing safe effective services through leading and directing the performance of the Hospital, however, very few of these meetings actually took place and in the minutes of meetings reviewed by the Investigation Team, there was little evidence to show that the Committee was effective in identifying or implementing actions aimed at addressing quality and safety issues within the Hospital. A Quality and Safety Executive Committee was also in place for the Hospital. The Investigation Team found this committee structure to be overly complicated and not effective (HIQA, 2015).

7.3.2.2 Culture

An assessment of patient safety culture was carried out at Portlaoise Hospital, with the majority of responses from staff groups reflecting a negative perception of a safety culture in the Hospital (HIQA, 2015).

At a team level, staff reported they felt they were not working in a blame-free environment. At an organisational level, they reported an absence of standard monitoring and a lack of a clear vision and mission for the Hospital (HIQA, 2015).

7.3.2.3 Person Centred Care

The HIQA Investigations Team identified a lack of cultural sensitivity; honest accounts not being given; and

frequent use of unprofessional behaviours and language. Insensitivity and a lack of empathy were common themes that were communicated. The specific descriptors provided by staff of the care in the immediate aftermath of perinatal deaths was found to have added to the distress rather than support to the families (Holohan, 2014). Some parents said they had been shown a lack of empathy, sensitivity and advocacy. One woman stated, "*staff she encountered seemed to lack a human touch*" (HIQA, 2015).

The Authority also concluded there were significant ongoing problems with workforce planning relating to Portlaoise Hospital. The absence of a clear vision for the Hospital, coupled with the national imperative to reduce the staff headcount, ensured that workforce planning was focused on counting staff rather than on the type of service the Hospital should be delivering and the workforce needed to deliver that service (HIQA, 2015).

7.3.2.4 Risk Management

The Investigation Team found that there was no effective risk management structure implemented within the Hospital, underlined by an absence of risk ownership in the Hospital. Risks were not comprehensively reviewed or addressed at a senior level in an effective and proactive manner. Risk Registers showed no evidence of ongoing systematic review or progressive management of risks and there was conflicting accounts of how the process worked (HIQA, 2015).

The end result was that serious risks remained unresolved at Portlaoise Hospital, such as staff shortages, unfit infrastructure in the Intensive Care Unit and the absence of an acute medical assessment unit on site (HIQA, 2015).

7.3.2.5 Incidents, Complaints and Audits

The process of incident management at Portlaoise Hospital was found to have been largely reactive and was focused on recording incidents that occurred. Incident forms were not entered on to the National Incident Reporting Database at a local level but were recorded only at a regional level. For the period from 1 June 2013 to 31 March 2014, an overall total of 1,338 incidents were reported at the Hospital. The Management Team at Portlaoise Hospital did not corporately collate, analyse, trend or use incident related information proactively to address risks, investigate incidents or share any learning as a result. Some senior hospital managers reported at interview that they were not made aware of the sentinel tragic events in a timely manner. Furthermore, when they were informed, senior managers stated that they did not have staff with the experience and expertise required to oversee the process of an investigation (HIQA, 2015).

Complaint management was assigned, along with multiple other duties, to one individual. The Hospital did not manage complaints in line with the national HSE complaints management process, in particular, complaints were not managed within recommended time frames and patients were not updated about delays in addressing their complaints. The Investigation Team found that there was no evidence that, following investigations into specific complaints, learning was put into practice for the benefit of other patients (HIQA, 2015).

The HIQA investigation found that there was no strategic plan for clinical audit across the Hospital. The regional clinical audit function in place at the time was described as '*supportive and advisory*', but no dedicated staff member was in place on site with oversight of an audit programme. In addition, the Hospital did not have the information technology structures necessary to support an effective system of multidisciplinary audit (HIQA, 2015).

7.3.3 Recommendations from the Portlaoise Perinatal Investigations Report

The following details some of the key recommendations arising from the HIQA report (HIQA, 2015):

- The HSE, in conjunction with the Chief Executive Officer of the Hospital Group should immediately address the local clinical and corporate governance deficiencies in the maternity and general acute services in Portlaoise Hospital.

- The HSE, along with the Chief Executive Officers of the Group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by:
  - **a)** a group-based system of clinical and corporate governance informed by the National Standards for Safer Better Healthcare.
  - **b)** a clearly defined, agreed, resourced and published model of clinical service delivery for each hospital within the group. This must be supported by clearly defined, agreed and documented patient care pathways to ensure that patients are managed in or transferred to the most appropriate hospital.
  - **c)** regular evaluation and audit of the quality and safety of services provided.
  - **d)** systems to support a competent and appropriately resourced workforce
  - **e)** a system to proactively evaluate the culture of patient safety in each hospital as a tool to drive improvement.
  - **f)** systems in place to ensure patient feedback is welcomed and used to improve services and that patient partnership and person-centred care is promoted.
  - **g)** effective arrangements to ensure the timely completion of investigations and reviews of patient safety incidents and associated dissemination of learning. These arrangements must ensure that patients and service users are regularly updated and informed of findings and resultant actions (HIQA, 2015).
- The HSE, the Chief Executive Officer of each Hospital Group and the State Claims Agency must immediately develop, agree and implement a memorandum of understanding between each party to ensure the timely sharing of actual and potential clinical risk information, analysis and trending data (HIQA, 2015).

7.4 Investigation into the quality, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (2012)

7.4.1 Background to the Investigation into the quality, safety and governance of the care provided by Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH)

In September 2009, HIQA received information relating to the health and safety of patients in the Emergency Department (ED) of the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) located in Tallaght Dublin. Particular concern was raised about the use of a corridor adjacent to the ED to accommodate patients. HIQA repeatedly sought assurances that these risks were being managed and in December 2009, HIQA requested a written report detailing the progress made by AMNCH.

In April 2010, HIQA conducted a health and safety assessment and issued AMNCH with an improvement notice. A formal performance monitoring process of AMNCH was implemented by HIQA as part of ongoing engagement. The Hospital informed HIQA that a number of actions were being put in place to address the concerns of the ED. Again, HIQA were not assured that immediate risks to patients were being controlled and appropriately managed. AMNCH provided HIQA with written confirmation detailing all immediate risk to patient safety had been addressed.

In December 2010, HIQA were advised that up to 50 patients were being regularly accommodated on the corridor adjacent to the ED awaiting an inpatient bed. In April 2011, the Acting Chief Executive of AMNCH advised HIQA of the unexpected death of a patient who was receiving care on the corridor while awaiting admission to an inpatient ward and an internal review of the management of care of the patient was in progress by the Hospital. In June 2011, HIQA instigated an investigation into the quality, safety and governance of care provided to patients who required acute admission, focusing on the period from 2010 to 2011 (HIQAb, 2012).

7.4.2 Summary of Findings from the Investigation into the quality, safety and governance of the care provided by AMNCH for patients who require acute admission

7.4.2.1 Governance

The HIQA Report found that the Board of the Hospital did not have effective arrangements in place to adequately direct and govern the Hospital nor did it function in an effective way (HIQAb, 2012). Collective membership

of the Board did not reflect the relevant diversity of knowledge, skills and competencies required to carry out the full range of oversight responsibilities necessary for the Hospital at this juncture. Nor was the appointment process in line with modern governance principles.

HIQA found little information as to how the Board, or any of its committees, oversaw and sufficiently assured themselves that the Hospital was delivering the required services in line with the service plan agreed with the HSE for the resources provided. In addition, during the course of the investigation, information came to the attention of the Authority that raised concerns about the effectiveness of the governance arrangements in place for financial management, financial transparency and commitment control. In particular, the Authority was concerned that the Hospital did not have the internal controls in place to ensure its compliance with public procurement legislation (HIQAb, 2012).

7.4.2.2 Culture

The HIQA Report (HIQAb, 2012) found that the Hospital did not have sufficient nor effective arrangements to facilitate staff to raise concerns about the quality and safety of patient care, nor were there effective arrangements to allow escalations of concerns to the Board for their consideration. The lack of such arrangements failed to foster a culture of safety, evidenced by staff engaging in the routine practice of accommodating patients on trolleys in corridors and tolerating this practice as acceptable.

In June 2010, external consultants identified significant risks for the Hospital in the ED and the corridor adjacent to the ED. However, the Hospital continued to use corridors to accommodate patients until HIQA's unannounced inspection (HIQAb, 2012).

7.4.2.3 Risk Management

The Hospital had an established Forum for Adverse Incident Review (FAIR), which was chaired by the CEO or the Deputy CEO and reported to the Clinical Governance Committee. FAIR met every four to six weeks and extraordinary meetings were held where a serious incident occurred within the Hospital. It was reported that there was no formal mechanism in place for the feedback from the FAIR meetings, however, members of the FAIR had the responsibility to report back to their peer groups for learning to be shared. (HIQAb, 2012).

During the HIQA investigation, it was found that the Risk Manager did not have accountability for the management of risk, as the organisation chart aligns risk management to the Director of Quality and Risk. The post for Director of Quality and Risk was vacant upon commencement of the investigation.

Issues relating to patient safety, and the events that occurred in the ED in March 2011, were brought to the attention of senior management. As a result, an independent internal group was requested to carry out a review of the incident. HIQA found the review did not effectively address patient safety issues and requested assurances were not provided to them.

The HIQA investigation noted that there was a gap in the arrangements in place for the oversight of quality and safety between the management of individual incidents and overall risk management (HIQAb, 2012).

7.4.2.4 Complaint Management

HIQA (HIQAb, 2012) noted the findings from the Hospital's Inpatient Experience Survey from 2010 and noted that 66% (n=170) of respondents were not aware of the Hospital's complaints procedure. Patients were also asked if they had a complaint and if they knew who to identify to discuss it with. 41% of the patients who responded chose not to discuss their complaint with a member of staff. Reasons for not discussing their complaint included:

- Staff not being available
- Staff were too busy

- Staff did not have the opportunity

Due to the post for Director of Quality and Risk being vacant, complaints were reviewed weekly by the acting Deputy CEO. Upon review of minutes of the FAIR meeting, HIQA noted that the complaints update had been deferred over three consecutive meetings. HIQA found there was limited arrangements in place for executive oversight of complaints and the implications for overall quality and safety (HIQAb, 2012).

7.4.3 Recommendations from the Investigation into the quality, safety and governance of the care provided by AMNCH for patients who require acute admission

The following details some of the key recommendations arising from the HIQA investigation into quality, safety and governance of the care provided by the AMNCH for patients who require acute admission (HIQAb, 2012):

- A fit for purpose Board should be established.
- The Board should be of a sufficient size (up to a maximum of 12), with expertise to effectively govern the organisation. The Board should be selected and appointed through an independent process established by the State and on the basis of having the necessary skills, experience and competencies required to fulfil the role effectively.
- A mandatory Board Induction Programme should be in place for all new Board members, and Executive Directors, covering such topics as the role and responsibilities of a board member, the role and responsibilities of executives, corporate and clinical governance, financial oversight, ethics and business conduct and their roles and responsibilities in achieving board objectives specific to the organisation.
- There should be a mandatory ongoing development programme for Board members, informed through the annual self-evaluation of the effectiveness of the board, covering topics such as emerging governance issues and practices, quality and safety and financial management as well as more detailed information on organisation-specific issues.
- All health and social care service providers in receipt of State funds should ensure their compliance with the Code of Practice for the Governance of State Bodies.
- All hospitals must have the necessary arrangements in place to ensure that there is a named consultant clinically responsible and accountable for a patient's care at all points in the patient journey and throughout their hospital stay.

7.5 Clinical Review of the Maternity Services at Portiuncula Hospital (2018)

7.5.1 Background to the Clinical Review of the Maternity Services at Portiuncula Hospital

Portiuncula University Hospital (PUH) is part of the Saolta University Health Care Group. In 2014, 1,983 babies were born in PUH and during that time six new-born babies were referred for Therapeutic Hypothermia. Due to the number of referrals, an internal clinical review was completed. On 21st December 2014, results of the preliminary review were presented to the Chief Clinical Director. As a result of the concerns detailed in the preliminary review, an external independent clinical review of Maternity Services at Portiuncula Hospital was commissioned by the Chief Clinical Director of Saolta University Health Care Group in February 2015.

After the external independent clinical review was established, a dedicated helpline was set up. Ten additional families (12 cases) requested their cases to be added to the external review. The additional cases took place from 2008 to 2014 and had a variety of clinical presentations. The addition of the twelve cases provided the review team with a wider review of the care provided over a longer timeframe.

7.5.2 Summary of Findings from the Clinical Review of the Maternity Services at Portiuncula Hospital

7.5.2.1 Governance

The HSE Review Report (2018) found that staff in PUH did not feel fully involved in the Saolta University Health Care Group and others felt they had no local ownership of clinical governance, support or guidance from the wider Group. Although PUH was within the Saolta University Health Care Group, there was no effective

integrated maternity clinical network or management structure to ensure that clinical care was at the highest level (HSE, 2018).

The Review found there was a lack of a strong onsite midwifery framework and midwifery input at clinical governance meetings and that there was a lack of support in acute areas due to understaffing of midwives and consultants and this was coupled with a lack of communication between staff groups.

7.5.2.2 Person Centred Care

In the HSE Review (2018) identified a failure to escalate problems as they arose within the Hospital with poor obstetric clinical handovers. In relation to the clinical findings in the Hospital, the following were noted:

- Failure to recognise an abnormal antenatal and intrapartum Cardiotocography's (CTG's).
- Failure to use secondary monitoring such as ultrasound or fetal blood sampling.
- Failure to escalate abnormal intrapartum CTG findings.
- Failure to expedite delivery of the baby.
- Prolonged decision to delivery interval in some cases.
- Incorrect use of oxytocin infusion in the presence of an abnormal CTG in some cases.
- Failure to appropriately escalate care to the obstetric consultant in some of the cases reviewed
- In some cases, poor system for contacting the paediatric staff on-call for resuscitation of the sick baby.

The review also found there was poor communication with families during labour and after an event and a lack of open disclosure was evident in some cases (HSE, 2018).

From the Investigation Team's review of the PUH training records, no evidence was found of a formal induction training programme and little evidence of mandatory in-house training for NCHDs which meant that many of the clinical staff were not facilitated in ensuring that their skills were up-to-date. The skills and training of some frontline staff appeared to the reviewers to be insufficient in cases in which there was clinical deterioration and a need to escalate care (HSE, 2018).

7.5.2.3 Incident Management and Audit

The report specifies that the management of incidents did not meet standard practice and PUH failed to ensure all necessary staff attend Incident Management Training and Systems Analysis Investigation of Incidents training. The Review Team found that governance structures and processes were not fully aligned to the requirements of the HSE Safety Incident Management Policy (HSE, 2018).

The Investigation Team recognised that audit activities within the maternity unit of PUH, and throughout the overall Group, required improvement so that learning could be achieved. It was found that common clinical maternity guidelines were not implemented throughout the Saolta University Health Care Group (HSE, 2018).

7.5.3 Recommendations from the Clinical Review of the Maternity Services at Portiuncula Hospital

The following details some of the key recommendations arising from the clinical review (HSE, 2018):

- Need to improve the governance structures to ensure the collection of robust data on outcomes, detect patterns and learn from serious incidents. There needs to be a structure with explicit lines of responsibility and accountability with the appropriate leadership.
- Improve the level of open disclosure occurring with the individuals involved in a serious incident.
- Need for the maternity services to be appropriately resourced, underpinned by strong and effective leadership, management and governance arrangements, and delivered by a skilled and competent workforce, in partnership with the women using the service.

- Need to ensure that local clinical staff receive appropriate training and hospital induction that clearly outlines their clinical roles and responsibilities for the period of their employment and that this information outlines the supervision structure in place for the locums.
- Need for a review of staffing numbers to ensure midwifery leadership is enhanced and there is a dedicated midwifery manager on each shift who can work in a supervisory capacity overseeing the labour ward.
- Improve the communications between midwives and medical staff and communications with families during labour and after an event.

8.0 COMMON THEMES ARISING BETWEEN THE INQUIRIES OF THE UK AND IRELAND

On review of the summary of the inquiries, specific themes are evident from the findings. The following section considers the commonality of these themes.

8.1 Governance

Throughout the Irish and UK inquires reviewed, governance, or the lack thereof, was identified as being central to systematic failures that facilitated catastrophic patient outcomes.

The misdirected guidance of the governing body was clearly evident within Mid Staffordshire Trust, with its leadership focused on financial issues, paying insufficient attention to the risk indicators in relation to the quality of service delivery (Francis, 2013). This was replicated by the Liverpool Community Health Trust who, in their desire to demonstrate a robust financial position in pursuit of goal to become a Foundation Trust, allowed patient safety to become a lesser concern (Kirkup, 2018).

Complex governance arrangements and large numbers of committees also led to identified issues within hospitals, with the Halappanavar Investigation recognising that a number of the Hospital's governance committees involved the same members, many of whom also had full-time clinical responsibilities (HIQA, 2013). The Portlaoise Investigation found that the committees responsible for providing safe effective services through leading and directing the performance of the Hospital did not address quality and safety issues, with overly complicated structures that were ultimately not effective (HIQA, 2015).

Inexperience in governance also contributed to major failings within the events reviewed. The HIQA AMNCH Report found that the collective membership of the Board did not reflect the diversity of knowledge, skills and competencies required to carry out the full range of oversight responsibilities necessary for the Hospital (HIQAb, 2012). At a lower managerial level, the Bristol Royal Infirmary Inquiry identified that clinicians, who were taking up managerial duties, lacked sufficient training, experience and time to recognise and respond to problems that may have existed in their area of responsibility (Kennedy, 2001).

The development of clear lines of accountability and responsibility were featured as shortcomings in the Mid-Staffordshire NHS Foundation, Morecambe Bay Trust and Liverpool Community Health NHS Trust, with conflicting roles and inaccurate job descriptions created confusion regarding individual roles and responsibilities. This was also reflected within the Scally Report (2018) where a significant portion of the CervicalCheck staff did not have job descriptions in place, including those in senior management positions.

Issues with clinical governance is also evident in many of the investigations and inquiries. It was identified that within Morcambe Bay, the Trust had poorly developed clinical governance, which meant there was no formal oversight of safety or other quality matters in clinical services (Kirkup, 2015). The required involvement of relevant parties in clinical governance was also identified as an important factor, which was reflected within the Portiuncula Clinical Review, with the lack of midwifery input at clinical governance meetings leading to a limited multidisciplinary view and a lack of communication between staff groups (2018). Within the Savita Halappanavar Inquest, it was identified that the clinical governance arrangements within the Hospital failed to recognise that vital hospital policies were not in use by staff nor were arrangements in place to ensure the provision of basic care within the wards (HIQA, 2013).

8.2 Organisational Culture

For many, the culture of an organisation is simply "*the way things are done here*", it is the customs and behaviour of the people within an organisation, an approach driven from the top down that is generally reflected in all aspects of a service. Evidence of inappropriate cultures are reflected throughout a number of the inquiry and

investigation findings reviewed.

The Mid Staffordshire Trust Inquiry identified the Trust's culture to be negative and uncaring, which it found to be detrimental to patient care (Francis, 2013). Criticism of management was not tolerated and any retractors were silenced through fear and disempowerment. This state of fear was also evident within the Liverpool Trust Inquiry findings, which showed the Trust enforced a blame culture that ensured that staff were unwilling to highlight incidents that could be learnt from (Kirkup, 2018). Staff within Portlaoise Hospital also reported working within a blame culture within the Inquiry, underlined by a lack of a clear vision and mission for the Hospital (HIQA, 2015).

The AMNCH HIQA Inquiry (HIQAb, 2012) also identified that staff were not facilitated to raise concerns about the quality and safety of patient care, nor were there effective arrangements to allow escalations of concerns to the Board for their consideration. This was also reflected within the Savita Halappanavar Inquiry which recognised that system–wide learnings were lost through poor communication systems and identified risks remained unchecked on an ongoing basis (HIQA, 2013).

Within Morcambe Bay, the Inquiry found the culture was one of self-protection and defence, with the midwives isolating themselves from the Obstetricians in the care of their patients, where their practice to pursue normal childbirth was deeply embedded irrespective of the patient's individual factors (Kirkup, 2015). This culture of segregation was also evident in the Bristol Royal Infirmary, where the Inquiry identified the divide between clinician and management, again reflecting an approach of self-protection between the parties, where retaining control was the priority rather than achieving optimal patient outcomes (Kennedy, 2001).

Within the Cervical Screening Inquest, Scally identified that confusion regarding the National Policy on Open Disclosure facilitated a culture of concealment that exacerbated the suffering of affected women. This too was reflected within Mid Staffordshire as the Inquiry found clear evidence that staff in the maternity unit at FGH failed to follow the duty of openness and honesty (Francis, 2013).

8.3 Person Centred Care

Person-centred care puts the patient at the centre of all that the service does. The inquiries reflected many examples of where the systems put in place to care for patients failed to ensure that their care was prioritised.

Implementing evidence based best practice is central to achieving good patient outcomes, however, in the case of Savita Halappanavar, the Inquiry found there was a lack of understanding regarding the correct processes to be followed in the provision of her care (HIQA, 2013). The Healthcare Commission too found deficiencies at virtually every stage of the pathway in emergency care in Mid Staffordshire. It was found that the Trust did not have clear protocols or pathways for the management of patients admitted as emergencies and the care and assessment of patients fell well below acceptable standards (Healthcare Commission, 2009). This was evident again within the Liverpool Community Trust Inquiry, where evidence-based standards were not uniformly applied during patient care (Kirkup, 2018).

Respecting patient rights is a cornerstone to the person-centred care approach. The patient's right to access their records was found not to be supported within Scally Inquiry. The report makes note of the difficulties many women encountered accessing their medical records, with unreasonable delays in providing women with access (Scally, 2018). The HIQA Investigations Team identified a lack of cultural sensitivity within the Portlaoise Hospital Inquiry, with honest accounts not being given and frequent use of unprofessional behaviours and language undermining patient rights and dignity (HIQA, 2015).

Insufficient staffing, and a lack of appropriate education and training of staff was consistently highlighted throughout the inquiries reviewed, which directly impacted on care provided to patients. Again, within the Liverpool Community Trust Inquiry, clinical capability to deliver the required patient care was found to be compromised by inadequate staffing levels, with clinical competence found to be lacking in some staff (Kirkup,

2018). Basic induction training programmes were found insufficient within the Portiuncula Hospital Inquiry (2018), while it was identified that the clinical staff had not received specific training in relation to the clinical care of a maternity patient with sepsis within the Savita Halappanavar Inquiry (HIQA, 2013).

The Morecambe Bay Investigation found that improvements in knowledge, skills, clinical assessment, investigation and management would have had a significant impact on clinical outcomes with the lack of knowledge and experience contributing to further deterioration of the patient's condition through inaction (Kirkup, 2015).

8.4 Risk Management

HIQA define risk management as "*the systematic identification, evaluation and management of risk, it being a continuous process with the aim of reducing risk to an organisation and individuals*" (HIQAb, 2016). In recent times, risk management has moved from being a reactive response to an adverse event or incident, to one which demands a proactive approach by an organisation to prevent harm or loss. The inquiries reviewed identified systematic failings in the organisations risk management approaches that directly impacted on quality and safety of the services provided to patients.

The Liverpool Community Health NHS Trust was found to have no clear and effective system in place to manage risk or to communicate identified risks to senior management within the wider NHS (Kirkup, 2018). The Mid Staffordshire NHS Foundation Trust also had deficiencies in their risk management and assurance system, which called into question the accuracy of their compliance with standards (Francis, 2013).

The Scally Report identified inherent weaknesses in the CervicalCheck risk management processes, including the manner in which the risks were identified, communicated and managed, and in particular the processes by which serious risks could be escalated (Scally, 2018). During the AMNCH HIQA Investigation, it was found that the Risk Manager did not have accountability for the management of risk and the post for Director of Quality and Risk was vacant upon commencement of the investigation (HIQAb, 2012).

HIQA identified that Portlaoise Hospital also had a poorly developed risk management structure, again reflected by the absence of ownership of risk. Risks were found not to be comprehensively reviewed, nor were they addressed at a senior level in an effective or proactive manner. The risks identified following the investigation of complaints and clinical incidents were not included in the Risk Register to drive containment or corrective actions. Staff members described an endless process of escalation that did not result in informative feedback or tangible results (HIQA, 2015).

8.5 Incident Management

Within a positive, open culture incident management can be a window into the soul of an organisation, a true reflection of the operational activities and a tool to drive continuous improvement. Where the systems are broken, incident management can become just another process providing little value, void of reflective data that could shine a light on the reality of service provision.

As can be the case during many system failures, the formal, documented incident management process within the Mid Staffordshire Trust was found to be appropriate, however, in practice the Inquiry found it to be ineffective. Staff were disengaged from the system as they saw no tangible impact by its application within the service. Inaction in response to incidents raised was also evident within Liverpool Community Health Trust Inquiry, where over a hundred SUI's recorded over a period of three years resulted in no improvement actions due to an ineffective, unsupported incident management process (Kirkup, 2018).

The failure to recognise root causes was identified as a core failure of the incident management process within Morecambe Bay, where investigations followed a pattern of superficiality and protectiveness, without an attempt to trend the data arising from the issues occurring. Within the Portlaoise Hospital Inquiry, the incident

management system was found to have been largely reactive and was focused on recording incidents that occurred rather than driving service improvement (HIQA, 2015).

8.6 Complaint Management

The effective management of complaints within an organisation is key to good governance (Kirkup, 2015). In many ways, the receipt of a complaint from a patient, or their family members, can be viewed as a gift as it can highlight a problem to the organisation that may well have otherwise gone undetected, but an effective complaints management system demands a reactive, communicative process that responds and addresses the complaints, with the affected party central to its approach. The inquiries reviewed identified significant failings in this regard for the implemented complaint management processes.

Communication failures were identified in the Mid Staffordshire NHS Foundation Trust Inquiry, where the Trust's Board appeared to be unaware of, or perhaps unconcerned by, the extent of the complaints being made. In either case, the complaints were not given sufficient priority in identifying issues and learning lessons (Francis, 2010). Comparable within Morcambe Bay, the focus on complaints lay only in their time to process investigations, rather than the information that could be sourced from their occurrence.

The complaint management process within Portlaoise Hospital at the time of the Inquiry was assigned, along with multiple other duties, to one individual and it was found that the process was not implemented in accordance to best practice. The Investigation Team found that there was no evidence of learning arising from investigations into specific complaints for the benefit of other patients (HIQA, 2015). Within the AMNCH Inquiry, HIQA noted a general lack of focus on complaint management, with the review of complaint data continually being deferred by governing committees and generally limited arrangements in place for executive oversight of complaints and the implications for overall quality and safety (HIQAb, 2012).

8.7 Audit

Effective audit programmes assess, evaluate and improve the provision of services in a systematic way in order to achieve best outcomes for patients, however, the process can be ineffective as a continuous improvement tool where inappropriately implemented.

Scally (Scally, 2018) found that the CervicalCheck audit process was established with laudable aims. However, its planning and governance appeared to be inadequate. There was little or no anticipation of challenges that arose and analysis of the audit results was sporadic and informal.

The HIQA AMNCH Inquest found that here was a regional clinical audit function which was described as '*supportive and advisory*', but there was no dedicated staff member on site with oversight of clinical audit (HIQAb, 2012). In addition, the Hospital did not have the information technology structures required to support an effective system of multidisciplinary audit. The audit activities within the maternity unit of Portiuncula University Hospital and the overall network were found to require improvement so that learning could be achieved (HSE, 2018).

9.0 DRIVING IMPROVEMENTS

The following reviews the key areas where healthcare service providers can identify learning opportunities from the failings of the past and respond with preventive measures to support the quality and safety of patient care provided.

9.1 Governance

HIQA have communicated previously that they believe that there is a clear link between good governance and better outcomes for service users (HIQA, 2015). The Chief Inspector of Social Services and Director of Regulation, Mary Dunnion, detailed that "*Regulation has shown that in order for any provider to deliver and sustain a good service there must be effective governance and management. The provider must have robust governance arrangements in place in order to ensure that a safe, quality service is being run.*"

The integration of corporate and clinical governance is recognised as being of the utmost importance for all health system changes (HSE, 2014). As a result, governance is central to all regulation frameworks, as reflected in ISQua's Guidelines and Principles for the Development of Health and Social Care Standards, the function of which relate to implementing policy, setting targets or goals for the future through planning and budgeting for the organisation's range of services, establishing processes for achieving those targets, allocating resources to accomplish those plans and ensuring that plans are achieved by organising, staffing, controlling and problem-solving (ISQua, 2015).

To achieve this function effectively, the governing body must:

- Be appropriately structured: The governing body must be appointed in a formal, rigorous and transparent manner (NHS, 2014). The body must ensure that there are clear lines of accountability and responsibility at all levels, including individual, team and service levels, with overall executive accountability for the quality and safety of the services delivered clearly allocated (HIQA, 2012). Formal and rigorous evaluation of the body's own performance must be completed on an ongoing basis (NHS, 2014).
- Be experienced: The governing body, and its committees, should have the appropriate balance of skills, experience, independence and knowledge of the organisation and the service provided to enable them to discharge their respective duties and responsibilities effectively (NHS, 2014). HIQA's Safer Better Healthcare standards incorporate as a requirement the need for those involved in governance to have the skills and competencies necessary to provide effective assurance of high quality, safe and reliable healthcare (HIQA, 2012)
- Provide appropriate guidance: A well-governed service is clear about what it does, how it does it, and is accountable to its stakeholders (HIQA, 2012). The Body needs to be able to deliver prudent and effective leadership and effective oversight of the organisations operations to ensure it is operating in the best interests of patients (NHS, 2014).
- Be knowledgeable of both the needs of patients and the regulatory requirements: The governing body must strive to ensure that the care provided reflects the patient's needs and is consistent and reflective of current, evidence based best practice, while adhering to the regulatory requirements of the sector.
- Have appropriate involvement in the service: This includes providing the required resources, understanding the organisational processes relating to the services provided, being actively supportive of the Quality and Safety Management Systems in place and understanding the outputs from each of these systems. All members of the workforce should be supported to exercise their personal and professional responsibility for the quality and safety of the services they are delivering. (HIQA, 2012).
- Monitor, evaluate and respond to data: Understanding the quality and safety of a healthcare service requires a comprehensive approach to collecting, analysing and discussing relevant data that is reflective of service indicators (HSE, 2014). The governing body must ensure appropriate action to taken to address the identified

risks. This is further addressed in 9.4 Risk Management.

- Effectively communicate: The governing body must be accessible to all internal and external stakeholders, including patients, staff and regulatory authorities through an effective communication framework. The communication framework should ensure staff are kept informed about key decisions made at Board level, including any changes that may be forthcoming in the service, and work towards engagement with patients, families and the public (HIQA, 2016). An effective communication framework is central to supporting a culture of safety.
- Recognise inter-dependencies: Good governance arrangements acknowledge the inter-dependencies between organisational arrangements and clinical practice and integrate these to deliver high quality, safe and reliable care and support (HIQA, 2012). The review of the inquiries reflected that governance must illustrate a balance of skills across the sector to ensure it is can be truly considerate of the risks associated with the provision of care.
- Share and Learn: Sharing information and experiences among health service providers leads to and supports a learning environment (HSE, 2014). To support learning, HIQA specified that Irish healthcare settings need to take proactive steps in analysing previous reports, reviews and investigations and apply system wide learning to increase safety and benefits for patients (HIQA, 2016).

9.2 Organisational Culture

Culture has been defined in a number of ways, but most simply it means the learned and shared behaviour of a community of interacting human beings (HIQA, 2015). A strong culture of quality and patient safety is always characterised by effective governance arrangements which place patient safety is at the top of the organisation's agenda (HIQA, 2015).

Reflecting on the findings of the inquiries, healthcare organisations should consider key factors that are vital for a compassionate, quality and safety culture to exist, including:

- Implementing effective arrangements in place to allow staff to be open on quality and safety issues, to raise concerns about the quality and safety of patient care and allow escalation of these concerns to the Board for consideration (HIQAb, 2012) (HIQA, 2015).
- Valuing, listening, and engaging with patients to identify improvements the patient's experience of care as well as overall service improvements (HSE, 2014).
- Routine checking of clinical practice (HIQA, 2015).
- Implementing a transparent, consistent approach to patients where things go wrong during the provision of care. Open disclosure must be central to the culture of healthcare if it is to be trusted and progressive towards continuous improvement. Organisations must ensure that their open disclosure processes are appropriately linked with their incident and complaints management processes.
- Continually working to instil shared values throughout the organisation, from top management to frontline staff.
- Providing strong, consistent leadership to motivate staff as well as ensure everyone understands and supports objectives of the service.
- Ensuring the governing body and leaders have direct contact with frontline staff, where they can reinforce the quality and safety culture message.
- Supporting all staff should have a "*questioning attitude, a rigorous approach and good communication skills*".
- Ensuring that when errors are reported, this is seen as a "*learning opportunity*" rather than a punishable offence.
- Continual reinforcement of the idea of "*patient-centred*" care at every opportunity. Ensuring everyone with any involvement with a patient should take personal responsibility for making sure everything they do is for the

benefit of the patient and this attitude is recognised and rewarded.

- Ensuring information on outcomes, such as patient experience and satisfaction, is made openly available to anyone who wants to view it, including the public.
- Ensuring patients are able to access their health care records and other information relevant to the provision of their care. (Nursing Times, 2013)

In an effort to improve patient safety, healthcare providers have been encouraged to assess the current state of their safety culture with a view to designing interventions to improve the safety of their organisations (HIQA, 2015). Although this approach is still emerging, the use of surveys to assist organisations in assessing staff perceptions of the organisation's patient safety culture is a proven one. Within the Portlaoise investigation, the completed '*Assessment of Safety Culture in Midland Regional Hospital Portlaoise using the Safety Culture Index©*' illustrated that the Hospital did not have a strong safety culture, there was an absence of standard monitoring and the lack of a clear vision and mission (HIQA, 2015).

Accreditation has also been used by some healthcare providers as an additional driver to embed a culture of excellence and continuous improvement. Through its application, the focus shifts from regulatory compliance to demonstrating a commitment to quality in care and demanding high quality outcomes for patients. One body of research identified that hospital accreditation contributed to the improvement of healthcare quality in general, and more specifically to patient safety, as it fostered staff reflection, a higher standardisation of practices, and a greater focus on quality improvement (Melo, 2016).

9.3 Person Centred Care

Health care organisations must place the patient at the centre of their delivery of care, focusing on the needs of the patient above the needs of the service. This includes the concepts of access, equity and protection of rights (HIQA, 2012). The patient is now an equal partner within the care process, and their wishes and goals must now be given real consideration in relation to the way care is provided and the care pathways applied.

This form of '*care individualisation*' must also be balanced by ensuring that current, evidence based, best practice care is provided consistently to all patients. Organisations must ensure that effective, clear policies, protocols, guidelines and pathways are developed, appropriately approved and made accessible to all relevant staff. Where National Clinical Guidelines are available, these must also be reflected within the care provisions via the controlled documentation.

The implementation of General Data Protection Regulation (GDPR) directly impacts on the management of personal data within the European Union and supports the rights of patients, specifically in relation to the management of their personal data and incorporates access to their patient records. Organisations are now required to implement effective information governance, ensuring personal data is handled legally, securely, efficiently and effectively in order to deliver the best possible care to patients (HIQA, 2017). This accessibility by patients to their data is supported by the open disclosure requirements that support a culture of quality and safety.

Errors due to ineffective staff training are also clearly evident throughout the inquires. Although staff training is usually an ongoing process within the vast majority of healthcare organisations, completing effective competency assessment still remains a challenge within the sector. To ensure an individual is truly competent in their role is time consuming and a laborious process to implement, drawing on internal resources due to peer review requirements.

9.4 Risk Management

Risk management historically was a reactive model within the healthcare sector, with the methodology applied in many cases being inflexible and documentation heavy, a negative approach to preventing negative outcomes. Development in best practice and, more compellingly, emerging regulatory requirements, now

require organisations to have a proactive approach to the management of risk, to be able to get out ahead of the potential issues and work to identify controls that, if not irradiate the risk, then at a minimum reduce their occurrence or potential impact.

Ultimately, the governing body is responsible for risk management and maintaining effective risk management systems within the organisation, specifically for determining the nature of the risks and extent of the risks it is willing to take in achieving its strategic objectives (NHS, 2014). Although risk management is everyone's business, it must be anchored by senior management and the appropriate leadership must be provided to create an environment where risk is reduced and quality and safety is seen as a priority (HSE, 2017).

Healthcare organisations need to be able to effectively use service indicators to feel the pulse of their organisation and be responsive to risk. The indicators, when harnessed from real time data, can provide them with a true reflection of the service activities and support the identification of issues that signals danger ahead. Indicators may arise from:

- patient-safety incidents and other incidents involving patients and staff
- complaints, concerns and compliments
- findings from risk assessments / gap analysis
- legal claims
- audits
- satisfaction surveys
- findings and recommendations from national and international reviews and investigations
- casemix, activity and performance data
  (HIQA, 2012).

Where the information from these indicators can be effectively gathered, extracted and analysed, it can provide real oversight of the service and can be effectively utilised to manage risk and develop quality improvement initiatives.

9.5 Incident Management

The reporting of incidents, near misses, concerns and errors should be welcomed and encouraged, but the focus must be from a systems perspective, i.e. how the systems in place allowed for the failure to occur. It is recognised that the staff need to be confident that the organisation will focus on system learning, not individual blame (Patient Safety Learning, 2018). Sir Liam Donaldson, former World Health Organization's Envoy for Patient Safety and Chief Medical Officer for England commented "*There is an urgent case to strengthen the defences in the health-care system as a whole. As much as possible, we need to do this without blaming individual health-care workers. That is not to say that individuals should never be held accountable for their actions. However, relying on the blame approach alone is likely to drive problems underground and impede an honest and effective strategy to improve patient safety*" (Donaldson, 2008).

The HSE's Incident Management Framework (HSE, 2018b) identifies the core principles for an effective incident management system, those being:

- Person centred: The needs of persons affected (patient and staff) are considered of primary importance and required supports are put in place from the outset and throughout any review process required.
- Fair and Just: That all persons affected (patients, and staff) are treated in a manner which is fair and just. Where issues of individual accountability are identified that the service responds to these in a manner which is proportionate and safety focused.

- Provides openness and transparency: That all persons affected by an incident are aware of the incident and the steps to be taken to learn from it.
- Is responsive: That the actions taken following the identification of an incident are taken in a timely and proportionate manner. Incident management systems must ensure effective escalation of events so that they can be appropriately analysed and an appropriate response taken.
- Is improvement focused: That incidents occurring are viewed by the service as an opportunity to improve.
- Provides Learning: That the incident management system is focused on learning both locally and within the wider service.

Serious incidents reviews may be required depending on the severity and impact of an incident. While holding the core principles of effective incident management central to the process, serious incident reviews require a comprehensive, independent review to understanding the failings of the service and detailed root cause analysis to ensure the source is addressed and learnings identified going forward. These reviews must be supported, monitored and actioned by the governing body to assure their impact on the quality and safety of the service.

On a broader scale, every healthcare system must ensure that national, regional and local systems learn from errors and strive to ensure they are not repeated. This includes learning from findings and recommendations of relevant investigations, inquiries and inquests nationally, and also internationally, where possible to ensure clinical practice and models of care are safe, effective and up-to-date (HIQA, 2016).

9.6 Complaints Management

It is exposed all too often within healthcare inquires that the patients voices were not heard, effectively silenced by the service that should have provided a haven of safety and care. In many cases, staff too have stood up and attempted to bring attention on the issues and risks shadowing the provision of services but, as illustrated in a number of the inquires reviewed, these too can also be ignored.

The HSE '*Your Service Your Say*' identifies the key elements that patients, and their families, want when they raise an issue relating to their care, those being:

- To be heard and understood.
- To be treated with dignity and respect.
- To receive open and transparent communication.
- To be supported throughout the complaints management process.
- To receive an honest explanation when something goes wrong.
- To be issued with an apology when appropriate.
- To be provided with reassurance that the organisation will learn from all feedback, especially complaints.

A robust complaints process is central to the effectiveness of complaint management. In the UK, the Parliamentary and Health Service Ombudsman developed, based on their 40 years' experience, six key principles for good complaints handling, those being:

- Get it right;
- Be customer-focused;
- Be open and accountable;
- Act fairly;
- Put things right;
- Seek continuous improvement
  (Ombudsman, 2009)

Again, it is up to the governing body as to whether complaints remain an underused data source or a snap-shot of the real service provision. Monitoring of complaints cannot be merely trending on volume or turn around times, their content requires focus, investigation and action to build and maintain trust with patients and their families. Ensuring that complaint management is appropriately resourced, monitored and analysed will assist in developing the culture of transparency and openness that learning and improvement can arise from.

9.7 Audit

System and clinical audit are the primary tools to ensure the healthcare service is systematically monitored, evaluated and continuously improved (HIQA, 2012). Audits may be used to bed down a new process, identify issues with current processes and, particularly within clinical audit, it is an internationally recognised way of getting evidence into practice (HIQA, 2012). Independence is auditing is key to ensuring a disciplined, impartial approach to evaluating and internal control processes and to drive continuous improvement (NHS, 2014).

Effective audit must have an agreed annual plan for audit, which incorporates participation in national audit programmes, and local, targeted audits conducted in line with service requirements and priorities (HIQA, 2012).

Monitoring by the governing body is required, and the head of risk management should have a direct reporting line to the governing body to bring the requisite degree of independence and objectivity to the role (NHS, 2014).

10.0 CONCLUSION

In 2013, the then HIQA Director of Regulation, Phelim Quinn stated, "*There is a fundamental and worrying deficit in our health system - namely the ability to implement system-wide learning from adverse events across the system in a timely and appropriate manner in order to prevent the recurrence of patient safety events that may cause harm, or worse, to patients*".

Each healthcare inquiry, review and investigation completed in response to system failures have provided lessons to be learned across the sector. Time and again, similar system failings have led to similar patient outcomes, with the recommendations to address these outcomes often mirroring previous reports.

Within the Portlaoise Perinatal Deaths Investigation Report, HIQA noted that six previous investigations into hospital care in Ireland have been carried out by them between 2007 and 2013 and a number of important findings and recommendations were made within these that were intended to be used by all healthcare services to inform and improve practice, however, this did not take place. The Report details "*Had the relevance of these investigation findings been reviewed in the context of Portlaoise Hospital, and the aligned recommendations been subsequently implemented, the Authority is of the opinion this could have vastly reduced the identified risks in the services being provided to patients*" (HIQA, 2015).

The provision of healthcare is a complex process, with an infinite number of variables that can impact on the outcomes, however, as reflected within this paper, it is often the same issues that create the stumbling blocks to safe, effective care, those being a lack of effective governance, a toxic organisational culture, an organisation that is blind to risk, deaf to patient concerns and ignorant of indicators of harm. The systems required to address these issues are neither simple nor immediate but they are understood should we have the desire to learn from the failings of others.

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12.0 LIST OF ABBREVIATIONS

FTP	Fitness to Practice
HEFT	Heart of England NHS Foundation Trust
GMC	General Medical Council
ACAS	Advisory, Consolidation and Arbitration Service
AMNCH	Adelaide and Meath Hospital Dublin incorporating the National Children's Hospital
BRI	Bristol Royal Infirmary
BRHSC	Bristol Royal Hospital for Sick Children
CCC	Conduct and Competence Committee
CCG	Clinical Commissioning Groups
CD	Controlled Drugs
CHPI	Centre for Health and the Public Interest
CPD	Consensual Panel Determination
CQC	Care Quality Commission
CRHP/CHRE	Council for Healthcare Regulatory Excellence
FGH	Furness General Hospital
FT	Foundation Trust
GP	General Practitioner
HIQA	Health Information and Quality Authority
HMP	HM Prison
HR	Human Resource
IG&QC	Integrated General and Quality Committee
LCH	Liverpool Community Health NHS Trust
LSA	Local Supervising Authority
MAC	Medical Advisory Committee
MCCD	Medical Certificate of the Cause of Death
MDT	Multidisciplinary Team
MOU	Memorandum of Understanding
NCHD	Non-Consultant Hospital Doctor
NHS	National Health Services
NMC	Nursing and Midwifery Council
NSS	National Screening Service
NW CQC	North West Quality Care Commission
NW SHA	North West Strategic Health Authority
OBE	Order of the British Empire
PCT	Primary Care Trust
PHMS	Portlaoise Hospital Maternity Services
PHSO	Parliamentary and Health Service Ombudsman
QIA	Quality Impact Assessment
RCA	Root Cause Analysis
RCN	Royal College of Nursing
RLI	Royal Lancaster Infirmary
SHA	Strategic Health Authority
SUI	Serious Untoward Incident
WMCIU	West Midlands Cancer Intelligence Unit

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