Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at Mallow General Hospital

13 April 2011

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority is the independent Authority established to drive continuous improvement in Ireland's health and social care services.

The Authority's mandate extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting directly to the Minister for Health, the Health Information and Quality Authority has statutory responsibility for:

Setting Standards for Health and Social Services – Developing person centred standards, based on evidence and best international practice, for health and social care services in Ireland (except mental health services)

Social Services Inspectorate – Registration and inspection of residential homes for children, older people and people with disabilities. Inspecting children detention schools and foster care services. Monitoring day and pre-school facilities[i]

Monitoring Healthcare Quality – Monitoring standards of quality and safety in our health services and investigating as necessary serious concerns about the health and welfare of service users

Health Technology Assessment – Ensuring the best outcome for the service user by evaluating the clinical and economic effectiveness of drugs, equipment, diagnostic techniques and health promotion activities

Health Information – Advising on the collection and sharing of information across the services, evaluating information and publishing information about the delivery and performance of Ireland's health and social care services

i Not all parts of the relevant legislation, the Health Act 2007, have yet been commenced.

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Executive Summary

Introduction

This report presents the findings from the Health Information and Quality Authority (the Authority) investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive (HSE) at Mallow General Hospital (MGH), Cork. MGH is a site of the Cork University Hospital Group (CUH Group).

The Authority received confidential information, which was not a formal complaint, in relation to the treatment of a patient with complex clinical needs in Mallow General Hospital. This information indicated that the type of care provided to patients receiving some services in the Hospital was not in line with the national recommendations made in the *Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis* (hereafter referred to as the Ennis Report). That report highlighted the risks arising from low numbers of patients being treated for certain conditions and the clinical staffing cover possible in such hospitals. As a result of receiving the information, the Authority sought assurances from the HSE about how patient care was provided in Mallow General Hospital (MGH), a hospital similar in size to Mid-Western Regional Hospital (MWRH) Ennis.

The Board of the Authority took the decision to instigate an investigation when it did not receive sufficient assurances from the HSE that the necessary arrangements were in place at the Cork University Hospitals Group (CUH Group) site at Mallow General Hospital for the provision of a safe, high quality service for acutely ill patients with complex needs. The Authority believed that this posed a risk to the health and welfare of these patients when receiving emergency, critical care and surgical services on site at MGH.

In carrying out the investigation, the Authority looked in detail at the *system of care* for acutely ill patients in place at MGH, rather than individual incidents or the practice of any specific practitioners. It went on to explore the governance arrangements for the provision of this service within the wider context of the CUH Group. The investigation also ascertained how managers and clinicians at national level in the HSE, and the associated governance arrangements, had addressed the implementation of previous recommendations made by the Authority in relation the provision of safe and sustainable systems of care for acutely ill patients.

Findings

At the commencement of the investigation, CUH Group provided the following services at MGH: 24-hour emergency care, general medicine, gastroenterology, general surgery (including major complex and day surgery), urology, cardiology, care of the elderly, Intensive Care Society (ICS) level 0/1 to level 3 critical care♦, radiology including Computerised Tomography (CT) scanning, general laboratory and blood bank services. The Investigation Team found MGH to be a clean well maintained hospital, held in good standing by the local community and general practitioners. The staff were committed to the patients whom they served.

Emergency services

The CUH Group's site at MGH provided a 24-hour clinically undifferentiated¥ walk-in emergency service to patients with up to 50% of the Hospital's admissions coming through the Emergency Department (ED). However, at the time of the Investigation the level of on-site clinical staffing out of hours, along with a lack of on-site critical care or anaesthetic expertise, raised concerns about the ability of MGH to safely treat patients presenting with acute conditions on a 24-hour basis.

The Authority concluded that, at the time of the investigation, the service did not have the essential requirements in place, including appropriate levels of on-site out-of-hours senior clinical decision makers. This deficit was subsequently addressed by the HSE South in February 2011.

Critical care and anaesthetic services

The Ennis Report recommended that the HSE should review critical care provision to ensure that services are being provided within safe practice guidelines. Where this is not the case, appropriate risk management measures, and the necessary service changes, were to be implemented and managed to protect patients.

♦ An approach, described by the Intensive Care Society (ICS), UK, for allocating levels of care to critically ill patients, in a hospital setting, according to their clinical needs. These descriptions reflect the Critical Care Minimum Dataset mandated in the UK.

ICS Level 0 (Ward): patients' needs can be met through normal ward care in an acute hospital.

ICS Level 1 (Ward at-risk): patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team.

ICS Level 2 (HDU): patients requiring more detailed observation or intervention including support for a single failing organ system or postoperative care and those stepping down from higher level care.

ICS Level 3 (ICU) patients requiring advanced respiratory support alone or basic respiratory support together with at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

Council of the Intensive Care Society. *Levels of Critical Care for Adult Patients Standards and Guidelines*. London: Intensive Care Society; 2009.

¥ In the context of this report, undifferentiated patient presentations refers to the presentation of any acute patient at MGH whose problems are not restricted to a single or small group of specialties.

Prior to September 2010, the CUH Group did not have in place arrangements to ensure safe integrated care whereby patients being cared for in the CUH Group sites who required ICS level 3 critical care were always accepted and transferred safely to CUH. Following concerns raised with the HSE South by the Authority, a mandatory acceptance policy and patient transfer protocol for level 3 critical care patients, and clinically unstable patients, were developed and implemented. Once these arrangements were implemented, MGH discontinued the provision of Level 3 critical care. The HSE must ensure that the cessation of the provision of critical care for level 3 and clinically unstable patients in MGH remains in place.

At the time of this investigation the planned reconfiguration of acute services and the HSE's National Acute Medicine Programme had designated Mallow General Hospital to become an acute medicine Model 2 hospital[∂] that would provide ICS level 0/1 critical care. The HSE must ensure that the current service at MGH has the necessary monitoring and evaluation controls in place to mitigate any potential risks to patients requiring Level 1/2 critical care up and until the Acute Medicine Programme is fully implemented.

General surgical and anaesthetic services

At the time of the investigation there were three whole-time equivalent consultant surgeons and three consultant anaesthetists, in post with MGH reporting in their Hospital In-Patient Enquiry (HIPE) data an average annual total of 50 high complexity surgical procedures being performed.

This volume of complex surgery being undertaken at MGH is relatively low. This volume of complex surgeries will continue to decrease with all major acute and major complex surgery ceasing at MGH with the planned reconfiguration of acute surgical and cancer services. The HSE must ensure that all major acute and complex surgery is ceased at MGH as intended. In advance of this change, the provision of surgical services must be kept under continuous review through clinical audit with specific monitoring of clinical outcomes.

In highlighting this issue, the Authority is not raising specific concerns about the competence of the existing surgeons; and a local review conducted by the CUHG found surgery undertaken was appropriate for the skill and experience of the surgeons currently in post.

∂ The AMP (Acute Medicine Programme) recommends four generic hospital models. The purpose of these models is to provide a clear delineation of hospital services based upon the safe provision of patient care within the constraints of available facilities, staff, resources and local factors. The level of service that can be safely provided in any hospital will determine which model applies. (Royal College of Physicians of Ireland. *Report of the National Acute Medicine Programme*. Dublin: Royal College of Physicians of Ireland; 2010.)

Throughout the transition process, it is important that arrangements are made to ensure the clinical experience and competencies of the clinical staff at MGH are recognised and maintained and fully utilised for the benefit of patients in the Cork locality.

Workforce

The Authority found that the system of care at MGH was predominantly consultant-delivered during core hours. The consultants facilitated and responded in a supportive and timely manner by providing clinical advice and providing out-of-hours consultations to review the patient as the need arose. If a clinical need arose outside of these hours, on-site consultants would remain on site. However, this arrangement was dependent on their willingness to provide this level of service and was not part of a clearly described or organised system of care.

At the time of the investigation the 24-hour on-site arrangements at MGH did not ensure consistent out-of-hours senior clinical decision making. As previously identified in MWRH Ennis, and notwithstanding the commitment of consultant staff and the clinical experience of the nursing staff in MGH, this variability of medical cover and the dependence on informal arrangements raised concerns about the Hospital's ability to continue to deliver safe, high quality patient care reliably and sustainably on a 24-hour basis.

Governance arrangements at CUH Group (incorporating MGH)

During the course of the investigation the Authority was provided with documentary evidence of the governance structures in place regionally, within the CUH Group, and locally at MGH. Whilst these structures illustrated defined governance structures, a variance in understanding and in practice was identified during the course of the investigation.

At a local level, at the time of the investigation, governance structures had been recently enhanced through the establishment of a senior management team and a Quality, Safety and Risk Committee. Whilst the benefits of these structures were reported during the course of the investigation, they are very new and should be reviewed and evaluated on an ongoing basis to ensure that they are fit for purpose and facilitate good governance at MGH as part of the wider Hospital Group.

Within the CUH Group, there were defined governance arrangements within Cork University Hospital itself. However, MGH did not appear to benefit from or contribute to the overall governance of the Hospital Group. This was being addressed by the Group during the course of the investigation. However, in addition to the formal changes which were taking place, there was a considerable cultural shift needed to ensure the sustainability and effective functioning of the revised governance structures.

Regional (HSE South) governance arrangements

At a regional level, there had been historical relationships between MGH and the HSE regional network structure in response to underdeveloped governance structures for MGH within the CUH Group. The Authority recognised that this was in the course of being addressed at the time of the investigation.

National Governance Structure through the implementation of the recommendations of the Ennis Report

In the period after the publication of the Ennis Investigation Report, the HSE has been in the process of implementing a number of organisational changes, including the disbanding of the National Hospitals Office (NHO) and Primary, Community and Continuing Care (PCCC) Directorates, establishment of new HSE directorates and the introduction of the new position of Regional Directors of Operations. Whilst a report on progress in implementing the Ennis recommendations was reported as being presented to the HSE Board Risk Committee, formal due diligence handover of accountability and responsibility for implementation of the recommendations at various levels within the HSE was found to be unclear, disconnected and inconclusive.

In addition, the focus on medium- to longer-term solutions for the safe configuration of hospital services has dominated the HSE at the expense of identifying, managing and addressing the specific clinical risks inherent in the systems of care in small hospitals today. National recommendations by the Authority explicitly aimed at signalling the need for urgent action in this respect only began to be addressed in a systematic way from the summer of 2010, 14 months after the publication of the Ennis Report, and only after prompting from the Authority's inquiries. This is not satisfactory for patients and the public.

Given the seriousness of the risks highlighted as part of the Ennis Investigation, it is of the utmost concern that the HSE's corporate and clinical governance systems failed to effectively disseminate learning from an adverse finding by a statutory regulator in one part of its organisation for the benefit of patients across the healthcare system. In the context of the clearest recommendations, which specified the governance and reporting mechanisms necessary for successful implementation, this represents a serious failing of corporate governance which potentially placed, and continues to place in some parts of the country, patients at risk and must be learned from and avoided in the future.

Conclusion

It is regrettable that it proved necessary for the Health Information and Quality Authority to carry out this investigation. The issues at stake had been exhaustively examined previously and the changes needed were set out as part of the Authority's 2009 Report of the investigation into the quality and safety of services and supporting arrangements at MWRH Ennis. The fact that the Authority found it

necessary to invoke its powers under section 9 of the Health Act 2007 to investigate services at Mallow General Hospital indicates a fundamental and worrying deficit in our health system – namely the ability to apply system-wide learning from adverse findings in one part of the service for the benefit of all service users – and most importantly, implementing the changes required to minimise clinical risk for patients and optimise the type and scope of services that can be safely provided in small stand-alone hospitals.

This investigation has revealed that while longer-term improvements are in train, the response of the HSE to key recommendations from the MWRH Ennis Report has been slow and inconsistent, with certain actions only happening recently in response to enquiries from the Authority. In Mallow General Hospital this resulted in a service that continued to be based on past practices, with no concerted effort being taken at a regional or hospital group level to identify and address clinical risks to patients and manage them in a proactive way in advance of planned longer-term change. The safety and quality of the service was dependent on the professionalism and willingness of all clinical staff at MGH, rather than a resilient and reliable system of care.

As signalled in the Ennis Report and echoed more recently in the national Acute Medicine Programme, and the regional Reconfiguration of Acute Hospital Services, Cork and Kerry Roadmap, hospitals such as MGH will have an important, active and vibrant role in providing healthcare to their communities. The national plan identifies Mallow General Hospital as becoming a Model 2 Hospital with medical, day surgery, women and children's and diagnostic services, with MGH consultant staff becoming part of a city-wide clinical network.

The HSE, the Department of Health, clinical leaders, managers and the public need to reflect on the findings of this report in consideration of their role in and accountability for planning, delivering, receiving and funding healthcare services to ensure system-wide learning from adverse findings in one part of the service is applied across the service for the benefit of all service users.

Later in 2011, subject to Ministerial approval, the Authority intends to publish national standards which will define how services should be organised and delivered to assure quality and safety of services. The launch of these standards will be the first step in the trajectory of a licensing system being established in the Irish healthcare system. Service providers should consider that the recommendations of this report are consistent with and indicative of the objectives of the above national standards and future licensing requirements being established in Ireland. The move towards a licensing system in Ireland will accelerate the requirement for these recommendations to be addressed in a proactive and timely manner across the healthcare system for the benefit of patient safety.

The Authority plans to monitor and evaluate the HSE's implementation of the recommendations from this investigation alongside its compliance with national standards.

Recommendations

The following are the recommendations following from this investigation.

System of care

SOC1. The HSE and all healthcare service providers must take prompt action to ensure that any hospital providing 24-hour, seven-days a week emergency care ensures that the system of emergency care includes immediate access to clinical triage and assessment, resuscitation and diagnostic support and full-time on site senior clinical decision makers with the required competencies. Where such arrangements are not achievable or sustainable, the HSE should make the appropriate arrangements to discontinue the emergency service.

SOC2. The HSE should, as a priority, agree and implement a national early warning score to ensure that there is a system of care in place for the prompt identification and management of clinically deteriorating patients.

SOC3. The HSE should develop a national suite of pre-hospital emergency care bypass protocols to ensure a safe system of emergency care. Arrangements should be in place for the routine collection, validation and reporting of data pertaining to the protocol. This information should be used to evaluate the effectiveness of the protocol, with areas for improvement identified and implemented.

SOC4. The HSE and all healthcare service providers must ensure that ICS level 2/3 critical care is delivered to patients at a unit where there are on-site senior clinical decision makers with the required competencies available. Where this is not achievable or sustainable, the HSE should immediately put in place the necessary arrangements to discontinue the critical care service.

SOC5. The HSE must take immediate action to put arrangements in place for the implementation of national mandatory patient transfer and acceptance protocols to ensure the immediate and safe transfer of critically ill patients to a unit providing ICS level 2/3 critical care. Consideration should be given to a national managed critical care network to optimise critical care capacity regionally and nationally.

SOC6. The HSE must put in place arrangements for the routine collection and evaluation of critical care services demand and capacity information to inform any planned clinical service change.

SOC7. The HSE and all healthcare service providers should ensure anaesthesia is delivered in a safe and appropriate environment in line with national and international best available evidence.

SOC8. The HSE and all healthcare service providers must review the current models of delivery of surgical services to ensure they are safe and sustainable. This review must take into account best available national and international evidence, the volume and complexity of surgical procedures and the required competencies. Where safe surgical services cannot be sustainably provided, the HSE should transfer the service and ensure the appropriate arrangements, facilities, and resources are in place to safely accommodate this transfer.

SOC9. The HSE should participate in a national programme for clinical audit that is designed to measure and improve surgical outcomes and ensure compliance with national and international best available evidence.

SOC10. The HSE and all healthcare service providers must put in place arrangements to ensure that clinical competencies are maintained.

Governance

G1. The HSE and all healthcare service providers should have a publicly available statement of purpose describing the services that they can safely provide including how and where they are provided. The HSE should ensure that arrangements are in place to monitor and evaluate that the services being delivered are within the scope of the statement of purpose.

G2. The HSE and all healthcare service providers should ensure that all hospitals and hospital groups have integrated corporate and clinical governance structures with clear accountability arrangements in place. Organisational codes of governance, which clearly identifies safety and quality as core objectives should be implemented, monitored and evaluated.

G3. Hospitals should ensure that effective arrangements are in place for the timely and accurate collection, monitoring and reporting of all activity data at each site. Activity data should be reported and managed through the hospital and/or hospital group's governance structure.

G4. The HSE should ensure that there are arrangements in place to develop and support clinical directors. The necessary clinical leadership development programmes and business and administrative supports must be put in place in order for the clinical directors to effectively fulfill their role

G5. The HSE as a priority should ensure that there are robust arrangements in place to safely and effectively manage change in clinical services. These arrangements should include:

- identification of a named accountable person responsible for managing the implementation of the change process
- rigorous evaluation of the impact of the service change to identify and address any unanticipated adverse consequences of changes implemented.

G6. The HSE should ensure, in advance of any clinical service change, that potential risks to patients associated with the current system of care are identified and analysed, with mitigation actions recorded and monitored through the local, regional and national risk register.

G7. The HSE should ensure that there are formalised arrangements in place for the coordination and alignment of the national clinical care programmes, the national cancer control programme and the regional configuration of acute hospital service.

G8. The HSE and all healthcare service providers must put arrangements in place to ensure that honest, open and timely information is communicated to patients once adverse events affecting them have occurred or become known.

G9. The HSE and all healthcare service providers should ensure that there are arrangements in place to promptly act upon the recommendations of national reports of reviews/investigations or enquiries in relation to the quality and safety of services provided by, or on behalf of the HSE. The HSE should ensure the system-wide application and dissemination of learning from these national reviews for the benefit of all service users.

G10. The HSE should nominate a specific director accountable for ensuring the development of an implementation plan for the recommendations of this investigation that includes a clear timeframe with milestones. The accountable director should ensure that implementation of these recommendations is monitored, evaluated and reported publicly through the HSE's monthly performance reports.

1. Introduction

This report presents the findings from the Health Information and Quality Authority (the Authority) investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive (HSE) at Mallow General Hospital (MGH), Cork. MGH is a site of the Cork University Hospital Group (CUH Group).

The Authority received confidential information, which was not a formal complaint, in relation to the treatment of a patient with complex clinical needs in Mallow General Hospital. This information indicated that the type of care provided to patients receiving some services in the Hospital was not in line with the national recommendations made in the *Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis*[1]. That report highlighted the risks arising from low numbers of patients being treated for certain conditions and the clinical staffing cover possible in such hospitals. As a result of receiving the information, the Authority sought assurances from the HSE about how patient care was provided in Mallow General Hospital, a hospital similar in size to MWRH Ennis.

The Board of the Authority took the decision to instigate an investigation when it did not receive sufficient assurances from the HSE that the necessary arrangements were in place at the Cork University Hospitals Group (CUH Group) site at Mallow General Hospital for the provision of a safe, high quality service for acutely ill patients with complex needs. The Authority believed that this posed a risk to the health and welfare of these patients when receiving emergency, critical care and surgical services on site at MGH.

In carrying out the investigation, the Authority looked in detail at the *system of care* for acutely ill patients in place at MGH, rather than individual incidents or the practice of any specific practitioners. It went on to explore the governance arrangements for the provision of this service within the wider context of the CUH Group. The investigation also ascertained how managers and clinicians at national level in the HSE, and the associated governance arrangements, had addressed the implementation of previous recommendations made by the Authority in relation the provision of safe and sustainable systems of care for acutely ill patients.

The findings are outlined in Chapters 3 and 4 and Chapter 5 sets out the conclusions to the investigation. The report is supported by a number of appendices to provide the reader with additional information. Before describing the Authority's findings and conclusions of its investigation, this report now provides the context for why this investigation was undertaken. Where the Authority has made recommendations for improvements, these are in blue boxes within the appropriate sections of the Report and are presented collectively in the Executive Summary. In the text these recommendations are referred to in bold text and in brackets.

1.1 Setting the scene

In April 2009, the Authority published its *Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis* (the Ennis Report).

This report outlined the need for systems of patient care that are clinically safe and appropriate. It described the potential risks to patients associated with small, stand-alone hospitals treating acutely ill patients, without a clearly described model of service describing what could (and what could not) be safely provided to patients in such hospitals. The report further identified opportunities for developing services that could be provided safely and well at such hospitals.

The Ennis Report highlighted the increased risks associated with treating low numbers of acutely ill patients in smaller, stand-alone hospitals without 24-hour on-site senior clinicians, or ways of ensuring that patients with complex needs are directed to hospitals with the necessary staffing and equipment for safe and effective care.

The Authority's report recognised the scale and complexity of a number of the required changes that were needed to address safety for patients and that these would not be achievable overnight. However, it also emphasised the need to ensure that current services for acutely ill patients were as safe as possible; and consequently that it was not acceptable to delay actions to protect patients in anticipation of long-term solutions. The Ennis Report therefore recommended that the HSE should carry out a systematic assessment of potential risks to acutely ill patients in hospitals similar to MWRH Ennis, and take appropriate steps to mitigate any immediate risks for such patients.

In the 16 months following the publication of the Authority's recommendations, the Authority had ongoing engagement with the HSE in relation to their implementation. The Authority received written updates in relation to the implementation of the local recommendations applicable to the HSE Mid-Western Regional Hospital network. However, the HSE had not produced a formal progress report against implementation of all the national recommendations and had not issued a public update since February 2010.

The HSE's reports did not indicate that a systematic review, for the purpose of patient safety as recommended by the Authority, had taken place. This led to concern on the part of the Authority that there were hospitals similar to MWRH Ennis that were continuing to provide care for acutely ill patients where the volume of patients was too low or the depth of clinical staffing cover insufficient for this to be done reliably and safely. Within this context, in April 2010 the Authority received information that raised concerns about aspects of the system of care provided at the Cork University Hospital Group's site at Mallow General Hospital.

The information indicated that, 14 months following the Authority's publication of the Ennis Report, patients with major or complex conditions were being treated on a 24-hour basis in the emergency department in MGH. The information also indicated that acutely ill patients were undergoing major complex surgery that required high level critical care support, in a hospital where low numbers of such procedures were being performed, and where 24-hour on-site supporting arrangements to provide this level of critical care were not in place and if their condition deteriorated, and in the absence of effective arrangements to transfer patients to a centre with the necessary facilities to meet their clinical needs.

This indicated that the system of care at the CUH Group site at MGH was not in keeping with the Authority's previous recommendations and raised concerns that the services provided potentially carried serious risks to the health and welfare of acutely ill patients receiving emergency, major surgery and critical care services.

The Authority sought assurances from the HSE that potential risks to patients in relation to the provision of surgical, emergency department and critical care services in MGH had been assessed and actions taken to mitigate them. This was through extensive correspondence and engagement at a regional and national level from 20 May 2010 to 29 July 2010. However, the HSE response did not provide the Authority with sufficient assurance that these potential risks were being effectively identified and managed.

The Board of the Authority met on 4 August 2010 to consider the information and responses received. Following careful consideration, the Board was not assured that MGH had the necessary arrangements in place for the provision of a safe high quality service for acutely ill patients. The Board believed that the absence of these arrangements posed a serious risk to the health and welfare of persons receiving those services and therefore decided to instigate an investigation under Section 9(1) of the Health Act 2007 (the Act). The Terms of Reference for the investigation, published on 9 August 2010, are as follows.

Terms of Reference

In the course of the Health Information and Quality Authority's (the Authority) previous investigation into the quality and safety of services provided by the Mid-Western Regional Hospital (MWRH) Ennis, a series of potential risks were identified associated with small, stand-alone hospitals treating acute (including emergency) patients. These risks arose from the low numbers of patients being treated for certain conditions and the low levels of clinical staffing cover possible in such hospitals. Accordingly, the Authority issued national recommendations aimed at ensuring that services would be reviewed in similar hospitals to MWRH Ennis with a view to implementing changes to minimise or eliminate such risks.

The Authority has not received adequate assurance that these recommendations have been considered and implemented at Mallow General Hospital (the Hospital). Whilst the Authority has been informed that there are long-term plans in place to change the role of the Hospital, the Authority believes that there may be a risk to the health and welfare of some patients undergoing certain treatments in the Hospital.

Consequently, in accordance with Section 9(1) of the Health Act 2007 (the Act), and having formed the opinion required by subsection 9(1)a of the Act, the Authority will undertake an investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive (HSE) at Mallow General Hospital, Cork.

In the Investigation, the Authority will seek to identify and quantify any serious risks to patients and to ascertain the safety and quality of services in place in the Hospital. Following this process, the Authority will make recommendations with a view to eliminating or reducing any identified risks to patients. The Investigation shall be carried out on the basis of the following terms:

1. The Authority will investigate what measures have been taken by the Hospital and the HSE to consider and implement the national recommendations from the Authority's April 2009 report into the quality and safety of services at MWRH Ennis and specifically whether risks to patient safety inherent in the service model at the Hospital (as described in the Ennis Report) have been identified, assessed and mitigated.
2. The Authority will assess whether the current arrangements for management and provision of clinical services in the Hospital minimise risks to patient safety including, but not be limited to:
   - critical care and anaesthetic services
   - surgical services
   - emergency services including acute medicine.

3. The Authority will assess how local, regional and national clinical and managerial governance arrangements are supporting safe care and transition towards new models of service provision.
4. The Authority will also take into account the relevant findings and recommendations of previous investigations undertaken by the Authority and the published report, *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance.*
5. The Investigation shall be carried out by the Authority in accordance with its statutory powers under Part 9 of the Health Act 2007 and in whatever manner and with whatever methodology the Investigation Team believes is the most appropriate. The scope of the Investigation will be limited to those aspects of safety and quality that the Investigation Team considers are most relevant and material to the Investigation.
6. If, in the course of the Investigation, it becomes apparent that there are reasonable grounds to believe that there is a further or other serious risk to the health or welfare of any person and that further investigation is necessary beyond the scope of these terms of reference, the Investigation Team may in the interests of investigating all relevant matters, and with the formal approval of the Authority, extend these terms to include such further investigation within their scope or recommend to the Authority and/or the Minister for Health and Children, that a new investigation should be commenced as appropriate.
7. The Investigation Team shall prepare a report which will be submitted to the Board of the Authority for approval and then published. This report shall outline the Investigation, its findings, conclusions and any recommendations that the Authority sees fit to make. In the interests of wider service improvement, national recommendations may also be made where the Authority considers appropriate.
8. The investigation will be conducted by an Investigation Team appointed and authorised by the Authority in accordance with Part 9 of the Health Act 2007. The Team will carry out the investigation and may exercise such powers as it has, pursuant to Part 9 of the Health Act 2007, including rights of entry, its rights to inspect premises, records and/or documents and its rights to conduct interviews.

These Terms of Reference were approved by the Board of the Authority on 4 August 2010 at a duly convened Board Meeting of the Authority.

2. Methodology

This section summarises the methodology used by the Authority in conducting this investigation, including the areas explored by the Investigation Team.

2.1 Overall approach

The Authority developed the investigation approach based on the terms of reference agreed by the Board of the Authority. The investigation was conducted through review and evaluation of information and evidence gathered from various levels within the HSE including at a national level to clarify the strategic and national perspective, at operational service levels with the HSE South Region and at the Cork University Hospital Group including its site in Mallow General Hospital.

2.2 Lines of enquiry

The Authority developed lines of enquiry to guide the investigation approach. These represented sets of questions designed to provide the Investigation Team with a framework for assessing the arrangements in place for the provision of high quality, safe services by the HSE at Mallow General Hospital. The lines of enquiry reflected the Authority's *Draft National Standards for Safer Better Healthcare*,[2] the findings of previous reviews and investigations carried out by the Authority[1][3-4] and the recommendations of the report of the Commission on Patient Safety and Quality Assurance.[5] The lines of enquiry were framed around themes as follows:

- governance, leadership and management
- safe and effective care
- workforce
- use of information
- the measures put in place by the HSE to implement the recommendations of the report of the investigation into the quality and safety of services at MWRH Ennis, April 2009.

2.3 Information review and evaluation

The Authority' investigation approach entailed review and evaluation of information derived from multiple sources including documentation, data, interviews and on-site inspection.

2.4 Documentation and data

The Authority issued formal requests to the HSE for documentation and data in accordance with Section 73 of the Act. (Appendix A)

The data required related to emergency services, as well as the surgical and critical care activity at the CUH Group's site at Mallow General Hospital for the six-month time period of 1 January 2010 to 30 June 2010. This sample time period was selected in order to review up-to-date activity data which was as close as possible to the current time.

The Economic and Social Research Institute (ESRI), with the consent of the CUH Group, provided the Authority with Hospital In-Patient Enquiry (HIPE) data concerning discharge and diagnosis information for CUH Group's site at Mallow General Hospital for the years 2007 to 2010. At the time of the investigation, complete HIPE data for the 12-month period of 2010 was not available. Whilst the Authority considered the data that was available for 2010 (1 January – June 2010) to inform the overall findings of the report, this data is not presented in this report, given that it would not be comparative to the complete 12-month data reported for 2008 and 2009.

The Authority reviewed and evaluated this information to further define the lines of enquiry and to inform the investigation findings.

2.5 Interview and on-site inspection

The Authority obtained information through interview with clinical and non-clinical HSE staff in accordance with Section 73 of the Act. This approach was used to clarify issues that may have been identified during the Authority's review of documentation and data and to inform the investigation findings.

In order to obtain information about the environment and physical facilities for the delivery of safe, high quality care to patients, the Authority inspected the premises at Mallow General Hospital. This included inpatient, diagnostic and therapeutic facilities.

2.6 The Investigation Team and Expert Advisory Panel

The Investigation Team was comprised of Authority staff authorised by the Minister for Health and Children in accordance with Section 70 of the Act for the purpose of this investigation.

To support the investigation process and provide external specialist technical advice, the Authority convened an Expert Advisory Panel comprised of nominees from the postgraduate training bodies including the Royal College of Surgeons in Ireland, Royal College of Physicians of Ireland, College of Anaesthetists, and the Joint Faculty of Intensive Care Medicine of Ireland to cover the clinical specialties of acute internal medicine, surgery and anaesthetics including critical care. In addition, the Authority sourced advisors from outside of Ireland in the fields of emergency care and healthcare management and governance. During the course of the Investigation information was brought to the attention of the Authority pertaining to radiology services. In light of this information the Authority included

a nominee from the Faculty of Radiologists of Ireland. The membership of the advisory panel is set out in Appendix B.

The role of the Expert Advisory Panel was to advise the Investigation Team in relation to the investigation findings. The scope of the advice provided encompassed:

- specific technical issues as they arose
- commentary on findings made by the Investigation Team
- contribution to the development of recommendations as necessary.

The findings, conclusions and recommendations in this report are those of the Investigation Team, operating on behalf of the Authority under section 9(1) of the Act and using powers set out in section 73 of the Act.

The report now sets out the findings of the Authority's investigation.

3. **Findings:** System of care at Cork University Hospital Group's site at Mallow General Hospital

This section sets out the Investigation Team's findings in the areas defined by its terms of reference. What the Investigation Team found is then described and the findings are summarised at the end of each section. Where the Authority has made recommendations for improvements, these are in blue boxes within the appropriate sections of the Report. In the text these recommendations are referred to in bold text and in brackets.

3.1 Introduction

Services should be planned, configured and delivered so that service providers, such as hospitals, can offer patients timely and appropriate access to services where safe, effective and integrated clinical care is provided. The scope of services provided should be clearly described ensuring that the people using and delivering the service can be confident that the resources and the capability of the services are matched to their purpose and being put to best use **(SOC1)**.

Safe and effective patient care requires healthcare staff with the necessary knowledge, skills and competencies treating the right types of patients in the right setting for their needs. In addition, service providers should have arrangements in place to ensure as far as possible that care is safe and effective. This includes patient transfer when such care cannot be provided safely and effectively.

3.2 Overview

MGH is a site of the Cork University Hospital Group (CUH Group). Other sites in the group include: Cork University Hospital (CUH), Cork University Maternity Hospital (CUMH) and St Mary's Orthopaedic Hospital (SMOH). The CUH Group is part of a network of hospitals in the HSE South providing a full range of clinical services. MGH was built in 1936 and, located 35 kilometres north of Cork, is one of the smaller general acute hospital facilities in the country. MGH has 76 beds and is a site for the education and training of nursing, medical and allied health professional students. The Investigation Team found MGH to be a clean well maintained hospital, held in good standing by the local community and general practitioners. The staff were committed to the patients whom they served.

At the commencement of the investigation, CUH Group provided at its site at MGH 24-hour emergency care, general medicine, gastroenterology, general surgery (including major complex and day surgery), urology, cardiology, care of the

elderly, Intensive Care Society[6] (ICS) level 0/1 to level 2 critical care♦, radiology including computerised tomography (CT) scanning, general laboratory and blood bank services.

In reviewing the clinical activity at MGH the Authority reviewed data submitted by the HSE South related to emergency services, as well as the surgical and critical care activity at the CUH Group's site at Mallow General Hospital for the six-month time period of 1 January 2010 to 30 June 2010. This sample time period was selected in order to review up-to-date activity data which was as close as possible to the current time.

In addition, the Economic and Social Research Institute (ESRI), with the consent of the CUH Group, provided the Authority with Hospital In-Patient Enquiry (HIPE) data concerning discharge and diagnosis information for CUH Group's site at Mallow General Hospital for the years 2007 to 2010. At the time of the investigation, complete HIPE data for the 12-month period of 2010 was not available.

Whilst the Authority considered the data that was provided by the ESRI for 2010 (1 January – June 2010) to inform the overall findings of the report, this data is not presented in this report, given that it would not be comparative to the complete 12-month data reported for 2008 and 2009.

HIPE is the main source of data on the clinical activity undertaken in the acute hospital sector. [7] The CUH Group is responsible for ensuring that its integrated governance arrangements allows the timely coordination, coding and reporting of all HIPE data pertaining to the four hospitals within the Group. However, at the time of the investigation MGH reported that it submitted its HIPE data independently of the CUH Group. This disparity was reflected in the national HealthStat report [8-9] where CUH consistently achieved the HSE target of 80% for the required number of cases entered into HIPE, with Mallow General Hospital reporting a compliance of 45%.

The Authority concluded that the disparity in reporting raises a question as to how a service within a hospital group governance structure can be effectively managed in the absence of timely and complete performance data. In the context of planned

♦ An approach, described by the Intensive Care Society (ICS), UK, for allocating levels of care to critically ill patients, in a hospital setting, according to their clinical needs. These descriptions reflect the Critical Care Minimum Dataset mandated in the UK.

ICS Level 0 (Ward): patients' needs can be met through normal ward care in an acute hospital.

ICS Level 1 (Ward at-risk): patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team.

ICS Level 2 (HDU): patients requiring more detailed observation or intervention including support for a single failing organ system or postoperative care and those stepping down from higher level care.

ICS Level 3 (ICU) patients requiring advanced respiratory support alone or basic respiratory support together with at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

Council of the Intensive Care Society. *Levels of Critical Care for Adult Patients Standards and Guidelines.* London: Intensive Care Society; 2009.

service changes, data such as that collected for the purposes of HIPE, across all hospitals within that Group, should be integrated and used as a key tool in modelling demand and capacity across the hospital group and region.

At the time of the investigation, there was a regional HSE programme in place to plan the reconfiguration of acute services in the HSE south. As signalled in the Ennis Report and echoed more recently in the national Acute Medicine Programme, and the regional Reconfiguration of Acute Hospital Services, Cork and Kerry Roadmap, hospitals such as MGH will have an important, active and vibrant role in providing healthcare to their communities. The national plan identifies Mallow General Hospital as becoming a Model 2 Hospital with medical, day surgery, women and children's and diagnostic services, with MGH consultant staff becoming part of a city-wide clinical network.

The report goes on to describe the Authority's findings at the time of investigation.

3.3 Emergency services

3.3.1 Introduction

Emergency services provided for undifferentiated[¥] (according to seriousness or severity) patients with acute and urgent illnesses or injuries should allow the consistent diagnosis and management of these acute conditions including the immediate assessment, resuscitation and clinical management of sometimes complex and rapidly changing patient presentations. Access to senior clinical decision-making should be readily available for such patients at all times.

3.3.2 What the Authority found

The investigation found that general practitioners (GPs) refer patients to the ED at MGH for diagnostic investigation, clinical assessment and treatment. In addition, GPs can secure direct emergency admissions for patients.

In relation to diagnostic support for emergency services, the Radiology Department provided plain film and cross-sectional imaging including ultrasound and computerised tomography (CT) scanning during core hours[±] and there was an on-call arrangement in place for emergency plain film radiology. However, there was no out-of-hours on-site CT scanning available at MGH; emergency CT scanning was provided in CUH. Laboratory services were provided on site up to 5pm Monday to Friday, while on-call emergency arrangements were in place in MGH for these services – including the transfer of specimens to CUH – up to

¥ In the context of this report, undifferentiated patient presentations refers to the presentation of any acute patient at MGH whose problems are not restricted to a single or small group of specialties.

± Core working hours at MGH can be classified as the working hours of 9am to 5pm, Monday to Friday.

midnight, and at weekends. After midnight and at weekends, the laboratory services in CUH provided on-call emergency laboratory services to MGH.

There were arrangements (called bypass protocols) in place for diverting more seriously ill patients brought by ambulance to the main centre in CUH. These appeared to have led to a reduction in the number of emergency presentations to the Emergency Department (ED). However, the ED service provided a 24-hour, seven-days-a-week walk-in emergency service for all patients. These patients were by definition undifferentiated according to the seriousness or severity of their presenting clinical condition. Consequently, the service should be designed to be able to deal unexpectedly with acutely ill patients having complex emergency needs. This principle also applies for inpatients that have a greater potential to deteriorate unexpectedly, such as those that have undergone major surgery. This should incorporate the use of a recognised system for determining the severity of patient illness and predicting patient outcomes, sometimes known as an Early Warning Score+ **(SOC2)**.

The investigation found that MGH had in place locally developed bypass protocols for maternity patients and children presenting at the ED. A regional pre-hospital emergency care ambulance bypass protocol was also in place which was intended to ensure that seriously ill patients were taken directly to the regional centre at CUH. However, evidence was not presented during the course of the investigation to demonstrate that the implementation of and adherence to this regional protocol, developed in 2006, had been formally evaluated **(SOC3)**.

The investigation identified that MGH was not part of the regional emergency care network and not formally supported by emergency medicine consultant staff. A consultant in emergency medicine from the CUH Group provided an 'administrative' function which involved the dissemination of regional ED policies and guidelines. However, the post-holder had no formal clinical role in the ED at MGH. Staff at MGH did participate in the regional reconfiguration discussions of ED services forums. This meant that there was no mechanism for the clinical staff in MGH to raise operational issues or concerns in relation to the emergency services on a daily basis.

The Investigation Team explored the detail of how ED services were delivered at MGH. Local policies reviewed by the Authority identified that all patients presenting to the ED were initially assessed by the nursing staff with the necessary skills and competencies, and the majority had post-graduate emergency care qualifications.

During Monday to Friday core working hours, immediate care for patients presenting with suspected acute surgical conditions or injuries was provided by an emergency-care surgical officer and ED nursing staff. The on-call medical team provided the immediate care to patients presenting with suspected medical conditions. Interns (doctors in their first year after medical school) did not attend the emergency department. The respective consultants on call in medicine and surgery

+ A physiologically based system of scoring a patient's condition to help determine severity of illness and predict patient deterioration.

held overall clinical responsibility for the delivery of care to patients presenting to the ED. During core hours, it was reported that there was access to senior decision making from on-site consultants. However, there was no routine consultant presence in the ED.

Out of hours, presenting patients were initially assessed by nursing staff, with immediate care provided by the members of the on-call surgical or medical teams. At the time of the investigation, the surgical on-call was provided on a rota basis by four surgical house officers who are not on a structured training programme. Medical on-call was provided on a rota basis from a pool of two specialist registrars (SpR), one registrar, five senior house officers and two interns. On-call consultants were available off site for out-of-hours consultation to the non-consultant on-call team.

Consequently, at the time of the investigation there was no consistent 24-hour access to on-site senior clinical decision making for patients attending the ED. This meant that patients attending out of hours, or whose condition deteriorated out of hours, may not have had prompt access to review by a senior clinician. Further to engagement by the Authority with the HSE South in relation to 24-hour senior clinical decision makers, the Authority was informed that a new roster providing 24-hour seven-day-on-site cover by medical registrars in MGH had been implemented in February 2011.

The Authority reviewed various data to validate its findings in relation to the ED services at MGH, primarily focusing on the period from 1 January to 30 June 2010.

Data submitted by the HSE South indicated that 5,871 patients attended the ED in MGH for this period. Of these, 49% (n=2,892) of patients were self referrals, 41% (n=2,390) were referred by GPs and 9.5% (n=560) attended via ambulance services (see Table 1).

Table 1: Source of referrals to Emergency Department, MGH

Source of referrals to MGH Emergency Department	Volume	%
Self referral	2,892	49%
GP referral	2,390	41%
Ambulance	560	9.5%
Attendance post inpatient discharge	29	0.5%
Total	**5,871**	**100%**

Source: Mallow General Hospital. Please note that data relates to 1 Jan - 30 June 2010 only

This data confirmed that the CUH Group's site at MGH continued to provide a 24-hour clinically undifferentiated walk-in emergency service to 49% of patients attending at the ED.

Hospital In-Patient Enquiry (HIPE) data and hospital documentation reviewed by the Investigation Team indicated that the main route of emergency admissions (51% - 2008/9) was primarily through the emergency department (ED) (see Table 2). Medical admissions account for 58% of all admissions, and of these, over 70% were emergency admissions. 91% of patients requiring admission from the ED were admitted in less than six hours according to the HSE's HealthStat reports.

Table 2: Number of patient admissions to MGH

Admissions	2008		2009	
All Admissions	**Volume**	**%**	**Volume**	**%**
Medical	3,933	58%	3,887	58%
Surgical	2,820	42%	2,766	42%
Total	**6,753**	**100%**	**6,653**	**100%**
All Admissions	**Volume**	**%**	**Volume**	**%**
Elective inpatient	1,039	15%	998	15%
Emergency inpatient	3,421	51%	3,394	51%
Day case	2,293	34%	2,261	34%
Total	**6,753**	**100%**	**6,653**	**100%**
Medical	**Volume**	**%**	**Volume**	**%**
Elective inpatient	248	6%	208	5%
Emergency inpatient	2,955	75%	2,883	74%
Day case	730	19%	796	21%
Total	**3933**	**100%**	**3887**	**100%**
Surgical	**Volume**	**%**	**Volume**	**%**
Elective inpatient	791	28%	790	29%
Emergency inpatient	466	17%	511	18%
Day case	1,563	55%	1,465	53%
Total	**2,820**	**100%**	**2,766**	**100%**

Source HIPE data.

The Authority's review of the 2009 HIPE data (see Table 3) found that the main conditions (known as principal diagnoses) recorded for emergency admissions of patients were: chest pain (n=187), abdominal pain (n=178), syncope and collapse (n=139) and chronic obstructive pulmonary disease (COPD) (n=104).

Table 3: Principal diagnoses for emergency admissions, MGH

Principal diagnosis for emergency admission source	Volume 2008	Volume 2009
Chest pain – unspecified and other	146	187
Abdominal pain	157	178
Syncope and collapse	85	139
Chronic obstructive pulmonary disease (COPD)	126	104
Pneumonia unspecified	89	88
Acute appendicitis unspecified	51	83
Atrial fibrillation and flutter	84	76
Unspecified acute lower respiratory infection	103	67
Cellulitis of lower limb	54	51
Congestive heart failure	53	48

Source HIPE data – patient numbers ranked by 2009 volumes.

The Authority explored the compliance with the pre-hospital emergency care ambulance bypass protocols for the top 10 clinical categories for patients transferred by ambulance to MGH. Table 4 reflects the top 10 clinical categories for ambulance referrals to MGH.

Table 4: Top 10 Clinical categories for ambulance referrals to MGH.

Top 10 clinical categories for Ambulance Referrals to ED	Volume
Sick person - specific diagnosis	156
Falls/back Injuries – traumatic	75
Chest pain	70
Breathing problems	63
Abdominal pain	31
Medical emergency admission/transfer	31
Cerebrovascular accident (stroke)	29
Road traffic accidents	29
Unknown diagnosis	22
Heart problems	21

Source: HSE National Ambulance Service. Please note that data relates to 1 Jan – 30 June 2010 only

This data (submitted by the HSE South to the Authority) suggested that patients with neurological conditions such as strokes (excluded from attendance to MGH by the bypass protocol) were being brought there by the ambulance service. As the regional bypass protocols have never been evaluated this finding could represent a data coding error or a breach of the bypass protocol that could potentially represent a serious risk to patients. These need to be the subject of a systematic review by the HSE and the principle must be established that protocols introduced for the protection of vulnerable groups of patients must be subject to periodic evaluation and review in all centres.

In addition, data submitted by the HSE National Ambulance Service, and the Regional HSE, in relation to the number of patients brought to MGH Emergency Department for the six-month period from 1 January to 30 June 2010 was reviewed. This review demonstrated a variance in reporting of patients (total 672 patients) transported by ambulance to the ED at MGH. The data submitted may suggest that potentially a number of the bypass protocols were not being followed.

3.3.3 Summary of findings: emergency services

Patients with acute and urgent illnesses and injuries need access to emergency services which allow the safe and effective diagnosis and management of such conditions. If a service is provided that allows patients to present on a 24-hour basis with potentially serious and complex conditions, it must be organised accordingly. This includes the immediate assessment, and clinical management, of acutely ill patients up to and including resuscitation or critical care where necessary. The service provider must ensure that this emergency patient care is delivered at all times of the day and night in a safe, clinically appropriate

environment and provided by clinical staff with the necessary experience, skills and competencies. This principle also applies for inpatients that have a greater potential to deteriorate unexpectedly, such as those that have undergone major surgery. This should incorporate the use of a recognised system for determining the severity of patient illness and predicting patient outcomes, sometimes known as an Early Warning Score.

The CUH Group's site at MGH provided a 24-hour clinically undifferentiated walk-in emergency service to patients with up to 50% of the Hospital's admissions coming through the ED. However, at the time of the Investigation the level of on-site clinical staffing out of hours, along with lack of on-site critical care or anaesthetic expertise, raised concerns about the ability of MGH to safely treat patients presenting with acute illnesses on a 24-hour basis. While the majority of patients attending the ED had minor injuries or less complex conditions, at the time of the investigation, the risks for patients attending with a complex acute illness requiring immediate clinical management remained, particularly outside of normal working hours. Further to engagement by the Authority with the HSE South in relation to 24-hour senior clinical decision makers, the Authority was informed that a new roster providing 24-hour, seven-day-on-site cover by medical registrars in MGH was implemented in February 2011 which is a necessity while 24-hour acute attendances continue to be accepted at MGH.

In addition, the efficacy of the pre-hospital emergency care ambulance bypass protocols had not been evaluated and the data submitted suggested that these were not consistently applied. This may result in patients being admitted to a service that did not have the essential attributes for the delivery of safe and effective care and treatment of complex, acute illnesses.

A key thrust of the Ennis Report recommendations was that the HSE should systemically identify and manage, on an ongoing basis, potential clinical risks in advance of and during any reconfiguration of services. This investigation found that this had not begun to happen until late in 2010 and the report deals with the reasons for this later. However, the consequence of this is that, whilst services in the HSE South are planned to be regionally and locally reconfigured, the system of emergency care in place at MGH does not ensure that acutely ill patients are consistently cared for in the most appropriate setting.

The Authority concluded that at the time of the investigation, the service did not, at all times, have the essential requirements in place, including appropriate levels of on-site out-of-hours senior clinical decision makers. This deficit was subsequently addressed by the HSE South in February 2011. In addition, at the time of the investigation, the ambulance bypass protocols, required to ensure MGH does not accept patients with conditions for which it is not staffed or equipped, had not been evaluated for effectiveness or compliance.

3.4 Critical care services

3.4.1 Introduction

Evidence-based clinical practices shows that patients with serious and complex conditions requiring critical care, including multi-organ support, should be managed in an Intensive Care Society (ICS) level 3 intensive care♦, unit or in a tertiary specialist centre[10-11]. If this is not available where patients present, they should be stabilised and transferred to an appropriate centre without delay. In centres where acutely ill patients may attend, clinical staff must have the key skills and competencies to stabilise and manage the complex needs of these patients. It also requires effective systems and processes to support the safe transfer of critically ill patients.

3.4.2 What the Authority found

MGH did not have an intensive care unit (ICU). Critically ill patients were cared for in a four-bedded unit that functioned as a combined coronary care/high dependency unit (CCU/HDU). Patients admitted to the unit remained under the care of the admitting medical or surgical consultant. MGH did not have specifically dedicated specialists in critical care. Consultant anaesthetists provided support and managed patients who required critical care. There were no non-consultant hospital doctors (NCHDs) in anaesthetic medicine, therefore all anaesthetic cover was provided by consultants **(SOC4)**.

Prior to the commencement of the investigation, the Authority raised specific concerns about the ability of MGH to ensure the continuous out-of-hours cover on the site by a registered medical practitioner with the appropriate training and experience to provide immediate treatment for acutely ill patients. In particular, this related to patients requiring acute respiratory, circulatory and airways support. In response to this concern, a mandatory airways training programme was put in place in September 2010 at MGH for all non-consultant hospital doctors. At the time of the investigation, the HSE South reported that just over half of NCHDs had completed the course. However, the Authority found that senior clinical decision-

♦ An approach, described by the Intensive Care Society (ICS), UK, for allocating levels of care to critically ill patients, in a hospital setting, according to their clinical needs. These descriptions reflect the Critical Care Minimum Dataset mandated in the UK.

ICS Level 0 (Ward): patients' needs can be met through normal ward care in an acute hospital

ICS Level 1 (Ward at-risk): patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team

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Council of the Intensive Care Society. *Levels of Critical Care for Adult Patients Standards and Guidelines.* London: Intensive Care Society; 2009.

making on-site cover was not available for four of the seven nights at MGH. This issue is addressed further in this report on the section on medical staffing in the Hospital.

The system of critical care services provided to patients at MGH was consultant delivered during core hours. Staff confirmed to the Investigation Team that there were arrangements in place for all patients to be clinically reviewed by consultants throughout the day with particular emphasis on early morning and late-at-night consultant patient rounds, although there was no formal policy to support these arrangements. Anaesthetic services were provided outside of core hours by an off-site on-call consultant anaesthetist. In addition, cardiology services at MGH were clinically supported out of hours by an off-site on-call consultant cardiologist, as part of HSE South city-wide cardiology services.

The Authority reviewed the data provided by the HSE South for the six-month period from 1 January to 30 June 2010 and found that the majority of patients admitted to the CCU/HDU at MGH were reported as requiring ICS level 2 critical care. In total, 258 patients were admitted for care. Of those, eight patients required ICS level 3 critical care, 180 patients required ICS level 2 critical care, with the remaining 70 MGH patients being reported by the HSE as requiring ICS level 1 critical care.

The review of the eight patients who required ICS level 3 critical care indicated that four were medical patients and four were post-surgery. Of these patients, five were transferred to another acute hospital following a period of 6 to 12 hours. Level 3 critical care for the remaining three post-surgical patients was provided in the CCU/HDU at MGH; this was required for 72 hours for two of these patients with one patient requiring level 3 critical care for three hours.

CUH is the only site of the CUH Group that has the resources and capability to provide ICS level 3 critical care. However, staff at MGH reported examples of difficulties in transferring ICS level 3 critical care patients in a timely manner to the CUH site. This supported the Authority's concerns, informed by information it had received, that there had been incidents of MGH patients, requiring ICS level 3 critical care, being declined admission by CUH which resulted in them being transferred to hospitals in other HSE regions **(SOC5)**.

Information from CUH confirmed that there were access difficulties for critical care beds in CUH with critical care facilities running at a bed occupancy rate of over 100% due, in some part, to nursing staffing shortages which had resulted in the closure of two critical care beds. However, CUH could not provide information on the number of occasions that it had been unable to provide access to the ICU. This information is essential to manage demand and capacity for the provision of critical care services **(SOC6)**.

Prior to September 2010, the CUH Group did not have in place arrangements to ensure safe integrated care whereby patients being cared for in the CUH Group sites who required ICS level 3 critical care were always accepted and transferred safely to CUH. Following concerns raised with the HSE South by the Authority, a mandatory acceptance policy and patient transfer protocol were developed. It was reported by the MGH site that the policy was in place and had been implemented successfully. It is important that the CUH Group monitors the application of this policy on an ongoing basis.

The Authority reviewed the data supplied by HSE South for the 180 patients who were reported as requiring ICS level 2 critical care. The majority of these patients (53%, n=96) had a cardiac (heart) condition, and 40% of these patients had undergone a cardiac procedure such as insertion of cardiac stents or an angioplasty to treat blocked arteries. 16% of patients required ICS level 2 critical care post-surgery, 13% of patients had a respiratory (breathing) condition and the remaining 18% of patients required ICS level 2 critical care for a variety of conditions such as an overdose or gastrointestinal (gut) bleed. Of the 180 patients, 27% (n=48) required non-invasive ventilatory support (bi-level positive airways pressure and continuous positive airways pressure) and/or therapeutic cardio-vascular support. This is demonstrated in Table 5.

Table 5: Overview of patients reported as requiring ICS Level 2 critical care in CCU/HDU, MGH by type of condition

Type of condition	Volume	%
Patients with a cardiac condition	96	53%
Patients with other condition	33	18%
Post surgical patients	28	16%
Patients with a respiratory condition	23	13%
Total	**180**	**100%**

Source: Mallow General Hospital. Please note that data relates to 1 Jan – 30 June 2010 only

In relation to critical care services, the Authority previously recommended in the MWRH Ennis Report that the HSE should ensure that such services provided in hospitals similar to MGH be delivered within safe practice guidelines. As part of this investigation, the Authority was informed by the HSE that this recommendation would be addressed within the reconfiguration process for acute services in the HSE Cork and Kerry region[13] and the National Acute Medicine

Programme∝. For example, the Acute Medicine Programme recommends the establishment of four generic hospital models (Models 1-4) to provide a clear delineation of hospital services based on the safe provision of patient care within the constraints of available facilities, staff, resources and local factors. The level of service that can be safely provided in any hospital will determine which model applies [14]. In the context of critical care services, it is proposed that a Model 2 hospital would provide ICS level 0/1 critical care only with Model 3 and Model 4 hospitals providing all ICS levels of critical care (levels 0/1 to level 3).

Prior to commencing the investigation there was no evidence provided to the Authority to demonstrate that a HSE regional or the CUH Group review of critical care services and/or measures had been planned or put in place to mitigate any clinical risks arising from the delivery of critical care services at the MGH site. Furthermore, the investigation found that no assessment or validation had been carried out by the CUH Group of current demand for critical care, including information about those patients it had been unable to accommodate. Accurate information about the capacity and demand for critical care is vital in planning for future service change.

3.4.3 Summary of findings: critical care services

The Ennis Report recommended that the HSE should review critical care provision to ensure that services are being provided within safe practice guidelines. Where this is not the case, appropriate risk management measures, and the necessary service changes, were to be implemented and managed to protect patients. Prior to September 2010, the CUH Group did not have in place arrangements to ensure safe integrated care whereby patients being cared for in the CUH Group sites who required ICS level 3 critical care were always accepted and transferred safely to CUH. Following concerns raised with the HSE South by the Authority, a mandatory acceptance policy and patient transfer protocol for level 3 critical care patients, and clinically unstable patients, were developed and implemented. Once these arrangements were implemented, MGH discontinued the provision of level 3 critical care. The HSE must ensure that the cessation of the provision of critical care for level 3 and clinically unstable patients in MGH remains in place.

At the time of this investigation the planned reconfiguration of acute services and the HSE's National Acute Medicine Programme had designated Mallow General Hospital to become an acute medicine Model 2 hospital that would provide ICS level 0/1 critical care. The HSE must ensure that the current service at MGH has

∝ The Acute Medicine Programme (AMP) is a clinician-led initiative between the Royal College of Physicians of Ireland (RCPI), the Irish Association of Directors of Nursing and Midwifery (IADNAM), the Therapy Professions Committee (TPC), the Irish College of General Practitioners (ICGP) and the Quality and Clinical Care Directorate (QCCD), HSE. It provides a framework for the delivery of acute medical services which seeks to substantially improve patient care through the establishment of four generic hospital models.

the necessary monitoring and evaluation controls in place to mitigate any potential risks to patients requiring Level 1/2 critical care up and until the Acute Medicine Programme is fully implemented.

3.5 General surgical and anaesthetic services

At the time of the investigation, a pre-operative anaesthetic room and one general theatre provided the inpatient and day case operating facilities at MGH. There was one side-room, within the area, that was used for endoscopy; this was used by both physicians and surgeons. The facilities for anaesthesia and surgery were basic and there was limited space to recover patients following surgery. Depending on the complexity of the surgical case the patient could have been monitored and recovered in the general theatre, endoscopy room or in the CCU/HDU. Patients who had minor or less complex surgery were recovered in a screened-off area within the theatre area. The Investigation Team found that the lack of resources for surgical and anaesthetic services and day facilities had been previously identified as a long standing deficit at MGH. However, no significant investment had been made by the CUH Group in improving the facilities **(SOC7)**.

In MGH, three consultant surgeons supported by non-consultant hospital doctors (NCHDs), including four senior house officers and two interns, provided the surgical service. The anaesthesia service was provided by three consultant anaesthetists. There were no non-consultant hospital doctors in anaesthetic medicine, therefore all anaesthetic cover was provided by consultants.

Interviews and review of the theatre register by the Investigation Team confirmed that the majority of day and inpatient surgical cases were performed within the core theatre working hours. However, the competing scheduling of medical endoscopy with inpatient and day case surgical procedures resulted in inefficient use of a scarce resource.

A review of HIPE data indicated that 53% of surgical cases were carried out as a day case procedure and 47% were carried out on an inpatient basis. Of these, 29% of patients were elective admissions and 18% following emergency admission (see Table 6).

Table 6: Surgical admissions in MGH

Surgical Admissions	2008		2009	
	Volume	%	Volume	%
Elective inpatient	791	28%	790	29%
Emergency inpatient	466	17%	511	18%
Day case	1563	55%	1465	53%
Total	**2820**	**100%**	**2766**	**100%**

Source HIPE data.

The HIPE data confirmed the most frequent surgical procedures as endoscopies, with the next most common procedures being repair of hernia (150 in the year 2009), tonsillectomy / adenoidectomies (138 in 2009) and cholecystectomies (127 in 2009). Table 7.

Table 7: Most frequent surgical inpatient and day case procedures in MGH

Inpatient Procedure	2008	2009
Panendoscopy to duodenum	93	177
Repair of hernia	116	150
Tonsillectomy / adenoidectomy**	144	138
Cholecystectomy (including laparoscopic)	120	127
Appendicectomy (including laparoscopic)	92	93
Fibre optic colonoscopy	58	68
Transurethral resection of prostate	63	68
Cystoscopy	61	45
Varicose veins	39	38
Male circumcision	17	24
Day case procedure	**2008**	**2009**
Fibre optic colonoscopy	516	555
Panendoscopy to duodenum	303	406
Cystoscopy	154	144
Myringotomy	110	100
Male circumcision	76	62
Laryngoscopy/microlaryngoscopy	52	51
Oesophagoscopy with biopsy	129	8

Source HIPE data.

***ENT (Ear, Nose and Throat) inpatient surgery has since ceased at MGH*

The HSE Performance Monitoring Unit's HealthStat performance monitoring target for a defined 'basket' of 24 day case procedures[15] is that 75% or more of these procedures should be treated as day cases. A review of the 2009 HIPE data suggests that of 617 patients treated at MGH – within the defined 'basket' of day cases – only 27% of those were treated as day cases.

This trend is in keeping with the HIPE data received for the early part of 2010. As of November and December 2010 the HSE HealthStat indicators report[8-9] showed MGH had managed approximately 25% of these procedures as day cases. While this may to some extent reflect the older age profile of patients attending MGH, it suggests that there had not been a focused drive by the CUH group to develop the infrastructure at MGH to maximise the number of day case procedures or that consideration had been given as to the effective use of MGH as a resource in managing the total surgical bed capacity requirements of the CUH group.

The review of HIPE data (Table 8) indicated that in 2009, 339 surgeries were performed on patients less than 16 years of age of which 68 were general surgery. Prior to the commencement of the Investigation, general inpatient and day case paediatric surgery was provided at MGH. See Table 8.

Table 8. Surgery on patients less than 16 years of age in MGH

Paediatric Surgical procedures	Volume 2008			Volume 2009		
	Day case	Inpatient	Total	Day case	Inpatient	Total
ENT	114	95	209	109	88	197
General surgery	35	50	85	25	43	68
Urology	51	10	61	51	10	61
Dental	22	0	22	11	2	13
Total	**222**	**155**	**377**	**196**	**143**	**339**

Source HIPE data.

Surgery on patients less than 16 years of age was discontinued at MGH in July 2010.

3.5.1 Volume of major complex surgical procedures

Internationally, an increasing body of evidence indicates that outcomes for patients (including lower large bowel surgery) are better, and fewer errors occur, when acute and complex surgical care is provided by teams treating higher numbers of patients. The literature also reports that hospitals treating elderly patients with colorectal cancer with high volumes of cases (over 150 cases per year) have lower death rates than hospitals with lower volumes (under 55 cases per year)[16-17].

Guidelines for commissioning of services in the United Kingdom suggest that surgeons should perform a minimum of 20 surgical procedures for colorectal cancer per year[18]. Whilst these figures pertain to cancer surgeries only, the Authority sought advice from the investigation Expert Advisory Panel, and was informed that these figures would be indicative of suggested volumes for other complex surgeries.

It is recognised that there are a multiple of factors which affect the quality of surgical services and patient outcomes. These include the skill and experience of the surgeons and their supporting teams and the volume of surgical cases performed **(SOC8).**

Prior to the commencement of the investigation, the Authority had raised questions with the HSE regarding the volume of acute and complex surgeries being carried out at MGH. In response, in July 2010 the CUH Group Clinical Director analysed surgical activity based on HIPE data for 2009 in MGH as part of an assurance process in risk identification and assessment of the service delivery. The Clinical Director's analysis concluded that the current profile of surgical activity was appropriate to the experience and competencies of the consultants in MGH.

The Authority's analysis of the HIPE data reported to the ESRI by MGH (see Table 9) found that low volumes of major and complex surgery were being performed in MGH. In 2009, MGH reported through HIPE that a total of 54 major and complex surgeries were performed at the Hospital, of these five were ear nose and throat (ENT) surgeries. At the time of the investigation, ENT surgery had been transferred to the South Infirmary Victoria University Hospital in Cork.

The HIPE data identified there were 36 patients with major bowel conditions operated on at MGH in 2009. In June 2010 as part of the National Cancer Control Programme (NCCP), rectal cancer surgery transferred from MGH to the specialist cancer centre at CUH with a plan for all colorectal cancer surgery to transfer from MGH in early 2011.

Table 9. Volumes of major and complex surgery at MGH

Low volume high complexity surgical procedures	Volume 2008	Volume 2009
Bowel procedures	21	36
ENT procedures	21	14
Gastrology procedures	2	1
Urology procedures	2	2
Thoracic procedures	0	1
Orthopaedic procedures	5	0
Total	**51**	**54**

Source HIPE data.

Subsequent to the investigation process, the Authority received additional information from MGH which suggested that the theatre register showed a total of 56 major bowel surgeries were performed in MGH in 2009 – 20 more than reported through HIPE. In addition, a 2009 review of surgical activity commissioned by the HSE South, and provided by MGH to the Authority at the time of this Report, had reported that the volumes of the most commonly performed procedures at MGH were adequate for the maintenance of surgical competencies.

This disparity between HIPE data reported by MGH to the ESRI and the subsequent 2009 data submitted to the Authority prior to the publication of the investigation findings raises a serious question as to the operation of the HIPE system at MGH and as to how a hospital within the CUH Group can be effectively managed and resourced or change safely implemented in the absence of accurate performance data.

In highlighting this issue, the Authority is not raising specific concerns about the competence of the existing surgeons, however, the HSE must ensure that any potential risks associated with decreasing volumes of surgical activity at MGH are subject to ongoing review supported by robust clinical audit with specific monitoring of key clinical outcomes in MGH and the new surgical services in other hospitals **(SOC9)**. In addition it is important that arrangements are made throughout the change process to ensure the clinical experience and competencies of the clinical staff at MGH are recognised and used fully for the maximum benefit of patients within the locality **(SOC10)**.

3.5.2 Summary of findings: general surgical and anaesthetic services

At the time of the investigation there were three whole-time equivalent surgeons in post, supported by three consultant anaesthetists, in MGH, with MGH reporting to HIPE a relatively low volume of complex surgery being undertaken at MGH. Plans for the transfer of colorectal surgery in early 2011, and the earlier transfer of rectal surgery, will further reduce this volume.

This situation will be further compounded during the planned HSE South reconfiguration of acute surgical services incorporating the transfer of elective inpatient general surgical services currently provided at MGH to Mercy University and South Infirmary Victoria University Hospitals in tandem with the transfer of all emergency surgical services to CUH. It is planned that day case procedures would continue to be provided at MGH as part of the configuration of acute surgical services with formalised city-wide consultant surgical rotation to support the delivery of the reconfigured surgical services in the HSE South. In addition, the national plan identifies Mallow General Hospital as becoming a Model 2 Hospital with medical, women and children's and diagnostic services. The HSE must ensure that all major acute and complex surgery is ceased at MGH as intended, and that any risks in the interim of this change being implemented, are identified and managed.

The Authority's investigation has not received information that raises concerns about the competence of the existing surgeons. However, the volumes of high complexity cases is low and set to decline as more surgical services transfer out of MGH as part of the National Cancer Control Programme. Consequently, the HSE South must ensure that any risks associated with low volume surgical activity at MGH and the transfer of additional services to other HSE South hospitals are kept under review and supported by robust clinical audit processes with specific monitoring of relevant clinical outcomes **(SOC9)**.

In addition, throughout the transition process, it is important that arrangements are made to ensure the clinical experience and competencies of the clinical staff at MGH are recognised and maintained and fully utilised for the benefit of patients in the Cork locality.

3.6 Workforce

3.6.1 Introduction

The safe and effective management of a patient's care throughout their journey requires healthcare staff with the necessary knowledge, skills and competencies, treating the right types of patients in the right setting for their needs. The quality of clinical care that the patient receives is linked to the continuous professional development of staff providing the care.

3.6.2 What the Authority found

All newly appointed staff at MGH attend the HSE South CUH Group induction programme. There was a system in place within MGH to centrally record all training that staff had attended. Training records reviewed were up to date with evidence that staff were participating in MGH mandatory training programmes; some of which included basic and advanced cardiac life support, infection control, haemovigilance, Children First: National Guidelines for the Protection and Welfare of Children[19] and venepuncture.

It was reported to the Investigation Team that a regular education forum for consultants and non-consultant hospital doctors was in place which included mortality and morbidity, clinical presentations and clinical audit. It was mandatory for medical staff to attend this programme. However, at the time of investigation no formal record of attendance was maintained.

MGH was inspected by the Royal College of Physicians of Ireland in 2009 when approval for one specialist registrar (SpR) post in high intensity general internal medicine and one SpR post in gerontology in low intensity general medicine was granted.

3.6.3 Medical staffing

During normal working hours at MGH, consultants delivered direct clinical care and the Investigation Team was provided with examples to confirm this. The majority of these consultants had a whole-time appointment to MGH with a small number providing designated sessions in Cork University Hospital (CUH) or in other Cork City hospitals. As previously described, the consultants, excluding those in anaesthetics, were supported by a team of non-consultant hospital doctors (NCHDs).

Prior to the commencement of the investigation, the Authority raised specific concerns about the ability of MGH to ensure the continuous out-of-hours cover on the site by a registered medical practitioner with the appropriate training and experience to provide timely clinical decisions and immediate treatment for acutely ill patients. In particular, this related to patients requiring acute respiratory, circulatory and airways support. In response to this concern, a mandatory airways training programme was put in place in September 2010 at MGH for all NCHDs. At the time of the investigation, the HSE South reported that 56% of NCHDs had completed the course.

To effectively manage patients whose clinical condition is deteriorating, or patients with complex clinical requirements, it is essential that the system of care ensures timely decision making and emergency response by appropriately qualified clinical personnel. The Investigation Team reviewed the emergency and out-of-hours on-call arrangements at MGH.

Outside core working hours, care was provided to patients by an on-call team. At the time of the investigation, the on-call was provided on a rota basis by NCHDs, with medical registrar cover provided on three nights per week, the remaining nights at senior house officer (SHO) and intern grades with four surgical house officers covering the surgical on-call rota. At the time of the investigation the HSE South reported that the ongoing airways management training programme ensured that there was normally at least one doctor on site out of hours who has been trained in airway management. On-call consultants were available off site for out-of-hours consultation to the non-consultant on-call team. However, at the time of the investigation, this arrangement meant that experienced out-of-hours on-site clinical cover was not available for four of the seven nights at MGH.

It was reported by all the clinical staff interviewed that if a clinical need arose, consultant staff did remain on site if required. It was also reported that all consultants would provide out-of-hours consultations, or review the patients as the need arose, and informal arrangements were in place for consultant anaesthetists to stay on site as required.

However, it was acknowledged through interview at a regional and hospital level that this arrangement was solely dependent on the commitment of the current consultant staff and their willingness to provide this level of service. It was not part of a clearly described or organised system of care. This raises concerns

about the long-term reliability and sustainability of the system of care in its current configuration. It further raises concerns about the potential for risks to patient safety if there is no appropriately rostered on-site medical cover, out of hours of sufficient experience and seniority to treat undifferentiated patient groups who are in MGH, or attend MGH.

In order to maintain the level of clinical services at MGH, locum consultants were appointed to cover consultant holiday and study leave. Service providers should ensure that doctors providing consultant cover have the necessary professional registration, level of qualifications, knowledge, skills and competencies to perform as a locum consultant.

However, it was reported that during the holiday periods of the consultant surgeons, the surgical outpatient services and elective surgery were cancelled. Nonetheless, emergency surgery continued to be performed by the resident Emergency Department (ED) surgical officer who was providing locum cover for consultant surgeons. This was a historic arrangement which had not been corporately evaluated in the context of MGH providing emergency surgical cover. This arrangement was not satisfactory and posed a potential risk to the quality and safety of patients receiving that service.

As a result of this issue, and in the light of planned holidays of a consultant surgeon being brought to the attention of the Investigation Team, the Authority wrote to the Chief Executive of the HSE on 17 September 2010 raising concern about the locum cover arrangements (Appendix C). The HSE responded promptly (Appendix D) and arranged the required consultant locum cover.

At interview, the Investigation Team was told that the CUH Group medical workforce management function was responsible for the appointment and validation of the professional registration for medical staff including locum consultants at the MGH site. However, although the Investigation Team was told that this consultant surgical locum cover had been a longstanding concern among the clinical staff at MGH, this concern had not registered as a potential risk to patient safety at group or regional levels. This is not satisfactory.

This raises questions about the governance and risk management of the service to ensure safety for patients, an issue that will be discussed further in subsequent sections of this report.

3.6.4 Nursing staff

The investigation found that all nursing staff at MGH were employed as registered general nurses with specialist nursing staff having qualifications at higher diploma level in peri-operative care, critical care, emergency nursing, haemovigilance, infection control and tissue viability. The nursing staff were reported as having extensive clinical experience which was reported as an integral constituent in effectively supporting the consultant-delivered system of care as described at MGH.

MGH is an approved An Bord Altranais nursing training site. Consequently, bachelor of science nursing students are on clinical placement from University College Cork. They also participate in post-graduate nurse training programmes.

In keeping with the regional reconfiguration of acute hospitals and national emergency care strategies, MGH had successfully secured site approval to develop two posts of advanced nurse practitioner in emergency nursing. However, at the time of the investigation it was reported that funding had not been provided to action this development.

3.6.5 Summary of findings: workforce

The Authority found that the system of care at MGH was predominantly consultant delivered during core hours. If a clinical need arose outside these hours, consultants would remain on site and the consultants facilitated and responded in a supportive and timely manner by providing clinical advice and providing out-of-hours consultations to review the patient as the need arose. However, this arrangement was dependent on the commitment of the current consultant staff and their willingness to provide this level of service and was not part of a clearly described or organised system of care.

At the time of the investigation the 24-hour on-site arrangements at MGH did not ensure consistent out-of-hours senior clinical decision making. As previously identified in MWRH Ennis, and notwithstanding the commitment of consultant staff and the clinical experience of the nursing staff in MGH, this variability of medical cover and the dependence on informal arrangements raised concerns about the Hospital's ability to continue to deliver safe, high quality patient care reliably and sustainably on a 24-hour basis.

3.7 Conclusion: System of care at the Cork University Hospital Group's site at Mallow General Hospital

The Authority found that the system of healthcare and the clinical services provided at MGH had evolved in isolation over time and not as part of a planned and coordinated development that considered the Hospital as an integral site of the CUH Group for the delivery of services to patients in the southern region. This will be further discussed in the Governance section of the Report.

The system of care at MGH was predominantly consultant delivered during core hours. At the time of the investigation, outside core working hours, care was provided to patients by an on-call team. At the time of the investigation, the on-call was provided on a rota basis by NCHDs, with medical registrar cover provided on three nights per week, and the remaining nights at senior house officer (SHO) and intern grades. MGH provided elective and emergency inpatient and day care surgical services. However, the volumes of major complex cases was relatively low and the recent transfer of rectal cancer surgery in 2010 and the planned transfer of lower gastrointestinal (GI) surgery in 2011 will further decrease the volumes of patients requiring complex surgery.

This decreasing volume of complex surgeries will continue, with all major acute and major complex surgery ceasing at MGH with the planned HSE South reconfiguration of acute surgical services. This transition will incorporate the transfer of elective inpatient general surgical services currently provided at MGH to Mercy University and South Infirmary Victoria University Hospitals, the creation of a city-wide consultant surgical rotation to include the MGH consultant staff and the city-wide transfer all emergency surgical services to CUH. Day case procedures would be maintained at MGH under the reconfiguration process. The HSE must ensure that all major acute and complex surgery is ceased at MGH as intended, and that any risks in the interim of this change being implemented, are identified and managed **(SOC8)**.

National pre-hospital emergency care ambulance bypass protocols were in place. However, MGH provided undifferentiated walk-in 24-hour emergency services which represented around 50% of admissions. MGH did not have a formalised system of care to ensure on-site availability of out-of-hours senior clinical decision making to support this service. In addition, the critical care system of care did not have the capacity or capability to safely manage unstable patients requiring ICS level 2 or 3 critical care. A mandatory patient transfer protocol had been implemented in September 2010 to address this deficit after the Authority had raised the concerns that led to this investigation.

The current provision of acute services at MGH are dependant on the willingness of the clinical staff to provide the existing level of service and are not part of a clearly described or organised CUH group system of care. This raises questions concerning the Hospital's ability to continue to deliver safe care reliably and sustainably on a 24-hour basis. At the time of the investigation the absence of on-site senior clinical cover out of hours potentially presented risks for acutely ill patients attending the emergency department or inpatients whose condition deteriorated. Further to engagement by the Authority with the HSE South in relation to 24-hour senior clinical decision makers, the Authority was informed a new roster providing 24-hour seven-day on-site cover by medical registrars in MGH was implemented in February 2011.

3.8 Recommendations: System of care

System of care

SOC1. The HSE and all healthcare service providers must take prompt action to ensure that any hospital providing 24-hour, seven-days a week emergency care ensures that the system of emergency care includes immediate access to clinical triage and assessment, resuscitation and diagnostic support and full-time on site senior clinical decision makers with the required competencies. Where such arrangements are not achievable or sustainable, the HSE should make the appropriate arrangements to discontinue the emergency service.

SOC2. The HSE should, as a priority, agree and implement a national early warning score to ensure that there is a system of care in place for the prompt identification and management of clinically deteriorating patients.

SOC3. The HSE should develop a national suite of pre-hospital emergency care bypass protocols to ensure a safe system of emergency care. Arrangements should be in place for the routine collection, validation and reporting of data pertaining to the protocol. This information should be used to evaluate the effectiveness of the protocol, with areas for improvement identified and implemented.

SOC4. The HSE and all healthcare service providers must ensure that ICS level 2/3 critical care is delivered to patients at a unit where there are on-site senior clinical decision makers with the required competencies available. Where this is not achievable or sustainable, the HSE should immediately put in place the necessary arrangements to discontinue the critical care service.

SOC5. The HSE must take immediate action to put arrangements in place for the implementation of national mandatory patient transfer and acceptance protocols to ensure the immediate and safe transfer of critically ill patients to a unit providing ICS level 2/3 critical care. Consideration should be given to a national managed critical care network to optimise critical care capacity regionally and nationally.

SOC6. The HSE must put in place arrangements for the routine collection and evaluation of critical care services demand and capacity information to inform any planned clinical service change.

SOC7. The HSE and all healthcare service providers should ensure anaesthesia is delivered in a safe and appropriate environment in line with national and international best available evidence.

SOC8. The HSE and all healthcare service providers must review the current models of delivery of surgical services to ensure they are safe and sustainable. This review must take into account best available national and international evidence, the volume and complexity of surgical procedures and the required competencies. Where safe surgical services cannot be sustainably provided, the HSE should transfer the service and ensure the appropriate arrangements, facilities, and resources are in place to safely accommodate this transfer.

SOC9. The HSE should participate in a national programme for clinical audit that is designed to measure and improve surgical outcomes and ensure compliance with national and international best available evidence.

SOC10. The HSE and all healthcare service providers must put in place arrangements to ensure that clinical competencies are maintained.

4.0 Findings: Governance

4.1 Introduction

Corporate governance is the organisational framework that incorporates systems, processes and behaviours which support the workforce to do the right thing or make the right decision at the right time and demonstrate the provision, management and evaluation of a quality service. The system of governance should define local, regional and national reporting structures and identify clinical and managerial lead persons accountable for effective, timely decision making, risk management, service evaluation and delivery. It includes defined accountability and responsibility for shared delivery of services to patients **(G1)**.

Clinical governance is a system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care is provided and will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

Effective governance arrangements recognise the inter-dependencies between corporate and clinical governance across the service and integrate them to deliver high quality, safe and reliable healthcare **(G2)**.

The absence of effective governance implies a system of care solely dependent on the degree of professionalism or commitment of individuals to ensure services are safe and of high quality. This is not a safe or reliable model for patients. Experience internationally and in Ireland suggests that, over time, this leads to services that are less safe, less accountable and less able to improve and manage change. The Authority's Ennis Report emphasised the importance of robust leadership, clear accountability and effective clinical and organisational governance.

The following chapter outlines the governance arrangements in three distinct areas:

- **local** – at the hospital level including in Cork University Hospital Group (incorporating Mallow General Hospital).
- **regional** – at operational service levels with the HSE South Region
- **national** – at HSE national level to clarify the national and local implementation of recommendations in the *Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis*.

4.2 Governance arrangements at the CUH Group (incorporating MGH)

The CUH Group consists of Cork University Hospital, Cork University Maternity Hospital, St Mary's Orthopaedic Hospital and Mallow General Hospital. The Chief Executive of the CUH Group has accountability and responsibility for the delivery of services and budgetary management. The Chief Executive is therefore directly accountable for clinical and financial outcomes and for the safety and quality of care delivered in the CUH Group. The Chief Executive reports to the Integrated Services Manager, who in turn reports to the Regional Director of Operations in the HSE South.

The Investigation Team explored the relationship, in governance terms, between MGH and the CUH Group. Whilst all four hospital sites within the group fall within the same governance structure, it was identified during the investigation that there was a disparity in the governance and reporting relationship of Mallow General Hospital site within the CUH Group structure to that of the other hospital sites.

The HSE identifies MGH as a constituent of the CUH Group, and it was reported to the Authority in the course of the investigation that the planning of the Group's services provision was regionally determined in consultation with the Group's executive. However, despite being part of a recognised hospital grouping, the clinical services and systems of care at MGH have evolved in isolation and were not planned as part of an integrated hospital group system. The disparity in the communication and coordination of HIPE data within the CUH Group to include MGH raises a question as to how a service within a group governance structure can be effectively managed in the absence of timely validated performance data **(G3)**.

In terms of local governance arrangements, Cork University Hospital had an established Executive Management Board (EMB) whose membership consisted of the CUH Group's Chief Executive, Director of Nursing of CUH and three CUH clinicians, one of whom was the CUH Group's Clinical Director.

The EMB is the primary decision-making forum for strategic and operational planning for the CUH Group. It was confirmed at interview that the EMB receives reports from the management team, the 15 clinical divisions and the clinical governance division. St Mary's Orthopaedic Hospital is represented at the EMB through the clinical division structure. However, there was no formal representation of the MGH site at the CUH EMB.

At the time of the investigation, the CUH Group's Chief Executive had delegated responsibility for the MGH site to the CUH Group's Acting General Manager, and the Investigation Team was informed that regular meetings between the Chief Executive and the Acting General Manager took place – although no documentary record of these was available. Operationally, MGH is represented by the Acting General Manager on the CUH senior management team. Nevertheless, at the time of the investigation there were no formal integrated clinical and managerial structures at MGH to report to CUH Group regarding performance of clinical services, clinical risk management or the safety and quality of care delivered at the MGH site. In addition,

at the time of the investigation MGH did not have representation on the Clinical Governance Committee or on any of the 15 Quality Improvement Teams at CUH.

On site at MGH, the Hospital Manager, who reported to the CUH Group's Acting General Manager, is responsible for administration, allied health professionals, laboratory and radiology services. The Director of Nursing (DON) was responsible for nursing and support services.

Prior to 2006, there had been an EMB in MGH whose membership consisted of the then CUH Group's Deputy General Manager, MGH Hospital Manager, Director of Nursing and consultant representatives. During interview, it was reported to the Authority that the EMB at MGH had been disbanded in 2006. The CUH Group's Deputy General Manager, the MGH Hospital Manager and Director of Nursing had continued to meet as an senior management team at MGH to discuss operational issues. This meant that for a number of years there had been little clinical input through any formal mechanism to the leadership of services on the MGH site of the CUH Group.

In May 2010, a senior management team was established in the MGH site whose membership consisted of the CUH Group's Acting General Manager, MGH Director of Nursing, Hospital Manager, a Consultant Physician representing the Consultant's Committee and a Consultant Anaesthetist representing a newly formed Quality, Safety and Risk Committee. The terms of reference of the team related to the strategic issues and hospital-wide operational planning for MGH. The Quality, Safety and Risk Committee had held its inaugural meeting immediately prior to the commencement of the investigation.

At the time of the site inspection, these structures had only been recently established and it was too soon for the Authority to judge their effectiveness. However, it was clear that despite being a part of the CUH Group, MGH had been operating outside the governance structure of the Group, and had been directly accessing the HSE South regional structures particularly in regard to clinical risk management.

4.2.1 CUH Group governance and MGH clinicians

It was confirmed during the course of the investigation that the MGH Hospital Manager reported to the CUH Group's Acting General Manager and was responsible for allied health professionals, laboratory scientists and radiographers.

The MGH Director of Nursing and consultants contractually reported to the Chief Executive of the CUH Group. These contractual reporting arrangements had not been formally amended to reflect the delegation of responsibility to the CUH Group's Acting General Manager. Consequently, at interview, the Authority found there was a variance in the understanding of these reporting arrangements.

In 2009, a clinical director had been appointed for the CUH Group and at the time of the investigation the MGH consultant staff reported professionally to the CUH

Group's Clinical Director. However, at the time of the investigation the MGH's recently appointed consultant in radiology held a joint appointments with the CUH Group and the Mercy University Hospital. This resulted in this consultant reporting professionally to different clinical directors and working within differing corporate governance structures.

In addition, it was reported during the investigation that dedicated administrative and clinical support arrangements were not in place to facilitate the effective fulfilment of the responsibilities of the Clinical Director **(G4)**.

The clinical relationships between MGH and other CUH Group teams were described to the Investigation Team as good on a personal level. Clinicians met informally and had also built good relationships with colleagues in other local and national hospitals over the years. However, at the time of the investigation there were no governance structures or formal arrangements within the CUH Group for the MGH clinicians to discuss clinical cases or issues in relation to operational clinical matters, for example, the cross-site care and transfer of critically ill patients.

This lack of a clearly defined clinical governance structure was a matter of concern in the context of a service for acutely ill patients that depends on the safe and effective transfer of care between MGH and CUH. The Authority has previously made recommendations in the Ennis Report about the benefits of group-wide appointments for consultants and other staff. In the context of planned service change, it is not sustainable for a small number of consultants to be appointed solely to a small hospital such as MGH.

4.2.2 Clinical audit

Clinical audit is one of the most important methods that any healthcare organisation can use to understand and assure the quality of care it provides to patients. It is the principal method used to monitor the quality of clinical care and when integrated into a wider set of processes it can provide a powerful means for ongoing quality improvement, identifying incidents when standards are not met and highlighting opportunities for improvement.

The Investigation Team was told that there were monthly mortality and morbidity meetings where patient deaths and complications were reviewed by the clinicians. However, this could not be verified as records of these meetings were not kept. Nevertheless, the Investigation Team was provided with examples of MGH-specific clinical audit activities which included, for example, critical care, surgical audit of elective and emergency care, outpatient attendances, comparing co-morbidities and age of medical patients, use of thrombo-prophylaxis, pressure ulcer point prevalence, infection control including hand hygiene and antibiotic usage. Evidence was submitted and reviewed which verified that clinical audit activities at MGH led to changes aimed at improving the delivery of clinical services. The Investigation Team was informed that the selection of clinical audit topics was prioritised by the consultant staff and Director of Nursing according to an assessment of risk.

In the CUH Group governance system, all of the 15 clinical divisions had associated Quality Improvement Teams. Clinical audit was supported by, and reported through, the clinical governance structure. However, as MGH was not represented as a clinical division it was not a part of the CUH Group clinical governance structure. This had resulted in no allocation of support or resources from the CUH Group to support MGH's clinical audit activity. More importantly, there were no formal arrangements to facilitate the comparison of patients' clinical outcomes across the sites.

4.2.3 Policies, procedures and guidelines

The Investigation Team reviewed a number of MGH clinical policies, procedures and guidelines (PPGs). However, at the time of investigation MGH had only recently established a centralised organisational structure, through the Quality, Safety and Risk Committee, to formally develop, approve, disseminate and evaluate these. However, there were no formal structures to link MGH with the PPG development system in the CUH Group which resulted in the development of separate PPGs.

The regional emergency care procedure manual, which was developed by the Regional Emergency Care Network and outlines the regional ED PPGs, was in use in MGH. At the time of the investigation MGH was not formally included in the regional ED network and consequently there was no formal evaluation system in place to monitor compliance with the required procedures.

It was reported in interview to the Investigation Team that an information management system was recently introduced at CUH Group. This system was primarily a compliance management solution to identify opportunities for improvement whilst facilitating the centralisation and dissemination of PPGs, audit, incident and document management. However, this system was not available at MGH and the Investigation Team identified no effective arrangements to ensure that corporate PPGs were disseminated and monitored throughout the CUH Group to include MGH.

4.2.4 Complaints management

A responsive complaints and concerns management system provides an essential pathway for patients and their relatives to question and understand what has happened to them. Engaging with service users in the complaints management process to ensure any resolution is satisfactory from both a service provider and service user perspective is imperative. In addition, it promotes accountability, affords the service providers with an opportunity to learn how the system of care could be improved and make decisions to implement change where required.

At the time of the investigation there was no record of any outstanding complaints at MGH. The Hospital Manager acted as the complaints officer in MGH. The Investigation Team was informed that the Hospital had implemented the national HSE comments, complements and complaints policy *Your Service Your say*[20] and had developed a supporting local complaint management process.

For the first six months of 2010, MGH had a total of eight complaints. While the Investigation Team did not meet with those who had made complaints, MGH informed the Authority that all of these complaints had been resolved. Up until June 2010, MGH did not have a formal forum to review patient complaints, monitor trends or follow through the resultant actions. However, at the time of the investigation the recently formed Quality, Risk and Safety Committee was identified as assuming responsibility for this.

Nonetheless, as MGH was not part of the CUH Group governance arrangements, the Authority concluded that the complaint management arrangements at MGH lacked sufficient engagement with, and support from, the complaints management governance structures of the CUH Group.

4.2.5 Risk management

Risk management is the systematic identification, evaluation and management of risk. Providers must ensure that every effort is made to avoid harm to patients by providing safe systems of care that minimise risks. In previously published reports the Authority identified robust risk management and complaints processes, which include the provision of appropriate staff training, as being integral to the delivery of a safe quality health service.

MGH did not have its own risk manager. At the time of the investigation, MGH accessed risk management training and support through the offices of the HSE Regional Network, rather than the CUH Group systems. During the investigation, training had started for MGH staff to commence, identify and complete a risk register. In addition, at the time of the investigation MGH had adopted the draft 2007 CUH incident reporting policy.

Incident management was primarily managed through the office of the Director of Nursing. Interviews indicated that this was a reactive process primarily through the incident reporting system. Incidents were entered on to the STARSweb system and these reports were sent for review on a quarterly basis to the Senior Management team at MGH. For the first six months of 2010, it was reported that MGH had no serious clinical incidents, 12 low-level clinical risk incidents and 62 low-level patient safety incidents reported. Through documentation review, the most frequent incidents recorded at MGH were slips, trips and falls – which would be similar to the national picture[21]. As a result of this, MGH had initiated a patient falls prevention programme which included staff training, patient assessment and information processes.

A Quality, Safety and Risk Committee had been established in MGH in June 2010. The terms of reference for the Committee pertained to the development and implementation of the clinical governance programme at Mallow General Hospital. This Committee consisted of the Director of Nursing, Hospital Pharmacist, Radiology Services Manager, Laboratory Manager, General Practitioner, a Consultant Physician, Hospital Manager and was chaired by a Consultant

Anaesthetist. Members of the CUH Group's clinical governance structure did not provide any formal support to the Committee with the Regional HSE Risk Advisor providing this function.

The policy of the HSE is 'to operate an integrated process for the management of risk' [22] This includes the development of a risk register to facilitate the identification of and mitigating action to deal with identified risks. Regionally, each local risk register is aggregated and reported nationally to the HSE to inform the national allocation of resources and the design of improvement plans to manage risk. At the time of investigation, MGH did not have a risk register – therefore the CUH Group did not have a formal process in place to overview the risk status of MGH or monitor any actions taken to mitigate risk or share learning. In addition, this omission implied that MGH was not included in the nationally submitted regional aggregated risk register which is indicative of a weakness in the governance structure at a hospital, regional and national level **(G6)**.

Overall, the Authority was not satisfied that these arrangements were sufficient to provide a comprehensive proactive risk management system at MGH and concluded the processes lacked sufficient engagement with, and support from, the risk management governance structures of the CUH Group. Similarly, the integration of all risk management systems would corporately and regionally facilitate a more patient-focused approach, supporting accountability through systems and processes which in turn would enable better decision making about what needs to be done in order to minimise risk and thereby provide greater assurance as to the quality and safety of services for patients.

4.2.6 Radiology

It was reported that the full time consultant radiologist post at MGH had not been filled for over seven years, with a number of locum consultant staff providing radiology services. At the time of the investigation a full-time permanent consultant radiologist had been recently appointed at MGH. The Authority has previously recommended that the HSE should review workforce planning at national and local levels to ensure that recruitment of consultants is more responsive to service needs and reliance on temporary staff is minimised. This principle remains relevant and the HSE should put measures in place to avoid long-term locum appointments, including creation of group-wide clinical departments.

During the course of the investigation, the Authority was made aware of two separate radiology related concerns. These involved suspected radiological reporting discrepancies dating from 2008 to 2009. Through review of documentation and interviews, the Authority found that independent reviews of the potential concerns had been facilitated in late 2009 by the Hospital Manager in MGH and the Regional Network Manager's Office. This approach, one of which was external to the governance structures of CUH, further exemplified the absence of effective risk management structures within the CUH Group in relation to its site at MGH.

The Investigation Team had concerns that the approach taken to respond to both of these concerns had not been not conclusive from the perspective of patient safety, scope of investigation, involvement of consultant staff in MGH, or appropriate follow up of findings.

Accordingly during the course of the Authority's investigation, the Authority initiated a parallel process of engagement with the HSE South, to ensure that a full formal review of the concerns raised was completed. This was subsequently conducted by the HSE South, with outside advice from the Faculty of Radiology, with progress reported to the Authority through a series of submitted action plans.

It is important to note it is recognised that within radiology, as in any clinical reporting system, a certain level of reporting discrepancies are inevitable.[23-25)] The full formal review of both concerns – commissioned by HSE South following the Authority's request – reported that the number of clinically significant discrepancies within the reviewed sample was within normal limits.

The locally commissioned review confirmed that one reporting discrepancy had led to one delayed patient diagnosis. No other adverse incidents were identified in the review. However, the review concluded the one identified delay had not adversely affected the prognosis of the patient concerned. At the time, the HSE decided not to engage in a formal communication process with patients or their families. The Authority does not agree with the approach taken and expects that patients and their families should receive honest, open and timely communication about adverse events that may have caused them harm **(G8)**.

In order to be assured that the approach taken by HSE South was sufficient to have identified any areas of concern, the Authority sought the advice from the Expert Advisory Panel in relation to the methodology undertaken in the initial review of these incidents. Based on this advice, the Authority was satisfied that the incidents had been adequately reviewed, follow-up actions taken and that there was no significant residual risk to patient safety.

However, the Authority was concerned at the lack of a clear process used by MGH, CUH Group or HSE South to ensure the incidents were reviewed according to best available evidence. Additionally, no clear actions had been identified to follow through any potential risks to patients as thoroughly as possible, and the formal conclusion of this process had only been commenced in direct response to the Authority raising the need for this to happen. This raised further concerns about the resilience of risk management systems as they relate to MGH and more widely within HSE South.

4.2.7 Summary of findings: governance arrangements in CUH Group (incorporating MGH)

Given the importance of effective governance in the delivery of safe, reliable and sustainable healthcare services, the Investigation Team looked in detail at the arrangements in the CUH Group, specifically as they related to MGH. Although

the Chief Executive of CUHG had delegated responsibility for MGH to the Acting General Manager, throughout this part of the investigation, it was notable that, although part of the CUH Group, MGH sat outside the majority of the most relevant and important governance arrangements. This was described to the Authority by one individual as a 'fractured' governance relationship between MGH and the CUH Group. The use of this description was reinforced by a range of findings by the Investigation Team. These included:

- absence of a formal representation of MGH at executive and governance level in the CUH Group through the clinical division structure
- reported challenges in effective communication from MGH with the required personnel at CUH in relation to the transfer of critically ill patients requiring intensive care
- absence of a formal relationship established with CUH for the reporting and management of risks at MGH
- disparity in the communication and coordination of HIPE data within the CUH Group.

At the time of the investigation, steps were being actively pursued to address the inclusion of Mallow General Hospital within the CUH Group structure. However, it was acknowledged at interview that these were at the early stages of development and a formal action plan had not been developed. Actions which had been taken around the time of the investigation included the:

- re-establishment in May 2010 of the senior management team at MGH to include representation from the MGH consultant staff and the CUH Group through the Acting General Manager
- formalisation in September 2010 of the role of the Acting General Manager as a MGH representative at the CUH Clinical Governance Committee
- invitation in September 2010 of a Mallow General Hospital representative to the CUH Quality and Safety Policy Evaluation Group (QSPEG), with extension to the Clinical Governance Committee
- introduction in September 2010 of a mandatory acceptance policy by CUH for the receipt of critically ill patients requiring ICS level 3 critical care.

It should, however, be noted that many of the above measures were initiated within the timeframe of the Authority commencing the investigation. In the absence of a formal approach and monitoring process by the CUH Group for the inclusion of MGH within the Group governance structure, the Authority concluded that there is substantive risk that current efforts to address this deficit would falter.

Whilst these structures and practices had started to be actively addressed by the CUH Group and MGH at the time of the investigation, through the initiatives outlined above, the Authority concluded that these processes lacked sufficient engagement with and support from the governance structures of the CUH Group.

There is a long established history of MGH being treated and behaving as a stand-alone entity, rather than as part of a coordinated group. Changing this will require clear leadership, strong and effective management and a concerted commitment from all concerned. It must be recognised that a cultural shift is required and this must be proactively considered and managed in any changes undertaken.

Specific to the implementation of the MWRH Ennis recommendations, at the time of the investigation the CUH Group had not formally reviewed the local implications of the MWRH Ennis Report in relation to the recommendations and the impact of these in the provision of safe quality patient services within the CUH Group, including MGH. In this context, and in light of proposed service change as part of reconfiguration plans, it is of serious concern that MGH had continued to effectively operate as an isolated entity until very recently.

4.2.8 Conclusion - governance arrangements at CUH Group (incorporating MGH)

There was a lack of robust and effective governance arrangements, risk and complaint management within the CUH Group's governance structures to include MGH. Consequently, the clinical services provided at MGH were not corporately supported within the CUH Group clinical division structure. As a result, the CUH Group had not reviewed the implementation of the MWRH Ennis Report recommendations in relation to the recommendations and the impact of these in the provision of safe quality patient services within the CUH Group, including MGH.

In addition, the HSE regional governance arrangements did not have effective controls in place to ensure the efficacy of the clinical governance arrangements at the CUH Group to include Mallow General Hospital.

4.3 Regional (HSE South) governance arrangements

The range of health and personal social services provided by the HSE, and its funded agencies, are managed by four Regions (Dublin Mid-Leinster, Dublin North East, South and West). The regional structure for the HSE South as reported by the HSE assigns a defined reporting relationship between the Regional Director of Operations (RDO), South, to the National HSE Director of Performance and Financial Management and the Director of Reconfiguration. The RDO is in turn responsible for the operational functions of the HSE South (finance, HR and communications), service management and reconfiguration, with supporting reporting arrangements in place to the RDO from each of the respective divisions. This structure was formally implemented in 2010. Prior to that, the regional operational structure was described as a regional network with a Network Manager holding operational responsibility.

The Investigation Team primarily explored the regional governance arrangements pertaining to the:

- implementation of the MWRH Ennis Report recommendations
- governance relationship with Mallow General Hospital.

The investigation found that the MWRH Ennis recommendations, and the impact of the report in relation to the safe delivery of patient care within the region, were regarded within the HSE as a component of the national reconfiguration of acute services by the HSE.

During the course of the investigation, it was confirmed that the Regional Director of Operations for the HSE South had an established working relationship with the National Director of Performance and Financial Management and the National Director of Reconfiguration. The RDO also works closely with the National Director of Quality and Clinical Care. The latter two relationships were not reflected in the organisational structures submitted by the HSE during the course of the investigation.

At the time of the investigation, national scheduled meetings had been established, attended by the above National Directors, national care programme leads and regional reconfiguration leads. It was reported at interview that this forum had been established for the purposes of formal communication and to ensure alignment of national and regional programmes of work.

As this formal forum was only recently established, the effectiveness, governance and engagement within the forum should be monitored and evaluated on an on-going basis.

Within the HSE South region, a regional management team had been established. Specific to reconfiguration, whilst the organisational structure identifies a Director of Reconfiguration for both the South West (Cork/Kerry region) and South East (Waterford/Tipperary/Kilkenny regions), at the time of the investigation, the Director of Reconfiguration HSE South West was in post. It was confirmed at interview that the Director of Reconfiguration participated at regional meetings, had a formal reporting relationship to the RDO in aspects relating to reconfiguration, and to the Cork University Hospital Group Clinical Director for clinical work.

During the investigation, the scale of engagement and communication at a regional level appeared to be extensive, with the reconfiguration process alone having established 33 clinical groups and six functional groups in the HSE South. From the range of interviews conducted, there was generally a positive response expressed by a number of interviewees to the approach taken at a regional level of the reconfiguration process

The reconfiguration of acute services identified an extensive reorganisation of the system of care currently delivered in the HSE South with a vision of acute hospitals offering varying degrees of clinical services depending on the complexity

of patient care each hospital provides. It was reported that the intention was to align the regional change process with the national care programme. At the time of the investigation the Reconfiguration Steering Group had published a roadmap to develop an integrated acute hospital network. However, though the roadmap identified some priority reconfiguration programme there was no definite timelines or published implementation plan with aligned evaluation controls.

In addition, there was no evidence to indicate that the HSE South regional structure had in the interim risk assessed, and where appropriate initiated, any remedial action to mitigate identified patient safety concerns within hospitals with a similar profile to MWRH Ennis.

4.3.1 Conclusion: Regional (HSE South) governance arrangements

During the course of the investigation the Authority was provided with documentary evidence of the governance structures in place regionally, within the CUH Group and locally at MGH. Whilst these structures illustrated defined governance structures, a variance in understanding and in practice was identified during the course of the investigation.

At a local level, at the time of the investigation governance structures had been recently enhanced through the establishment of a senior management team and a Quality, Safety and Risk Committee. Whilst the benefits of these structures were reported during the course of the investigation, they are very new and should be reviewed and evaluated on an ongoing basis to ensure that they are fit for purpose and facilitate good governance at Mallow General Hospital as part of the wider Hospital Group.

Within the CUH Group, there were defined governance arrangements within Cork University Hospital itself. However, Mallow General Hospital did not appear to benefit from or contribute to the overall governance of the Hospital Group. This was being addressed by the Group during the course of the investigation, however, in addition to the formal changes which were taking place, there was a considerable cultural shift needed to ensure the sustainability and effective functioning of the revised governance structures. A formal action plan to address the intended changes should be developed.

At a regional level, there had been historical informal relationships between MGH and the HSE regional network structure in response to underdeveloped governance structures for MGH within the CUH Group. The Authority recognised that this was in the course of being addressed at the time of the investigation and recommends that this is formally supported as required through the HSE Regional Office to ensure a shared understanding of the revised governance structures.

In summary, it was evident throughout the course of the investigation that MGH had been essentially absent from the governance structures within the Cork University Hospital Group for a number of years. An effective, safe quality system of care is dependent on clear, responsive governance. A well governed system in CUH Group should have had robust governance arrangements which included MGH to ensure the clinical and corporate inter-dependencies were integrated to promote the delivery of a high quality, safe and reliable system of healthcare across the four CUH Group sites.

The HSE at a regional level and the CUH Group at a local level should not have allowed this situation, irrespective of the historical reasons, to have continued, especially in light of national recommendations from the Authority identifying potential risks relating to the care of acutely ill patients in hospitals similar to MWRH Ennis, of which MGH is one.

It is imperative that effective corporate and clinical monitoring and evaluation processes are implemented to support the ongoing delivery of safer, better healthcare for patients by the HSE at local, regional and national level. This is particularly important in the course of planned service changes.

4.4 Governance: Implementation of recommendations of MRWH Ennis Report

As detailed previously, the Authority launched this investigation into the services and supporting arrangements at MGH following concern that the Authority's previous recommendations from a national report, intended to mitigate risks to the safety of acutely ill patients attending hospitals like Mallow General Hospital, had not been fully or systematically implemented by the HSE. In the course of the Authority's previous investigation into the quality and safety of services and supporting arrangements provided by the HSE and the Mid-Western Regional Hospital Ennis (the Ennis Investigation), a series of potential risks were identified associated with small, stand-alone hospitals treating acute (including emergency) patients.

The report highlighted that such hospitals, receiving acutely ill patients, need to be able to rapidly escalate the level of treatment or support they provide and ensure that this is provided by readily available clinical staff with the right level of experience to safely manage their care at any hour. It was recommended that this should be achieved by expressly limiting the types of patients with particular conditions who would be treated in such a hospital and that such smaller hospitals should be managed and organised as part of a wider network that included the major regional centre.

Other issues of concern were the low volumes of activity for clinical staff to maintain their technical skills, the absence of a clear definition of what level of care and support a hospital can provide safely and the acceptance of all medical patients by small hospitals without any measures in place to prevent patients with serious, complex or unstable conditions attending there.

The Authority's report made a number of recommendations with local (to the Mid-West) and national implications for the wider HSE. Importantly, the Ennis Investigation Report recommended that the HSE should systematically review services in all hospitals similar to MWRH Ennis (which includes MGH) with a view to identifying whether specific services were as safe as possible. The recommendations made it clear that, in hospitals where configuration changes are needed, appropriate clinical risk management measures should be put in place until those changes have been introduced.

In line with its terms of reference, this investigation into the quality and safety of services and supporting arrangements provided by the HSE and MGH, sought to ascertain what measures were taken by the HSE to consider and implement the national recommendations of the MWRH Ennis Report, since its publication in April 2009, and specifically whether risks to patient safety inherent in the service model at Mallow General Hospital had been identified, assessed and mitigated where necessary.

This section sets out the Authority's findings in respect of these issues.

4.4.1 National governance structure within the HSE

The HSE Board is ultimately accountable to the Minister for Health for the provision and commissioning of services provided by, or on behalf of the HSE, its stewardship of public funds and the extent to which key performance targets have been met. The HSE Chief Executive reports to the HSE Board. It should be noted that in September 2010, following the start of this investigation, a new Chief Executive for the HSE took up post.

In October 2009, six months after the publication of the MWRH Ennis Report, the HSE implemented a number of organisational changes which led to the abolition of its National Hospitals Office and Primary, Community and Continuing Care (PCCC) Directorates and the establishment of an Integrated Services Directorate (ISD) and a Quality and Clinical Care Directorate (QCCD).

At the same time, the post of national director responsible for service reconfiguration was created to oversee and bring cohesion to the various regional approaches to this agenda which were, and remain, at various stages of progress. This role was given as an additional role to an existing national director.

The post of national director for the National Cancer Control Programme remained in place as part of this re-organisation.

The organisational changes also saw the introduction of the posts of four Regional Director of Operations (RDOs), reporting to the national director for Integrated Services, to be the ultimate accountable officer for all health services in each region. These posts were appointed in early 2010.

In November 2010, during the course of this investigation it was announced that this new structure was to undergo further change through the appointment of

a Chief Operations Officer, and a restructuring of the Quality and Clinical Care Directorate into two separate directorates: one responsible for Quality and Risk and the other responsible for Clinical Care.

Following publication of the MWRH Ennis investigation Report, the Authority recommended that progress against the recommendation-implementation plan be made public and be reported to the Board of the HSE with regular progress reports to the Minister for Health and Children. At the time of the investigation, the HSE had published one formal progress report against implementation of the national recommendations[26] and the local recommendations as they related to the MWRH Ennis and it was reported by the HSE through documentation that progress reports had been made available to the Minister for Health and Children. However, while there was ongoing engagement between the Authority and the HSE since the publication of the report, in the absence of formal arrangements for reporting against the recommendations, the HSE was unable to demonstrate that the recommendations and their implications had been considered for Mallow General Hospital, with risks to patient safety inherent in the service model at the Hospital having been identified, assessed and mitigated.

4.4.2 Accountability for implementation of national and local recommendations

The Authority's Ennis Report recommended that the HSE Executive Management Team should nominate a specific director accountable for ensuring the development of an implementation plan for the recommendations, to include a clear timeframe with milestones and that this should be made public and reported to the Board of the HSE. Prior to its corporate re-organisation, the National Director identified as accountable for developing an implementation plan was the then Director of the HSE National Hospitals Office (NHO). Subsequently, this responsibility was delegated to the HSE's newly appointed Director of Quality and Clinical Care.

However, whilst this national director had responsibility for developing an implementation plan, clearly all national directors bore some responsibility for implementation, given the nature of the Ennis Report recommendations which encompassed clinical care models, service configuration and day-to-day clinical risk management.

The Authority recommended a clear implementation plan with a clear timeframe and milestones. This would require defined arrangements for the coordination of the delivery of the implementation plan between the different national directors and effective arrangements for the dissemination of responsibility for implementation to the local level.

Individuals interviewed as part of the investigation indicated that this coordination of responsibilities between national directors happened predominantly at the HSE Senior Management Team meetings. However, it was also conceded that the

integration between the different national functions was not always as effective as it could be, in the context of extensive organisational change. It was also acknowledged that the dissemination of responsibility for implementation of the recommendations to local level through the regions had been variable, as had been the subsequent ability to get information back from the regions on local arrangements for implementation.

This view was supported by the Authority's findings at local level where it found in HSE South that responsibility had not been clearly delegated and there was little evidence that the recommendations had been formally disseminated at regional and local levels, with no formal process in place for assessment of the implications of the recommendations. During this time of organisational change, the process for due diligence handover of accountability and responsibility for the implementation of the recommendations, from national to regional level, had been fragmented as staff moved into new roles.

The report now explores the respective roles of the new directorates in implementing the Ennis Report recommendations.

4.4.4 Quality and Clinical Care Directorate

The Quality and Clinical Care Directorate (QCCD) was established to help improve patient care throughout the health system by defining how health services are delivered, measured and resourced. The QCCD had not yet been established at the time of the publication of the MWRH Ennis Report. However, it was reported at interview that the report's national recommendations did inform the overall agenda of the Directorate in its formation in June 2009.

At the commencement of the QCCD in June 2009, an initial focus was taken to develop the necessary documentation and capacity to deliver change, including the implementation of the MWRH Ennis Report recommendations.

In its approach, the QCCD adopted a programmatic approach through the formation of 20 clinical programmes, led by clinical leads. It was reported at interview that the initial areas of focus for these programmes were based on the recommendations of the MWRH Ennis Report and additional identified risks within the service such as delays in outpatient waiting times and chronic disease management.

This approach also sought to describe a clear national acute medicine hospital model[14] in line with Recommendation 5.4 from the Ennis Report. At the time of the investigation, the operational implementation of this model was yet to commence, although preparatory 'diagnostics' in some hospitals had taken place as an initial assessment phase for the implementation of the models.

It was reported at interview that the implementation of the work of the Acute Medicine Programme was expected to commence in 2011 and this is supported by the HSE 2011 Service Plan[26]. However, it was highlighted during the course

of the investigation that the scale of the change to be implemented across the healthcare system had required extensive stakeholder engagement and change management in tandem with developing sufficient capacity within the QCCD as a newly formed Directorate.

It was confirmed at interview that this period of change and establishment of new structures (and the time taken to do so) was an essential step needed before implementing the findings and recommendations of the MWRH Ennis Report. Notwithstanding the change and stakeholder engagement required, it is the view of the Authority that, in the interim, insufficient focus was placed by the HSE on ensuring effective clinical risk management processes were in place to identify, assess and manage the potential risks to patients in advance of longer term changes. This point will be expanded upon later in the report.

4.4.5 Integrated Services Directorate

The Integrated Services Directorate: Performance and Financial Management was established in October 2009 as part of the HSE's management restructuring to enable integration of services. It has responsibility for the delivery of all health and personal social services including hospital, primary, community and continuing care services. The management of this is delegated through the four regional structures with a Regional Director for Operations (RDO) for each region reporting directly to the National Director of Performance and financial Management. Within each region there will be several designated areas called Integrated Services Areas (ISAs) some of which had been established at the time of the investigation, although not in the HSE South.

It was reported that a key objective of the Integrated Services Directorate was the implementation of the national reconfiguration of acute services.

4.4.6 Reconfiguration process

It was reported to the Investigation Team that the reconfiguration process was commenced by the HSE in order to build a sustainable health service with patient safety and quality care at its core, through the integration of hospital and community services to ensure services are integrated within and across each area.

Since 2008, the HSE had established a number of regional reconfiguration programmes – each under the leadership of a senior clinician. The stated intention of these programmes was aimed at delivering a plan for service configuration to address the safety and sustainability of hospital services. However, some interviewees expressed the view that there had been a disjointed approach as the reconfiguration programmes had commenced in advance of the national organisational restructuring of the HSE in June 2009. In addition, one view expressed at interview to the Investigation Team was that across the system, some local managers were wary of introducing local changes in response to risks for fear of this being interpreted as pre-empting or 'railroading' reconfiguration.

During the course of the investigation, it was reported that there had been concern in 2010 in relation to the effectiveness of the overall coordination of the reconfiguration projects. Consequently, different criteria may have been used to decide what services were appropriate in different regions. To address this, a national director for reconfiguration was appointed to bring greater cohesion and coordination to these projects.

At the time of the investigation, reconfiguration was a separate entity to the work of the clinical programmes under the QCCD and operational delivery through the ISD directorate. Whilst all divisions of the HSE are responsible for delivering aspects of the significant change to the health system, at the time of the investigation a forum for the programmes of change to be discussed had only recently been established. This had contributed to a disjointed approach to change, with a variable understanding across the health system as to the reconfiguration process.

Additional protocols were introduced to formalise the alignment of the change process and implementation strategies of the reconfiguration process. This included the approval of regional reconfiguration plans by the National Director for Reconfiguration and the National Director of the QCCD. However, it was reported at interview that these protocols were in the early stages of implementation.

4.4.7 Integration between HSE Directorates

During the course of the investigation, and in consideration of the necessity of complete integration of the programmes of work delivered by each of the above Directorates, the investigation team noted potential weaknesses in the communication and alignment of the work of the Directorates. This included the:

- commencement of reconfiguration process by the Integrated Services Directorate in advance of the Quality and Clinical Care Directorate being fully established
- responsibility for the implementation of the MWRH Ennis Report recommendations traverses Directorates with possible overlap and/or duplication of effort across parallel programmes which may be at the risk of becoming misaligned or at cross-purposes
- relationship between the Quality and Clinical Care Directorate, reconfiguration and Integrated Services Directorate at an early stage of development and the associated potential challenges in the alignment of the change process and implementation strategies of the reconfiguration process **(G7)**.

The investigation identified that the HSE placed an over-reliance on strategic change as the answer to all the issues raised in the Ennis Report at the expense of focusing on managing current clinical risks to patients on a day-to-day basis.

Notwithstanding the intention of the people leading these programmes to be aligned, the findings of the Investigation Team identified that there had been no

structured process for driving implementation of the Ennis Investigation Report recommendations to the local level other than in the HSE Mid-West. This meant that, on the ground, key risks to acutely ill patients were not systematically understood or addressed 18 months after they were highlighted by the Authority's national report. This is an unacceptable situation, the consequences of which are now further explored in this report.

4.4.8 Progress with implementation of the Ennis Investigation Recommendations

Following publication of the MWRH Ennis Report in April 2009, the Authority recognised that its recommendations had significant implications across the healthcare system and that developing an action plan for implementing them would take time. Consequently, the Authority had a number of meetings with the HSE to discuss progress in formulating its implementation plans. In the course of these discussions, the Authority was given some updates as to progress which centred predominantly on the HSE Mid-West.

The HSE published its first and only public progress report against implementation of the national recommendations, and the local recommendations as they related to the MWRH Ennis, in February 2010[26]. However, this report also focused mainly on the HSE Mid-West with reporting against national recommendations limited to prospective commentary on the development and implementation of regional reconfiguration plans.

Following further requests for a formal report on progress with implementing the Ennis Report recommendations, the Chief Executive of the Authority wrote to the Chief Executive (at the time) of the HSE in June 2010 requesting a report on progress against the full range of recommendations and in particular those relating to hospitals similarly configured to MWRH Ennis. This coincided with correspondence from the Authority seeking assurances from HSE South that the key recommendations from the Ennis Report had been implemented in Mallow General Hospital.

In September 2010, subsequent to the launching of this investigation, the Authority received for the first time a HSE report setting out, by HSE region, issues raised in the Ennis Report recommendations as they related to acute clinical services in similarly sized hospitals to MWRH Ennis. This HSE report was also the first evidence received by the Authority of a systematic approach to assessing and addressing the relevant issues in hospitals similar to MWRH Ennis – a central thrust of the Ennis Report recommendations. The report identified such hospitals as:

- Our Lady's Hospital, Navan
- Louth County Hospital
- Midland Regional Hospital, Portlaoise
- St Columcille's Hospital, Loughlinstown

- MWRH Ennis
- MWRH Nenagh
- St John's Hospital, Limerick
- Roscommon County Hospital
- Mallow General Hospital
- Bantry General Hospital.

The Authority considered this HSE report to be of serious concern in that it suggested that, 18 months after the publication of the Ennis Investigation Report, a number of these hospitals continued to receive 24-hour emergency attendances with insufficient measures outlined by the HSE as to how clinical risks were being identified and managed. There were apparently few systematic arrangements for mitigating the risks to patients in these services, as highlighted previously in the Ennis Report, beyond protocols for ambulance bypass for major trauma patients in some cases.

The Authority wrote again to the HSE in November 2010 requesting clarification as to what measures were in place to identify and mitigate clinical risks to patients currently using these services, and in advance of medium- to long-term configuration changes. The HSE's response was that work was in train to develop risk-mitigation plans, and that these would be completed by the end of 2010 and implemented from the beginning of 2011 with progress-reporting against them to begin from March 2011.

The Authority received, in February 2011, an updated version of the tabulated report covering the above hospitals (Appendix E). This described further actions taken, such as the introduction of additional ambulance bypass protocols for some of the hospitals. However, it continued to outline many of the actions to manage current risks for patients as happening some time in the future, rather than what is or should be currently put in place. By early February 2011, the risk mitigation plans for each site had yet to be completed or implemented by the HSE. This is not satisfactory and consequently, there is a potential for patients receiving acute services in such hospitals to continue to be at risk.

Given the above evidence, the Investigation Team concluded that no formalised systematic review of risks relating to small, stand-alone hospitals, as highlighted in the Ennis Investigation Report, took place until summer 2010 at the earliest, well over a year after the publication of the Ennis Investigation Report. It also concluded that having reviewed these risks, the HSE has not provided sufficient evidence that they were being effectively managed currently to reduce potential risks to acutely ill patients in a number of such hospitals.

Neither was there any evidence that standardised gathering and evaluation of key clinical safety measures was implemented in any of these centres. This means that, while the HSE has focused on planning for strategic changes in service provision (by means of reconfiguration and implementation of the Acute Medicine

Programme), day-to-day risks to seriously ill patients arising from the model of service in small hospitals have been allowed to continue unassessed and without effective measures taken to mitigate them.

4.4.9 Summary: Implementation of recommendations from MRWH Ennis Report

Implementation of some recommendations of the report of the investigation into the quality and safety of services and supporting arrangements provided by the HSE and Mid-Western Regional Hospital Ennis have been taking place since the publication of the Ennis Report. At the time of the investigation, changes had occurred in the HSE Mid-West itself, and also in the HSE North East, in line with the implementation of the recommendations. The Authority is currently engaging with those areas in order to be assured that the HSE is managing change and transition safely and effectively for patients.

In the period after the publication of the Ennis Investigation report, the HSE has been in the process of implementing a number of organisational changes, including the disbandment of the NHO and PCCC Directorates, establishment of new HSE directorates and the introduction of new post of the Regional Directors of Operations. While these changes were happening, lines of accountability for implementation of the recommendations at national, regional, corporate and local level were unclear. Whilst a report on progress in implementing the Ennis recommendations was reported as being presented to the HSE Board Risk Committee, formal due diligence handover of accountability and responsibility for implementation of the recommendations at various levels within the HSE was unclear, disconnected and inconclusive.

During the investigation, it was identified through interview and review of documentation that the Ennis Report recommendations had not been disseminated fully to local level. Neither had their implications been considered or assessed at corporate and local level. The HSE had not put in place a clear arrangement for reporting publicly on the implementation of the recommendations and the timelines associated with it.

At a local level in HSE South, the HSE did not demonstrate that there was a formal arrangement in place for consideration of the recommendations and their implications for Mallow General Hospital, with risks to patient safety inherent in the service model at the Hospital having been identified, assessed and mitigated where necessary. Information obtained from the corporate HSE in the course of this investigation indicates this remains the case in other areas of the country. While the planning for the reconfiguration of acute hospital services was underway at the time of this investigation, there was limited evidence of effective interim actions taken to identify and mitigate potential patient safety issues in the present whilst the reconfiguration plan was being implemented.

In the course of the investigation, it was highlighted during interview that configuration changes such as centralising acute services are themselves not without risk – especially in the context of capacity pressures in the larger centres. The Authority highlighted this in the Ennis Report and identified and recommended the need for effective resource planning and change management for changes in the configuration of services.

However, it would appear that, although risk management processes are reportedly being implemented across the HSE through its Quality and Risk Framework, the focus on medium- to longer-term solutions has dominated the discourse within the HSE at the expense of identifying, managing and addressing the specific clinical risks inherent in the systems of care in small hospitals today. National recommendations explicitly aimed at signalling the need for urgent action in this respect only began to be addressed in a systematic way from summer 2010 and only after prompting from the Authority's inquiries. This is not satisfactory for patients and the public.

Given the seriousness of the risks highlighted as part of the Ennis Investigation, it is of the utmost concern that the HSE's corporate and clinical governance systems failed to disseminate effectively learning from an adverse finding by the statutory regulator in one part of its organisation for the benefit of patients across the healthcare system. In the context of the clearest recommendations, which specified the governance and reporting mechanisms necessary for successful implementation, this represents a serious failing of corporate governance which potentially placed, and continues to place in some parts of the country, patients at risk and must be learned from and avoided in the future **(G9, G10)**.

4.5 Recommendations: Governance

Governance

G1. The HSE and all healthcare service providers should have a publicly available statement of purpose describing the services that they can safely provide including how and where they are provided. The HSE should ensure that arrangements are in place to monitor and evaluate that the services being delivered are within the scope of the statement of purpose.

G2. The HSE and all healthcare service providers should ensure that all hospitals and hospital groups have integrated corporate and clinical governance structures with clear accountability arrangements in place. Organisational codes of governance, which clearly identifies safety and quality as core objectives should be implemented, monitored and evaluated.

G3. Hospitals should ensure that effective arrangements are in place for the timely and accurate collection, monitoring and reporting of all activity data at each site. Activity data should be reported and managed through the hospital and/or hospital group's governance structure.

G4. The HSE should ensure that there are arrangements in place to develop and support clinical directors. The necessary clinical leadership development programmes and business and administrative supports must be put in place in order for the clinical directors to effectively fulfill their role

G5. The HSE as a priority should ensure that there are robust arrangements in place to safely and effectively manage change in clinical services. These arrangements should include:

- identification of a named accountable person responsible for managing the implementation of the change process
- rigorous evaluation of the impact of the service change to identify and address any unanticipated adverse consequences of changes implemented.

G6. The HSE should ensure, in advance of any clinical service change, that potential risks to patients associated with the current system of care are identified and analysed, with mitigation actions recorded and monitored through the local, regional and national risk register.

G7. The HSE should ensure that there are formalised arrangements in place for the coordination and alignment of the national clinical care programmes, the national cancer control programme and the regional configuration of acute hospital service.

G8. The HSE and all healthcare service providers must put arrangements in place to ensure that honest, open and timely information is communicated to patients once adverse events affecting them have occurred or become known.

G9. The HSE and all healthcare service providers should ensure that there are arrangements in place to promptly act upon the recommendations of national reports of reviews/investigations or enquiries in relation to the quality and safety of services provided by, or on behalf of the HSE. The HSE should ensure the system-wide application and dissemination of learning from these national reviews for the benefit of all service users.

G10. The HSE should nominate a specific director accountable for ensuring the development of an implementation plan for the recommendations of this investigation that includes a clear timeframe with milestones. The accountable director should ensure that implementation of these recommendations is monitored, evaluated and reported publicly through the HSE's monthly performance reports.

5. Conclusion

This investigation was started by the Authority in response to concerns that the system of care in place at the CUH Group site of Mallow General Hospital for acutely ill patients was not as safe as it should be, potentially placing at risk the health and welfare of critically ill patients in that Hospital. This was compounded by a concern that risks previously highlighted by the Authority in respect of hospitals similar to MWRH Ennis (which includes MGH) had not been assessed and responded in a timely manner by the HSE at MGH.

In the course of the investigation, the Authority has looked in detail at the system of care in place at MGH and the supporting arrangements within its 'parent' Hospital Group of Cork University Hospital Group. The Authority has explored regional and national governance arrangements in place to support safe, high quality care and service transition. In particular, the arrangements by the HSE to implement national recommendations from the Authority's previous investigation at MWRH Ennis were examined.

5.1 System of care at Cork University Hospital Group's site at Mallow General Hospital

At the time of the investigation the Authority found that while services were consultant-delivered during core hours, and these consultants would stay on-site when necessary, acutely ill patients could present to MGH on a 24-hour basis and senior clinicians were not routinely on site outside of normal hours. This meant that if a seriously ill patient attended the Emergency Department, or the condition of an inpatient deteriorated out of hours, they may not have had senior clinical input available to them in a timely way.

Furthermore, the absence of on-site anaesthetic expertise could mean the safety of patients requiring respiratory or airway support were at greater risk unless robust controls were in place. This meant that caring for patients who required ICS level 3 critical care at MGH was not appropriate. Nonetheless, the Authority became aware of cases where this had happened, and in the face of difficulties with gaining access to critical care beds in CUH, patients had required transfer out of the area for treatment, adding further risk to their safe care. Following concerns raised by the Authority that led to this investigation, a 'no refusal' policy for patients requiring critical care, referred from MGH to CUH, has been introduced, and in February 2011 it was reported that 24-hour, seven-day on-site roster for senior clinical decision-making was implemented.

While arrangements (called bypass protocols) were in place to ensure ambulances took more seriously ill patients to CUH, data (submitted by the HSE South to the Authority) suggested that patients with neurological conditions such as strokes (excluded from attendance to MGH by the bypass protocol) were being brought there by the ambulance service. As the regional bypass protocols have never

been evaluated, this finding could represent a data coding error or a breach of the bypass protocol that could potentially represent a serious risk to patients. This needs to be the subject of a systematic review by the HSE and the principle must be established that protocols introduced for the protection of vulnerable groups of patients must be subject to periodic evaluation and review in all centres.

The infrastructure supporting the surgical theatre at the Hospital was poor. There had been no significant capital investment in MGH to develop the general theatre and day care facility.

The Authority's investigation has not received information that raised concerns about the competence of the existing surgeons. However, there is evidence which indicates that outcomes for patients (including lower large bowel surgery) are better, and fewer errors occur, when acute and complex surgical care is provided by teams treating higher numbers of patients. The planned HSE South reconfiguration of acute surgical services incorporating the transfer of elective inpatient general surgical services currently provided at MGH to other hospitals in the region will decrease the volume of in-patient surgical cases performed at MGH. The HSE must ensure that all major acute and complex surgery is ceased at MGH as intended, and that any risks in advance of this change being implemented, are identified and managed **(G5)**.

The Hospital itself was well maintained and very clean. In the course of the investigation, the Authority found staff at MGH to be professional and very committed to the patients. There was a clear commitment to training and development as well as clinical audit. However, it was clear that the system of care in place depended on the willingness and commitment of individual staff to make themselves available when circumstances required. However commendable, this situation is not safe or sustainable in the longer term and transition towards a system and model of care which is more appropriate to the capacity of MGH needs to begin as soon as possible.

As signalled in the Ennis Report and echoed more recently in the national Acute Medicine Programme, and the regional Reconfiguration of Acute Hospital Services, Cork and Kerry Roadmap, hospitals such as MGH will have an important, active and vibrant role in providing healthcare to their communities. The national plan identifies Mallow General Hospital as becoming a Model 2 Hospital with medical, day surgery, women and children's and diagnostic services, with MGH consultant staff becoming part of a city-wide clinical network. However, this needs to be within a clear framework or statement of purpose, that sets out the range of services that can be (and cannot be) safely provided in a hospital on that size.

In the meantime, robust controls and monitoring of key indicators must be put in place to ensure services to acutely ill patients are as safe as possible, with actions taken to reduce risk where this is indicated.

5.2 Supporting arrangements in Cork University Hospital Group and the Region

Given the Authority's previous recommendations relating to MWRH Ennis, a hospital similar to MGH, the Authority would have expected even greater scrutiny of what was happening in that Hospital and robust arrangements to assess and mitigate risks to patients, for example, those requiring Level 3 critical care support. Instead the Authority discovered that before the investigation was launched, MGH had not been integrated into the corporate or clinical governance structures within the CUH Group despite formally being a part of that Hospital Group. This extended to the support and governance in relation to risk management which was overseen through an arrangement with the HSE South Regional/Network structure, rather than through the Hospital Group.

A consequence of this somewhat dislocated arrangement was that services in MGH had evolved over time rather than as part of a clear, integrated plan within the hospital system in the HSE South.

Discussions and initial planning in relation to a region-wide reconfiguration programme were well advanced at the time of the investigation and envisaged MGH becoming an acute medicine model 2 hospital as part of a region-wide network[13]. The Authority concluded, however, that at the regional level there was an over-reliance on these medium- to long-term changes to deliver solutions envisaged by the Ennis Report at the expense of identifying and managing day-to-day clinical risks present in the existing system of care. One view expressed at interview to the Investigation Team in the course of the investigation was that across the system, some local managers were wary of introducing local changes in response to risks for fear of this being interpreted as pre-empting or 'railroading' reconfiguration. There was no specific evidence that this was the case in the HSE South. However, it is of serious concern that there should even be a suggestion of factors other than patient safety figuring in these decisions by local managers.

5.3 National arrangements

The Authority examined how the national structures supported the delivery of safe high quality healthcare and in particular the arrangements for implementing the national recommendations from the MWRH Ennis Report.

A programme of changes, including the creation of Quality and Clinical Care Directorate, has been underway within the HSE. These represented a welcome move towards increasing clinical involvement in and leadership of healthcare services. It was put to the Investigation Team that until these changes had been introduced, the HSE simply did not have the capacity to introduce the reform implied by the MWRH Ennis recommendations and this is why many recommendations are only now beginning to be implemented.

This may in part explain the Investigation Team's finding that the initial focus of the HSE, in terms of reporting against the recommendations, had been primarily on changes in the HSE Mid-West itself, with reporting on national recommendations

restricted predominantly to unspecific prospective commentary on future plans for reconfiguration. To date the only public report on progress with implementing the MWRH Ennis Report recommendations was in February 2010.

The establishment of numerous clinical programmes to specify the expected nature and scale of services across the country is to be welcomed and addresses the Ennis Investigation Report recommendations that sought to highlight the risks to patients that arise from lack of clarity about what should or should not be provided in certain settings. Important as they are, these are predominantly 'strategic' changes that will pay dividends over time. In the meantime patients continue to be referred or present themselves to small local hospitals with emergency departments on the presumption they have the staffing and infrastructure in place to meet all their needs, when this may not be the case.

In a health system built (correctly) on the premise that local access to services is maximised, it is absolutely vital that the mechanisms for identifying, and directing to the right place, patients who need care in specialist centres are as effective as possible. Given the potential risks to such patients of finding themselves with a complex or rapidly deteriorating condition in a centre with inadequate clinical staffing or facilities, this should be a major focus of those responsible for planning and providing services. The interests of such patients should be at the heart of clinical governance, risk management and performance management in the health service. The Investigation Team found that in many areas, measures have been taken to 'stream' patients towards the right care setting through, for example, ambulance bypass protocols. However, it is only since late summer 2010 that anything like a systematic approach to ensuring this is happening emerged.

The Authority acknowledges that the clinical programmes currently under development have the potential to deliver significant benefits for patients and the tax payer through more effective and efficient use of the significant resources used for healthcare. However, in advance of this, managers and clinicians at all levels need to focus their attention and efforts on protecting the interests of the most vulnerable of patients – namely, those about whose condition little is known because they have walked in off the street or are inpatients whose condition is deteriorating rapidly. Such a focus should not be a matter of local discretion. Patients in the midlands should be confident that they will receive the same level of care as those in the south or the West. Whilst developments currently in train are aimed to deliver this, based on the findings of this investigation, this is not yet the case.

5.4 Concluding remarks

It is regrettable that it proved necessary for the Health Information and Quality Authority to carry out this investigation. The issues at stake had been exhaustively examined and the changes needed set out as part of the Authority's 2009 report of the investigation into the quality and safety of services and supporting arrangements at MWRH Ennis. The fact that the Authority found it necessary to invoke its powers, under section 9 of the Health Act 2007, to investigate services at Mallow General

Hospital indicates a fundamental and worrying deficit in our health system – namely the ability to apply system-wide learning from adverse findings in one part of the service for the benefit of all service users.

This investigation has revealed that while longer-term improvements are in train, the response of the HSE to key recommendations from the MWRH Ennis Report has been slow and inconsistent, with certain actions only happening recently in response to enquiries from the Authority. In Mallow General Hospital this resulted in a service continuing to be based on past practices, with no concerted effort being taken at a regional or hospital group level to identify and address clinical risks to patients and manage them in a proactive way in advance of planned longer-term change. The safety and quality of the service was dependent on the professionalism and willingness of individual consultants supported by experienced clinical staff at MGH, rather than a resilient and reliable system of care.

The HSE, the Department of Health, clinical leaders, managers and the public need to reflect on the findings of this report because all concerned in planning, delivering, receiving and funding healthcare services have a role in ensuring that the public get the healthcare they need and deserve.

Leading on from this, the Board of the HSE in particular needs to reflect on what further it can do to ensure that the safety and effectiveness of services to patients are paramount above all other considerations and that these issues receive the Board's and management's attention that they should demand. This should include consideration of whether the implementation of national recommendations should come before the Board itself rather than a committee of the Board.

Finally, this investigation arose from confidential information that the Authority received, in relation to the treatment of a patient with complex clinical needs in Mallow General Hospital. Whilst the investigation has not looked specifically at the circumstances of the care provided, it has focused on the system of care required for patients with complex clinical needs. Later in 2011, subject to Ministerial approval, the Authority intends to publish national standards which will define how services should be organised and delivered to assure quality and safety of services. The launch of these standards will be the first step in the trajectory of a licensing system being established in the Irish healthcare system. Service providers should consider that the recommendations of this report are consistent with and indicative of the objectives of the above national standards and future licensing requirements being established in Ireland. The move towards a licensing system in Ireland will accelerate the requirement for these recommendations to have been addressed in a proactive and timely manner across the healthcare system for the benefit of patient safety.

The Authority plans to monitor and evaluate the HSE's implementation of the recommendations from this investigation alongside its compliance with these national standards.

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Glossary of terms and abbreviations

Accountability: accountability is demonstrated by the service provider accepting responsibility for their decisions and behaviours as a service provider and for the consequences for service users, families and carers

Acute lower respiratory tract infection (LRTI): rapid onset or short duration of an infection of the lower part of the trachea (windpipe) through which air enters and leaves the body.

Acute hospital: an acute care hospital is a facility offering surgical and medical patient care for individuals facing an unexpected medical problem that needs immediate assessment and treatment.

Adenoidectomy: surgical removal of the adenoids – a mass of lymphatic tissue between the back of the nose and the throat.

Acute Medicine Programme (AMP): a national initiative that is clinician-led, providing a framework for the delivery of acute medical services which seeks to substantially improve patient care.

Advanced nurse practitioner (ANP): an autonomous, experienced practitioner who is competent, accountable and responsible for their own practice. They are highly experienced in clinical practice and are educated to masters degree level (or higher).

Adverse event: an incident which results in harm to a patient.

Anaesthetic: substance that produces partial or complete loss of sensation.

Angioplasty: is a surgical procedure used to widen blocked blood vessels and restore normal blood flow.

ALOS: average length of stay.

An Bord Altranais: or the Irish Nursing Board which is the regulatory body for the nursing profession in Ireland.

Appendicectomy: surgical procedure to remove the appendix.

Appendicitis: inflammation of the appendix.

Atrial fibrillation: rapid and irregular heart beat causing palpitations and shortness of breath.

Bi-PAP: or bi-level positive airway pressure, a type of non-invasive ventilation that helps keep the upper airways of the lungs open by providing a flow of air delivered through a face mask. The air is pressurised by a machine, which delivers it to the face mask through long, plastic hosing.

Bypass protocol: is an agreed patient management plan to ensure that a patient is brought directly to the most appropriate healthcare setting bypassing a service which may be more local but does not have the appropriate clinical expertise.

CPAP: or continuous positive airway pressure, a method of non-invasive or invasive ventilation assisted by a flow of air delivered at a constant pressure throughout the respiratory cycle. CPAP may be given through a ventilator and endotracheal tube (tube to the windpipe), through a nasal cannula (plastic tube), or into a hood over the patient's head.

Cardiac stent: a wire mesh used in the treatment for coronary arteries (blood vessels in the heart muscle) that are narrowed or blocked by plaques.

Cardiology: the study and treatment of medical conditions of the heart.

Case mix: the types of patients and complexity of the patients' conditions treated by a healthcare service, including diagnosis, treatments given and resources required for care.

Cellulitis: an acute spreading bacterial infection below the surface of the skin.

Cerebrovascular accident (CVA)/stroke: occurs when a blood vessel, carrying oxygen and nutrients to the brain, bursts or is blocked by a clot, causing an interruption of the blood supply to part of the brain.

CEO: Chief Executive Officer.

Cholecystectomy: surgical removal of the gallbladder.

Chronic obstructive pulmonary disease (COPD): long-term (chronic) lung condition where the airways and air sacs are obstructed making it difficult to exhale and breathe normally.

Clinical audit: the systematic, critical analysis of the quality of care, including procedures used for diagnosis and treatment, use of resources and resulting outcome and quality of life for the patient.

Clinical director: the senior clinical leader with delegated responsibility and accountability for patient safety and quality throughout a healthcare organisation.

Clinical governance: clinical governance defines the culture, values, processes and standards that must be put in place, along with clear responsibility and accountability arrangements in order to achieve sustained quality of care in healthcare organisations.

Clinical nurse manager (CNM): a nurse more senior than a staff nurse but more junior than an assistant director of nursing. A CNM 2 is more senior than a CNM 1.

College of Anaesthetists of Ireland: the college responsible for the continued guidance, training and examination of anaesthetists in training.

Consultant: a consultant is a registered medical practitioner in hospital practice who, by reason of his / her training, skill and experience in a designated specialty, is consulted by other registered medical practitioners and undertakes full clinical responsibility for patients in his / her care, or that aspect of care on which he / she has been consulted, without supervision in professional matters by any other person. Consultants include surgeons, physicians, anaesthetists, pathologists, radiologists, oncologists and others.

CUH: Cork University Hospital.

CUHG: Cork University Hospital Group.

CUMH: Cork University Maternity Hospital.

Colectomy (sub-total colectomy): this is a surgical procedure to remove all (total) or part (sub-total) of the large intestine (colon).

Colostomy: a surgical procedure that involves connecting a part of the colon (bowel) on to the anterior abdominal wall to allow the patient to eliminate waste products. It can be permanent or temporary.

Computerised tomography (CT): the practice of taking images of the body in a number of selected planes using radiography, and thereby building a three-dimensional image of an area.

Congestive heart failure: the inability of the heart to supply sufficient blood flow to meet the body's needs.

Consultant: a senior hospital doctor, including physicians, surgeons, anaesthetists, pathologists and others.

Core hours: core working hours can be classified as the working hours of 9am to 5pm, Monday to Friday.

Coronary care unit (CCU): a hospital unit that is specially equipped to treat patients with heart conditions.

Cystoscopy: use of a scope (narrow tube with small camera attached) to examine the bladder.

Dermatology: the branch of medicine that is concerned with the physiology and pathology of the skin.

Director of nursing (DoN): the senior nurse in a hospital.

DNAs: did not attends – a term used when referring to patients who have not attended appointments in a healthcare setting.

Early Warning Score: is a physiologically-based system of scoring a patient's condition to help determine severity of illness and predict patient outcomes.

Emergency department (ED): the department of a hospital responsible for the provision of medical and surgical care to patients arriving at the hospital in need of immediate care.

Elective surgery: a planned, non-emergency surgical procedure.

Endoscopy: examination of the upper digestive tract (oesophagus and stomach) including the first portion of the small intestine (duodenum) using a very narrow flexible tube with a tiny camera attached (endoscope).

ESRI: Economic and Social Research Institute.

ENT: Ear, nose and throat.

Evidence-based practice: practice which incorporates the use of best available and appropriate evidence arising from research and other sources.

Fibreoptic colonscopy of caecum +/- biopsy: an examination of first part (caecum) of the large intestine (colon) using a narrow flexible tube with a tiny camera attached (colonoscope).

Gastrology procedures: surgical procedures relating to the stomach.

Governance: the function of determining the organisation's direction, setting objectives and developing policy to guide the organisation in achieving its objectives and stated purpose.

GI: gastrointestinal – relating to both the stomach and the intestine.

GP: general practitioner.

Haemovigilance: a set of surveillance procedures from the collection of blood and its components to the follow up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

Hartmann's procedure: removal of a section of the large bowel or colon.

HealthStat: a databank of performance information from Irish public health services.

Hemicolectomy: a procedure (also referred to as right- or left-hemicolectomy) to remove part of the large bowel (colon).

Hernia: the protrusion of an internal organ or part of an organ through the wall of a body cavity that holds it.

Hospital In-Patient Enquiry (HIPE): an information technology system used to collect information on inpatients at Irish acute hospitals. Information is provided by the hospitals to the central system administered by the Economic and Social Research Institute (ESRI).

High dependency unit (HDU): a unit in a hospital that offers specialist nursing care and monitoring to ill patients. It provides greater care than is available on general wards but less than is given to patients in intensive care.

HSE: the Health Service Executive.

ICGP: Irish College of General Practitioners.

ICS: Intensive Care Society

ICS Level 0 (Ward): patients' needs can be met through normal ward care in an acute hospital.

ICS Level 1 (Ward at-risk): patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team.

ICS Level 2 (HDU): patients requiring more detailed observation or intervention including support for a single failing organ system or postoperative care and those stepping down from higher level care.

ICS Level 3 (ICU): patients requiring advanced respiratory support alone or basic respiratory support together with at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

ICT: information and communications technology.

Ileorectal anastomosis: a surgical operation in which the ileum is joined to the rectum, usually after surgical removal of the colon.

Ileum: final section of the small intestine.

Infection control: the discipline and practice of preventing and controlling Healthcare Associated Infections and infectious diseases in a healthcare organisation.

Integrated care pathways: structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical condition.

Intensive care unit (ICU): a unit in a hospital providing complex support for multi-organ failure and or advanced respiratory support.

Intensivist: a physician who specialises in the care of critically ill patients, usually in an intensive care unit.

Intern: a doctor in training more junior than a senior house officer.

Invasive ventilation: the use of a mechanical ventilator to inflate and deflate the lungs.

Integrated Services Directorate (ISD): The Integrated Services Directorate was established in October 2009 as part of the HSE's management restructuring to enable a greater integration of services.

Key performance indicator (KPI): specific and measurable elements of practice that can be used to assess quality of care.

Laryngoscopy/microlaryngoscopy: procedure used to view the inside of the larynx or voice box.

Locum: doctor who does the job of another doctor who is on leave.

Male circumcision: the surgical removal of the foreskin of the penis.

Medical assessment unit (MAU): a unit in a hospital to facilitate patients who require a more urgent medical assessment as opposed to waiting for an outpatient appointment. The MAU acts as a 'gateway' to the hospital. Often linked to the emergency department, patients can be assessed in this unit for discharge or admission.

MGH: Mallow General Hospital.

Mortality rate: refers to the measure of the number of deaths in a given population.

Morbidity rate: refers to the incidence or the prevalence of a disease or medical condition in a given population.

Multidisciplinary: a term used to describe an approach to treatment planning and delivery of care to a patient by a team of doctors and other healthcare professionals who are experts in their field (discipline). This team of healthcare professionals come together at multidisciplinary team meetings to discuss the results, care and treatment plan of the patient.

Myringotomy: surgical procedure used in the treatment of inflammation in the middle ear.

National Hospitals Office (NHO): an office of the Health Service Executive that had been responsible for acute hospitals and the ambulance service that has since been disbanded.

Non-consultant hospital doctor (NCHD): includes registrars, senior house officers and interns.

Oesophagoscopy: a diagnostic procedure, which involves direct visualisation of the oesophagus using a fibre optic scope.

On call: the provision or availability of clinical advice in addition to or outside of core working hours.

Out of hours: outside of core working hours (9am-5pm, Monday to Friday).

Outreach services: whereby health professionals from a hospital travel to another hospital or to the local community to provide specialty services, for example, antenatal services.

Orthopaedic: the branch of medicine that deals with the prevention or correction of injuries or disorders of the skeletal system and associated muscles, joints, and ligaments.

Panendoscopy to duodenum with biopsy: examination of the upper digestive tract including the first portion of the small intestine (oesophagus, stomach and duodenum) using a very narrow flexible tube (panendoscope). The doctor can view the tissue lining and take a tissue sample (biopsy).

Perioperative care: that is given before, during and after surgery.

Pneumonia: an inflammation of the lung, usually caused by an infection.

Policies, procedures and guidelines (PPGs): a set of statements or commitments to pursue courses of action aimed at achieving defined goals.

Pressure ulcer: an area of skin that breaks down when constant pressure is placed against the skin.

Primary, Community and Continuing Care (PCCC): a directorate within the HSE responsible for the planning, management and delivery of all primary, community and continuing care services, excluding acute hospital services.

Protocol: a detailed plan of a medical treatment or procedure.

Registrar: a medical or surgical doctor more senior than a senior house officer. Registrars can be participating in specialist training.

RDO: Regional Director of Operations, HSE.

Risk management: risk management is the systematic identification, evaluation and management of risk. It is a continuous process with the aim of reducing risk to organisations and individuals.

Risk register: a tool developed and used to collect and provide a high level overview of a services' risk status at a particular point in time. It can be used for the monitoring of actions to be taken to mitigate risk.

Royal College of Physicians of Ireland (RCPI): a postgraduate medical institution in Ireland with a mission to develop and maintain high professional standards in medicine. The college provides training and education opportunities to all physicians who have graduated from medical school.

Senior house officer (SHO): a medical or surgical doctor more senior than an intern but more junior than a registrar. Senior house officers may be participating on a training programme.

SMOH: St Mary's Orthopaedic Hospital – a specialist hospital in Cork, managed by the Health Service Executive.

STARSweb: is a national database established and maintained by the Clinical Indemnity Scheme of the State Claims Agency to record adverse clinical incidents and 'near misses' reported by hospitals.

Syncope and collapse: fainting with loss of consciousness.

Terms of reference: a set of terms that describe the purpose and structure of a project, committee or meeting.

Tertiary hospital: a hospital in which the clinical services provided are more specialised than those provided in a secondary acute hospital, for example, neurosurgery, oncology, transplant services.

Thoracic procedures: surgical procedure relating to the chest.

Thrombo-prophylaxis: measures taken to prevent blood vessels being obstructed by a blood clot.

Tonsillectomy: surgical removal of tonsils or a tonsil.

Transurethral resection of prostate (TURP): a surgical procedure to remove all or part of the prostate – a gland in the male reproductive system.

Tissue viability: refers to the prevention and treatment of tissue damage.

The Authority: the Health Information and Quality Authority.

The College of Anaesthetists of Ireland: the college responsible for the continued guidance, training and examination of anaesthetists in training.

Ultrasound: a procedure in which high-energy sound waves are bounced off internal tissues or organs and make echoes. The echo patterns are shown on the screen of an ultrasound machine, forming a picture of body tissues called a sonogram.

Undifferentiated emergency services: the provision of emergency services to any acute medical patient whose problems are not restricted to a single or small group of specialties.

Urinary tract infection (UTI): a bacterial infection that affects any part of the urinary tract – or urinary system.

Urology: the medical and surgical specialty that involves the urinary tracts of males and females and the reproductive system of males.

Varicose veins: veins that have become enlarged and tortuous.

Vascular surgery: surgery for the treatment of diseases of the vascular system – the network of vessels for the circulation of fluids throughout the body.

Venepuncture: surgical puncture of a vein for the purpose of intravenous therapy or obtaining a blood sample.

Ventilator: a machine that mechanically moves breathable air into and out of the lungs.

Whole time equivalent (WTE): the total number of hours that staff are contracted to work.

Appendices

Appendix A

Request for information and data

Requests for information made for the purpose of the above investigation, instigated under section 9(1) of the Health Act 2007 (the Act) and pursuant to Section 73 of the Act.

REQUEST FOR DOCUMENTATION

MALLOW GENERAL HOSPITAL, CORK UNIVERSITY HOSPTIALS GROUP, HSE SOUTH

Mallow General Hospital

1. Leadership, Governance and Management

Corporate and Clinical Governance arrangements

- Organogram, terms of reference and supporting documentation for the corporate and clinical governance arrangements (including clinical risk management) at Mallow General Hospital (MGH).
- Organogram, terms of reference and supporting documentation relating to the clinical governance arrangements for the provision of emergency department (ED) services in MGH.
- List of categories of staff that are on the emergency response team (core hours) at MGH.
- List of categories of staff that are on the emergency response team (outside of core hours) at MGH.
- Organogram, terms of reference and supporting documentation relating to the clinical governance arrangements for the provision of ED services in Cork University Hospitals Group (CUH Group) and the HSE South.
- Organogram, terms of reference and supporting documentation relating to the clinical governance arrangements for the provision surgical services in MGH, including 24-hour surgical cover arrangements.

- Organogram, terms of reference and supporting documentation for the corporate and clinical governance arrangements (including clinical risk management) at Cork University Hospitals Group incorporating MGH.
- Organogram, terms of reference and supporting documentation for the corporate governance arrangements for the HSE South, incorporating Cork University Hospitals Group and MGH.

2. Effective Care: Safety, Quality and Risk Management Arrangements

- Terms of reference and supporting documentation for the clinical risk management arrangements at MGH.
- Terms of reference and supporting documentation for the clinical risk management arrangements at Cork University Hospitals Group incorporating MGH.
- Risk register for MGH and appropriate control mechanisms identified.
- Terms of reference and supporting documentation for the management of adverse events, clinical incidents, complaints and compliments including quality improvement initiatives implemented by MGH as an action following investigation of any identified clinical incidents/adverse events for the six-month period of 1 January 2010 to 30 June 2010.
- Copy of bed management policy for MGH.
- Copy of the last two completed annual self-assessment reports based on the HSE Quality and Risk Management Standard (2007) for Mallow General Hospital.
- Local policies and procedures relating to safety, quality and risk management at MGH.
- Description of the organisational arrangements, or the policy/procedure, in place in MGH for reviewing and responding to complaints and compliments and implementing any subsequent quality improvement actions.

Referrals to other hospitals

- Description of or policies/procedures in place for, patient referrals made to other hospitals and the forms that are in use. (Please attach a copy of the form.)

Clinical Audit Activity

- Terms of reference and supporting documentation in relation to clinical audit activity

including the implementation of quality improvement initiatives.

- Description of, or reports of any audits, both internal and external, which have taken place in your hospital in the past six months (please provide the results and quality improvement plans arising out of any of the audits, where available).

3. Emergency Department (ED)

- Policy/guidelines for ED triage category system in use at MGH.
- Please provide copies of all patient bypass protocols, including ambulance bypass protocols, that are in place in MGH.

4. Critical Care Services

- Admission, discharge and transfer protocols for critical care services at MGH.
- Protocols for clinical guidelines for the management of ventilated patients.

5. Surgical Services

- Copy of 'out of hours' Operating Theatre protocol.
- Guidelines used at MGH to describe major and minor surgical procedure classifications.

6. Laboratory Services

- List of the laboratory testing services provided on-site in MGH.
- Description of the governance structures in place for the provision of on-site laboratory services.
- Description of, or policy/procedure for the reporting arrangements for onsite and off-site (third party) routine/on-call/emergency laboratory testing?
- Description of, or policy/procedure for, communication of laboratory results to GPs.

7. Radiology Services

- Overview of the radiology service provided at MGH, to include third parties providing services (public and private) on behalf of MGH.
- Description of, or policy/procedure for, the on-call and emergency cover arrangements for radiology at MGH.
- Copies of the contracts of agreement between MGH and the third-party providers (public and private) of radiology services on behalf of MGH.
- Copies of reports forwarded to the HSE Quality and Clinical Care Directorate in response to the national radiology survey undertaken in 2010.

8. Workforce

- Policies and/or procedures for verifying registration status with regulatory bodies for permanent and temporary clinical staff including consultant and nursing staff.
- List of the in-service training provided per category of staff identifying those elements that are mandatory for staff in MGH.
- Copy of the induction programme for new staff including NCHDs, nurses, support staff.
- Description of the process, or the policy/procedure, for maintaining records of mandatory training and continuous professional development.
- Attendance records for the recently provided training/upskilling programme in intubation, ventilation and resuscitation.
- Most recent reports from the professional bodies (Medical Council and An Bord Altranais) and colleges regarding the training of relevant specialties and professionals within Mallow General Hospital.

Cork University Hospital Group

Effective Care: Safety, Quality and Risk Management Arrangements

- Copy of the Risk Register for Cork University Hospitals Group.
- Copy of admission and discharge policy/procedure for patients to general intensive/critical care.
- Copy of CUH Group bed management policy.
- Bed management protocols in use at Cork University Hospital (CUH) to include acceptance of patients requiring intensive/critical care being transferred from other hospitals to CUH and the referral and transfer of patients from CUH intensive care/critical care unit to other hospitals.
- Copy of 'No refusal' policy implemented at CUH for level-3 critical care patients being transferred from MGH to CUH.
- Copy of the most recently completed annual self-assessment based on the HSE Quality and Risk Management Standard (2007) for the CUH Group (to include Mallow General Hospital).

HSE South

- Copy of the analysis of surgical activity at Mallow General Hospital, Clinical Director, CUH Group.
- Arrangements both during, and outside of core hours, for arterial blood gas analysis at Mallow General Hospital.
- Copy of the report, Securing clinically safe and sustainable acute hospital services: A review of acute services in HSE South and an action plan for Cork and Kerry (2008-2012).

REQUEST FOR DOCUMENTATION

HSE NATIONAL

1. Leadership, Governance and Management

Implementation of National Recommendations of the (MWRH) Ennis report

- Organogram for the national governance arrangements of the Health Service Executive.
- Organogram terms of reference and supporting documentation relating to the implementation of the Authority's national MWRH Ennis recommendations.
- Copy of national implementation plan for each of the Authority's national MWRH Ennis recommendations.
- Relevant reports and/or implementation plans produced in response to the Authority's national MWRH Ennis recommendations for every hospital with a similar resource and activity profile to MWRH Ennis. (MWRH, Ennis Refs R1.4, R2.7, R4.5.)

Reconfiguration in HSE South

- Terms of reference and supporting documentation relating to the implementation of the national reconfiguration plan in the HSE South.

National Cancer Control Programme (NCCP) in HSE South

- Terms of reference and supporting documentation relating to the implementation of the National Cancer Control Programme/plan in the HSE South.

Acute Medicine Programme

- Terms of reference and supporting documentation relating to the national implementation of the Acute Medicine Programme.
- Copy of the national implementation plan for the Acute Medicine Programme.

Alignment between HSE Programmes

- Organogram, terms of reference and supporting documentation relating to HSE Directorates responsible for the implementation of the Authority's MWRH Ennis national recommendations, the national reconfiguration plan for the HSE South, the National Cancer Control Programme/plan for the HSE South, and the national plan for the Acute Medicine Programme.

2. Effective care: Safety, Quality and Risk Management Arrangements

- Terms of reference and supporting documentation relating to the radiology review conducted at Mallow General Hospital for the period 2008-2010.
- Terms of reference and supporting documentation relating to the review of CTs performed at Mallow General Hospital.

REQUEST FOR DATA/INFORMATION

Investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at Mallow General Hospital, Cork

Requests for information made for the purpose of the above investigation, instigated under section 9(1) of the Health Act 2007 (the Act) and pursuant to Section 73 of the Act.

HIPE DATA - Hospital In-Patient Enquiry System (ESRI)

The data request related to the following information.

Hospital : Mallow General Hospital

Year of discharge: 2007, 2008, 2009 and 2010

Data: Total discharges

Total number of discharges by month of admission for medical and surgical discharges by elective and emergency admission for day and inpatients.

Numbers admission from A&E to hospital by medical and surgical split by month of admission.

Top 20 principal diagnosis for discharges with Admission Source 4-7 (Emergency) and mode of emergency admission = 1 (A&E) by month.

Top 20 principal procedures for discharges with Admission Source 4-7 (Emergency) and mode of emergency admission = 1 (A&E) by month.

Data: ICU-related discharges

Number of discharges by month of admission to hospital, for ICU cases with average age and total length of stay in ICU.

Number of discharges in ICU with procedure block code 569 (Continuous ventilatory support) by age and total length of stay in ICU.

Discharge Destination Report for discharges admitted to ICU by month of admission and discharge.

Principal diagnosis report for discharges from ICU by month of admission to hospital.

Data: Surgical discharges

Top 20 surgical procedures excluding excision of lesions, by quarter (based on month of admission), for day and inpatient cases.

Number of bowel procedures by case type, by month of admission and principal procedure consultant code.

Number of stomach procedures by case type, by month of admission and principal procedure consultant code.

Number of breast procedures by case type, by month of admission and principal procedure consultant code.

Number of all gynaecology procedures by case type.

Number of all urology procedures by case type.

Number of emergency caesarean sections.

Data: Discharges <16 years (broken down by >2 years, 2-15 years)

Total number of discharges aged <16 by month of admission for medical and surgical discharges by elective and emergency admission for day and inpatients.

Numbers admission aged <16 from A&E to hospital by medical and surgical split by month of admission.

Principal diagnosis for discharges aged <16 with Admission Source 4-7 (Emergency) and mode of emergency admission = 1 (A&E) by month.

Principal procedures for discharges aged <16 with Admission Source 4-7 (Emergency) and mode of emergency admission = 1 (A&E) by month.

Number of discharges aged <16 by month of admission to hospital, for ICU cases with average age and total length of stay in ICU.

Number of discharges aged <16 in ICU with procedure block code 569 (continuous ventilatory support) by age and total length of stay in ICU.

Surgical procedures by month of admission, for day and inpatient cases aged <16

Number of discharges by month of admission aged <16, by Consultant specialty (general surgery 5000 and general medicine 2600)

REQUEST FOR DATA

Mallow General Hospital

Activity data for MGH for the six-month period of from 1 January 2010 to 30 June 2010

1. Effective Care: Safety, Quality and Risk Management Arrangements

- What is the number of clinical incidents/adverse events reported at MGH for the six-month time period?
- What is the number of clinical incidents/adverse events reported by MGH to CIS for the six-month time period?
- What is the number of patient safety incidents reported at MGH for the six-month time period?
- What is the number of patient safety incidents reported by MGH to CIS for the six-month time period?
- What is the number of clinical related complaints and claims at MGH for the six-month time period?

2. Emergency Department (ED) services

- Is there a 24 hour/7-day emergency service provided at MGH?
- What clinical emergency services are not managed in the ED at MGH, (e.g. maternity, paediatric, vascular)?

- What is the number of ED patient attendances at MGH for the six-month period?
- For the total number of ED patient attendances at MGH for the six-month period, please indicate referral source (e.g. general practitioner, self referral, ambulance)?
- Of the total number of ED patient attendances at MGH for six-month period, what is the total number and percentage of patients transferred from the ED at MGH to other hospitals?
- Of the total number of patients transferred from the ED at MGH to other hospitals, what is the total number of patients that were transferred within one hour of decision to transfer?
- Of the total number of patients transferred from the ED at MGH to other hospitals that were waiting transfer ≥1 hour, what was the average waiting time for transfer?
- Of the total number of patients transferred from the ED at MGH to other hospitals, please list clinical reasons for transfer.
- Of the number of ED patient attendances at MGH for the 6 month period what is the total number of patients admitted to the hospital?
- Of the number of patients admitted to the hospital, please provide the breakdown by time from registration at the ED to admission

  a) admitted ≤ 6 hours from registration

  b) admitted ≥6 hours from registration.
- Of the number of patients admitted to critical care from ED, please provide the breakdown by level/classification if critical care

  a) Level 1

  b) Level 2

  c) Level 3.
- Of the total number of patients that were admitted to MGH for the six-month time period, how many patients required emergency surgery for the six-month time period?

Emergency Admissions

- For the six-month time period, what is the total number of patients admitted as an emergency admission directly to a hospital ward (i.e. do not get admitted from ED)?
- Of the total number of patients admitted as an emergency admission directly to a hospital ward, please indicate for each patient, the referral source, diagnosis, whether medical (indicate whether critical care required) or surgical (indicate theatre case classification).

3. Critical care services

- How many ICU beds are available in MGH?
- How many CCU beds are available in MGH?
- How many HDU beds are available in MGH?
- What levels/classification of critical care are provided at MGH?
- What is the total number of patients admitted to critical care for the six-month time period? Please provide breakdown by ICU/CCU/HDU.
- ICU
- CCU
- HDU
- Of the number of patients admitted to ICU for the six-month time period, please provide a breakdown for the level/classification of critical care required.
- Level 1
- Level 2
- Level 3
- What is the number of patients in MGH that required ventilation during the six-month time period?
- Is there on-site 24-hour/7-day anaesthetic cover at MGH?
- If not, what are the cover arrangements in place 24-hour/7 days per week at MGH?

Data for critical care services at MGH for the six-month period from 1 January 2010 to 30 June 2010

Condition type	Number of patients admitted with condition	Reasons for admission

- Please describe the clinical classification system in use at MGH to categorise patients requiring critical care levels 1, 2 and 3?
- For the six-month time period, please provide a list of patient diagnoses for all patients requiring Level-2 critical care.
- What was the average length of stay for patients requiring level-2 critical care for the six-month time period

- For the six-month time period, please provide the patient diagnosis for all eight patients that required Level-3 critical care including the length of stay for each patient.

4. Surgical Services

- What are the theatre operating times for elective surgery?
- Is there a 24-hour/7-day emergency surgical service available at MGH?
- What time does emergency theatre cover commence?
- Is the theatre and recovery room staffed on site for emergency surgical services?
- Is there a designated recovery room available for emergency surgical services?
- If no, where are post-operative patients recovered?

Data for all surgical services at MGH for the six-month period from 1 January 2010 to 30 June 2010

Procedure	Specialty (for example, gynaecological, vascular maternity, ENT)	*Major		*Minor		*Aged under 2 years	*Aged 2-16 years	*>16 years
		elective	Emergency	Elective	Emergency			

- Does elective surgery, at MGH finish at 5pm Monday to Friday?
- If elective surgery does not finish at 5pm, what are the arrangements to complete the elective list?
- Where surgery has taken place outside of core hours (either elective or emergency) during the six-month time period, please indicate the number of surgeries that have taken place according to MGH Theatre case classification.

	Number of surgeries (cases)	Monday-Friday After 5pm	Weekend/public holiday between 8-5	Weekend/public holiday after 5pm
Minor				
Intermediate				
Major				
OGD				
Colonoscopies				
Other (please specify)				

- Please list the procedures carried during the six-month time period for those patients aged under 16 years.
- Please indicate the number of emergency surgeries carried out during core hours for the six-month period according to MGH Theatre case classification.

5. Radiology

- Waiting times for radiology diagnostic tests per test.

	Waiting time (MGH)	Waiting time third-party providers
Please enter name of radiology diagnostic test		
Please enter name of radiology diagnostic test		

- image reporting time turnaround for inpatients
- image reporting time turnaround for outpatients
- image reporting time turnaround for critical care
- image reporting time turnaround for patients in ED
- image reporting time turnaround for GP referrals.

	Reporting turnaround time
Please enter name of radiology diagnostic test	
Please enter name of radiology diagnostic test	

6. Workforce

Nursing

1. Nursing staff: Emergency Department			
Title (CNM 3, 2, 1, CNS, Staff Nurse, ANP}	Category (see A below)	Commenced Employment at MGH on:	ED Qualifications (Post-grad, H-dip, Msc)

2. Nursing staff: Intensive Care Unit (ICU)			
Title (CNM 3, 2, 1, CNS, Staff Nurse, ANP}	Category (see A below)	Commenced Employment at MGH on:	Intensive care Qualifications (Post-grad, H-dip, Msc)

3. Nursing staff: Coronary Care Unit (CCU)			
Title (CNM 3, 2, 1, CNS, Staff Nurse, ANP}	Category (see A below)	Commenced Employment at MGH on:	Coronary care Qualifications (Post-grad, H-dip, Msc)

4. Nursing staff: High Dependency Unit (HDU)			
Title (CNM 3, 2, 1,CNS, Staff Nurse, ANP}	Category (see A below)	Commenced Employment at MGH on:	CCU/ICU Qualifications (Post-grad, H-dip, Msc)

5. Nursing staff: Operating Theatre (OT)			
Title (CNM 3, 2, 1, Staff Nurse, ANP}	Category (see A below)	Commenced Employment at MGH on:	Operating theatre qualifications (Post-grad, H-dip, Msc)

A.Categories: Permanent (P); Temporary (T); Full Time Locum (FL); Part-time Locum (PTL); Part-time Permanent (PTP); Part-Time Temporary (PTT)

Medical staff

1) Medical consultants (including medical, surgical, emergency and anaesthetic consultants)						
Title	Specialty	Category (see A below)	Commenced Employment at MGH on:	Sessional commitment to MGH only (please state number of sessions per week)	Joint appointment with other hospital (please state name of other hospital and number of sessional commitments per week in MGH)	*Visiting consultants (y/n)

2) Non-consultant hospital doctors (NCHDs)								
Title	Training /Non training	Category (see A below)	Medical Team Category (see B below)	Specialty (medical, surgical, ED, anaesthetic)	Clinical Team Consultant Name	Commenced Employment at MGH on:	Sessional commitment to MGH only (please state number of sessions per week)	Joint appointment with other hospital (please state name of other hospital and number of sessions per week in MGH)
A.Categories: Permanent (P); Temporary (T); Full-time Locum (FL); Part-time Locum (PTL); Part-time Permanent (PTP); Part-time Temporary (PTT)								
B.Categories: Specialist registrar (SpR); Surgical registrars (SR); Medical registrars (MR); SHO (SHO); Intern (I)								

- Please list the in-service training provided per category of staff at MGH, identifying those elements that are mandatory for staff at MGH.

	Type of inservice-training	Mandatory -Yes/No
Category		
Category		

- What categories and percentage of staff per category, have attended CPR training for the previous 12-month period to July 31 2010?
- What categories and percentage of staff per category, have attended ACLS, ATLS or other similar training from the previous 24-month period to July 31 2010?
- What categories and percentage of staff per category, have attended incident reporting training for the previous 12-month period to July 31 2010?

- What categories and percentage of staff per category, have attended risk assessment training for the previous 12-month period to July 31 2010?
- What categories and percentage of staff per category, have attended Systems Analysis (Root Cause Analysis) training for the previous 12-month period to July 31 2010?
- What categories and percentage of staff per category, have attended 'Your Service Your Say' training for the previous 12-month period to July 31 2010?

General information

Patient administration system

- Do you have a PAS system? (If yes please indicate the year it was implemented.)
- What data items are collected on the PAS Patient Master Index system? (Please attach a list.)
- What activities are captured on your PAS, e.g. Outpatients clinics, Admissions, Chart tracking etc.?
- Are all patients registered on PAS (if not please identify which patients are and which are not registered on PAS)?
- Is the quality of data held on the PAS audited (if yes please describe the audit types and frequency)?

Emergency department

- Are there any IT systems used in the emergency department other than PAS? (If yes please provide name of this system.)
- If yes, what data items are collected on this system? (Please attach a list.)

HIPE data

- What does HIPE data at MGH cover (e.g. admissions, day cases)?
- What is the usual time delay between activity occurring and the coding of this activity?
- List the data items collected on the HIPE database locally. (Please attach a list.)
- Has a quality audit been carried out on MGH HIPE data? If yes, please describe the audit types and frequency.

Other systems

- Are there any other IT systems used in the hospital (e.g. CCU, HDU, Operating Theatres, surgical wards, bed management)? (Please list and describe the general functions of any systems.)
- Is there a linked system which pulls data directly from another hospital system(s)? (Please indicate any linkages and describe the flow of data between each system.)
- If no please enclose any forms that are used in the hospital to collect data.
- What performance management systems are in place at MGH?

REQUEST FOR DATA

Cork University Hospital Group

1. Critical Care Services

Data for Cork University Hospital for each month for the 12-month time period from 1 August to date

Answer (Total number/ details)			Aug 09	Sep 09	Oct 09	Nov 09	Dec 09	Jan 10	Feb 10	Mar 10	Apr 10	May 10	Jun 10	Jul 10	Aug 10
CUHG. DaR.1	The total number of intensive care beds														
CUHG. DaR.2	Of that, (CUHG.DaR.1) the number (and %) of beds designated for general intensive care.														
CUHG. DaR.3	The number of closures of general intensive care beds. If any, please provide details														
CUHG. DaR.4	The general intensive care bed occupancy rate (%) per month														
CUHG. DaR.5	Of the total number of intensive care beds, (CUHG.DaR.1) the number (and %) of designated specialist intensive care beds (e.g. cardio thoracic neurosurgery) per specialty.														
	Specialty														
	Specialty														
CUHG. DaR.6	The number of closures of specialty intensive care beds, by specialty. If any closures or unavailability, please provide details.														
	Specialty														
	Specialty														
CUHG. DaR.7	The total number of specialist intensive care beds occupied by patients requiring general intensive care by specialty and month														
	Specialty														
	Specialty														
CUHG. DaR.8	The number of Coronary Care beds available														

CUHG. DaR.9	The number of High dependency beds available	
CUHG. DaR.10	The total number of requested referrals to CUH for patients requiring intensive /critical care by Mallow General Hospital (MGH). Please indicate the level of critical care required) for transfer	
	Critical care level 1	
	Critical care level 2	
	Critical care level 3	
CUHG. DaR.11	Of the total, (CUHG.DaR.10), the number of referrals accepted by CUH, by level of critical care required	
	Critical care level 1	
	Critical care level 2	
	Critical care level 3	
CUHG. DaR.12	Of the total, (CUHG.DaR.10), the number of referrals refused by CUH by reason for refusal	
	Reason for refusal	
	Reason for refusal	
CUHG. DaR.13	The total number of requested referrals to CUH for patients requiring intensive/critical care by other hospitals. Please give hospital name and the level of critical care required.	
	Hospital name	
	Critical care level 1	
	Critical care level 2	
	Critical care level 3	
	Hospital name	
	Critical care level 1	
	Critical care level 2	
	Critical care level 3	
CUHG. DaR.14	Of the total, (CUHG.DaR.13), the number of referrals accepted by CUH. Please give transferring hospital name and the level of critical care required.	
	Hospital name	
	Critical care level 1	
	Critical care level 2	
	Critical care level 3	
	Hospital name	
	Critical care level 1	
	Critical care level 2	
	Critical care level 3	

CUHG. DaR.15	Of the total, (CUHG.DaR.13), the number of referrals refused by CUH. Please give transferring hospital name and reason for refusal														
	Hospital name														
	Reason for refusal														
	Reason for refusal														
	Reason for refusal														
	Hospital name														
	Reason for refusal														
	Reason for refusal														
	Reason for refusal														
CUHG. DaR.16	The total number of patients requiring intensive/critical care that were transferred from CUH to another hospital, by hospital name and level of critical care required.														
	Hospital name														
	Critical care level 2														
	Critical care level 3														
	Hospital name														
	Critical care level 2														
	Critical care level 3														

2. Workforce

Medical consultant staff (including medical, surgical, emergency and anaesthetic consultants) of Cork University Hospital with session commitments at Mallow General Hospital

Title	Specialty	Category (see A below)	Commenced employment at CUH on:	Sessional commitment to MGH only (please state number of sessions per week)	Visiting consultants* (y/n)
A. Categories: Permanent (P); Temporary (T); Full-time Locum (FL); Part-time Locum (PTL); Part-time Permanent (PTP); Part-Time Temporary (PTT) * Please include information in relation to visiting consultants.					

REQUEST FOR DATA

HSE SOUTH

- the number of days per week out of hours on-site cover at Mallow General Hospital is provided by medical registrars
- the % of NCHD staff who have currently successfully completed the airway management programme
- Current out of hours on-site cover at Mallow General Hospital provided by medical registrars.

REQUEST FOR DATA

HSE Ambulance Service

Activity data for HSE Ambulance services in relation to Mallow General Hospital (MGH) and HSE south for the six-month period from 1 January 2010 to 30 June 2010

- Total number of patients brought to the Emergency Department at MGH for the six-month time period.
- Of the total number of patients brought to the Emergency Department at MGH for the six-month time period, the total number of patients for each clinical category (list clinical categories).

	Number of patients
Clinical category	
Clinical category	

- Total number of patients transferred out of MGH by ambulance to another acute hospital for the six-month time period and diagnosis for each?

	Total number
Diagnosis	
Diagnosis	

Appendix B

Membership of the Expert Advisory Panel convened by the Health Information and Quality Authority

Name	Representative organisation
Arthur Tanner	Royal College of Surgeons in Ireland
Diarmuid O'Shea	Royal College of Physicians of Ireland
Brian Marsh	Joint Faculty of Intensive Care Medicine of Ireland
Jeanne Moriarty	College of Anaesthetists of Ireland
Ian Sturgess	Associate Medical Director Patient Safety, East Kent Hospitals University NHS Foundation Trust. Clinical Lead Delivering Quality and Value, Emergency Care, NHS Institute (2005 to 2010)
Representative	Faculty of Radiologists of Ireland[§]

§ While not a member of the Expert Advisory Panel, Dr Barry Kelly of the Faculty of Radiologists of Ireland provided expert advice in relation to the radiology incidents referred to in section 4.2.6 to the Authority.

Appendix C

Letter to Health Service Executive

Cathal Magee
Chief Executive Officer
Health Service Executive
Dr Steevens' Hospital
Dublin 8

17 September 2010

Ref: TC/HC/CM/170910

Dear Cathal,

Investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive (HSE) at Mallow General Hospital (MGH), Cork

As you are aware, the Health Information and Quality Authority (the Authority) is currently undertaking an investigation into the quality and safety of services at Mallow General Hospital (MGH), in accordance with section 9(1) of the Health Act 2007 and this work is ongoing.

In the course of the investigation, an issue has been identified by the Investigation Team that the Authority believes may have the potential to pose serious risk to the health and welfare of persons requiring emergency surgical services at MGH, Cork while the permanent and temporary consultant surgeons are on leave. This issue has been identified from information provided by MGH and from a series of interviews conducted to date. While these issues and this correspondence will be referred to in the report of the investigation on its conclusion, the Authority believes it is important that this is brought to your attention now, in advance of its conclusion. This is being done so that the issue may be addressed and managed by the HSE as a matter of urgency.

Locum Surgical Consultant Cover

Currently, the provision of the surgical services at MGH is Consultant led and delivered by two permanent and one temporary Consultant surgeons. In the case of annual or study leave for the permanent or temporary consultants all out-patient clinics, admissions and theatre sessions are cancelled. However, the hospital continues to provide 24/7 undifferentiated emergency cover for walk-in patients who may require emergency surgery.

Currently, the locum cover for the consultant surgeon's on-call emergency commitment is provided by MGH's emergency department surgical officer.

Can you review this as a matter of urgency and provide assurances that the on-call emergency surgical cover at MGH is provided by a person with the relevant surgical training, experience and seniority and is registered as a specialist on the Specialist Division of the Register of Medical Practitioners.

If in the course of the investigation, further potential serious issues relating to the health and welfare of patients receiving services in the HSE, South are identified then these will be brought to your attention.

Yours sincerely,

DR TRACEY COOPER

Chief Executive

CC: Dr Barry White, National Director of Clinical Quality Care
Pat Healy, Regional Director of Operations, HSE South
Michael Scanlan, Secretary General, DoHC
Jon Billings, Director of Healthcare Quality and Safety, HIQA

Appendix D

HSE response to HIQA correspondence

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Oifig an Phríomhfheidhmeannaig
Feidhmeannacht na Seirbhise Sláinte
Urlár 1
Ospidéal an Dr. Steevens
Baile Átha Cliath 8

CEO's Office
Health Service Executive
1st Floor
Dr. Steevens' Hospital
Dublin 8

Tel: (01) 635 2000
Fax: (01) 635 2211
Email: ceopa@hse.ie

29th September 2010

Dr Tracey Cooper
Chief Executive
Health Information & Quality Authority
Unit 1301
City Gate
Mahon
Cork

RE: Investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at Mallow General Hospital

Dear Tracey,

I wish to refer to your correspondence to me of 17th September, 2010 in relation to HIQA's investigation into the quality and safety of services and supporting arrangements provided by the HSE at Mallow General Hospital. You have requested that assurance would be provided to you that the identified risk relating to the provision of on call emergency surgical cover at Mallow General Hospital is being addressed through the employment of a person with the relevant surgical training, experience and seniority.

Management in the Cork University Hospital Group, which has responsibility for Mallow General Hospital, have confirmed that the previous arrangements of utilising the services of the Emergency Department Surgical Officer to provide on-call emergency surgical cover has ceased with immediate effect and that on-call emergency surgical cover will only be provided by a person with the relevant surgical training experience and seniority.

Yours sincerely

Cathal Magee
Chief Executive Officer

Appendix E

Update on implementation of the recommendations of the Ennis Report received from the Health Service Executive (HSE) in February 2011.

Health Service Executive

Update on the HIQA report on Ennis Hospital: Local recommendations – Update January 21, 2011

Update on implementation of the recommendations of the Ennis Report received from the Health Service Executive (HSE) in February 2011.

Recommendation		DNE		DML		West				South	
		Navan No significant updates since Dec update	**Louth Co.** No significant updates since Dec update	**Portlaoise** Updates for jan inserted	**Columcille** No significant updates since Dec update	**Ennis** No significant updates since Dec update	**Nenagh** No significant updates since Dec update	**St Johns** No significant updates since Dec update	**Roscommon** Updates for jan inserted	**Mallow** Updates for jan inserted	**Bantry** Updates for jan inserted
1.1	**Patients with major or complex emergency conditions should not be treated in the emergency department in the Mid-Western Regional Hospital Ennis. In exceptional circumstances where such patients arrive in Mid-Western Regional Hospital Ennis they should be stabilised and transferred, as a priority, to a specialist centre.**										
	Are major or complex emergency cases accepted?	No ambulance presentations. Self presenters assessed and diverted to OLOL	No	Yes	Yes.	No	No	No	Yes.	Yes	Yes
	Is there a plan to cease acceptance?	Yes	Complete Minor Injury Unit	No	Yes.	N/A	N/A	N/A	Yes-part of Reconfiguration process	Yes	Yes
	Date by which it will cease?	Surgical - possibly 2011, following formation of Louth/ Meath Surgical dept dept. Medical -Contingent on devt of additional bed capacity & WTE's in OLOLH	N/A	Does not apply to MRHP. Current rotocols have been forwarded to G Cooke Dec 10	To be agreed with St Vincent's as part of reconfiguration	N/A	N/A	N/A	To be confirmed	**June 2011**	June 2011
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Protocol in place to manage surgical attendances. Acute surgical cases transferred Monitoring of surgical activity ongoing. Regional transfer policy in place. Bypass protocol in place for Trauma maternity & Paeds.. Assoc. Specialist Reg appointed. ED Consultant 4 sessions per wk.	MIU protocol in place including monitoring of inappropriate attendances	Major Trauma bypass implemented January 2011. Note: Major cases only, and only if they do not require stabilisation. Refers to approx 10-20 patients per year . Policy developed by Dr Sean ORourke, ED Consultant.	Pilot MAU in place with 24 hour ED. Trauma bypass in place. ED protocols.	Protocols adopted and in place	Protocols adopted and in place	Protocols adopted and in place	Pts stabilised and transferred. Reconfiguration commenced. CD appointed for Galway/Roscommon hospital group. Cross cover sessions for ED. 17/01/11 – By pass protocols being drafted based on the Mid West protocols	Ambulance bypass protocols in place. Mandatory acceptance policies in place with CUH for patients requiring level 3 critical care or tertiary services.	Ambulance bypass protocols in place. If major cases present, stabilised and transferred Mandatory acceptance policies in place with CUH for patients requiring level 3 critical care or tertiary services

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1.2	**The current provision of a 24-hour emergency care service is unsustainable and should be discontinued. A day-time minor injury service, as indicated by current activity, operating as a satellite of the regional centre should be developed and introduced.**										
	Is there a 24HR ED?	Yes	No	Yes	Yes	No	No	No	Yes	Yes	Yes
	Is there a plan to convert to a daytime MIU operating as a satellite?	Yes. In context of Transformation programme 2006 & proposed national Acute Medicine Programme.	Complete MIU	No: This will be discussed as part of the DML reconfiguration process. A group has recently been established in this regard.	Yes	Converted	Converted	Minor Injuries Unit in place since 1st July 2001 as part of ED	No	Yes	Yes
	Date of conversion	TBC. Dependant on additional bed capacity OLOL & WTE's & final agreement re Hosp Model for OLH	July 2010		2011.	Apr 09	Apr-09	2001	Reconfiguration Process.	**June 2011**	**June 2011**
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Emergency Care Clin. Governance Group reports quarterly to LHMG Quality and Risk Steering Comm. Restricted scope of practice for ED. Maternity, paeds and trauma bypass protocols for mgmt of surgical presentations including on-call hosp transfer rota. MAU in place. Consultant physician/ lead cover.	Protocol in place with monitoring of inappropriate attendances.	Yes. Protocols in place.	Trauma bypass in place. ED protocols. Pilot MAU.	N/A	N/A	N/A	ED pts under care of Med/surgical teams on call. Reconfiguration commenced (Plan available end Q4). CD appointed. 17/01/11 – By pass protocols being drafted based on the Mid West protocols Discussions have commenced with Ambulance re by pass.	Mandatory acceptance policies in place with CUH for pts requiring level 3 critical care / tertiary services. ED supported by sessions from ED consultant and regional ED policies in use.	Ambulance bypass protocols. ED pts stabilised & transferred

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1.3	**The Health Service Executive must take prompt action to review the role of the Mid-Western Regional Hospital Ennis emergency department as part of the development of an urgent care network across the Mid-Western Hospital Network.**										
	Is the emergency department part of an urgent care network?	Yes	Yes	No. MRHP has an ED Department.	No	Yes	Yes	Yes	No	No	No
	Is there a plan to become part of a network?	Multidisciplinary Consultant Led ED Network established in 2006.	MIU within ED network.	Not at this time. Reconfiguration as outlined.	yes: Part of Reconfiguration plan	N/A			Yes.	Yes	Yes
	Date for implementation				To be confirmed (reconfiguration)	Since April 2009	Since April 2009	Since July 2009	To be confirmed (reconfiguration)	Mar-11	Mar 2011. Reconfiguration plans to include governance of minor injuries/ urgent care centres
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	As per 1.2	As per 1.2	Protocols are in place for current services.	Shared protocols with St Vincent's. Trauma bypass. Clinical Director in place. Clinical protocols. Risk Register. Mau pilot.	Protocols in place	Protocols in place	Protocols in place	ED Consultant from GUH attends once a week. Reconfiguration plan available from Q4. CD appointed. 17/01/11- no up-date	ED supported by sessions from ED consultant and regional ED policies in use.	No

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2.1	**The Mid-Western Regional Hospital Ennis should not provide acute or elective inpatient surgical services. All acute and major surgery, including major elective and cancer surgery, should be transferred to the Mid-Western Regional Hospital Limerick.**										
	Are acute or elective inpatient surgical services accepted?	Acute – No. Transfer protocol in place. Elective - Minor & Intermediate procedures	Acute – No Elective - Minor & Intermediate procedures	Yes	Yes,	No	No	Yes, elective only	Yes	Yes	Yes
	Is there a plan to cease acceptance?	Yes, in the context of Transformation / Reconfig. Program	No. Changes planned to current arrangements.	No	Yes,	N/A	N/A	No	Yes.	Yes	Yes
	Date by which it will cease?	Louth Meath Surgical reconfiguration plan to be progressed in 2011	N/A		Plan to cease acute but not elective Surgical Service by year end.	N/A	N/A	N/A	Reconfiguration plan commenced and available from Q4. CD for Galway and Roscommon Hosps appointed.	June 2011	June 2011
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Protocol for management of emergency Surgical presentations incl. on call rota for referral Hosps Maternity /Paeds & Trauma Bypass	Louth Hosp Dept of surgery. with Consultant Lead. Dept Protocols in place for emergency elective surgical transfers.	There is currently no arrangement to transfer surgery to another site. This will be considered as part of the reconfiguration process.	Trauma bypass protocols in place	N/A	N/A	Elective non-cancer and 5-Day surgery only since July 2009	Yes - only minor surgical procedures and some acute surgeries performed at RCH. All major elective and cancer surgery are transferred to GUH. 17/01/11 – QCCA audit on 16/12/10. QCCA to request Surgical Lead to review RCH surgical activity& comment on its appropriateness and complexity.	Surgical and anaesthetic service is consultant provided. Anaesthetic pre-assessment on all surgical patients. Surgery not carried out where level 3 critical care may be required.	Case profiles of appropriate surgical procedures agreed between CD and Professor. Consultant surgeon participates in CUH training.

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2.2	**The Health Service Executive should review day surgery provision at Mid- Western Regional Hospital Ennis and consider the feasibility of a new regional surgical service based at Mid-Western Regional Hospital Limerick providing an outreach day-surgery and day-procedure service, including endoscope procedures, in the Mid-Western Regional Hospital Ennis using regionally agreed integrated protocols and care pathways.**										
	Has there been a review of day surgery at regional hospital linked to this site?	Yes. Surgical Dept to be integrated to Louth Meath Surgical Dept as per Transformation programme 2006..	Yes. Complete.	No	Yes	Yes	Yes	No	No	Yes.	Yes. Surgical review by CD
	Is there a plan to convert to day surgery for smaller sites?	Change programme includes focus on day services in outreach areas.	Change programme includes focus on day services in outreach areas.	Not applicable at this time.	Day and Minor Elective Surgery to continue.	Yes	Yes	No. Day surgery, Elective, Non-cancer and 5-Day surgery will continue as part of surgical re-configuration in the region.	Part of reconfiguration plan	Yes. Reconfiguration plan for HSE- SW being finalised, Q4 2010. Work to commence on identifying surgical activity (by speciality / procedures) which can be done on day basis in smaller hosps.	Yes. Reconfiguration plan being finalised.
	Date by which will have occurred?	2011 TBC Dependant on additional bed capacity OLOL& WTE's & final agreement re Hosp Model for OLH	Complete Louth Hosp Dept of Surgery in place.	N/A	Ongoing	Oct-09	Oct-09	July 2009	To be agreed.	Jun-11	Jun-11
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Being reviewing on an ongoing basis. Weekly audit taking place	Being reviewing on an ongoing basis.	There are currently no plans / proposals for outreach day services as MRHP has a full surgical service at this time.	Reconfiguration plan ongoing.			Reconfiguration plans ongoing	Yes. 17/01/11 – No up-date	Surgical activity is reviewed on a periodic basis by CD to identify activity which can be carried out on a day basis or relocated to other hospitals	N/A

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2.3	**In order to create maximum capacity at the regional centre in Limerick, the day surgery review should include consideration of an extended range of surgical specialties at the Mid-Western Regional Hospital Ennis to allow the transfer of some current elective day surgery activity from the Mid-Western Regional Hospital Limerick to create capacity on that site.**										
	Has there been a transfer of day surgery from regional hospital to this site?	Yes	Yes	Not applicable.	No	Yes	Yes	No. Day surgery in place for years. Day surgery, Elective, Non-cancer and 5-Day surgery will continue as part of surgical re-configuration.	17/01/11 No. Day surgery in place for years. Day surgery, Elective, Non-cancer and 5-Day surgery will continue as part of surgical re-configuration.	No	No
	Is there a plan for transfer?	Scope for further transfer of day surgical services following establishment of Louth Meath Surgical Dept	Complete	Not at this time.	To be agreed.				Yes	Yes	Yes
	Implementation date?	2011 TBC	Complete	N/A					??2011	Q2 / Q3 2011	Sep-11
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Surgical reconfiguration group established to progress development of plan for Louth Meath surgical services.	Complete	Issue may be addressed as part of reconfiguration plans.					Colonoscopy & urology only implemented at this stage.	N/A	

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3.1	**All women with symptoms of breast disease who present to the Mid-Western Regional Hospital Ennis should be referred immediately on to the designated symptomatic breast disease service at the Mid-Western Regional Hospital Limerick. The current breast review clinic at the Mid- Western Regional Hospital Ennis should cease.**										
	Are patients with symptoms of breast disease seen at this hospital?	No	No	No. Referrals from the Laois area are made to St James's /St Vincents Hospital. Consultant Surgeon at MRHP provides breast service at St James's Hospital.	No	No	No	No	No	No	No
3.2	**Tailored awareness and education programmes for general practitioners (GPs), community services and the public in the Mid West about new regional referral pathways and protocols, in particular for breast disease, should be developed and implemented**										
	Has awareness program been completed?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3.3	**The Health Service Executive should regularly audit the care pathways of patients with symptomatic breast disease, within the Mid Western region, to ensure agreed best practice including access arrangements, is being complied with.**										
	Is there a regional audit program for Breast diseases?	Yes	Yes	N/A as the service has ceased.	No	MWRH programme			N/A	Yes	Yes
	If not when will it be in place?	Scope for further transfer of day surgical services following establishment of Louth Meath Surgical Dept	Complete			MWRH programme			N/A	Dec-10	Dec-10
	Are measures planned or in place to mitigate risks and if planned, when will be implemented?	2011TBC	Complete	MRHP will co-operate with NCCP in relation to any national audits	MRHP will co-operate with NCCP in relation to any national audits				N/A	Audit of referral processes complete. Full program to be developed	Audit of referral processes complete. Full program to be developed

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4.1	**The Mid-Western Regional Hospital Ennis should not care for patients requiring level 2/3 critical care services. Patients requiring level 2/3 critical care services should be taken directly to the Mid-Western Regional Hospital Limerick by the ambulance services. Where patients self-attend, or deteriorate at the Mid-Western Regional Hospital Ennis and require level 2/3 critical care services, they must be stabilised by appropriately trained staff and safely transferred as a priority to the Mid-Western Regional Hospital Limerick, or other appropriate centre with Level 2/3 critical care resources.**										
	Are for patients requiring level 2/3 critical care services accepted in the hosp?	Yes	No	Yes	Yes	No	No	Yes	Yes -	Yes	Yes
	Is there a plan to cease acceptance?	Yes in context of Transformation programme & AMP	N/A	National Clinical Care Programme awaited.	Yes: to cease level 3.	N/A	N/A	Under review as part of medical reconfiguration.	Yes (Reconfiguration)	Yes. Once Acute Medicine Program is finalised, work will commence on reconfiguring of critical care services. Will require development of additional capacity in Cork city hospitals.	Yes. Once Acute Medicine Program is finalised, reconfiguring of critical care services to begin.
	Implementation date?	Plans to transfer L2 and L3 ICU contingent on capital build additional bed capacity & WTE's at OLOL & transfer of acute medicine.	N/A	N/A at this time.	As soon as possible	Apr-09	Apr-09	To be decided	To be agreed	Dec-11	Dec-11
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Maternity Paediatric &Trauma bypass. No major emergency surgery. Full Critical Care service in place to support Acute Medical service	No acute services Transfer protocol in place for any inappropriate attendances .to Hosp.	MRHP currently accepts level 2/3 critical care patients and there is no plan at this time to cease.	Reconfiguration plans ongoing	Protocols adopted and in place	Protocols adopted and in place	Protocols adopted and in place	Patients stabilised and transferred only. 17/01/11 – Draft protocol in place agreed with GUHin Dec 2010 that GUH will accept pt from RCH as if it was from one of its own wards/Dept.	Mandatory acceptance policy for Level 3 pts where clinical decision is made to transfer. Enhancement of NCHD cover and upskilling in airway mgnt and ACLS	Mandatory acceptance policy for Level 3 patients where clinical decision is made to transfer.

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4.2	**In the interim while acute medical and surgical services are provided at the Hospital, the level of care provided at the Mid-Western Regional Hospital Ennis should be consistent with level 0/1 only.**										
	Is service provided consistent with only level 0 / 1 care presence?	No	Yes	No. All critical care patients are accepted at this time. Transfer is based on clinical decision making (eg major head trauma)	No	Service is delivered as outlined in 4.1 above. Stabilisation and rapid transfer only.	Service delivered largely in line with 4.1 above. Stabilisation and rapid transfer only.	No	No	No	No for medical. Yes for surgical activity
	Is there a plan to cease care inappropriate to level 0 / 1 care provision?	Yes As per 4.1	N/A	Not at this time.	Yes	Yes	Yes	Under review as part of medical reconfiguration	No	Yes. Once Acute Medicine Programme is finalised, work will commence on the reconfiguring of critical care services. Will require development of additional capacity in Cork city hospitals. Surgical activity will be reconfigured to day activity, minor and intermediate by Mar'11	Once Acute Medicine Program finalised, reconfiguring will commence.
	Implementation date?	As per 4.1	N/A	N/A	As soon as possible	Feb 2011	Feb 2011	Under review as part of medical reconfiguration	Reconfiguration plan commenced and plan available from Q4. 17/01/11 – Reconfiguration plan expected by Q2 2011	Dec-11	Dec-11
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	. As per 4.1	As per 4.1	As above all patients are currently accepted.		Yes	Yes	Yes	Yes - patients stabilised and transferred if they deteriorate. Clinical Director for Galway & Roscommon Hospital in place	Mandatory acceptance policy for Level 3 pts where clinical decision is made to transfer. Enhancement of NCHD cover and upskilling in airway mgnt and ACLS	Mandatory acceptance policy for Level 3 pts where clinical decision is made to transfer.

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4.3	**The relevant transfer and bypass protocols must be regularly reviewed on a multidisciplinary basis, compliance audited and updated as necessary.**										
	Has such a review of transfer and bypass protocols occurred?	Yes	Yes.	No. Reconfiguration has not yet been applied.	Yes	Yes	Yes	Yes	Yes	No	No
	Has there been audit of compliance?	Yes Ongoing Monitoring of surgical activity and all inappropriate attendances..	Yes. Inappropriate attendances in MIU audited	N/A	Yes	Yes	Yes	Yes	Ongoing 17/01/11 – By pass protocols being drafted –using the Mid West by pass protocols as template	No	No
	Have protocols been updated as necessary?	Yes In context of service reconfiguration	Yes. Hospital bypass protocol in place.	N/A		Yes	Yes	Mar-10	Yes 17/1/11 – by pass protocols currently in place will be reviewed as part of the overall development of by pass protocols.	Ambulance bypass protocols currently being updated.	Ambulance by-pass protocols being updated
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Surgical protocol & over arching Inter hospital transfer policy.	MIU Protocol & over arching Inter hospital transfer policy.	Will be addressed as part of reconfiguration		Suite of protocols in place	Suite of protocols in place	Suite of protocols in place	Reconfiguration plan commenced and plan available from Q4. CD for Galway & Roscommon Hospital appointed. 17/01/11 – once decision re the opening hours of ED agreed.	Protocols in place	Protocols in place

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4.4	**The Mid-Western Hospital Network should review its provision of critical care services within the region to ensure safe patient services that comply with safe practice guidelines.**										
	Has regional/ Network review taken place?	Yes Teamwork 2006 & Saunders Critical Care review 2008	Yes Teamwork 2006	Not applicable to MRHP	Yes	Yes	Yes	Yes	No	Yes. As part of the preparation of reconfiguration plan.	Yes. Part of reconfiguration plan
	Have recommendations of review been implemented	No	Yes	N/A	Part of reconfiguration	Ongoing	Ongoing	Under review as part of medical reconfiguration		Phase 1 completed with level 3 critical care ceased. Phase 2: capacity for level 2 in progree	Phase 1 completed with level 3 critical care ceased.
	Date for review if not completed?	N/A	N/A	N/A		2011	2011		Ongoing at present		
	Date for implementation of recommendations if review has taken place	Plan to transfer L2 and L3 ICU contingent on capital build additional bed capacity & WTE's at OLOL & transfer of acute medicine	N/A	N/A	Dec-10	2011	2011	2011		Completed by Dec-11	Completed by Dec-11
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	No major surgery in Navan. Bypass protocol in place for ambulance trauma Maternity & Paeds cases Full Critical care service in place for acute medicine & Elective Ortho	Protocol in place for inappropriate attendances.	Clinical Decision making		Additional ICU/ HDU capacity planned in limerick	Additional ICU/HDU capacity being delivered in Limerick				Mandatory acceptance policy for Level 3 pts where clinical decision is made to transfer.
						Review of the MWRH Group by Prospectus Awaiting final report. Additional ICU/HDU capacity being developed in Limerick.					

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5.1	**The range of general medical services provided at the Mid-Western Regional Hospital Ennis should be reviewed by the Health Service Executive in light of the changes recommended to the emergency department, surgical and critical care services. A clear protocol-driven medical service model should be implemented that specifies which conditions can (and cannot) be treated safely in Mid-Western Regional Hospital Ennis. These protocols should be subject to regular audit.**										
	Has review of General Medical services taken place?	Yes	Yes	No similar recommendations have been made re the ED, surgical & Critical Care services at MRHP. Discussions regarding Acute Medical Programme have taken place. Level still to be decided.	Yes	Ongoing	Ongoing	Under review as part of medical reconfiguration	No 17/01/11 – agreed that RCH would be Model 2 Hospital in AMP	No. This will take place once the Acute Medicine Programme has been signed off.	No. Will be done with implementation of Acute Medicine Program
	Have protocols been developed for all medical services?	No. MAU SOP in place. Other protocols will be further developed as services reconfigure.	Yes.	Changes not yet recommended.	Yes	No	No	No	No	No. This will take place once the Acute Medicine Programme has been signed off.	No.
	If not, date for completion?	Depends on service reconfiguration. & recommendations of acute medicines programme.	Ongoing as services reconfiguration progresses.	N/A	Depends on AMP	Depends on implementation dates for the new medical model	Depends on implementation dates for the new medical model	2011	Depends on AMP dates and reconfiguration process.	Acute medicine programme date	Acute medicine programme date
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Full Critical care service in place. Specific treatment protocols are being developed by QCCD.	Louth Hospital Medical dept with Consultant lead.	No planned changes to the ED, surgical and critical care services at MRHP at this time.		Yes	Yes			Close links to specialist services in CUH including cardiology. GP selected referral	Links to specialist services in CUH. GP selected referral.

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5.2	**The Health Service Executive should seek to ensure that as wide a range of medical services as possible, including out-patients, day procedures, day patient facilities and inpatient services, are safely provided in the Mid-Western Regional Hospital Ennis. These should be fully networked with the Mid-Western Regional Hospital Limerick with clear patient pathways designed and implemented.**										
	Has revised plan for medical services for this hosp within the network completed?	Yes. Transformation and awaiting recommendations of AMP	Yes. Work in Progress	No changes have been recommended to the medical services at MRHP	Yes	Yes	Yes	Under review as part of medical reconfiguration	Yes	No	No
	Has it been implemented?	No. Surgical services under consideration at present.	Yes	N/A	No	Depends on implementation dates for the new medical model	Depends on implementation dates for the new medical model	2011	Depends on AMP dates	N/A	
	If not, when will it be implemented?	TBC Dependant on additional bed capacity OLOL & WTE's	Work in progress	N/A	Dec-10					Reconfiguration will determine date	Reconfiguration will determine date
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Full Acute Medical service in place.	Protocols in place.	No changes proposed to medical services at this time.						N/A	
						Awaiting sign off of medical protocols nationally					
5.3	**For as long as the acute medical services remain on site, dedicated elderly care services should be re-established to provide an appropriate integrated approach by a multidisciplinary team.**										
	Are acute medical services still provided? See 5.1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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	If yes, have dedicated elderly services been set up?	No. But Consultant Geriatrician in place. 4 x General Rehab beds.. Dedicated Elderly Memory assessment Clinic in place	Yes. Stroke Rehab Unit, Consultant Geriatrician Elderly day Assessment unit incl. direct access for Community Intervention team, Step down unit in place.	No. However elderly patients are treated at the hospital, and a Consultant Geriatrician is being appointed	Yes	Yes	Yes	No	Consultant Geriatrician in place, and elderly care provided at Roscommon Hosp & Sacred Heart Hosp	Yes, Age Care Evaluation clinics set up in 2008 with Out Reach Clinics at Kanturk, Fermoy and Nazerath House every 6 wks	Yes
	Date for set up if required?	TBC. Dependant on additional bed capacity OLOL & WTE's also recommendations of teamwork and AMP.	N/A	Consultant Geriatrician is being recruited in 2011.	Reconfiguration plans				as above	N/A	
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?		Protocols in place.	Consultant Geriatrician is being recruited in 2011		Yes	Yes	Yes	as above	N/A	
5.4	**The Health Service Executive should work with the relevant professional bodies to develop a national model for acute medicine that is stratified to allow centres to be designated as fit to provide services up to a certain level so it is clear which centres should provide which services. This acute medicine model should include taking into account the location of other acute services such as surgery, anaesthetics, maternity, children's and critical care at any one centre.**										
		The Acute Medical Programme under the direction of the National Director for Quality and Clinical Care has developed a model for acute medicine. This has been developed in collaboration with clinicians within the HSE, the Royal Colleges and Professional Bodies. It has been peer reviewed internationally and endorsed by the Department of Health and Children. An implementation plan is being developed for the roll out of this model and the plan will be completed by year end 2010. HIQA has a copy of document outlining the Acute Medical Model.									
5.5	**In order to make the best use of in-patient beds, the Health Service Executive should work with relevant professional bodies to identify a "basket" of conditions suitable (in the absence of agreed contraindications) to ambulatory (non-inpatient) patients requiring medical services.**										
		Basket has been identified nationally									

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5.6	**Having identified conditions to be managed on an ambulatory basis, these should be monitored routinely and published on an institutional basis. They should then be considered as part of annual service planning at national and local levels.**										
		These are reported on monthly and published through Healthstat									
6.1	**Acutely ill children should not be cared for at the MWRH Ennis. The ambulance service should take children directly to the paediatric service in MWRH Limerick. Where children are brought to Ennis by other means they must be stabilised and transferred to the regional services in the MWRH Limerick.**										
	Are acutely ill children accepted in the hospital?	No	No	Yes	No	No	No	No	Yes - to ED if brought in by parents/guardians. Ambulance by pass in place for Paeds.	No. .	No. In exceptional cases patients stabilised and transferred.
	Are there stabilisation and bypass protocols in place?	Yes	Yes	No. N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	If not when will they be in place?	N/A	N/A	No plans to cease service at MRHP		04 2009	04 2009	04 2009		N/A	
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Regional Transfer policy in place	Protocol in place for inappropriate attendances.	Consultant led paediatric service in place		protocol in place	protocol in place	protocol in place	Yes ambulance by pass and stabilise & transfer policy in place	In exceptional life saving circumstances, pts are stabilised and transferred, as priority to CUH. Ambulance bypass protocols in place.	In exceptional cases patients stabilised and transferred. Ambulance bypass protocols in place.
6.2	**There should be immediate cessation of elective inpatient paediatric surgery.**										
	Is inpatient Paediatric surgery carried out in the hospital?	No	No	Yes	No	No	No	No	No	No	No

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	If still carried out, when will it cease?	N/A	N/A	Currently no plans to cease		N/A	N/A	N/A	N/A	N/A	N/A
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Inappropriate attendances monitored	Inappropriate attendances monitored	Strong linkages with tertiary paeds service.					Paediatric dental surgery once a wk: trained nurses on duty and no other patients treated in the day services unit during the dental list.	N/a	N/a
6.3	**The Health Service Executive should consider the feasibility of the Mid-Western Regional Hospital Limerick paediatric services providing a paediatric outreach day-surgery service in the Mid-Western Regional Hospital Ennis with integrated regional protocols and care pathways. Any surgical and anaesthetic day-case services must be provided in a child appropriate environment by healthcare teams competent in the clinical care and resuscitation of children.**										
	Has the feasibility of this been considered?	Yes	Yes	N/A	N/A	No	No	No	No	Yes	Yes.
	Has recommendation been made and if so when will it be implemented?	Yes, Completed No plans to introduce surgery patients < 14yrs	Yes, Completed No plans to introduce surgery patients < 14yrs	No						Yes, 2011	No
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	N/A	N/A	N/A						part of reconfiguration process	part of reconfiguration process
						This matter is being addressed under the Mid-West Reconfiguration project					
7.1	**Women with pregnancy related conditions should not be brought by the ambulance services to the Mid-Western Regional Hospital Ennis. These patients should be brought directly to the Mid Western Maternity Hospital Limerick. Patients self presenting to the hospital should be transferred as a priority to the regional centre at Mid Western Maternity Hospital Limerick.**										
	Are ambulance maternity cases accepted?	No	No	Yes	No	No	No	No	No	No	No

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	Are self presenters transferred?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes.	Yes.
	Is there a plan for bypass and transfer?	yes	yes	N/A	Yes	Yes	Yes	Yes	as above	in place	In place
	Implementation date?	N/A	N/A	N/A		04 2009	04 2009	04 2009	implemented	N/A	N/A
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Bypass protocol in place. Inappropriate attendances monitored	Bypass protocol in place. Inappropriate attendances monitored	Consultant led service provided. 24/7 med, anaesthetic and obs/ gynae in place. No plans to transfer maternity cases.	Bypass protocol in Place.	Protocol in place	Protocol in place	Protocol in place	No 17/1/11 – by pass protocol in place – will be reviewed using the Mid west Template	Only in emergency situations, where women are about to give birth, in communication with CUH (Maternity).	Only in emergency situations, where women are about to give birth, in communication with CUH (Maternity).).
7.2	**The Mid Western Maternity Hospital Limerick should review the provision of ultrasound scans for women attending its outreach service in the Mid Western Regional Hospital Ennis to ensure it is consistent with the service provided at its regional centre**										
	Has a review taken place?	Yes.	Yes.	N/A	N/A	Yes	Yes	N/A	N/A	Service no longer provided	No
	Implementation date for review output?	Complete	Complete	N/A		2010	2010				Jan-11
	If no review, when will one commence?	N/A	N/A	N/A							
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Outreach service is within the remit of Women & Children's Health Governance Structure.	As per Navan	Full Maternity Services provided at MRHP with strong linkages with tertiary centres.							

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7.3	**The Mid Western Maternity Hospital Limerick should regularly audit its outreach services to ensure they are consistent with services at the regional centre.**										
	Has audit taken place?	No	No	N/A	N/A	Yes	Yes	N/A	N/A	N/A. Service no longer provided	no
	If not, when will audit commence?	Group awaiting commencement of audit	Group awaiting commencement of audit							Jan-11	December 2010
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Agreed quality standard across all sites. Service is monitored by the Women's Health Governance Structure.	Agreed quality standard across all sites. Service is monitored by the Women's Health Gov. Structure.			Audit tool developed for outreach services	Audit tool developed for outreach services		N/A		The service is an outreach provided service from CUMH. Agreed CUMH protocols and procedures for outreach service in BGH.
8.1	**The future role of diagnostic services in the Mid-Western Regional Hospital Ennis should be clearly defined. A strategic review of the radiology and laboratory services should be undertaken leading to these services being outreach services from the Mid Western Regional Hospital Limerick with centrally agreed integrated protocols and care pathways that will be fit for purpose in supporting the changes in services outlined in this report**										
	Has the role been defined?	Pathology – No role will be defined in the context of reorganisation of services in AMP & Transformation. Radiology – Yes	Pathology – yes Radiology - Yes	No. Radiology Services are provided at MRHP with the exception of CT out of hours. Transferred to MRHT. MRI Services for the Midlands are provided at MRHT. Laboratory services provided at MRHP. Currently, there are national discussions re cold labs. Discussions are currently taking place re transfer of microbiology to MRH Tullamore from Portlaoise and Mullingar.	Yes	Yes	Yes	No	No	Yes.	Yes.

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	Has a strategic review been carried out?	Pathology - No Level of service agreed in context of transformation programme. Radiology - Yes Saunders 2008 Gover'ce review. Level of service will be defined by AMP & Transformation.	Pathology - Yes Level of service agreed in context of transformation programme. Radiology - Yes Saunders 2008 Governance review	No	Lab-yes. Radiology-yes	Yes	Yes	No	No	Yes.	Yes.
	Implementation date for review output?	In context of service reconfiguration	Complete.	N/A	Dec-10	2011	2011	Pathology work-stream in place as part of reconfiguration project	As part of the reconfiguration plan	commencing 2011	commencing 2011
	Are measures planned or in place to mitigate risks and if planned, when will be implemented?	Pathology - Louth Meath Lab Manager & Clinical lead. Radiology - Clinical Lead and Clinical Governance in place. LM Governance Committee advancing clinical Governance programmes in accordance with National recommendations Radiology Risk assessment process in place.. Will implement further change in context of national QA.	Pathology. Group Lab Manager & Clinical Lead for pathology services As per Navan	Robust risk management system in place. Review of Radiology planned with QCCD and Faculty of Radiologists. All incidents are reviewed locally. (Ref Incident Review meeting planned with mgmt team Thurs to discuss 2 cases) Risk issues are discussed at governance meetings.				Will participate in the QA program run byQCCD 7Faculty of Radiologists	A joint Department of Radiology exists with Portiuncula Hospital & Roscommon County Hospital.	Clinical audit process in place in Radiology for review of films in conjunction with the CUH Radiology Dept.	Clinical audit in progress for review of films in collaboration with CUH.
	A National QA Programme has been established by the HSE and the Faculty of Radiologists in Ireland. This is being rolled out in 2011										

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8.2	**A quality assurance system, which includes rigorous procedures and protocols for requesting, prioritizing, reading and reporting radiology examinations, with defined timelines and volumes, should be implemented, regularly reviewed and compliance audited.**										
	Has a radiology QA system been implemented?	Yes. Work in progress which will be guided by National QA programme 2011.	Yes. As per Navan	No	Yes	No	No	Will participate in the QA program run byQCCD 7Faculty of Radiologists	No	No	No
	When did audit commence or is planned to commence?	Work in progress Local QA system in place to audit volume's & Turnaround time through Clinical Governance.	As per Navan.					Not commenced.	Commenced	Mar-11	First audit completed.
	Are measures planned or in place to mitigate risks and if planned, when will be implemented?	Ongoing monitoring by GM. Additional capacity introduced incl. weekend initiatives & outsourcing. Will implement further change in context of national QA. Programme. Progressing Louth Meath RSM position Risks are migrated via Clinical Gov Groups. QIP's in place	As per Navan	Review of Radiology planned with QCCD and Faculty of Radiologists.		Yes	Yes	Yes. X-rays are reported within days	All radiology reported on day of procedure	Ongoing audits. Shared staff with tertiary hospital.	Ongoing audits.
	A National QA Programme has been established by the HSE and the Faculty of Radiologists in Ireland. This is being rolled out in 2011										

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8.3	**The Mid Western Regional Hospital Ennis should implement reliable mechanisms, for example multidisciplinary clinico-radiological meetings, whereby the referring clinician, including GPs, can discuss the imaging findings in complex cases in more detail with the radiologist or other individual who has reported the examination.**										
	Have clinico-radiological meetings commenced?	Yes	Yes	Yes (excludes GPs)	Yes (excludes GPs)	No	No	No	Yes - in house only	No.	No
	When did they commence/planning to commence?	2009	2009		2006			No	ongoing	No.	No
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Further change in structure is envisaged in context of National QA programme.	As per Navan	Referring Consultant and Radiologist in communication. Meetings to be minuted to include attendees, schedule and terms of reference, etc.		Informal review and meetings in place	Informal review and meetings in place	Informal review and meetings in place	Yes	Radiologists attend weekly consultant meetings. Case by case discussions between consultants.	Informal discussions between clinicians/ radiologists
	A National QA Programme has been established by the HSE and the Faculty of Radiologists in Ireland. This is being rolled out in 2011										
8.4	**A robust system for the safe, timely management and reporting of all tests, both at local and regional laboratory level, should be developed, implemented and regularly audited. This system should involve the prioritisation of test reporting and protocols for the follow up of the reports by the identified clinician**										
	Has a system been developed?	Yes	Yes	Yes	Yes	Yes	Yes	Online access to results for all hosp clinicians and phone call system for urgent and abnormal unexpected results in place.	yes	Planned installation of APEX computer system in Labs by year end giving online access to GPs, all clinicians and wards in MGH.	Yes
	When did audit commence or is planned to commence?	Full programme will be in place Q1 2011	In Place	Full audit process in place in Laboratory	Yes	Yes	Yes	Turnaround times audited quarterly and reported to Quality Manager	No	Yes. Regular audits are preformed in the Laboratory to INAB requirements	Yes. Regular audits are preformed in the Laboratory to INAB requirements

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	Are measures planned or in place to mitigate risks and if planned, when will be implemented?			Joint Pathology Committee between 3 hospitals. INAB accreditation for haematology and blood transfusion.		Weekly audit meetings locally (not MDT)	Weekly audit meetings locally (not MDT)	Risk Register non-conformance reporting system in place. There is send/return monitoring of tests to external labs.	Blood Transfusion lab accredited.	N/A	Blood bank section is audited.
	A National QA Programme has been established by the HSE and the Faculty of Radiologists in Ireland. This is being rolled out in 2011										
9.1	**The bypass protocols for the maternity and children must be fully implemented immediately and the HSE should systematically evaluate all of its bypass protocols through audit and, as required, identified improvements should be implemented**										
	Have bypass protocols for maternity & children services been implemented?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Date of implementation	2002	2002	N/A		04 2009	04 2009	04 2009	2009	2003	2003
	When has evaluation taken place?	ongoing	ongoing	N/A		yes	Yes	Yes	Not yet evaluated	No	No
	When have improvements identified been implemented?					Yes	Yes	Yes		N/A	N/A
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	All obstetric & paediatric attendances trigger formal incident review.	All obstetric & paediatric attendances trigger formal incident review.	Maternity & Paeds services on-site.		Protocol in place	Protocol in place	Protocol in place		N/A	N/A

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9.2	**The HSE must ensure that there are appropriate numbers of suitably qualified ambulance staff to provide a safe emergency and non-emergency patient transport service in the Mid West region within an established duty rota that does not rely on an on-call rota for the basic provision of the service.**										
	Have appropriate numbers of qualified ambulance staff been put in place?	Yes	Yes	Ambulance Service managed centrally and not at MRHP.Yes	Yes	Yes	Yes	Yes	Yes	No	No
	Does the service rely on an on-call rota?	No	No	No	No	Yes	Yes	Yes	No	Yes	Yes
	If so, date by which this will cease?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Proposals under consideration and discussion with staff	Proposal under consideration and discussion with staff
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?					On-call in Scariff, Ennistymon and Kilrush. Discussion ongoing	On-call in Scariff, Ennistymon and Kilrush. Discussion ongoing	The ambulance service is operated by the HSE		Advanced Paramedics will be deployed early in 2011.	Advanced paramedics on 24/7 based in Bantry
10.1	**The Mid Western hospital network should systematically evaluate its bed management processes, through audit, with required improvements implemented and re-evaluated to confirm continuous quality improvement. This should incorporate a robust discharge planning policy, which commences on admission and states that appropriate and open information must be provided to the patient and or their family members and the receiving care provider to ensure transfer and ongoing patient care pathways are safe and of a high quality.**										
	Has audit taken place, and if not when?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Is there a discharge planning policy, and if not when?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes,	Yes. Draft policy in place. Expected to be finalised by March 2011.	Yes. Draft policy being worked on. Will be finalised by Dec 2010.

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	Is open information provided to service users and receiving care providers?	Yes	Yes	Yes	Yes	Yes - Self assessment on HC records and integrated d/c planning - July 2010 as MWRH group	Yes - Self assessment on HC records and integrated d/c planning - July 2010 as MWRH group	Yes.	Yes	Yes	Yes
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?			Discharge planning through the JIG (Joint Implementation Group) Regular audits done. ALOS 3.2 days. Bed Utilisation study completed in 2010. JIG formally adopted as the mechanism for bed management at MRHP, which is managed by the Director of Nursing. Escalation Policies in the Midlands are currently being reviewed and a bed bureau for 3 regional hospitals under consideration		Yes. Bed Utilisation survey, Self Assessment of HC records & Integrated d/c planning done in MWRH network.	Yes. Bed utilisation survey, self-assessment of healthcare records and integrated d/c planning done in MWRH network.	Yes. Bed utilisation survey including d/c planning completed in June 2010. Self-Assessment of healthcare records and integrated d/c planning completed.	ongoing		New discharge checklist being drafted.

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10.2	**The HSE should systematically evaluate all of its discharge protocols, through audit, and as required identified improvements should be implemented and the protocols re-evaluated to confirm continuous quality improvement.**										
	Has audit taken place and if not when?	Yes - two audits have taken place under the National IDP framework	Yes - two audits have taken place under the National IDP framework	Yes	Yes	Yes	Yes	Yes	Yes	Yes: Self assessment carried out against the Integrated Discharge Planning standards, e.g. daily and weekly audits performed.	Yes: Self assessment carried out against the Integrated Discharge Planning standards, e.g. daily and weekly audits performed.
	Have identified improvements been implemented and re-evaluated?	Yes – a QIP has been developed and is currently being implemented, As a quarterly report is required the QIP is monitored and reviewed every few months.	Yes - a QIP has been developed and is currently being implemented, As a quarterly report is required the QIP is monitored and reviewed every few months	ongoing	Yes	Ongoing	ongoing	Yes	ongoing	In the process of indentifying KPIs and establishing a group to address standards	Yes. KPIs established and implemented.
	If not when?									Nov-11	
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	The Louth Meath Joint Implementation Group oversees and reviews the QIP and makes recommendations and amendments if actions are not being met.	The Louth Meath Joint Implementation Group oversees and reviews the QIP and makes recommendations and amendments if actions are not being met	Self assessment as part of National D/C Planning Program		Yes	Yes	Yes	Audit ongoing as part of the IDP quality programme	N/A	
						Self Assessment on Healthcare Records and Integrated D/C Planning in July 2010 in the MWRH network. JIG established.					

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11.1	**All acute hospitals contributing to the Midwest region acute care system should form a hospital group under an integrated operational governance and management structure, based at the Midwestern Regional Hospital Limerick. The group should be led by a management board with executive accountability and the appropriate skills and experience to discharge these responsibilities and to manage the changes required in the transition of patient services across the areas. Satellite centres should have clear and appropriate day to day onsite operational management arrangements.**										
	Has a governance structure been implemented?	Yes	Yes	Governance structure of MRHP consists of Clinical Director, Director of Nursing, Hospital manager and Governance Committee. Reporting relationship is to Asst National Director of the Midlands Hospital Group	No.	Yes	Yes	Hospital is a service provider to the HSE under section 38 of the Health Act 2004	No	Yes: MGH part of CUH Group. GM CUH chairs mgt team MGH and is part of mgt team in CUH. Clinical director CUH group has responsibility for MGH.	Yes: MGH part of HSE SW Hospital Group. Network manager is accountable manager for the hospital. Clinical director CUH group has responsibility for MGH.
	Have satellite centres clear operational arrangements?	Yes	Yes	N/A	Planning in progress	Yes	Yes	Yes	No	Yes	Yes
	If not, when will this be in place?			N/A							
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Louth Meath Executive Management Board & Senior Management Team in place. Local review in progress		Midland Group governance structure developed. Clinical Governance in the process of developing. Further measures will be considered as part of the wider acute hospital reconfiguration process, management / governance structures will be reviewed both locally and regionally.	Clinical director across St Vincent's and this hospital.				Yes		
						No Board but Senior management Team in place.			New CD of Galway & Roscommon in place since Jul 2010		
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										

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11.2	**The hospital group should be led by a CEO who is ultimately accountable for the provision and management of the services provided by the group and who is accountable to the Network Manager. The CEO should lead an executive management board consisting of directors who have the appropriate skills and experience to discharge their responsibilities and who are accountable to the CEO. This board will be responsible for the provision of all services and implementation and management of the transition of patient services across the area. The Smaller hospitals in the group should have clear and appropriate day to day operational management arrangements reporting to the group management board.**										
	Has an accountable CEO or equivalent been appointed?	Yes	Yes	Asst National Director of the Midlands Hospital Group	Yes	Yes	Yes	Chief Executive reports to management Committee of Hosp	Yes	CUH group has CEO	Yes; network Manager
	Are a board / team of appropriate managers / directors in place?	Yes	Yes	Clinical Director, Director of Nursing and Hospital manager all report to the Asst National Director of the Hospital Group.	Hospital manager in [place reporting to RDO	Yes	Yes	Yes	Hospitals has its own management team, GUH has HMB to be broadened to include smaller hospitals	Yes	Yes; Hosp has its own mgnt team. Hosp Network Mgr works with Mgrs/CDs thro' direct reporting relationship or service arrangements for non-statutory hosps.
	Have smaller hospitals in the group clear operational arrangements including reporting arrangements to group management team / board?	Yes	Yes	No		Yes	Yes	Hospital is a service provider to the HSE under Section 38 of the health Act 2004	Not yet defined	Yes	Yes
	If not, when will this be in place?			Reconfiguration process					Working with Clinical Director to meet this objective		
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Local review of Louth Meath Management structure in progress.	Local review of Louth Meath Management structure in progress. I	QSR Framework on Clinical Governance being considered.					Yes		Reporting to Network manager
						CEO, Board and Directors appointed in GUH only					
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										

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11.3	**A code of governance should be established that sets out the management board's roles and responsibilities including an oversight role in respect of safety and quality of health services provided. This must include clear lines of accountability and devolved decision making.**										
	Has a code been established?	Yes	Yes	While a code is yet to be established with clear responsibilities in place, the Hosp Mgr, Clin Dir and DoN are aware of their roles. All 3 report to Asst National Director who has overall responsibility.	No	Yes	Yes	St Johns operates under a management scheme approved by the High Court	Yes	Yes; Exec Mgnt Board (EMB) has terms of reference. Chairs CUH clin governance group are part of and are accountable to EMB for quality & risk	Yes: Role of network manager clear
	If not, when will it be?			Part of reconfiguration process	Part of reconfiguration process					N/A	N/A
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Local review in progress in context of National HSE Accountability framework.	Local review in progress in context of National HSE Accountability framework.	There are difficulties in this area due to reporting relationships, etc. However, a governance committee has been established on site, directed by Asst National Director of the Hospital Group.						Robust quality, safety and risk management process and structure in place. risk sub group	Regional management team has established sub-group on quality, safety and risk.
						A Mid West Acute Services Governance Committee on QRS in place. Includes TOR					
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										

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11.4	**The regional management tier at network level in conjunction with the executive management board of the hospital group should focus on strategic governance of the region, stakeholder engagement and performance management and monitoring of the hospitals.**										
	Has such focus been put in place?	Yes	Yes	No	No	Yes	Yes	Hosp is a service provider to the HSE under section 38 of the health act 2004	No.	Yes	Yes.
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	LMHG service Plan Monitoring and Control meetings between the Management team of the hospital and the network, Regional acute hospital forum which looks at the more strategic issues in the region the meetings between the network office and the RDO		Regular performance meetings with Hosps and RDOs.	Will be in place within weeks			There is a Service Level Agreement in place with the HSE	Commencing at early stage		
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										
11.5	**The HSE should establish an active programme to address historical anomalies in reporting arrangement in order to achieve clearer lines of accountability for clinicians and managers at hospital level. This should include all clinical consulting teams being appointed to and organized from the mid western regional acute hospital group as part of a regional service.**										
	Has a programme been put in place?	Yes	Yes	No	Yes	Yes	Yes	Yes. All Consultants, DON and Senior Admin Mgrs report to the Chief Executive	No	Yes. All consultants report to CEO CUH group.	Yes. All Consultants, DON, and hosp manager report Network Mgr

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	Are all appointments made as outlined above?	Yes	Yes		Yes			Not to-date		No. However all new appointments have clause in contract referring to changing roles following reconfiguration.	No.
	If not when will these be in place?								To be decided	In implementation of reconfiguration of acute hospital services.	Following implementation of Acute medicine Program.
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Work in progress in line with national HSE Accountability Framework Including further development of speciality lead Clinician roles. Louth Meath Clin Director in place	Work in progress in line with national HSE Accountability Framework Including further development of speciality lead Clinician roles. Louth Meath Clin Director in place..		Clinical Director in place				No	Yes. Clinical Director of CUH has responsibility for Mallow Gen Hospital	Yes. Clinical Director of CUH has responsibility for Bantry General Hospital
						Clinical Directorship role being developed					
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										

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11.6	**Clinical teams in the Mid Western Regional Acute hospital group should come under a unified clinical governance system led by a regional clinical specialty groupings based in the regional centre in Limerick. This should incorporate the development of agreed patient pathways owned by the regional clinical departments each under the leadership of a clinical director.**										
	Is such a unified clinical governance system in place?	No	Yes	No	Yes	No	No	No	No	No	No
	If not when will it be?	Surgical Reconfiguration group established to progress devt of plan for Louth Meath Surgical Dept. Integration of the Medical Dept will be progressed as services are reconfigured, this is contingent on additional bed capacity in OLOL and AMP. Louth Meath Clin director in place.	Final medical Model to be agreed in context of AMP.			Work in Progress	Work in Progress	Separate employer to the HSE with clinicians holding their contracts with the hosp. Clinical Director role does not fit in with our scheme of management and the role requires further review.	No	June 2011. Work has begun on assimilating the Management Team in Mallow to the EMB in CUH. The operations manager in CUH chairs the Mallow Management Team. The chair of Mallows Quality Safety and Risk Committee is also a member of CUH's quality safety and policy group	June 2011. Work on implementation to commence following publication of Reconfiguration Plan. Will be dependent on national decisions on governance and management structures.
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Clinical Director in place. Consultant lead identified for individual service transfers. Protocols in place.	Clinical Director in place. Consultant lead identified for individual service transfers. Protocols in place.	Clinical Director has been appointed. Will be addressed as part of reconfiguration					Not yet but is being dealt with by the Clinical Director of Galway & Roscommon	Clinical Director for CUH has responsibility for MGH.	CD for CUH responsible.
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										

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11.7	**For as long as an emergency service continues to be provided at the Mid Western Regional Hospital Ennis, formal clinical accountability and reporting arrangement must be established immediately for emergency care physicians working in the emergency department.**										
	Are formal clinical accountability and reporting arrangements in place?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
	If not, when will they be in place?					Complete	Complete	Complete			
	Are measures planned/ in place to mitigate risks and if planned, when will be implemented?	Senior Clinician cover 5 days weekly. Consultant Physician / Surgeon on call. Can seek advise from ED Consultant in OLOLH out of hrs..	ED Consultant Governance structure in place for MIU with linkage to OLOLH			Complete	Complete	Complete	As part of the reconfiguration plan		Regional ED policies used in Bantry.
12.1	**The MWRH Ennis should ensure that a pro-active patient centred approach to risk management is taken and implemented throughout the hospital according to national policies. This should include improving integration between its risk management, complaints and FOI systems to facilitate timely patient focused responses and to enable shared learning.**										
	Has such an approach been implemented?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	If not, when will it be?	Work in progress	Work in progress								

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	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Proposal for the phased integration of all Q&R processes in Louth Meath	Proposal for the phased integration of all Q&R processes in Louth Meath	Complaints mgr/ quality mgr/risk mgr have worked closely to provide pt focused response. Policies still in place. However, MRHP are going to encounter difficulties as the quality mgr / risk mgr / support to complaints officer have retired / resigned via the exit schemes. These issues are being considered locally & regionally. Solutions being generated.				Complaints Officer /Quality Mgr and Risk Mgr work closely and there is an active Patient Partnership Group in place.	Risk Advisor post in Roscommon County Hospital. Patient forum in GUH.		
12.2	**The MWRH Ennis should undertake a regular audit of the views of complainants to ascertain how the Hospitals approach to complaints and concerns can be improved and the necessary changes identified in such audits should be implemented.**										
	Has audit taken place?	N	N	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
	If not, when?	Not planned at present	Not planned at present					Nov 2010			
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?	Internal Review of complaints process completed. Proposed to integrate complaints within Risk Mgt and Quality Structure.	. Internal Review of complaints process completed. Proposed to integrate complaints to the Q & R Dept	Complaints review standard item on monthly governance meetings					Yes	Informal reviews of complaints and Pt Satisfaction Surveys completed. Also incident forms are reviewed at the QSR committee meetings.	Informal reviews of complaints. Patient Satisfaction survey completed.

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12.3	**As recommended by the Authority in a previous investigation report, the MWRH Ennis should ensure than an effective independent advocacy service for patients is in place in the hospital. These advocacy services should support and facilitate patients coming forward to raise concerns and have them addressed.**										
	Has a service been put in place?	Patients advised re contact details of patient focus	Patients advised re contact details of patient focus	No	Yes	Yes	Yes	Yes-	Yes-	Establishment of a Patient advocacy service is being explored.	Yes. Advocacy service in place in St Joseph's Unit. (Care of the elderly facility) The first meeting of the BGH Patient Forum Group took place on 14.12.2010
	If not, when?			2011						June 2011	Completed
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Interim arrangement involves liaison with Patient groups	.Interim arrangement involves liaison with Patient groups.	Mgmt working with Dir of Advocacy services. Consumer reps to be recruited. Patient Service User Group to be established nationally.				An active partnership Forum in place and meets monthly.	patient focus group established	User groups are to be established in Nov. 2010	User groups to be established by Nov 2010.
12.4	**The HSE should ensure that the new regional risk management structures in the Midwest have clearly defined lines of responsibility and levels of accountability. The processes must be transparent; patient focused and have clear learning pathways.**										

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	Are regional risk management structures in place, with clear accountabilities?	Regional accountability structure for risk management is clearly defined and arrangements are in place for mgmt of SI's, oversight of Q&R Framework and other compliance requirements. A Quality and Risk Manager has been appointed to the region and further development of the quality and risk structures and processes is taking place. The risk associated with the reconfiguration process is being actively managed at RDO Level and is reflected on the RDO Risk Register	As per Navan	Yes	Yes	Yes	Yes	Has own risk management structures in place. Hosp staff also participate in regional Risk Mgmt groups	No,	Yes. Reg Mgnt Team established sub-group on quality, safety and risk. -Area manager for quality, safety and risk reports to RDO. -Hosp Network mgr is part of subgroup on quality, safety and risk. -quality frameworks, risk registers and serious incident reports from all hospitals Are reviewed by quality, safety and risk sub Group.	
	If not, when will they be in place?								To be decided		
	Are measures planned or in place to mitigate the risk and if planned, when will these be implemented?			Midlands has an integrated model of risk mgmt in place with Risk Registers as agenda item at governance meetings and quarterly assurance reports. Risk Register for MRHP developed and issues escalated initially in Dec 09.					Plan to put in place regional group as part of reconfiguration.		

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12.5	**At a regional level the risk management process should be regularly monitored and audited with the outcomes reported through the national risk management structure to the CEO of the HSE**										
	Has regional monitoring and outcome reporting taken place?	Yes Will be progressed within the framework of Regional accountability structure.	Yes	Yes	Yes	Yes	Yes	Has own risk management structures in place.	No	Yes	Yes
	If not, when will this take place?								To be confirmed		
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?			Appropriate risks included in Regional Risk Register. Risks not mitigated on site were escalated in Dec 2009 with monthly updates.		Risks register process at local level. Draft risk register at regional level.			Yes as part of risk register		
12.6	**The HSE should identify a suitable independent person or organization agreed with individuals / persons that request it to offer mediation with a view to discussing in detail and resolving any residual concerns in the way with which their complaint was dealt.**										
	Has such a person / organization been put in place?	Yes. In part	Yes. In part	?RDO	Yes	Yes	No	Yes. Complainants are advised to seek a review by the Ombudsman if they remain dissatisfied following hosp review of their complaints.	No	No	Yes
	If not, when will this be in place?									No plans	Yes

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	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Area Manager for consumer affairs in place	Area Manager for consumer affairs in place	Complaints appeals process in place.					Consumer Affairs department in Tullamore supports	HSE Complaints Policy	HSE complaints policy
13.1	**The local change programme should be led by an experienced senior manager and the implementation programme must incorporate significant engagement with service user and clinical stakeholders**										
	Has leader been put in place?	Yes	Yes	Yes – Clinical Director	Yes.	Yes	Yes	Yes	Yes	Yes	Yes.
	Has engagement taken place?			Yes	Reconfiguration plans continuing	Yes	Yes	Actively participating in the reconfiguration of Acute Services Project.	No	Yes.	Yes.
	If not, when will these occur?								Starting Sept 2010		N/A
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?	Transformation Leadership Group Louth Meath Steering Group. Project team in place	Transformation leadership Group Louth Meath Steering Group. Project team in place. All change initiatives progressed in a Multidisciplinary Project team approach incl. PCCC services.	CD has been been appointed to the Reconfiguration team in DML		Yes	Yes	Yes	lead appointed		N/A

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13.2	**A comprehensive programme of change that is effectively led and managed needs to be undertaken. This will take time to implement and the HSE need to ensure that appropriate facilities resources and staff are in place throughout the current mid western acute hospital network in order that changes in the location of patient care can be safely accommodated**										
	Has such a programme been undertaken?	Yes	Yes	No. Reonfig team has met once.	Yes, reconfiguration plans ongoing	Yes	Yes	Yes	No	Yes. Action plan to improve safety and reduce risk is overseen by Hosp Network Mgr. Programme for reconfiguration of acute hospital services commenced.	Yes. Action plan to improve safety and reduce risk is overseen by Hospital Network Manager. Programme for reconfiguration of acute hospital services commenced.
	If not when will such a programme be undertaken?					Ongoing	Ongoing	Ongoing.	Starting Sept 2010		
	Are measures planned / in place to mitigate risk and if planned, when will be implemented?	Louth Meath Steering Group will implement and monitor the reorganisation of services in OLH	Louth Meath Steering Group established to implement and monitor the change process.	Reconfiguration commenced in DML							

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		Navan	**Louth Co.**	**Portlaoise**	**Columcille**	**Ennis**	**Nenagh**	**St Johns**	**Roscommon**	**Mallow**	**Bantry**
		No significant updates since Dec update	No significant updates since Dec update	Updates for jan inserted	No significant updates since Dec update	No significant updates since Dec update	No significant updates since Dec update	No significant updates since Dec update	Updates for jan inserted	Updates for jan inserted	Updates for jan inserted
13.3	**The HSE should as a priority undertake a review of the clinical and non-clinical management leadership and governance arrangement at MWRH Limerick to ensure that the governance arrangement and organizational structure are fit for purpose, and that clinicians and managers in key positions have the capacity and capability to manage the new role for the Hospital**										
	Has review taken place?	Yes	Yes	No	Clinical Director in place	Yes	Yes	Hosp operates under a management scheme approved by the High Court.	No	No	No
	If not, when will it take place?										
	Are measures planned / in place to mitigate risks and if planned, when will be implemented?			Reconfiguration commenced in DML. Difficulties with organisational structures at MRHP have been escalated through the risk register.					Will be part of reconfiguration programme.	Will be part of reconfiguration plan No risk identified	Will be part of reconfiguration plan No risk identified.
	An Accountability Framework; "Achieving Excellence in Clinical Governance" has been approved by the HSE Management Team. A roll out plan is being developed and it will be implemented in all HSE hospitals in 2011										

For further information please contact:

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