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.