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Introducing national healthcare safety investigators for patient safety

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Providing safe healthcare in general—and surgery in particular—depends on a wide range of factors that span the entire healthcare system. It is inevitable that errors or near-miss events will sometimes occur and when patients are inadvertently harmed, the reasons are rarely simple or straightforward[1]. Serious patient safety incidents may have multiple sources, including mishaps within surgical teams, resourcing decisions by managers, poor equipment design and inadequate regulatory oversight[2-3]. Improving patient safety therefore depends on investigating, understanding and addressing these complex networks of causal factors at all levels of the healthcare system in a coordinated way.

Safety investigations spanning entire systems are routine in other sectors such as the aviation, rail and maritime industries. Permanent national safety investigation bodies independently examine the causes of safety issues and issue non-punitive and learning-focused safety recommendations that support system-wide improvement[4]. This system-wide approach is now being emulated by major new initiatives in the Norwegian and English healthcare systems, thus becoming the first two countries to establish dedicated, independent safety investigation bodies for healthcare. In 2017, England established the Healthcare Safety Investigation Branch (HSIB)[5] and Norway approved legislation for the National Investigation Board for the Health and Care Services (NIBHC)[6]. The investigation bodies will build new and innovative approaches to improving safety and facilitate system-wide learning[7]. However, many challenges lie ahead.

The core objective of these new investigation bodies is to regularly undertake learning-focused and system-wide investigations into serious patient safety issues that span the healthcare system. The aspiration is that these bodies will draw on multidisciplinary investigation teams with deep clinical, human factors and safety science expertise and will use sophisticated methods to develop detailed analysis reports and practical recommendations.

These will target all parts of the healthcare system—from the 'sharp-end' of practice and delivery to the 'blunt-end' of regulation and policymaking. Current mechanisms for responding to adverse events in healthcare, such as root cause analysis[8], supervisory investigations or prosecutions[9-11], all have limitations[12] and can sometimes hinder, rather than help, efforts to learn[13]. Local-level investigations are unable to look beyond the immediate healthcare organization; regulatory investigations are unable to examine the regulatory failings that may have contributed to an issue; and legal inquiries are focused on establishing individual liability and blame rather than identifying opportunities for systems-improvement[4]. Permanent investigation bodies, such as the new HSIB and NIBHC in England and Norway, can build reliable structures, methods, and expert teams to routinely conduct system-spanning safety investigations for the sole purpose of learning and improvement.

While these new bodies in England and Norway will differ in operation and approach, they share key foundational principles: independence, system-wide, learning-focused, and multidisciplinary, as depicted in Figure 1.

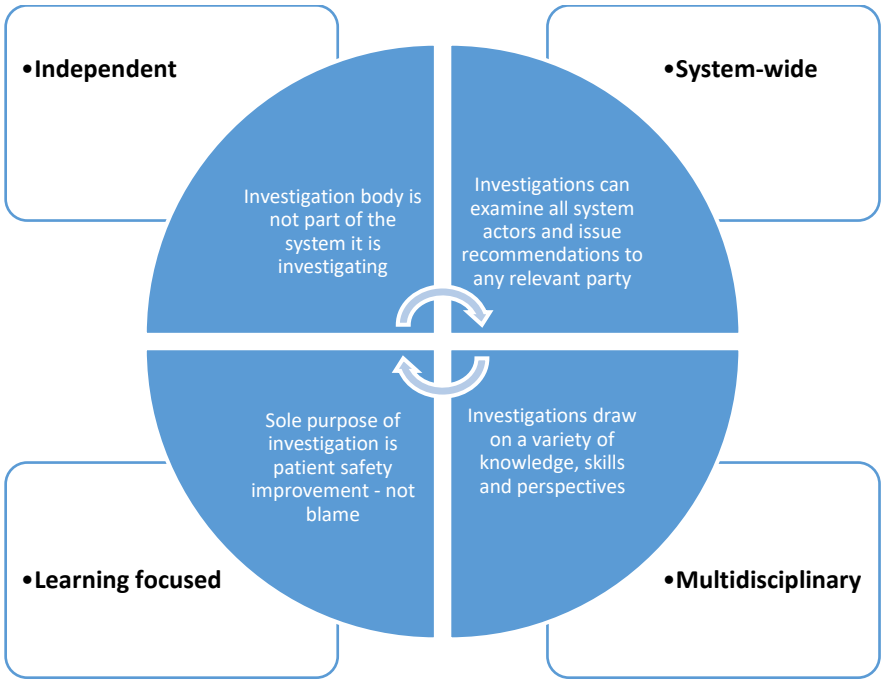

Figure 1: Key foundational principles of national independent safety investigations

Their *independence* means they have no regulatory or punitive function, are not part of the system under investigation and have considerable freedom to select when and what—and how—to investigate. In the Norwegian law, NIBHC will investigate 'severe adverse events' (death or severe harm, where the outcome is unexpected given the foreseeable risk) or 'severe conditions' (circumstances that can be assumed to cause severe adverse events); the latter may include large hospital merger processes, or a series of safety events and near misses[14].

Having a *system-wide* view is essential. It ensures investigations can encompass all potential actors and decisions that influenced an event, from front-line practice to regulatory and commissioning levels—which are usually not included in investigations.

Learning-focused means that no one will be blamed or punished for providing information to a safety investigation. Fear of punishment and reputational damage can hamper learning by acting as an obstacle in the way of disclosure[15]. Accordingly, in Norway it is mandatory for healthcare professionals to provide information to the NIBHC (upon request by the NIBHC) but that information cannot be used by any other body, such as an employer or the police, for punitive purposes. The information provided to HSIB in England is likely to be treated in the same way[16], clearly separating processes of investigation and learning from those of blame and punishment.

A *multidisciplinary* approach is critical given the complexity of healthcare and patient safety. To develop a full understanding of a safety risk — and the actions required to address this — investigations need to draw on a variety of clinical and practical expertise, alongside a variety of different safety-relevant disciplines such as human factors, systems engineering, risk regulation and improvement science. Building these investigation organizations is therefore going to be challenging. They must be both independent from and deeply embedded in the healthcare systems they are investigating. They must be capable of taking a broad, system-wide view while also developing highly targeted, practical recommendations. And

they must grapple with the complexities of clinical practice and medical science, as well as the nuances of organizational culture and regulatory architecture. This will require careful development of the processes, methods, staffing and design of the investigation agencies themselves.

Perhaps one of the most important opportunities for these new investigation bodies is to fully engage with the perspectives of patients, families and caretakers, as well as healthcare professionals and other stakeholders. The newly developed investigation bodies owe much of their existence to the tireless campaigning of patients and families, many of whom have faced enormous difficulties in finding out why they themselves or their loved ones have come to harm.

In Norway, patients, users, and close carers will have rights to report events to the NIBHC, present their perspective and comment on any draft report before publication to ensure it sufficiently incorporates their perspective. Likewise, in England, the HSIB is seeking to ensure patients and families are deeply and genuinely engaged throughout an investigation. This is essential to build trust in the investigation bodies and their findings. It is also essential because patients and families are often the only people with an integrated view of how harm unfolds along a complex care pathway. One of the greatest challenges of these new investigation bodies may therefore be to ensure that patients, families, carers, healthcare workers, regulators and many other stakeholders are all deeply engaged with and trusting of the investigation process[17-18] — while also ensuring that the investigations conducted by these new bodies are focused solely on learning, improvement and system-wide change.

A key question is how may learning, improvement and system-wide change result from the investigations? Research is required to evaluate the processes and outcome in both countries over the coming years. Each investigation will result in a publicly available report including safety recommendations[6], and this should act as a foundation for system-wide

learning. Through issuing recommendations, the responsibility to improve is publicly placed on key stakeholders[14]. For instance, HSIB recently published an investigation report into the implantation of wrong prostheses during joint replacement surgery. Safety recommendations have been directed to different system levels such as the British Standards Institute, Department of Health and Social Care and National Joint Registry to undertake actions including amending the national prosthesis verification standards, and developing and implementing a scanning system to identify wrong prostheses prior to implantation. Deeply engaging with key stakeholders and professional communities is therefore key in these learning processes, in order to establish specialist working groups to further evaluate and actually improve current systems, training and practices.

Ultimately, learning from system-wide safety investigations is a collective responsibility. National investigation bodies do not have the power to require changes or mandate improvements—and nor should they, as that would remove their independence. Investigation bodies can set the stage for system-wide learning through the quality of their investigation analyses, reports, recommendations and stakeholder engagement. But real learning and improvement can only come about from the collective efforts, critical reflection and material changes made by stakeholders working together to improve safety across the healthcare system.

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