National Institute for Health and Care Excellence

Patient safety update

This report provides an update on patient safety matters at NICE for the period of September 2019 to September 2020.

The Board is asked to receive this update on patient safety matters at NICE.

Professor Kevin Harris

NICE Senior Responsible Officer (SRO) for Patient Safety

November 2020

Introduction

The paper ‘Developing a shared understanding of NICE's role and responsibilities for patient safety’ was presented to and agreed by SMT on 14 May 2019. It highlighted the potential for a clearer leadership structure for patient safety issues across NICE, with more explicit management of patient safety implications across teams and co-ordinated partnerships with external organisations with key patient safety roles.

The following recommendations were made at that time:

* To create and assign an SRO role
* Develop a central patient safety monitoring and response system as a feature of a data management strategy.
* Develop patient safety policy and procedures that summarise NICE’s approach to joint working with external organisations and enhances staff awareness of NICE’s patient safety role.

Professor Kevin Harris (Director of the Interventional Procedures Programme) was appointed as the SRO for patient safety in September 2019, with Dr Hannah Patrick (consultant clinical advisor in the Managed Access Team) as deputy SRO for patient safety.

Since the SRO for patient safety appointments, there have been a number of significant changes to the operational and strategic landscape of health and care. These have required adaptation in the approach to the role and include:

* Organisational changes within NICE, including the appointment of a new Chair and CEO.
* The COVID-19 pandemic, during which the main focus of the NHS became managing the pandemic. A number of NHS governance structures and reporting mechanisms were temporarily suspended to allow the NHS to focus its resources where they were most needed. Only now are these being re-established. In order to support the NHS in managing the pandemic, NICE concentrated on the production of rapid COVID-19 guidelines and ceased much of its existing work programme.
* The publication of the Independent Medicines and Medical Devices Safety (IMMDS) Review in July 2020. This report was commissioned in February 2018 by Jeremy Hunt, the then Secretary of State for Health and Social Care. The purpose was to examine how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices and to consider how to respond to them more quickly and effectively in the future. The publication of the report was delayed due to COVID-19, but in the interim NICE (the SRO for patient safety) worked with system partners to support the implementation of improvements to patient safety.

Patient safety remains at the forefront of health and social care practice and planning. To illustrate, recent activity in the broader health and social care system includes continuing progression of the NHS Patient Safety Strategy. Patient safety is also among the issues considered in the Care Quality Commission (CQC)'s State of Care 2020 report. Within NICE, patient safety was among the factors incorporated into the Board strategy day in October 2020.

This paper provides an update on patient safety matters at NICE from September 2019 to September 2020 and identifies priorities for the coming year. The update has been discussed and approved by the Senior Management Team (SMT) prior to its submission to the Board.

Update on patient safety matters at NICE

The SRO for patient safety has acted as a source of advice for many areas within NICE, bringing together strands of patient safety across the organisation.

In practice, this has involved:

* 1. Identifying and developing oversight of patient safety enquiries to NICE from external bodies, including those from HM Coroner (Regulation 28 letters), the Healthcare Safety Investigation Branch (HSIB), the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA). In addition, there has been oversight of enquiries related to patient safety concerns which were received through the corporate office and enquiry handling.
	2. Working collaboratively with colleagues across the Directorates at NICE who held the primary responsibility for the issue being raised to support them in responding to external agencies.
	3. Becoming a permanent member of NICE's Guidance Executive to allow oversight of potential patient safety issues relating to guidance prior to publication.
	4. The SRO (or deputy SRO) representing NICE on a number of key national system committees which have oversight of safety, such as the National Quality Board and the National Patient Safety Committee.

The SRO for patient safety's role in NICE's response to the IMMDS review illustrates how the role brings together and co-ordinates internal and external patient safety components:

* 1. The overall system response has been co-ordinated by the DHSC through weekly meetings (attended by the SRO for patient safety).
	2. The SRO for patient safety has acted as a single point of contact at NICE for all enquiries relating to the IMMDS Review. This has required co-ordination of responses from different Directorates within NICE.
	3. In addition, the SRO has ensured NICE is represented on a number of subgroups led by other system partners including NHSE/I, MHRA and NHSX, which have been established to consider the Review's recommendations.
	4. A paper outlining considerations for NICE as a result of the IMMDS Review has previously been presented to the NICE Board on 16 September 2020; the accepted recommendations for action are listed in Table 1 below.

While establishing the SRO for patient safety role, it became clear that there are already well established and effective mechanisms for dealing with and responding to such enquiries within NICE, although there is no single or centralised process. Given external system pressures and the rapidly evolving system safety landscape, the SRO decided the optimal approach in the short term was to support the existing processes and strengthen their governance by providing oversight, rather than implement a new central patient safety monitoring and response system.

Although not subject to a formal analysis, the subjective impression is that patient safety enquiries to NICE have progressively increased in volume over the past few years. In part, this may be due to the creation of new bodies / NHS committees with responsibility for safety and who expect or require responses from NICE (for example, HSIB was only created in 2018). However, there has also been an increase in enquiries from established bodies (for example, 14 Regulation 28 letters were received from HM Coroners between Sept 2019 and Sept 2020 compared to only 5 for the same period between 2015 and 2016.)

Table 1: Actions identified in the IMMDS Review: Considerations for NICE paper, September Board Meeting 2020

|  |  |
| --- | --- |
| Area | Actions |
| Sodium valproate | Explore opportunities for NICE to work with other stakeholders including MHRA and patient groups to:* Advise on the establishment of a prospective registry
* Improve the Pregnancy Prevention Programme
* Enable clinicals to follow guidance regarding prescribing
 |
| Surgical mesh | Undertake an exceptional review of NG123: urinary incontinence and pelvic organ prolapse in women: management. |
| Patient Decision Aids | Recommended actions are:* Scoping of NICE’s potential role in leading a collaboration with the health system on the production of patient decision-making aids for each surgical procedure or intervention
* SMT consideration of the form and resourcing of NICE’s interim role following completion of the scoping work
* Explore links with NICE Connect, as it is envisioned that its functionality will be a significant enabler to this area
 |
| Data collection | Recommended actions are:* Work with NHS X and other system partners to co-create databases and registries meeting the Review’s recommendations, which could be used to inform our guideline development
* Work with MHRA on implementing necessary work on device regulation and approval.
* Consider the impact of the Medicines and Medical Devices Bill on implementation of an effective response to Recommendation.
 |
| Guidance implementation | Work with regulators and professional organisations to reinforce the use of NICE guidelines through their professional standards and inspection or accreditation processes |
| Additional steps | Additional actions include:* Assess the resource consequences of the above actions
* Further review of potential resource implications by SMT once more information has been gathered.
* Consider position in relation to external patient safety bodies, particularly if landscape alters, for example, with potential introduction of Patient Safety Commissioner or revision of the MHRA.
 |

Priorities for the next year

Priorities for the coming year include providing oversight of NICE’s response to the IMMDS report, conducting a review of patient safety mechanisms at NICE with a view to creating a sustainable, pan-organisational structure for patient safety, and continuing to represent NICE within the broader external patient safety system.

This has been discussed by the Senior Management Team (SMT) and it has been agreed that a patient safety task and finish group will be established to support these priorities.

Establishing a patient safety task and finish (T&F) group

The task and finish group will be established with cross-directorate membership to ensure that the group is inclusive of each directorate’s interests and can facilitate a pan-organisational approach to patient safety.

1. Initial membership of the group will draw on the following directorates, with membership evolving as different aspects of patient safety at NICE are considered:
* Centre for Health Technology Evaluation (CHTE)
* Health and Social Care
* Science, Evidence and Analytics

The group will provide oversight of NICE’s response to the IMMDS review, facilitating and co-ordinating across directorates the actions identified in the September 2020 paper to the Board.

The group will identify existing workstreams already in progress within NICE which relate to the IMMDS review, identify connection points with key external stakeholders and, where possible, promote synergies across workstreams.

The group will also conduct a review of patient safety activity at NICE and recommend a sustainable model for managing patient safety issues in a structured and systematic way, as well as the potential resources required to support such changes.

The group will consider how new technology such as artificial intelligence could be utilised to inform NICE's decision making in relation to patient safety and to facilitate this, the group will include a representative from the Science, Evidence and Analytics directorate.

The review will inform a patient safety policy summarising NICE's patient safety approach to make procedures explicit across the organisation, with internal communications raising awareness of these procedures and the support available, as patient safety is relevant to all at NICE.

The group will produce 6-monthly reports on patient safety to SMT, with an annual report to the Board.

Working with the external patient safety system

The SRO and deputy will continue to ensure NICE is appropriately represented on key national / system committees which have oversight of safety, while remaining responsive to changes in external patient safety bodies.

NICE's response to the IMMDS Review also provides an opportunity to align our approach to patient safety with the framework agreed by the broader health and care system and co-ordinated by the DHSC.

Issues for decision

The Board is asked to receive this update on patient safety matters at NICE and endorse the proposed approach for patient safety matters over the next year.

© NICE 2020. All rights reserved. [Subject to Notice of rights](https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

November 2020