Royal College of Nursing Response to the MHRA Call for Evidence: National Commission into the Regulation of Artificial Intelligence in Healthcare

Introduction

The Royal College of Nursing (RCN) is the world's largest professional body and trade union for nursing staff, representing over half a million members across the United Kingdom. Our membership spans Registered Nurses, Midwives, Health Visitors, Nursing Associates, nursing students, health care assistants, and nursing support workers. Collectively, they deliver care in every setting of the health and care system, from acute hospitals and community teams to mental health, child health, community, learning disability services, and the independent and voluntary sectors.

The RCN's mission is to promote patient and nursing interests, influence health and care policy, and safeguard professional standards. We collaborate with governments, regulators, employers and international partners to ensure nursing and midwifery voices are central to reform.

We have and continue to express our concerns regarding the unintended consequences of the rapid introduction of AI into the workforce context without adequate safeguards through robust, integrated and transparent regulation. Furthermore, we welcome the opportunity to contribute to the Professional MHRA Call for Evidence: National Commission into the Regulation of AI in Healthcare.

Background

The MHRA has launched a call for evidence to inform the work of the National Commission into the Regulation of AI in Healthcare, which will recommend how AI should be safely and responsibly integrated into the NHS. The Government intends for the NHS to become "the most AI enabled healthcare system in the world," and the Commission will shape the regulatory framework that governs how AI is developed, deployed and monitored.

AI is already used in screening, diagnostics, clinical decision support, administrative automation and patient facing tools. These technologies bring potential benefits, but also significant risks. AI used for medical purposes is currently regulated as a medical device, requiring premarket assessment, compliance with safety and performance standards, lawful data handling, and ongoing post-market surveillance. AI in healthcare also sits across multiple regulatory systems, including professional regulation and service regulation.

New forms of AI, including large language models and systems that continuously learn, raise questions about safety, accountability, liability, transparency and public trust. The MHRA therefore sought evidence on whether the current framework is sufficient and what changes may be needed.

The RCN's response draws on established policy positions: AI must never replace professional judgement, must always be subject to mandatory human oversight, and must be deployed within existing regulatory frameworks that protect patients and staff. Regulatory protections must not be suspended or weakened, and oversight must involve professional bodies, trade unions and nursing representation. AI should augment, not substitute for, the nursing workforce. Public transparency and democratic accountability are essential.

Section 1 – Respondent Information

Q1: Are you responding as an individual or on behalf of an organisation?
b) Organisation

Q3.1: Name of organisation
Royal College of Nursing (RCN)

Q3.2: Type of organisation
Professional Body

Q3.2.1: Which of the following best describes your organisation?
My organisation does not develop healthcare AI products.

Q3.3: Can the MHRA publicly identify your organisation as a respondent?
Yes

Q4: Contact details
Dr Stephen Jones, UK Head of Nursing Practice, Stephen.jones@rcn.org.uk

Section 3 – Consultation Questions

Q1. View on the need to change the UK's framework for regulating AI in healthcare

b) Minor adjustments: The current framework works but requires small changes.

The RCN is clear that while AI has potential to bring benefit to services, it must be done safely. Proper scrutiny, risk management and governance is required to ensure trust in systems as AI is adopted. The risk is a rollout environment where implementation pressure outpaces governance. Any regulatory adjustment should strengthen clarity on accountability, transparency and minimum deployment conditions rather than accelerating adoption.

No barriers to appropriate AI implementation exist within the regulatory framework in the health sector that cannot be addressed through existing structures for regulation. Should regulation need to be changed to allow for the implementation of a desirable AI tool in a specific setting or role, this should be carefully considered as all other technology would be within those existing structures. If there are areas where regulation needs to be amended, these amendments can go through existing mechanisms, which include parliamentary and appropriate oversight along with public engagement. It is inappropriate to develop or test AI in real world settings outside of those existing regulatory frameworks.

Q2.1–Q2.5. Sufficiency of the current regulatory framework

For all five items, the RCN selects: "Neither agree nor disagree."

The RCN's primary concern is not that the existing regulatory framework is inherently insufficient, but that AI must not be deployed outside existing service and professional regulatory frameworks. No barriers to appropriate AI implementation exist within the regulatory framework in the health sector that cannot be addressed through existing structures for regulation.

Proper scrutiny, risk management, governance, continuous monitoring and public transparency are essential to maintain trust and protect patients and staff. AI is new, and it makes mistakes. These mistakes, if introduced into healthcare, have significant life-changing outcomes, particularly without the safety of existing regulatory frameworks. AI should always be an augmentation tool in healthcare; it cannot replace professional standards, judgement and must always be subject to human oversight.

Q3. Impact of the current framework on innovation

c) About right

AI should not be treated differently than any other technology. Merits can and should be assessed on a case-by-case basis to ensure that each tool is appropriately deployed and regulated to ensure safety and security. Speed of implementation cannot be prioritised over safety.

Q4. How the UK's regulatory framework could be improved

The RCN is clear that while AI has potential to bring benefit to services, it must be done safely. Proper scrutiny, risk management and governance is required to ensure trust in systems as AI is adopted. Nursing representation should be embedded in procurement and implementation governance, reflecting nurses as safety-critical end-users.

Healthcare is extensively regulated, both in terms of the services and the professionals, and the introduction of AI into healthcare settings should proceed within existing service and professional regulatory frameworks. It is inappropriate to develop or test AI in real world settings outside of those existing regulatory frameworks.

The MHRA's current framework includes premarket assessment, classification of risk, and post market surveillance. The RCN's position is that no barriers to appropriate AI implementation exist within the regulatory framework in the health sector that cannot be addressed through existing structures for regulation. Should regulation need to be changed to allow for the implementation of a desirable AI tool in a specific setting or role, this should be carefully considered as all other technology would be within those existing structures. If there are areas where regulation needs to be amended, these amendments can go through existing mechanisms, which include parliamentary and appropriate oversight along with public engagement.

AI should not be treated differently than any other technology across the public sector. Merits can and should be assessed on a case by case, sector by sector basis to ensure that each tool is appropriately deployed and regulated to ensure safety and security. Speed of implementation cannot be prioritised over safety.

AI should always be an augmentation tool in healthcare; it cannot replace professional standards, judgement and must always be subject to human oversight. AI is not appropriate for automation within clinical settings where it would replace, downgrade, or diminish the professional input of staff. Patient safety, quality of care, and professional accountability must remain the responsibility of qualified practitioners.

Policy must be governed by a holistic approach, not driven solely by data or technology and certainly never by financial motive. It must centre on ethics, human oversight, rights, protections, and principles. Technology companies should not influence regulatory decisions where they have a profit motive. Their role should be limited to providing technical evidence, not shaping governance and certainly not in any body with power to suspend or alter regulatory systems that benefit their business interests.

Oversight must prioritise patient safety, professional accountability, and public trust. Mandatory involvement of professional bodies such as the RCN, alongside regulators and trade unions, is essential to ensure decisions reflect clinical realities and workforce protections. Nursing representation is required on all oversight committees, recognising nurses as core designers and end users and safety critical decisionmakers. Public transparency, including a public register of participating projects alongside regular reporting of incidents, decisions, and outcomes, is essential to maintain trust.

This approach ensures that the regulatory framework maintains the integrity of healthcare regulation while enabling safe and responsible access to AI technologies.

Q5. How post market surveillance should be managed

AI is still largely in its infancy, and mistakes at this stage would have real world detrimental impact on patients and staff. Testing with real world patients without sufficient checks and balances could lead to misinformed decision making. Not only does this risk patient safety, experience and outcomes, it also exposes nursing staff to risk in relation to their own professional regulation. The RCN therefore supports robust post market surveillance within existing regulatory frameworks.

Within these frameworks, controls should be framed as minimum safeguards proportionate to risk, recognising healthcare as a complex high-risk setting with the need for robust protections. Minimum requirements should include mandatory human oversight: AI must not operate autonomously or become a single point of failure in clinical pathways. Clear accountability frameworks are required, ensuring that responsibility for decisions remains with registered professionals.

Continuous monitoring is essential for patient safety, equality impacts and workforce consequences, with the ability to pause systems rapidly. Public transparency is required on incidents, outcomes, and decision-making processes. Workforce impact assessment is necessary, monitoring impacts on workload, equality impacts, and safe staffing.

The MHRA's post market surveillance requirements introduced in June 2025, such as trend reporting, safety update reports, and corrective actions, align with the RCN's emphasis on continuous monitoring and rapid suspension powers where risks emerge. The RCN's position reinforces that these requirements must be applied rigorously to AI systems, including those capable of continuous learning or updating.

AI should not be used to fix issues with the domestic workforce pipeline. The risk of unintended consequences of overreliance on AI due to long-term workforce shortages must be recognised. AI should always be an augmentation tool in healthcare; it cannot replace professional standards or judgement.

Information sharing between healthcare provider organisations and manufacturers must support post market surveillance, but this must occur within existing regulatory and data governance frameworks. Patient safety, professional accountability, and public trust must remain central.

This approach ensures that post market surveillance maintains the integrity of healthcare regulation and protects both patients and staff.

Q6. View on the current legal framework for liability

b) Gaps exist

Mistakes made outside the protection of service regulation frameworks could present major patient safety risks to the public.. Likewise, mistakes made outside the security of professional regulation frameworks could expose nursing staff to fitness to practice processes. These gaps are likely to be addressed by meeting this consultation's aims and objectives, yet important to articulate in the context of the current regulatory framework and at this point of the review process.

Q7. How responsibility should be shared

Mandatory human oversight is essential: AI must not operate autonomously or become a single point of failure in clinical pathways. Clear accountability frameworks are required, ensuring that responsibility for decisions remains with registered professionals. Professional accountability and public trust must be prioritised, particularly in high-risk sectors such as healthcare.

Mandatory involvement of professional bodies such as the RCN, alongside professional regulators and trade unions, is required to ensure decisions reflect clinical realities and workforce protections. Nursing representation is essential, recognising nurses as core designers and end users and safety critical decisionmakers, and nursing leadership should be embedded in governance. Furthermore, robust systems should be in place to ensure the voices of marginalised groups are part of the design, delivery and evaluation process.

Public transparency, including regular reporting of incidents, decisions, and outcomes, is essential to maintain trust. Clear escalation routes for safety concerns, including immediate suspension powers where risks to patients or staff emerge, are required.

This approach ensures that responsibility is shared in a way that protects patients, staff, and the integrity of healthcare regulation.

Q8. Where liability should lie in adverse outcomes involving AI

The RCN is clear that AI must always be subject to human oversight and cannot replace professional judgement. Responsibility and accountability for clinical decisions must remain with registered professionals. Mistakes made outside the protection of service regulation frameworks could have lifechanging or life ending consequences for patients, and mistakes made outside the security of professional regulation frameworks could expose nursing staff to career ending consequences.

AI should not be used autonomously, and its use should always be under human supervision and decision making. AI is not appropriate for automation within clinical settings where it would replace, downgrade, or diminish the professional input of staff. Patient safety, quality of care, and professional accountability must remain the responsibility of qualified practitioners.

Issues of implementation or poor user experience must not be the sole responsibility of clinicians. Organisations have a responsibility to ensure they follow good governance practices across their systems and services. Responsibility for safe deployment and accountability for the implementation of AI tools or devices in services need to sit with the board, with a named individual holding oversight; as is the case for information governance and other specific regulatory functions. This approach ensures that liability is managed in a way that protects patients, staff, and the integrity of healthcare regulation.

Technology companies should not influence regulatory decisions where they have a profit motive. Their role should be limited to providing technical evidence, not shaping governance or liability frameworks. Failures to follow regulation should lead to clear liability measures and sanctions.

Q9. Additional evidence

N/A