



Original research

Healthcare AI risk management: an innovator-informed approach from frameworks to practical worksheets for proportionate regulatory evidence capture

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ABSTRACT

Introduction Artificial intelligence (AI)-enabled healthcare systems introduce clinical safety, operational and governance risks across development, deployment and postdeployment stages. Although multiple AI risk assessment frameworks exist, they are often cross-sector, lengthy and difficult to operationalise in ways that support proportionate evidence generation and regulatory use.

Methods We conducted a targeted evidence synthesis and framework mapping exercise drawing on review-level evidence, scientific databases and regulatory sources. Three core review studies informed framework identification and mapping. Selected frameworks and guidance, including NIST AI RMF, the Fraunhofer IAIS AI Assessment Catalogue, ALTAI, the ICO AI and Data Protection Risk Toolkit, MHRA guidance, the NICE Evidence Standards Framework, SPIRIT-AI and CONSORT-AI, were mapped across lifecycle stages using a structured extraction matrix. Framework concepts were translated into healthcare-oriented worksheets and refined through structured engagement with healthcare AI innovators.

Results Frameworks varied substantially in scope, lifecycle coverage, terminology and implementation approach. Innovator feedback identified recurring themes including cognitive burden, usability, need for clearer intended purpose, lifecycle support, actionable examples and improved regulatory traceability. Participants highlighted challenges applying frameworks across diverse healthcare contexts and AI roles. Worksheet refinement introduced simplified

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Artificial intelligence (AI) risk frameworks are available, but they vary in scope and terminology and are often designed for cross-sector use. They may be challenging for healthcare innovators to apply in practice, particularly when translating outputs into evidence and planning postdeployment risk management.

WHAT THIS STUDY ADDS

⇒ We described a systematic method for translating established AI risk frameworks into healthcare-oriented worksheets, refined through structured innovator engagement and iterative codesign to support proportionate evidence capture, uncertainty documentation and action planning.

HOW THIS STUDY MIGHT AFFECT RE-SEARCH, PRACTICE OR POLICY

⇒ By centring on the experiences of innovators, this study offers practical, codesigned worksheets that can help innovators adopt lifecycle risk management in routine development practice and can support more consistent, usable documentation for governance and early regulatory discussions while remaining adaptable as systems evolve.



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domains, healthcare-specific context prompts, evidence and action fields and stage-aware guidance.

Discussion AI risk frameworks are necessary but not sufficient for healthcare innovation unless translated into practical tools. A codesigned

worksheet approach can support proportionate evidence capture and iterative risk management while remaining adaptable across use cases and maturity levels.

INTRODUCTION

Healthcare artificial intelligence (AI) systems are increasingly being developed for applications including diagnosis, clinical decision support, triage, workflow optimisation and population health management. These systems introduce risks that extend beyond conventional software, including clinical safety risks, performance variability, bias and fairness concerns, cybersecurity vulnerabilities, data protection issues, usability challenges and disruption to clinical workflows.^{1,2}

Unlike traditional medical technologies, AI-enabled healthcare systems may undergo iterative software updates, model revisions or changes in deployment configuration during their lifecycle. These changes can alter system behaviour or performance after deployment and therefore require ongoing monitoring and reassessment.^{3,4} Regulatory bodies have increasingly recognised these challenges. The MHRA Software and AI as a Medical Device Change Programme highlights the need for clearer approaches to software and AI regulation while maintaining patient protection across the product lifecycle.⁵

To support responsible development and deployment, a growing number of AI risk management and governance frameworks have been proposed by regulators, standards organisations and research groups. These frameworks aim to provide structured approaches to identifying, assessing and mitigating risks across the AI lifecycle, including domains such as fairness, transparency, robustness and accountability.^{6,7} Systematic evidence suggests substantial variation in framework structure, intended use and implementation approaches.^{8,9}

Many available frameworks are cross-sector in scope and differ in terminology, structure and operational detail. This variation may create challenges for healthcare innovators seeking to translate high-level framework concepts into actionable processes and evidence suitable for governance and regulatory use.¹⁰ Challenges may include defining what constitutes sufficient evidence, documenting uncertainty and maintaining traceability across development and postdeployment phases.¹¹ Emerging evidence also suggests that software development and evaluation increasingly rely on iterative and lifecycle-oriented approaches rather than fixed development pathways.¹² However, a gap remains between the availability of high-level frameworks and the need for practical tools that can be integrated into routine workflows while supporting healthcare-specific regulatory requirements.

This study aims to address this gap by translating selected AI risk assessment frameworks into practical, healthcare-oriented worksheets. The work combines a targeted evidence synthesis and framework mapping exercise with structured engagement and codesign with healthcare AI innovators. As a proof-of-concept study, it focuses on recent and relevant frameworks rather than attempting to capture all available approaches, with the aim of developing tools that support proportionate evidence capture, lifecycle risk management and regulatory alignment.

METHODS

Study design

This was a proof-of-concept, innovator-informed study combining targeted evidence synthesis, framework mapping, worksheet development and structured engagement. The objective was to identify and translate relevant AI risk assessment and governance frameworks into practical, healthcare-oriented worksheets that support proportionate evidence capture, lifecycle risk management and early regulatory readiness for healthcare AI innovators.

Targeted evidence synthesis and framework mapping

A targeted evidence synthesis was undertaken to identify review-level evidence and established AI risk assessment and governance frameworks relevant to healthcare AI innovation. Searches were conducted across Google Scholar, Scopus, PubMed, IEEE Xplore and the ACM Digital Library, supplemented by targeted searches of regulatory, standards and institutional websites. Reference lists and citations of relevant review articles were also examined to identify additional frameworks. The purpose was to support framework identification, comparison and translation into implementable worksheets rather than to synthesise evidence on clinical effectiveness.

Search terms combined concepts relating to artificial intelligence, risk and governance using Boolean operators. Search concepts included (“artificial intelligence” OR “AI” OR “machine learning”) AND (“risk assessment” OR “risk management” OR “impact assessment”) AND (“governance” OR “trustworthy AI” OR “responsible AI”) AND (“framework” OR “toolkit” OR “assessment catalogue”). Systematic reviews, systematic mapping studies, scoping reviews and comparative analyses that synthesised AI risk or governance frameworks were prioritised. Searches were intentionally broad because relevant material was distributed across peer-reviewed literature and institutional guidance.

Records and candidate frameworks were screened against predefined criteria: recognition or publication by regulators, standards organisations, public bodies or established research institutions; practical rather than solely conceptual intent; relevance to healthcare AI or transferable AI risk management principles;

alignment with UK expectations concerning safety, accountability, data protection and evidence; and apparent usability across one or more stages of the AI lifecycle. Purely speculative discussions without an implementable framework, assessment process or guidance component were excluded. Selection was undertaken iteratively by the study team, with uncertain cases discussed to reach agreement; formal duplicate screening was not undertaken because the exercise was designed for framework translation rather than as a systematic review of effectiveness.

Three review-level studies were selected as anchor sources because they provided complementary coverage of the review objectives. Xia *et al*⁸ examined the characteristics, responsible AI principles, stakeholders, lifecycle stages, target domains and assessment methods represented across AI risk assessment frameworks. Batool *et al*⁹ reviewed AI governance in relation to who governs, what is governed, when governance occurs and how it is implemented. Schmitz *et al*¹⁰ compared approaches to risk aggregation, including the conceptualisation and quantification of risk, application context and trade-offs between risk domains. Together, these studies informed the identification of framework domains, lifecycle coverage and implementation gaps.

We additionally reviewed selected regulatory and institutional frameworks relevant to healthcare AI, including the NIST AI Risk Management Framework, Fraunhofer IAIS AI Assessment Catalogue, ICO AI and Data Protection Risk Toolkit, ALTAI, MHRA Software and AI as a Medical Device guidance, NICE Evidence Standards Framework, SPIRIT-AI,

CONSORT-AI and the International Medical Device Regulators Forum Good Machine Learning Practice guiding principles.^{5–7 13–18} For each framework, information was extracted into a structured matrix covering purpose, target users, principal risk domains, governance functions, lifecycle coverage, evidence expectations, expected outputs, implementation guidance and healthcare relevance. Comparative mapping was used to identify common domains, complementary strengths and practical gaps that informed worksheet development. The selected frameworks and their contribution to the mapping and worksheet development process are summarised in [table 1](#).

Framework mapping across the AI development lifecycle

Following the targeted evidence synthesis, identified frameworks were mapped to key stages of the healthcare AI lifecycle to examine how risk assessment activities were distributed across development, validation, deployment and postdeployment phases. This mapping highlighted differences in emphasis across frameworks, with some focusing on early-stage design and governance and others providing stronger support for validation or postmarket monitoring. [Figure 1](#) illustrates how selected AI risk frameworks align with early concept development, prototyping, risk and regulatory mapping, validation and evidence generation, premarket readiness, deployment and postmarket lifecycle management. The mapping informed the worksheet pathway by identifying the stages at which particular risk domains and evidence requirements were most relevant.

Table 1 Selected frameworks and their contribution to the mapping and worksheet development process

Framework or guidance	Primary emphasis	Contribution to this study
NIST AI Risk Management Framework ⁶	High-level governance and risk management functions	Provided the map, measure, manage and govern structure for initial risk organisation.
Fraunhofer IAIS AI Assessment Catalogue ¹³	Detailed trustworthiness criteria and assessment measures	Provided granular domains including fairness, autonomy and control, transparency, reliability, safety and security, data protection and traceability.
ICO AI and Data Protection Risk Toolkit ¹⁴	Data protection risks and impacts on individuals	Informed worksheet questions on data governance, privacy, accountability and evidence of mitigation.
ALTAI ⁷	Self-assessment of trustworthy AI	Supported consideration of human agency, oversight, robustness, fairness, transparency and accountability.
MHRA Software and AI as a Medical Device guidance ⁵	UK regulatory and lifecycle expectations	Informed regulatory alignment, intended purpose, evidence planning and lifecycle oversight.
NICE Evidence Standards Framework ¹⁵	Evidence standards for digital health technologies	Informed proportionate evidence generation and consideration of product maturity.
SPIRIT-AI ¹⁶	Protocol guidance for clinical trials involving AI interventions	Informed worksheet questions on intended use, algorithm specification, input data, human–AI interaction and planned evaluation.
CONSORT-AI ¹⁷	Reporting guidance for clinical trials involving AI interventions	Informed transparent reporting of AI interventions, performance, errors, human–AI interaction and evaluation findings.
Good Machine Learning Practice guiding principles ¹⁸	Lifecycle quality principles for AI/ML-enabled medical devices	Reinforced multidisciplinary development, representative data, independent test sets, human–AI team performance, monitoring and management of deployed models.
AI, artificial intelligence; ALTAI, Assessment List for Trustworthy Artificial Intelligence; CONSORT, Consolidated Standards of Reporting Trials; IAIS, Intelligent Analysis and Information Systems; ICO, Information Commissioner's Office; MHRA, Medicines and Healthcare products Regulatory Agency; NICE, National Institute for Health and Care Excellence; NIST, National Institute of Standards and Technology; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.		

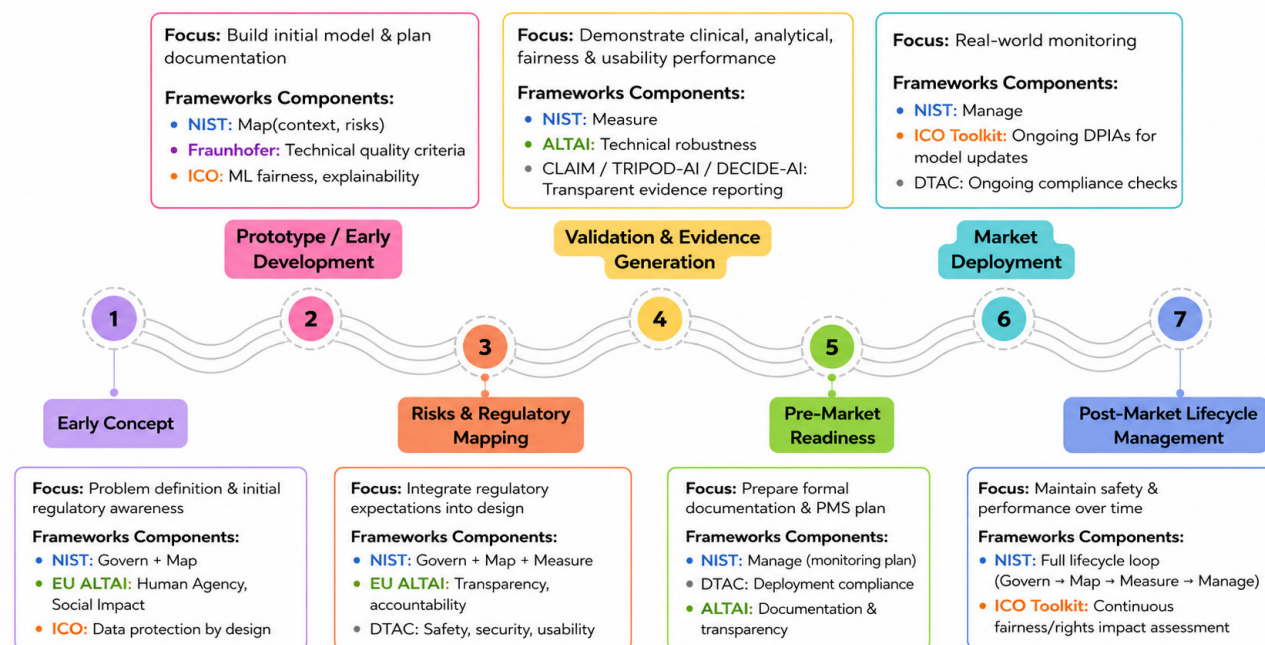


Figure 1 Mapping of AI risk frameworks across the healthcare AI lifecycle. ALTAI, Assessment List for Trustworthy Artificial Intelligence; DECIDE-AI, Developmental and Exploratory Clinical Investigations of DECision support systems driven by Artificial Intelligence; DTAC, Digital Technology Assessment Criteria; NIST, National Institute of Standards and Technology; ICO, Information Commissioner's Office; TRIPOD+AI, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis–Artificial Intelligence.

Worksheet preparation process

In the worksheet preparation process, we focused on a limited number of recent and widely referenced frameworks, including NIST AI RMF, the Fraunhofer IAIS AI Assessment Catalogue, the ICO AI and Data Protection Risk Toolkit and relevant UK regulatory guidance. These frameworks were selected because they collectively represent different but complementary approaches to AI risk management, including high-level governance structures, detailed assessment criteria and regulatory-oriented guidance.

This selective approach was adopted to enable a proof-of-concept translation exercise, ensuring that the worksheet design remained interpretable, coherent and usable for innovators. Including a broader set of frameworks risked introducing unnecessary complexity, duplication and conflicting terminology, reducing practical usability. The intention was therefore not to provide exhaustive coverage, but to explore how representative frameworks could be operationalised into a unified, healthcare-oriented tool that supports proportionate evidence capture and lifecycle-based risk management.

The process began with the original frameworks. Figure 2 shows how selected AI risk frameworks were translated into practical healthcare-oriented worksheets. The process began with source frameworks, followed by identification of core risk domains. For NIST, the main functions were Map, Measure, Manage and Govern. For Fraunhofer, key domains

included fairness, autonomy and control, transparency, reliability, safety and security, data protection and traceability.

Framework concepts were translated into plain-language worksheet questions. These questions were adapted for healthcare by including intended purpose, deployment setting, clinical pathway role, users, human involvement and consequence of error. Worksheet fields were then created for evidence, uncertainty, gaps, planned actions, owners and timelines.

Innovator engagement and refinement

Innovator engagement followed a two-stage process. The first workshop introduced the selected frameworks, draft guidance and worksheet structure. Between workshops, participants applied the worksheets to their own use cases. The second workshop used structured discussion to identify what worked, what was unclear and what was missing. Figure 3 summarises innovator testing, feedback synthesis and iterative refinement. Participants were recruited through the RADIANT CERSI network, including advertisements on LinkedIn, and included healthcare AI innovators from start-ups, small and medium-sized enterprises and academic spin-outs, alongside participants with technical, product, clinical safety, regulatory and governance roles. Feedback was captured through recorded structured roundtable discussions, survey responses and iterative review of worksheet drafts. Recordings were used to support note-taking

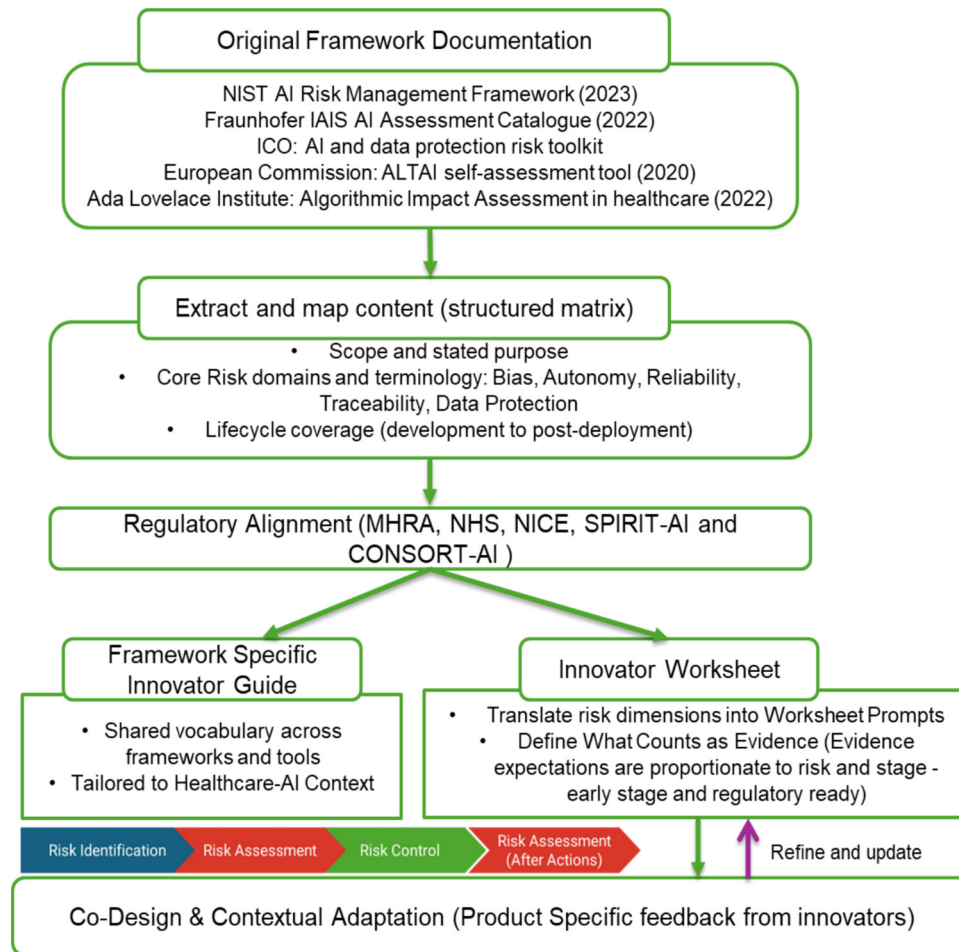


Figure 2 Generalised workflow for healthcare AI worksheet preparation. AI, artificial intelligence; ALTAI, Assessment List for Trustworthy Artificial Intelligence; CONSORT, Consolidated Standards of Reporting Trials; IAIS, Intelligent Analysis and Information Systems; ICO, Information Commissioner's Office; MHRA, Medicines and Healthcare products Regulatory Agency; NICE, National Institute for Health and Care Excellence; NIST, National Institute of Standards and Technology; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

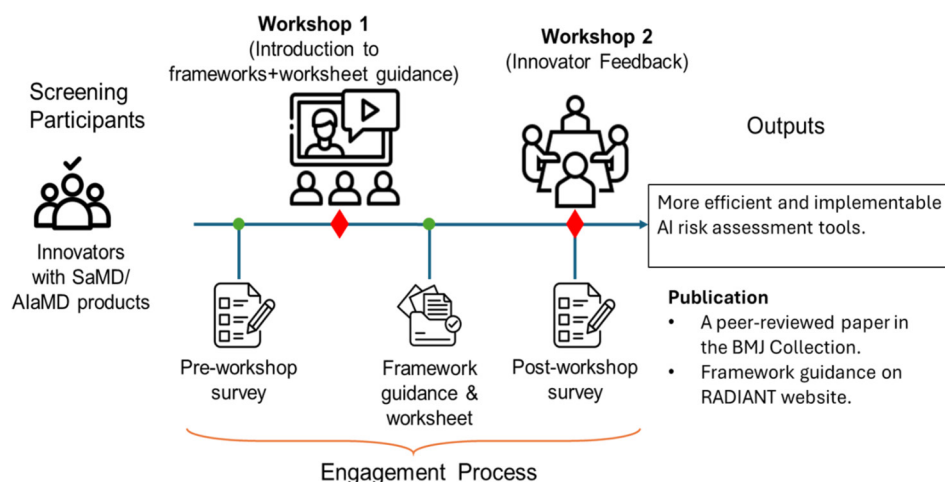


Figure 3 Innovator engagement process. AlaMD, Artificial Intelligence as a Medical Device; SaMD, Software as a Medical Device.

and thematic organisation of feedback rather than verbatim qualitative transcription.

Resources and supporting materials

To support practical implementation beyond the workshops, supplementary materials and supporting resources were made available to participants. These included worksheet templates, framework guidance, worked examples and links to relevant educational resources developed through the RADIANT programme. The materials were designed to support the ongoing use and adaptation of the worksheets, as well as to provide additional context for applying risk assessment concepts in practice. Resources are available through the RADIANT CERSI Website and relevant Innovator Masterclass programme: <https://radiant-cersi.org/radiantcersi-innovator-masterclass-sessions>.

Patient and public involvement statement

Patients and members of the public were not involved in the design, conduct, reporting or dissemination plans of this research. The study focused on AI risk assessment frameworks and structured engagement with healthcare AI innovators to support the development and refinement of practical risk assessment tools.

RESULTS

Framework identification and mapping findings

The targeted evidence synthesis identified three complementary review-level anchor studies and a selected set of regulatory and institutional frameworks for detailed mapping. The mapping identified substantial variation in structure, terminology and practical usability. Some frameworks provided broad governance principles, whereas others offered detailed assessment catalogues, toolkits or process guidance. NIST AI RMF supported high-level sense-making through its Map, Measure, Manage and Govern functions. Fraunhofer IAIS offered a more detailed trustworthiness catalogue but required greater effort to navigate. Lifecycle coverage was uneven, and postdeployment concerns such as monitoring, model drift, software change, retraining and postmarket reassessment were not always operationalised in ways that were readily usable by innovators. The mapping also identified a tension between comprehensiveness and usability: detailed frameworks enabled deeper reflection but could increase cognitive burden, whereas simpler structures were easier to use initially but could provide less support for iterative post-deployment work.

Worksheet traceability

The worksheet preparation process shown in [figure 2](#) preserved traceability to source frameworks while reducing complexity. Each worksheet began with an AI profile covering intended purpose, users, clinical or operational setting, AI role and consequence of error. This was followed by domain-specific worksheet

questions addressing safety, reliability, fairness, transparency, autonomy and control, data protection and traceability. Innovators were asked to document what was known, what evidence existed, what remained uncertain and what action was planned. Evidence expectations were framed as proportionate to product maturity and risk: early-stage innovators could record emerging or planned evidence, whereas regulatory-ready innovators were encouraged to identify more mature evidence, supporting documentation and residual risks.

Themes from innovator feedback

Innovator feedback highlighted several cross-cutting themes relating to the usability, interpretation and practical application of AI risk assessment frameworks. Participants viewed NIST as more accessible at first use, while Fraunhofer was valued for depth but seen as more resource intensive because it required frequent reference to supporting materials. Participants also emphasised the need for iterative, lifecycle-oriented risk management. Fraunhofer was viewed as more suitable for revision, re-examination and postmarket surveillance, whereas NIST was sometimes interpreted as more static unless adapted into a living process. Clearer framing of intended purpose, deployment context and AI role was also considered essential, where systems may be stand-alone, advisory, human-in-the-loop, workflow-integrated, triage-based or automated. Participants noted challenges applying frameworks across diverse healthcare contexts. Some frameworks were easier to apply to biomedical or device-oriented settings than to mental health or service-based AI, where biopsychosocial evidence may be important, and evidence generation standards may differ. Study participants have also highlighted that supporting documentation should set clear expectations regarding the level of detail to be provided by innovators at the reporting stage. It has been noted that this can be very important for the design of Risk of Bias studies. The key themes identified during innovator engagement and the corresponding worksheet refinement actions are summarised in [table 2](#).

Worksheet refinements

The worksheets were refined in response to feedback. Scaffolded guidance was added to reduce initial cognitive burden, and more explicit worksheet questions were introduced on intended purpose, human involvement, deployment setting and AI role. Sections addressing evidence gaps, interim evidence and planned mitigations were strengthened. The worksheets were also reframed as living tools rather than one-off assessment documents, allowing risk documentation to be revisited when the model, use context, workflow, evidence base or regulatory status changed. This refinement aligned with lifecycle-based risk management

Table 2 Themes from innovator feedback and worksheet refinement actions

Theme/generalised feedback	Worksheet refinement action points
Ease of use and cognitive burden Innovators preferred frameworks that were easier to engage with at first use. More detailed frameworks were perceived as resource intensive and required frequent reference to supporting materials. Participants commented that NIST Risk Management framework was easy to use, whereas with Fraunhofer they had to refer to the catalogue all the time.	Further need for scaffolded guidance, clearer signposting and more embedded support within the worksheet itself.
Iterative and lifecycle-oriented use Innovators valued approaches that supported ongoing revision. Iterative and lifecycle-oriented use of Fraunhofer framework was viewed as better suited to ongoing revision and re-examination compared with perceived one-off reporting in NIST.	Modify design of some worksheets as living tools rather than one-off exercises.
Context and intended purpose Innovators highlighted the need for clearer framing of intended purpose, deployment context, and AI role in defining associated risk.	This indicated the need for refining worksheet questions on intended purpose, human involvement and deployment setting.
Actionable examples and regulatory traceability Innovators wanted the worksheets and examples to be more detailed, specific and easier to translate into their own settings. Participants suggested adding reporting guidance and worksheet questions that better support regulatory compliance.	This pointed to the need for worksheets to connect more clearly with governance, evidence generation and reporting expectations.
Worksheet Application Challenges across diverse healthcare contexts Some frameworks were experienced as easier to apply in biomedical or device-oriented contexts than in broader service or mental health settings. One comment noted that many frameworks appear biased towards a biomedical model and do not easily accommodate biopsychosocial models of care.	The team decided to create a mental-health care context-specific example in a future iteration.
Multiple AI roles In feedback on the Fraunhofer guidance, one participant noted a presumption that AI is in an advisory role in our worksheets, whereas AI may also support triage, automation, prioritisation, monitoring or other functions.	This suggested that inclusion of some worksheet questions to explicitly define AI roles within worksheets.
AI, artificial intelligence.	

and recent post-market surveillance expectations for ongoing monitoring after deployment.

DISCUSSION

This study found that existing AI risk assessment frameworks are valuable but often require translation before they can be used effectively by healthcare innovators. Frameworks provide important structure, but their practical use depends on how easily innovators can convert high-level concepts into evidence, uncertainty, gaps and actions. We also found that one size does not fit all in healthcare AI risk management. Different AI systems have different intended purposes, users, clinical roles, evidence needs and deployment risks. A worksheet that supports proportionate documentation and iterative reassessment may therefore be more useful than a fixed checklist.

Interpretation in relation to existing literature

The findings are consistent with Xia *et al*,⁸ who showed that AI risk assessment frameworks vary in scope, principles, lifecycle coverage and assessment methods.⁸ They also align with Batool *et al*,⁹ who emphasised that AI governance requires clearer specification of stakeholders, governed elements, lifecycle timing and implementation mechanisms.⁹ Schmitz *et al*¹⁰ further highlighted variation in how frameworks conceptualise, quantify and aggregate risk, supporting our finding that healthcare context and intended use must be made explicit when applying frameworks.¹⁰

The findings are also consistent with current UK regulatory developments. The MHRA Software and

AI as a Medical Device Change Programme highlights the need for clearer requirements for software and AI-based medical devices while maintaining patient protection.⁵ Recent MHRA activity on proposed medical device reforms and postmarket surveillance requirements also supports the need for risk documentation that can address both premarket evidence and post-deployment monitoring.^{19 20}

Operationalising risk assessment for innovators

For innovators, the worksheets provide a practical route from framework concepts to structured documentation. They can support early risk reflection, evidence planning, identification of gaps and preparation for governance or regulatory conversations. By including intended purpose, AI role, deployment context and consequence of error, the worksheets help innovators avoid abstract risk assessment and instead focus on how risks arise in their specific use case. The worksheets will be useful for early-stage innovators who need to understand what evidence may be required later, and for regulatory-ready innovators who need to organise evidence, uncertainty and mitigations in a concise format.

Suggestions for regulators and support organisations

For regulators, accelerators and innovation support teams, this work suggests that guidance is more likely to be usable when accompanied by practical templates, examples and stage-aware worksheet questions. Frameworks alone may not be sufficient for small or resource-constrained innovators. Implementation support is

needed to translate risk domains into evidence expectations, documentation outputs and postdeployment monitoring plans. The findings also suggest that future guidance should account for diverse healthcare contexts, including mental health, service-based AI and workflow tools. Evidence requirements may differ across these settings, and risk assessment tools should not assume a narrow biomedical device model.

Strengths, limitations and future work

The worksheet development process was grounded in review-level evidence and refined through direct innovator engagement. The three anchor studies provided complementary coverage of AI risk assessment, governance and risk aggregation. However, the study was designed as a proof of concept and did not attempt to identify, appraise or synthesise every available AI risk framework. The targeted evidence synthesis did not use formal screening, methodological quality appraisal tools such as AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews 2) or ROBIS (ROBIS: Risk of Bias in Systematic Reviews), primary-study overlap analysis or certainty-of-evidence grading because its purpose was framework identification and operationalisation rather than a formal overview of systematic reviews. The selected frameworks were chosen for their recency, relevance, institutional recognition and practical value for translation into healthcare-oriented worksheets. Innovator feedback came from a limited group and may not represent all healthcare AI domains or regulatory classifications. Further testing is needed across a broader range of product types, clinical areas and maturity levels. Future work will evaluate whether use of these developed worksheets improves the quality, consistency and usability of risk documentation. Further refinement is needed for mental health, service-based AI and biopsychosocial care contexts. Future iterations will also explore how worksheet outputs can align with clinical safety cases, quality management systems, postmarket surveillance documentation and regulatory submissions.

CONCLUSION

AI risk assessment frameworks are important for responsible healthcare AI but can be difficult to operationalise in practice. This study shows how selected frameworks can be translated into practical healthcare-oriented worksheets through targeted evidence synthesis, framework mapping and innovator engagement. A one-size-fits-all approach is unlikely to meet the needs of diverse healthcare AI systems. These lifecycle-based worksheets can support proportionate evidence capture, clearer regulatory alignment and iterative risk management across development, deployment and post-deployment change.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Ethics approval was obtained from Brunel University of London (reference: 51213-A-Jan/2026-54958-1). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information. The framework mapping and worksheet development are fully described in the manuscript; example worksheet templates are available from the RADIANTCERSI's official website. The underlying stakeholder consultation data are not publicly available because they contain potentially identifiable or confidential information.

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