NICE National Institute for Health and Care Excellence

Evidence generation plan for ProKnow cloud-based system for radiotherapy data storage, communication and management

Implementation support

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1 Purpose of this document

NICE's assessment of ProKnow cloud-based system for radiotherapy archiving communications and management recommends that further evidence is generated while it is being used in the NHS.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technology in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps.

The company is responsible for ensuring that data collection and analysis takes place. Support for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business case approval. This will be in the form of funding for evidence generation consortia, bringing analytical partners and implementation sites together with developers for evidence generation.

Guidance on commissioning and procurement of the technology will be provided by NHS England, who is developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the company does not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (2 years), the developer should submit the evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether the technology can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The company can strengthen the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. Addressing these other evidence gaps will help the committee to make a recommendation by ensuring it has a better understanding of the benefits of the technology for patients and the NHS.

2.1 Essential evidence for future committee decision making

Impact of ProKnow on quality assurance for radiotherapy treatment planning

There is a desire to increase standardisation of radiotherapy treatment planning protocols across radiotherapy centres in the NHS. ProKnow could help reduce variation between centres through:

- supporting national data collection
- scorecard use
- training
- peer review
- potentially linking to local or national clinical registries to test for associations and outcomes.

Treatment plan quality (dosimetry, variance and spread) could be monitored over time through scorecard outputs.

Evidence appraised in the assessment included 8 service evaluations or audits of plan

quality variance between up to 227 individual treatment plans. But none of the evidence used a patient cohort or dataset for prospective treatment planning or quality assurance, and the largest sample patient dataset size uploaded was 2. Evidence for using the technology to evaluate large or prospective patient datasets is important for considering the benefits of the technology in the NHS.

Understanding whether ProKnow affects day-to-day clinical practice, and what changes healthcare professionals think its use has brought about, will support the committee in determining the usefulness of the technology.

Impact on staffing and treatment planning resources

It is important to understand the impact of the technology on resource use, including planning and auditing time, workflow, usability, and ease of retrieving and storing data. This will support the committee in assessing the real-world uptake and use of the technology in radiotherapy treatment planning.

2.2 Evidence that further supports committee decision making

Impact on staff training

ProKnow can support healthcare professional training through a contouring accuracy module. This could lead to an increase in standardisation and potentially improve patient outcomes over time (see section 2.1). Data collection of contouring accuracy scores and module uptake could show changes over time.

Changes in radiotherapy treatment accessibility

Access to some radiotherapy treatments, such as stereotactic ablative radiotherapy could be supported by ProKnow. This could make it easier to share treatment plans and specialist knowledge between NHS services. This is important for people who may be able to access specialist treatments in their local services after review by external healthcare professionals.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them. More information on the studies in this table can be found in table 9 in the external assessment group report. After publication of NICE's health technology assessment of ProKnow, no evidence directly related to the evidence gaps was identified (search completed 27 April 2023). No new ongoing studies were identified.

Table 1 Evidence gaps and ongoing studies

Evidence gap	Existing and real-world evidence	Ongoing studies
Impact on quality assurance for radiotherapy treatment planning	Limited evidence available	Ongoing study
Impact on staffing and treatment planning resources	Limited evidence available	Ongoing study
Changes in access to radiotherapy treatment	Limited evidence available	No ongoing studies
Impact on staff training	Limited evidence available	Ongoing study

In March 2022, NHS England (NHSE) commissioned an evaluation of ProKnow across 49 specialist cancer centres. Funding has been provided until March 2025 as part of the Radiotherapy Transformation Programme. This programme aims to improve the quality and reduce variability of radiotherapy service delivery across the NHS. Data collection within the NHSE evaluation is not mandatory, and uptake of ProKnow is optional and variable.

3.2 Data sources

There are several data sources, with different strengths and weaknesses, that could potentially support evidence generation. NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a

specific research question.

Because data on patient radiotherapy treatment plans is uploaded to and analysed in ProKnow, this would be the main data source for evidence generation. In the NHSE evaluation, each NHS Trust with access to ProKnow acts as its own data controller. Treatment plan information can be uploaded to local workspaces from local treatment planning software. From there, it can also be uploaded to national workspaces in an anonymised format. National collection workspaces are organised into themes based on cancer type, population and treatment modality. Plans uploaded to national datasets are being used to develop national guidance and service improvement toolkits. They are also being used to develop sets of scorecards for treatment plans in areas with enough data, such as lung stereotactic ablative radiotherapy, which could be used for system quality improvements.

Linking ProKnow data to other routinely collected data, such as cancer registries and the National Radiotherapy Dataset, could provide additional information, such as clinical outcomes. But this would be challenging to achieve within the evidence generation period, and would provide limited information related to the evidence gaps.

The quality and coverage of real-world data sources are of key importance when they are used in evidence generation. Active monitoring and follow up through a central coordinating point is an effective and viable way of ensuring good-quality data with broad coverage. It could also be assisted through national linkage efforts. Currently, all specialist radiotherapy services in England have access to ProKnow as part of the NHSE evaluation. Central active monitoring of the national workspace is overseen by the ProKnow Clinical Leadership and Implementation Group.

3.3 Evidence collection plan

The proposed approach to addressing the evidence gaps for ProKnow is a combination of real-world data collection and cross-sectional survey-based data collection. Real-world data collection could be through a time-series study or an alternative quasi-experimental design over the course of the NHSE evaluation period.

Cross-sectional survey

Feedback from staff with ProKnow access could be collected periodically (for example, annually) by survey. This should cover user experience on key issues, including the impact

of ProKnow on quality assurance for radiotherapy treatment planning and on staff time and resources. This study approach could also collect data on uptake of the contouring accuracy training module for the technology, providing evidence for the impact on staff training (see section 2.2).

Real-world time-series study

The impact of the technology on quality assurance for radiotherapy treatment planning, staffing and resources can be measured through a time-series analysis of data collected from each centre. This would allow periodic analyses of data collected as part of the NHSE evaluation. It would also allow the adoption of more formal evaluation methods such as before and after studies, interrupted time-series analysis and stepped wedge analyses. This could provide increasingly robust quantitative evaluations of the relative impacts of changes in ProKnow use or address specific questions as they arise during the NHSE evaluation.

Data should be analysed and compared across defined timepoints showing trends over time. This includes:

- local and national workspace uptake
- variability (positive deviance) and spread of treatment plans according to plan quality metrics (such as scorecards or benchmarking against national standards)
- peer reviews
- local and national workspace use.

This may highlight centres that are performing well, which may provide lessons to emulate, and centres that are performing less well, which may provide opportunity for improvement. This approach allows for monitoring of adherence to existing clinical guidance, and quantifies the variation in clinical practice over time.

Changes in access to specific treatments, such as stereotactic ablative radiotherapy, could also be considered within this study design.

Data analysis should ideally capture the use of ProKnow for prospective treatment planning and quality assurance.

Data collection should follow a predefined protocol. Also, quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies.

3.4 Data to be collected

The following information has been prioritised for collection within each of the recommended study designs:

- Survey data, reported on an annual basis, including:
  - number of audits done and planned
  - usability and ease of retrieving and storing data
  - use of ProKnow contouring accuracy training module
  - perceived impact of ProKnow on:
    - treatment planning
    - access to peer review for treatment planning
    - quality assurance activities such as scorecard development or analysis, or completion of audits
    - number of treatment planning errors and their causes
    - any adverse events and their causes and
    - staff time and resource.
  - open questions covering:
    - impacts of ProKnow on improving treatment planning and quality assurance activities, such as peer review and audit
    - negative impacts of ProKnow, for example, on staff time or resources
    - development of guidance through using ProKnow and case examples of the impact of the technology on practice

    - ◇ the impact of using ProKnow on day-to-day clinical practice, including any perceived benefits or challenges

- time-series data on:
    - essential outcomes, such as:
        - ◇ number of patient treatment plan uploads to local workspaces across all NHS centres per month
        - ◇ number of patient treatment plan uploads to local workspaces that are uploaded to national workspaces (by cancer type and treatment modality) across all NHS centres per month
        - ◇ any adverse events associated with ProKnow, for example, data transfer resulting in changing of labelling conventions or dosimetry data because of lack of interoperability with other treatment planning or software systems
    - desirable outcomes, such as:
        - ◇ plan variance and spread (between acceptable and major or minor deviations) according to scorecard metrics, which includes dosimetry data
        - ◇ quarterly or annual data analysis of treatment plans uploaded for 1 to 3 core metrics per scorecard.

3.5 Evidence generation period

This should be 2 years to align with the commissioning position of the technology, and to allow for the evidence to be sufficiently mature to support future decision making.

4 Monitoring

Companies must contact NICE:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence and
- annually to confirm that the data is being collected and analysed as planned.

Companies should tell NICE as soon as possible about anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the companies should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Implementation considerations

The company currently does not have access to any data entered into ProKnow as part of the NHS England (NHSE) evaluation. The following considerations around implementation and the feasibility of the evidence generation process as part of this evaluation have been identified through working with system partners:

- A ProKnow snapshot survey was done at the start of the NHSE evaluation in April 2023, for which around half of all centres submitted a response. This survey could be repeated in April 2024 (during NHSE evaluation) and April 2025 (at the end of the NHSE evaluation) to capture data relating to using ProKnow at the different stages of its implementation to monitor uptake and use of the technology over time.
- Survey results depend on comprehensive distribution of the survey across the NHS and on the sample of respondents being representative of the target population. The survey is an additional to the existing workload and demands on staff. Data collection should be restricted to essential outcomes only and the survey widely distributed across the target audience.
- Currently, there are no mandatory data collection stipulations as part of the NHSE evaluation (up to March 2025). This can lead to differences in what is reported between services. Some treatment plan data (such as 4D imaging that may be used in people with breast cancer) cannot be uploaded to ProKnow. So, the data collection may not be generalisable to all cancers or treatment modalities.
- National guidance for some aspects of radiotherapy treatment planning may be lacking. For example, the Royal College of Radiologists recommends using departmental protocols for peer review, plan definitions and quality assurance. So, practice may differ between centres and standards may not be available to audit against.
- Communication with data-holding centres may encourage data completeness, but inherent biases may remain in both local and national data collections. So, the robustness of the desirable outcomes within the time-series study should be considered.
- Resources and communication to increase awareness and engagement with data collection and analyses should be considered. This could be through existing

professional groups and steering organisations involved in the NHSE evaluation.

- Staff time and resources to support data entry to ProKnow should be considered. Burdens could be alleviated by providing analytic or scripting support to ease data transfer.
- Clear processes for reporting adverse events associated with ProKnow should be in place, for example, reporting interoperability issues to the ProKnow Clinical Leadership and Implementation Group or company.

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