NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early value guidance consultation document

ProKnow cloud-based system for radiotherapy data archiving, communication and management: early value assessment

Early value assessment (EVA) guidance provides rapid recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technology advisory committee has considered the evidence and the views of clinical experts. This topic is the one of the first pilots using the new EVA approach. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. Although there are uncertainties, the evidence does not suggest a risk to patient safety. NICE has included considerations for early access to treatment in this guidance.

Further evidence will be generated over the next 3 years to assess if the benefits of the technology are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

1 Recommendations

1.1 ProKnow can be used while further evidence is generated. This includes use of all 3 ProKnow modules:

- ProKnow DS – a database used for importing, analysing and storing patient data
- ProKnow CA – a contouring accuracy tool to practise, study and improve anatomical contouring

- ProKnow PS – a platform for creating and comparing radiotherapy treatment plans.

Potential benefits of early access

- **Access:** In March 2022, NHS England (NHSE) commissioned a pilot of ProKnow (including all 3 modules) across 49 specialist cancer centres with funding provided until March 2025 as part of the Radiotherapy Transformation Programme. The programme aims to improve quality and reduce variability in radiotherapy services across the NHS.

- **System benefit:** Early evidence suggests that ProKnow may help to increase the number of treatment plans that are peer reviewed, either within or between centres. This could reduce variation in practice and improve knowledge sharing between healthcare professionals. This could lead to greater adherence to national guidance and local peer review protocols, and to improvements in the overall quality of radiotherapy treatment plans. ProKnow also offers clinical oncology training tools, which can be used to improve staff training in radiotherapy treatment planning.

- **Equality:** ProKnow enables clinicians to access and peer review radiotherapy treatment plans remotely, so it may particularly benefit smaller centres by providing access to clinical oncologists from other centres and improving care across the UK. ProKnow may also provide greater benefit in cases relating to rare or complex cancers, when there is more need for plans to be peer reviewed.

Considerations for early access

- **Information governance**: Adverse events relating to patient care are not expected when using ProKnow, but potential risks include confidentiality breaches or issues accessing or retrieving data. So, all centres should ensure they have appropriate IT infrastructure and information governance protocols in place.

- **Outcomes**: ProKnow is not expected to directly affect patient outcomes. How much ProKnow improves the quality of treatment plans is likely to be difficult to

quantify and attribute costs to. Surrogate outcome measures may be needed to quantify the quality of radiotherapy treatment plans.

- **Costs**: ProKnow may help to increase the number of treatment plans that are peer reviewed and provide a place to document their quality assurance, which may lead to benefits for people having radiotherapy. Increased peer review is likely to increase staff time and costs, which should be considered in addition to the cost of purchasing ProKnow.

1.2 Further evidence should be generated on:

- the impact on quality assurance for radiotherapy treatment planning, including surrogate, qualitative, and quantitative measures such as:
  - structural changes to radiotherapy treatment plans
  - dose prescription changes
  - dose volume distributions
  - scorecards
- healthcare professionals' experience of using ProKnow including usability
- ease of retrieving and storing patient data
- radiotherapy treatment planning time (including difference in time to start of treatment)
- changes in the number of internal and external peer reviews
- the impact on staffing and treatment planning resources
- the impact on clinical oncology training for healthcare professionals who contribute to radiotherapy treatment planning
- the ability for data linkage to national registries (including change in the number of treatment plans added to national registries)
- changes in inequality of access.

Find out more in the evidence generation section in this guidance.

2 Value proposition

2.1 ProKnow is a cloud-based system that can potentially help quality improvement in radiotherapy, by enabling the following:

- Remote peer review within and between centres. This could potentially lead to greater adherence to national guidance and local peer review protocols, and higher quality radiotherapy treatment plans. The peer review process is intended to improve standardisation and reduce variation in practice, and improve knowledge sharing between healthcare professionals involved in treatment planning.
- Increased ease in archiving and retrieving patient data for analysis. This could lead to reduced staff resources needed for data collection, for example audits to monitor peer review.
- Reduced adverse events and costs associated with treatment planning errors.
- Standardised scoring systems and analysis of multiple datasets. This could lead to changes in treatment modality, doses or fractionation. An improved understanding of treatment could lead to changes in thresholds in national guidance.
- Training support using the ProKnow CA and PS modules. This could lead to improvements in radiotherapy treatment planning competency or quality over time

3 The technology

Technology

3.1 ProKnow is a system used in radiotherapy offering a cloud-based data repository, communication tools and analytics software. The technology is used for people having image-guided 3D planned radiotherapy, and allows centres to compare radiotherapy plans and collect images and dosimetric data. ProKnow can be used to view treatment plan information, visualise images and the structures they contain, and inspect dosimetric data, such as dose volume histograms and dose distributions. Custom

treatment plan quality metrics can be extracted, such as local radiotherapy control, survivorship, and side effects. ProKnow allows teams to work together to mark the areas of interest on images, in a process known as contouring. This can be done from any computer, without the need for a dedicated workstation, and so allows collaboration and peer review of treatment plans between centres that are using ProKnow.

Comparator

3.2 The comparator is standard care, which varies across centres. In most NHS centres, the treatment planning team uses local protocols for peer review. Treatment planning includes clinical oncologists, radiographers, dosimetrists and medical physicists, with the qualified clinical oncologist taking overall responsibility for planning and final sign off. Peer review is an important step in treatment planning, to ensure the proposed plan will deliver safe and effective treatment, and to identify issues that could affect quality of care. The peer review process is also intended to improve standardisation and reduce variation in practice, and improve knowledge sharing between healthcare professionals involved in treatment planning.

Current use

3.3 Guidance from the Royal College of Radiologists (RCR) on radiotherapy target volume definition and peer review (2022), says that departments should have agreed radiotherapy protocols for each tumour subsite. These protocols should include target volume guidelines, be agreed by the departments working together, and should be standardised across operational delivery networks, as well as nationally or internationally if possible. There are several different methods, software and technologies used for peer review in NHS practice.

3.4 In March 2022 NHS England (NHSE) commissioned a pilot of ProKnow (including all 3 modules) across 49 specialist cancer centres with funding provided until March 2025.

4 Committee discussion

Unmet need

4.1 There is a need to increase standardisation of radiotherapy treatment planning protocols across radiotherapy centres in the NHS. The clinical experts noted that peer review is done by clinical oncologists using different methods, such as in person or using Microsoft Teams. But, when there is a shortage of staff to do peer reviews or a backlog in radiotherapy treatment planning, peer review may not take place. ProKnow could help address the large variation between centres through training, data collection, score cards and linkage to national registries.

4.2 The clinical experts agreed that smaller centres with lower numbers of radiotherapy staff have more difficulty allocating time for peer review. So they may benefit more from using a platform which allows upload of radiotherapy treatment plans for external review. For rare and complex cancers, when there may only be one specialist in a centre, ProKnow would allow communication with clinicians in other locations using a standardised format. The peer review function within ProKnow also does not need users to be online, so both clinicians do not need to be present during the peer review process, which would be the case for in person or virtual meetings. The committee concluded that ProKnow may enable an increase in the number of radiotherapy treatment plans undergoing peer review, which would bring clinical practice more in line with the RCR guidelines.

Further evidence

4.3 Further evidence will be generated while ProKnow is in use to explore the impact of the technology on patient outcomes and radiotherapy treatment planning resource. The clinical experts noted that ProKnow is unlikely to have any direct effect on patient outcomes, but the technology may increase adherence to national guidelines and have a positive impact on clinical oncology training. Additional efficiency-related metrics may also be

collected to estimate the impact on staffing and resource. The committee concluded that ProKnow can be used for radiotherapy data archiving, communication and management while further evidence is generated.

Clinical-effectiveness overview

4.4 The evidence includes 8 service evaluations or audits of treatment plan quality and 4 service evaluations or audits assessing the use of ProKnow during training. Two audits or evaluations were done exclusively in a UK or NHS population. The evidence highlights the versatility of ProKnow to enable data sharing, including radiotherapy treatment plans, and tools to enable quality assurance and review. The evidence also shows the functionality of ProKnow as a training tool for treatment planning and contouring. The clinical experts said that this could improve clinicians' skills in radiotherapy treatment planning and reduce variability between clinicians. Future uses of ProKnow may include evaluation of artificial intelligence (AI) technologies for treatment planning and contouring. It could also be used to link data to national routine datasets to determine the impact of ProKnow on patient outcomes. But, the committee noted that there is a lack of prospective and comparative evidence for ProKnow. This means that it is not possible to show the impact of ProKnow on treatment planning outcomes, quality assurance, or hospital resource use. The committee concluded that the evidence base is very limited for ProKnow. See the Assessment Report for full details of the clinical evidence.

Costs and resource use

4.5 The External Assessment Group (EAG) considered the costs and resources associated with ProKnow's use in the peer review process within the care pathway. The EAG identified the key parameters affecting the cost of ProKnow. They are the length of peer review activity and the cost of purchasing the technology, which is based on the number of linear accelerators and amount of data storage needed per year. The EAG also did a scenario analysis, in which they changed the length of peer review

and the number of people ProKnow was used for. A conceptual 1% increase in the proportion of plans being peer reviewed for 15 minutes, 30 minutes and 45 minutes would cost an additional £0.62, £1.23, and £1.85 per person respectively.

4.6 The EAG was able to outline key cost parameters and do a scenario analysis to estimate the cost of ProKnow per year. But, they noted that the broader staff and resource impact of introducing ProKnow into the process of radiotherapy treatment planning hasn't been quantified. ProKnow could increase the proportion of treatment plans undergoing peer review. This would incur an additional cost because of the increase in staff time needed to do peer review that was previously not done, but this activity could lead to improved patient outcomes. Any potential cost savings because of improved patient outcomes or more efficient resource use would also have to be included in an economic evaluation. The committee concluded that more data on these cost parameters is needed.

Evidence gap overview

4.7 The key evidence gaps relate to the care pathway and key outcomes. The committee concluded that the evidence is very limited, so evidence generation is needed to address the following key evidence gaps:

- There is large variation in peer review practice across the NHS, including the proportion of treatment plans undergoing peer review, who does peer review, and the tools to support how peer review is done in the NHS. Additional work is needed to quantify this variation and the uncertainty associated with the costs of delivering standard care in radiotherapy treatment planning.
- There is a lack of evidence to quantify the impact of ProKnow on patient outcomes. It is possible that increased peer review will lead to an improvement in the quality of radiotherapy treatment plans resulting in better patient outcomes, but this is difficult to quantify.

- There is limited (qualitative or non-qualitative) evidence reporting on the usability or clinician user experience of ProKnow and the ease of retrieving or storing patient data.
- There is no comparative evidence or validated competency assessment exploring the impact of ProKnow on clinical oncology training.
- There is an evidence gap relating to adverse events in large case datasets, which could be addressed as part of the NHS England (NHSE) commissioned pilot of ProKnow. No publications reported adverse events specifically relating to the use of ProKnow. The EAG noted that adverse events relating to patient care would not be expected for the evidence included. But adverse events may relate to confidentiality breaches or issues accessing or retrieving data, which were not reported in the included publications.
- There is limited evidence available for the economic modelling. The EAG was able to outline key cost parameters and conduct a scenario analysis to estimate the cost of ProKnow per year. But it noted that further research is needed to quantify the broader staff and resource impact of introducing ProKnow into radiotherapy treatment planning. This should include any impact on overall radiotherapy treatment planning time.

5 Evidence generation recommendations

5.1 The committee recommended further evidence generation for the use of ProKnow. The committee considered that the key outcomes could be addressed through service evaluations associated with the commissioning of ProKnow across the NHS in England. Evidence generated as part of a large national evaluation would be reflective of practice in the NHS across the UK and is likely to be sufficient for future decision-making.

The key outcomes that were prioritised by the committee for evidence generation include:

- the impact of ProKnow on quality assurance for radiotherapy treatment planning
- changes in the number of internal and external peer reviews done
- usability and ease of retrieving and storing patient data
- radiotherapy treatment planning time
- the impact on staffing and treatment planning resources
- the impact on clinical oncology training
- changes in inequality of access for patients

6 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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