NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

ProKnow cloud-based system for radiotherapy data archiving, communication and management

Final scope

1 Technology

1.1 Description of the technology

ProKnow is a system used in radiotherapy offering a cloud-based data repository, communication and analytics software. The technology is used for people having image-guided 3D planned radiotherapy, allowing centres to compare radiotherapy plans and enabling the collection of imaging and dosimetric data. Patient data can be imported from existing DICOM (Digital Imaging and Communications in Medicine) systems. ProKnow's intended use covers radiotherapy treatment planning broadly without being specific to certain disease areas. The main functionalities of ProKnow are contouring of radiotherapy images and peer review of treatment plans. Users can archive, inspect, analyse and interact with radiotherapy patient data for both retrospective and prospective studies. Supported functions include visualising images and anatomical structures, inspecting plan information, creating and analysing dose distributions, inspecting dose volume histograms and extracting metrics. This can be applied to single patient datasets or collections of datasets. ProKnow consists of three separate modules, which each have their own functionalities. ProKnow DS is the database system which is used for importing and analysing patient data. ProKnow PS is a platform for creating and comparing radiotherapy treatment plans and ProKnow CA is a contouring accuracy tool which allows users to practice, study and improve anatomical contours. ProKnow is compatible with all types of external beam

radiotherapy planning software systems, so it can be used across the existing NHS infrastructure. Introductory online training is provided by the company, this is expected to take users no more than 4 hours to complete. Further one to two hour live sessions are regularly run via Microsoft Teams. There is no additional cost for training.

1.2 Relevant diseases and conditions

Radiotherapy is a treatment where radiation is used to kill harmful cells, such as cancer cells. Statistics from NHS England show that there were 103,348 radiotherapy episodes in England in 2020. According to Cancer Research UK, during 2013-2014, 27% of all patients diagnosed with cancer had curative or palliative radiotherapy as part of their primary cancer treatment.

ProKnow is intended for use in radiotherapy treatment management, specifically for treatment planning data archiving, analysis and communication. Peer review of proposed radiotherapy plans is used to minimise the likelihood of errors passing through the treatment plan and to have processes examined by peers to work towards best practice. The process of peer review is intended to facilitate communication and standardisation, potentially reducing practice variation and improving knowledge sharing among healthcare professionals.

1.3 Current management

Most NHS centres implement local protocols for planning peer review, which usually involve the local treatment planning team. Radiotherapy planning involves a wide range of healthcare professionals, including clinical oncologists, radiographers and medical physicists. In most cases, a qualified clinical oncologist is responsible for treatment planning and final sign-off.

The Royal College of Radiologists has published guidance on Radiotherapy target volume definition and peer review. The guidance states that departments should have agreed radiotherapy protocols for each tumour subsite. These should be agreed between departments working in partnership and be ratified by the appropriate subgroup of the regional Cancer Alliance or

equivalent in the devolved nations. It is recommended that target volume guidelines are specified in protocols, which should be standardised across a clinical network or ideally nationally. For peer-review specifically, the guidance specifies that prospective peer review of contours should occur in cases where significant individual judgement is required. In all other situations, a proportion of contours should be quality assured retrospectively.

1.4 Regulatory status

ProKnow received a CE mark in April 2020 as a class I medical device for radiotherapy data archiving, communication and management.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Improved treatment planning, which could lead to better patient health outcomes
- Increased standardisation across the healthcare system, which reduces treatment variability

The benefits to the healthcare system claimed by the company are:

- More efficient communication between clinicians in different geographical locations, to review, assess and modify tumour contouring and patient treatment plans
- Supports services to participate in regular treatment plan quality audits, to improve the quality of radiotherapy and reduce unnecessary variation
- Provides teaching and training resources for healthcare professionals, such as a contouring accuracy tool
- Big data analysis can be used to explore the impact of treatment plan quality on short and long-term clinical outcomes, data can also be linked to other cancer data sources for comparison and outcomes measurement
- Enables local systems to take greater ownership of service development implantation by providing a platform for quality assurance activities

2 Decision problem

Population	People having planned radiotherapy with 3D dose distribution
Intervention	ProKnow (includes ProKnow DS, ProKnow PS and ProKnow CA)
Comparator	Standard care

Outcomes	The outcome measures to consider include:
	• Impact on radiotherapy treatment planning quality assurance, including surrogate, qualitative and quantitative measures such as:
	  • structural changes to radiotherapy treatment plans
	  • dose prescription changes
	  • dose volume distributions
	  • scorecards
	• usability/user experience
	• ease of retrieving and archiving patient data
	• radiotherapy treatment planning time (including difference in time to start of treatment)
	• number of internal and external peer reviews performed
	• impact on staffing and treatment planning resources
	• impact of the system on clinical oncology training (including training of all healthcare professionals contributing to radiotherapy treatment planning)
	• ability for data linkage to national registries (including change in the number of treatment plans added to national registries)
	• reduction in inequality of access

Economic analysis	A health economic decision model will be developed comprising a cost-comparison analysis. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on cost-comparison estimates.
Other considerations	49 specialist cancer centres in the NHS currently have access to ProKnow. It is being used as part of the Radiotherapy Transformation Programme, aiming to improve the quality and reducing the variability of radiotherapy service delivery across England.

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable.	
Related NICE recommendations	None	
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan Royal College of Radiologists (2017) Radiotherapy target volume definition and peer review	