

National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT770 ProKnow cloud-based system for radiotherapy data storage, communication and management

Consultation comments table

There were 42 comments from 3 groups:

- 24 comments from 1 healthcare professional
- 15 comments from 1 professional society
- 3 comments from 1 professional organisation

Comment no.	Consultee ID	Group	Section	Comments	NICE response (including changes made to MTCD, if applicable)
General (n = 2)					
1.	2	Professional society	General	<p>A distinction should be made throughout the guidance between peer review of radiotherapy contours and peer review of treatment plans. These are different activities, usually led by different staff groups.</p> <p>Contour peer review mainly involves clinical oncologists and can lead to contours changing in about 10% of cases. Most peer review is within a department - usually on-line in ad-hoc or formal meetings but occasionally off-line. The only scenario ProKnow might help with is off-line contour peer review between departments where ProKnow is essentially used as a platform to share contours. On-line reviews between departments can be done very effectively on Teams or similar platforms.</p> <p>In contrast, plan peer review involves looking at the final dosimetric plan from physics and dosimetry teams to see if it can be improved. This is usually physics/dosimetry led with some clinical input. ProKnow may enable the comparison of different plan metrics. We agree that Proknow provides opportunities to compare plans before treatment and to collect national data on plans between centres to audit and assess variation.</p> <p>We think Proknow has a very small role in enabling contour peer review as the barriers to contour peer review (number of oncologists, protected time in job plans etc) would not be impacted by the technology.</p> <p>Greater clarity on terminology could also be offered by explicitly outlining certain basics of radiotherapy planning. For example, for contour peer review, anatomically defined clinical target volume (CTV) based volumes can be defined according to protocols eg whole breast, prostate and craniospinal. The benefit of peer review for every case is likely to be small. Gross</p>	<p>Thank you for your comment.</p> <p>Changes have been made throughout the document to describe peer review of radiotherapy contours and treatment plans separately.</p> <p>In section 4.2 of the guidance, it has been clarified that ProKnow can facilitate peer reviews without the need for clinicians to be online at the same time.</p>

				tumour volume (GTV) based volumes are too variable to be defined by protocols other than explaining the overall approach, appropriate GTV-CTV margins etc. These are more likely to be improved by a peer review process.	
2.	1	Healthcare professional	3.1 Technology	ProKnow doesn't really help with this, as the data needs to first be collected locally (it would not be collected within ProKnow as a primary repository). *if* the collected data is then transferred to ProKnow, the custom metrics system can be used to store, or to compare different metrics, but NONE of the parameters mentioned are currently being recorded in a systematic or standardised way, and ProKnow will have no effect on initial recording of this data.	Thank you for your comment. It is agreed that there is no current standardised process for data collection, but ProKnow is intended to facilitate data collection. This would need to be done by first collecting the data on a primary repository and then transferring the data to ProKnow.
Recommendations (n = 1)					
3.	1	Healthcare professional	1.1 Recommendations	I would recommend removing these items from the review/recommendations. The CA module is (I believe) 'open access' and is not CE marked. PS requires specialist configuration by the manufacturer before use for each individual plan comparison study. Neither CA nor PS are included in the NHSE pilot funding.	Thank you for your comment. Clinical experts confirmed that only ProKnow DS is being funded as part of the NHSE pilot, but the ProKnow CA and ProKnow PS modules have been made available for NHS clinicians to use. Although the information stated within your comment is accurate, we propose that data collection should continue for all 3 modules during the pilot period.
4.	1	Healthcare professional	3.4	No. to my knowledge, only the ProKnow DS module was commissioned. The CA and PS modules are entirely separate, perform separate tasks, and should not be included in this evaluation	Thank you for your comment. Please see the response to comment 3.
Potential value (n = 13)					
5.	2	Professional society	2.1 Potential value	Proknow CA may improve contouring accuracy, not planning	Thank you for your comment. The wording for this bullet point under section 2.1 has been changed to note that training using the ProKnow CA module may lead

					to improvements in contouring accuracy.
6.	2	Professional society	4.1	Clinical oncologists perform contour peer review. This is not necessary for every set of radiotherapy contours (eg those that are for protocol-specified treatments). The reasons for peer review not being performed are complex and include lack of time in job plans. The final sentence is not relevant to contour peer review.	Thank you for your comment. It is recognised that peer review does not take place for every treatment plan or contour, however, a peer review process should be in place at each centre particularly for more complex cases.
7.	2	Professional society	4.2	Proknow will only help contour peer review when used cross-site and off line. This is likely to be a very small number of reviews compared to other methods (face-to-face, on-line between centres).	Thank you for your comment. The committee agreed that ProKnow is more likely to be of benefit for communication between rather than within centres. Peer review is currently done using many different methods and ProKnow may offer increased standardisation in the way that peer review is done.
8.	2	Professional society	4.3	Proknow is more likely to be of benefit to physics and dosimetry training than clinical oncology training.	Thank you for your comment. Clinical experts highlighted that ProKnow has the potential to benefits both physics and dosimetry and clinical oncology training.
9.	3	Professional organisation		Originally ProKnow was seen as a major tool to support Peer review particularly between centres (not particularly within centres) – I think this needs amending	Thank you for your comment. This was agreed with by the committee, although there may still be benefit for some centres in using ProKnow as a tool for communication within their own centre. The wording throughout the document intends to reflect this by stating that ProKnow can be used for collaboration between and within centres.

10.	3	Professional organisation		The dosimetry audits are where we think we will get the most gain (see comment below) and this is really our focus particularly during COVID centres organised themselves via Teams so having this as the main benefit is now a bit dated and also a turn off for centres – we need to emphasise its importance in ensuring equity of access to quality treatments and driving improvement in plan quality	Thank you for your comment. The evidence generation plan includes proposed outcomes to capture changes in equity of access to treatments and changes in radiotherapy treatment plan quality.
11.	1	Healthcare professional	2.1 Potential value	It's not clear that standardised scorecards would lead to change in doses or fractions, as the scorecard need to be configured per dose/fraction. The second sentence does not follow on from the first sentence.	Thank you for your comment. This section has now been changed to 'Standardised scoring systems and analysis of multiple datasets. In some cases, this could lead to changes in treatment modality, doses or fractionation. An improved understanding of treatment could lead to changes in dosimetry thresholds in national guidance.' This change reflects that the use of scorecards can support improvements in the understanding of treatment. Collated data from numerous radiotherapy treatment plans may be used to inform future improvements in radiotherapy delivery.
12.	1	Healthcare professional	2.1 Potential value	This is not included in the NHSE funded ProKnow pilot study, and there are no plans or system to even use or test this in a methodical way. This should be removed	Thank you for your comment. Please see the response to comment 3.
13.	1	Healthcare professional	4.1	NO. this does not follow on from the previous sentence. ProKnow will have (almost) no effect on staff shortages, and lack of peer review (in fact, it may create more work/greater need for trained staff) - it does not 'perform' peer review - although it *could* facilitate peer review in some cases.	Thank you for your comment. ProKnow does have the potential to facilitate peer review, rather than being an automated tool which can perform peer review. It is not expected to have a direct impact in relation to staff shortages, but it may

					help to increase levels of peer review between centres. This may particularly benefit small centres or in cases involving complex cancers.
14.	1	Healthcare professional	4.1	NO. almost none of these items would improve peer review, or be affected by peer review. linkage to databases would not (in itself) 'reduce variation' or improve standardisation.	Thank you for your comment. Improved training and data collection using ProKnow may benefit centres, and linking data to national registries may support audits to improve understanding and delivery of treatment. Widespread use of ProKnow across centres may increase standardisation and bring practice as a whole more in line with the RCR guidance.
15.	1	Healthcare professional	4.2	NO. again, ProKnow *could* facilitate peer review in departments who choose to use it, both internal and external, but it cannot replace lack of staff, or shortages of trained staff within in given department. this is just untrue and misleading. It is also possible that smaller centres might not have the staff and resources available to configure and manage ProKnow, and gain experience with it, so it's possible this could operate counter to your arguments here.	Thank you for your comment. It is possible that some centres may face issues with adopting ProKnow. Data collection during this period is intended to gain an improved understanding of ProKnow's potential benefits and identify key areas for improvement.
16.	1	Healthcare professional	4.2	Again, this is conflating different ways of working, and attributing them all to use (or not) of ProKnow. the word 'online' is confusing - users MUST be online, as ProKnow is a cloud based system. It is true that ProKnow does not *have* to be used synchronously (in real-time) by all users, but this is the case for many systems and processes, and in fact some of the real benefits of ProKnow DS may be precisely the ability to perform real-time contour and plan review with all users able to view and edit at the same time, as the most valuable learning and communication tool. I really don't understand what this previous sentence is trying to indicate, or why we would consider this to be a benefit linked only to ProKnow?	Thank you for your comment. For clarity, the wording in this section has been changed to 'The peer review function within ProKnow also does not need users to be online at the same time, 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.'

17.	1	Healthcare professional	4.4	it is not clear what this means.	Thank you for your comment. ProKnow could be used to upload data onto national datasets. Analysis of these datasets may help to understand any changes in patient outcomes that could be attributed to the use of ProKnow.
Care pathway and clinical need (n = 3)					
18.	2	Professional organisation	Potential benefits of early access: System benefit	'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'. This seems to confuse the two types of peer review outlined above. Local protocols will usually be relevant to contour peer review, not plan peer review.	Thank you for your comment. This statement has been reworded.
19.	2	Professional organisation	3.2	the treatment planning team uses local protocols for peer review'. We are not sure what this means. Departments will have local/network radiotherapy protocols specifying technique, dose etc. These protocols should make reference to whether peer review is required for that tumour site. (as explained in 3.3). This is not quite the same as 'local protocols for peer review'	Thank you for your comment. Section 3.2 has been reworded.
20.	1	Healthcare professional	3.1	Standard care is variable across many centres, but will also evolve over time, even on the timescale of this project, so this will be extremely challenging to use this correctly as a comparator. The comparator only seems to be discussing peer review - is this the only functionality of ProKnow DS being evaluated ? this would seem to miss an opportunity to see how departments can use ProKnow as a quality improvement tool, above and beyond simple peer review	Thank you for your comment. The data collection for ProKnow relates to all 3 modules, and encompasses all functionalities for which it is being used within the NHS. This includes radiotherapy treatment quality improvement.
Clinical evidence (n = 6)					
21.	2	Professional society	Potential benefits of early access: System benefit	Given the above ambiguity regarding peer review of contouring and treatment plans, the 'early evidence' referred to in the first line should be further explained.	Thank you for your comment. Section 4.4 contains a link to the EAG's Assessment Report, where all relevant evidence is outlined.
22.	3	Professional organisation	Considerations for early access: Outcomes	There is some early evidence that ProKnow – via the national collections and scorecard development is identifying where bowel dose (organ at risk) is greater in some cases than others	Thank you for your comment.

				where an ODN is working to the same protocol – whilst this is early days there is something about comparative dosimetry audits to drive plan quality reduce dose to organs at risk and improve outcome – could this be considered please	The guidance notes that evidence should be generated on the impact on quality assurance for radiotherapy treatment planning and that this should include changes to dose prescription and dose volume distribution. Your comment will be shared with the team working on the evidence generation plan for ProKnow.
23.	1	Healthcare professional	4.2	A lot of these papers are NOT relevant to the clinical evaluation of ProKnow DS. They often refer to the Contouring CA and Plan comparator PS modules, or to a very specific use of ProKnow across a single workspace (different from the 49 centre use in NHSE pilot). Many of these papers are not relevant to prospective or real-time clinical 'peer review' for real clinical patients	Thank you for your comment. The EAG have identified and reviewed studies that meet the criteria outlined in the decision problem of the scope. We agree that the evidence base for ProKnow is not complete and the committee have recommended further evidence generation.
24.	1	Healthcare professional	4.2	NO. this is not included in the NHSE pilot study, and is not relevant to ProKnow DS or the roll-out of AI tools. There is nothing in ProKnow DS that would either benefit or hinder evaluation of AI, and the two things should not be conflated.	Thank you for your comment. This section of the guidance refers to ongoing studies in which ProKnow has been used for different purposes, such as evaluation of AI technologies.
25.	1	Healthcare professional	4.7	it's possible that this is primarily for other modules CA and PR , not the DS module	Thank you for your comment. Clinical oncology training using ProKnow is specifically in relation to the ProKnow CA module.
26.	1	Healthcare professional	4.7	this is because the included publications were almost exclusively related to anonymised test plans, or to retrospective studies, so IG issues and adverse effects were eliminated from the studies by design. Or the publications were not looking at	Thank you for your comment. No adverse events were reported relating to confidentiality or information governance. It is

				large numbers of (real) patient datasets potentially being share across multiple departments	possible that this was influenced by the factors mentioned in this comment.
Equality considerations (n = 2)					
27.	2	Professional society	Potential benefits of early access: Equality	Again – contour and plan peer review seem conflated. Access to clinical oncology expertise for contour peer review can easily be achieved on Teams. We agree that systems that improve both contour and plan peer review may especially benefit centres treating fewer patients.	Thank you for your comment.
28.	2	Professional society	3.1	The technology is used for people having image guided 3D planned radiotherapy...’ Radiotherapy increasingly uses 4D datasets. Please comment on the utility of ProKnow in this setting	Thank you for your comment. ProKnow is not currently compatible with 4D patient datasets. Section 3.1 has been updated to highlight this.
Evidence generation (n = 11)					
29.	2	Professional society	Considerations for early access: Outcomes	We suggest changing to ‘How much ProKnow improves the quality of radiotherapy contours and treatment plans...’	Thank you for your comment. The proposed changes have been accepted and made to the guidance document.
30.	2	Professional society	4.7	1st bullet point: We suggest ‘....across the NHS, including the proportion of treatment contours and plans undergoing peer review,...’	Thank you for your comment. Section 4.7 has been updated with the following wording: ‘There is large variation in peer review practice across the NHS, including the proportion of treatment contours and plans undergoing peer review, who does peer review, and the tools to support how peer review is done in the NHS.’
31.	2	Professional society	5.1	It would be helpful to have the evidence divided according to the 3 Proknow modules	Thank you for your comment. As there is significant overlap in the proposed outcomes for data collection and the potential uses of each ProKnow module, the

					evidence generation plan has not been dividing for each module.
32.	1	Healthcare professional	1.1	this is absolutely true - but seems to be contradicted by some of the outcome measures proposed later in the document for evidence gathering	Thank you for your comment. To recognise the difficulty of quantifying changes in patient outcomes, Section 1.1 states that surrogate outcome measures may be needed to quantify the quality of radiotherapy treatment plans.
33.	1	Healthcare professional	1.2	it's not clear that this sentence means	Thank you for your comment. The wording has now been updated to say 'changes to radiotherapy treatment plans'.
34.	1	Healthcare professional	1.2	it's not clear what this means	Thank you for your comment. Scorecards refer to an automated analysis tool within ProKnow which extract metrics from a radiotherapy treatment plans.
35.	1	Healthcare professional	1.2	this will be extremely difficult to record or measure, and is also subject to many other factors which are unrelated to ProKnow, such as workload, staff sickness, software systems other than ProKnow. It is unlikely this will produce any meaningful data	Thank you for your comment. The committee agreed that ProKnow may not have a significant effect on radiotherapy treatment planning time, but this outcome has been proposed for data collection to identify whether ProKnow does have a measurable effect in this regard.
36.	1	Healthcare professional	1.2	It's not clear how the ProKnow DS module would help with this ? I believe this is conflated with the CA and PS modules, which I recommend are not to be evaluated within this report	Thank you for your comment. Please see the response to comment 25.
37.	1	Healthcare professional	1.2	This in principle is already (technically) possible, but there are governance and other issues which limit this - nothing to do with the ProKnow DS module itself	Thank you for your comment. ProKnow has demonstrated an ability to link data to national

					registries. Each centre requires information governance arrangements to be in place in order to do this.
38.	1	Healthcare professional	4.3	these two sentences seem to contradict each other. if expert advice is that ProKnow DS will have no direct effect on patient outcomes, why are patient outcomes be included in the evidence gathering exercise, and repeated in many instances within this draft?	Thank you for your comment. Although all 3 ProKnow modules are not expected to have a direct effect on patient outcomes, collection of these outcomes during the pilot period will quantify any potential patient benefits of this technology.
39.	1	Healthcare professional	4.4	on multiple occasions within this document, it has been stated that ProKnow DS will have no direct impact on patient outcomes, and yet this seems to be repeated as an evaluation or evidence gathering priority. this needs to be carefully reviewed and better thought -through	Thank you for your comment. The guidance document recognises that that ProKnow is unlikely to have any direct effect on patient outcomes, but the proposed outcomes for evidence generation attempt to capture all potential benefits of the technology.
Costs (n = 2)					
40.	2	Professional society	Considerations for early access: Costs	This seems to confuse contour and plan peer review	Thank you for your comment. This section does not intend to differentiate between peer review of contours or treatment plans. The text has been amended to 'ProKnow may help to increase the number of treatment plans and contours that are peer reviewed...'
41.	2	Professional society	4.5	Please clarify whether these costs are related to contour peer review or plan peer review	Thank you for your comment. These cost comparison results are from the EAG's sensitivity analyses. The cost of a clinical oncologist was used which means this relates to radiotherapy treatment plan peer

					review. Contour peer review would be done by physics or dosimetry leads who are employed at a lower band than clinical oncologists within the NHS.
Clarifications (n = 1)					
42.	1	Healthcare professional	3.2	is Current Use meant to indicate current use of ProKnow DS? this section is not clear.	Thank you for your comment. This section refers to current use of ProKnow within the NHS. The heading for Section 3.3 has been amended from 'current use' to 'current use of ProKnow'.