NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

Artificial intelligence (AI) software to help clinical decision making in stroke

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 26 April 2022
Theme: Technology costs

Comment number	Name and organisation	Section number	Comment	EAG considerations
1	Viz.ai	2.17	The costs indicated in this table for Viz.ai changed as we went through the NHS Framework and so our annual license fee list price for CSC is £30000 (for both lowest and highest price) and our annual license fee list price for PSC is £15000. All other costs remain the same. We would be grateful if this could be amended for the final report. Thanks in advance.	We will amend this information ahead of final publication.
2	Cardiff and Vale University Health Board	2.5 to 2.17	I am grateful for the inclusion of all of these products and am concerned that no fees are attached to some of these products. I worry that the cost might drive some of the decisions among clinicians and it may be worth considering highlighting the point specifically that the cost should not be sole determinant. I think this might ally itself with comments made about how each product serves a different purpose.	This is outside the remit of the EAG

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Theme: Model structure

Comment number	Name and organisation	Section number	Comment	EAG considerations
3	Addenbrooke's Hospital, Cambridge	Committee papers document Figure 7, page 93	Decision tree diagram- would it be worth considering including intervention (thrombectomy – yes/no) before the functional status (health state) column for the group where LVO was detected	

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4	NHS England & Improvement	3.13	Can NICE add “at this time” to the end of this sentence just to make it more clear that further evidence is expected in the future that might make the committee change their assessment. “The committee concluded that it was unable to recommend the routine use of the AI-software technologies to help guide treatment decisions in stroke”.	

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5	Addenbrooke's Hospital, Cambridge	3.4	There is acknowledgement of exclusion of patients over 80, small vessel disease in published studies. Another group that could merit consideration is patients who have had previous strokes- with long standing changes, image interpretation is challenging and may impact AI tool performance by affecting threshold detection.	
6	Addenbrooke's Hospital, Cambridge	3.6 and 4.1	Positive selection bias is raised as an issue which impacts interpretation of change in treatment administration times as false negative may delay treatment for some. In line with new NOSIP guidance regarding time frame outside the 4.5 hour window, it would be worth considering impact on those patients who present with wake up strokes/unclear onset times. This could be included in the recommendations for further research.	
7	NHS England & Improvement	3.2	"…developed using CT scans held by the company…before an updated static algorithm is released for use in clinical practice." Currently, there is unclear regulatory guidance on the threshold to the point where an update to an algorithm would constitute "a change in use case" and therefore requires a review of its regulatory status? Additionally, technologies are keen to make update using real life data to train their systems, however, there are questions around data access approval in this instance. These may have constituted to why technologies can't update rather than not wanting to. Would this be a place for NICE to recommend to regulatory bodies and policy makers that updates and further training to an algorithm	

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			using real life clinical data as a gold standard (following all appropriate and reasonable data access approval)?	
8	NHS England & Improvement	3.6	How does the apparent issue with the studies being retrospective and therefore apparent requirement for prospective studies match with the desired move of NICE to consider more real-world evidence for decision-making?	
9	Cardiff and Vale University Health Board	1.5	I think these further research recommendations are quite appropriate and I think that without this data clinicians could be advocating for and using a technology that has no statistically significant benefit in clinical practice. This will have knock-on effects for healthcare expenditure at a time when the NHS must focus on prudent spending.	No response required
10	Cardiff and Vale University Health Board	3.6	Since becoming aware of AI in acute stroke I have wondered how it might truly speed the process up. I can see that it might help the clinician feel more confident when reviewing scans, but much of the discussion out of hours resolves around deciding on suitability (ie Is this actually a stroke? What is the risk of post-thrombolysis bleed?). I would want to see research data specifically looking at this.	Point for discussion in relation to future research recommendations. No response required
11	NHS England & Improvement	3.7	The reason why many studies look at the time to thrombolysis is because thrombolysis constitutes a marker for ‘clock stop’ and time from scan to thrombolysis is a measure that can be analysed through SSNAP and or HES (real-world) data. Saying that “data needs to be gathered from everyone having imaging, and not just from those who were subsequently offered treatment” without clearly specifying what outcomes NICE would like to see measured (using real-world datasets) is not very helpful. It would be much more helpful if NICE	

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			could recommend more suitable outcomes e.g. % of patients who are thrombolysed within one hour before and after scan implementation. I note that only time to thrombectomy is then recommended as a time-saving related outcome in sections 4.2 – 4.4.	
12	Addenbrooke's Hospital, Cambridge	3.3 to 3.8	ICH detection is mentioned as an evaluated parameter in this table. Sensitivity and specificity of ICH detection is mentioned in table 7. Note is made of negative predictive value of ICH detection around 90%. Is there any data on thrombolysis been administered based on AI assisted CT head interpretation and subsequent post tPA? It will be useful for future work to evaluate ICH detection acutely especially where changes may be subtle (eg sub arachnoid haemorrhages) and incorrect tPA administration may lead to harm.	
13	Cardiff and Vale University Health Board	3.8	I was concerned that this was not more evident in the research data and think that this should be a big consideration when considering the products. A reliance on something that has a high percentage risk of failure can lead to delays.	Point for discussion in relation to future research recommendations. No response required

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14	Cardiff and Vale University Health Board	General	I think the consultation group have approached this is a thorough manner and I agree with the statements made. The introduction of new technology does not always bring with it a definite benefit. There seems to be a lack of robust research in this area. A new medication would be expected to follow a thorough process of evaluation and I see no reason why this technology should not follow the same.	No response required
15	Cardiff and Vale University Health Board	1.2	I am not aware of any other AI systems than these listed and therefore this is a complete and appropriate list.	No response required
16	NHS England & Improvement	General	Were the relevant companies consulted for this report? In certain instances, some of the AI companies would have further research that are not published for commercially sensitive reasons.	
17	Cardiff and Vale University Health Board	3.1	I am very surprised that patient outcome was not a feature of the trials so far and congratulate the team on including this section.	No response required
18	Cardiff and Vale University Health Board	3.2	I wonder that the lack of adaptability is not something that we should be so accepting of. We all must learn as clinicians and if AI is not also updating itself as new scanners are introduced how can we be sure that the product is still as accurate as previously. I would worry that this would then incur further costs to introduce the next iteration of the product to ensure we remain up to date.	Comment on the potential effects of regulation on how AI products are implemented and upgraded. This may be a relevant point for discussion but cannot be addressed by the EAG.
19	Cardiff and Vale University Health Board	3.9 to 3.13	I agree with all comments.	No response required
20	icometrix	General	No comments on the document	No response required

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21	Aidoc	General	No comments	No response required