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ARIA

Is Image Fusion Advanced Guidance For Complex and Simple Aortic Procedures Really Worthwhile And Cost Effective: Why Is It A Question And Do We Need A Trial?

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Disclosures

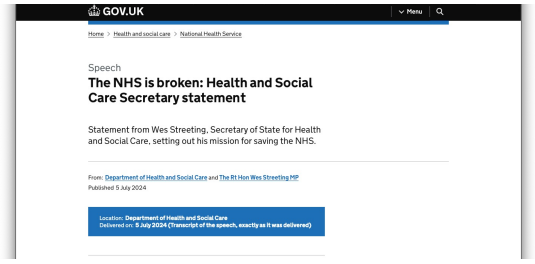
Speaker name: Rachel Clough

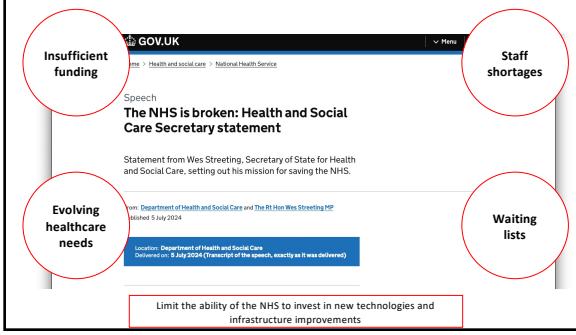
I have the following potential conflicts of interest to report:

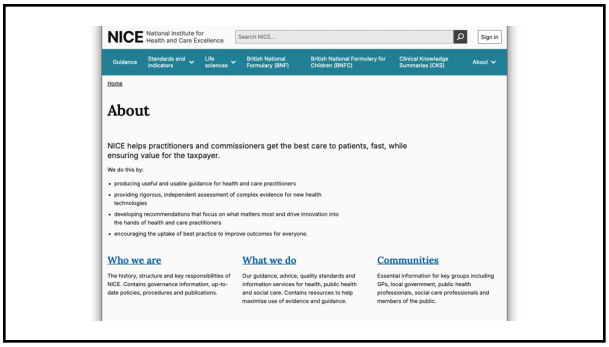
- ✓ Consultant: Cydar Medical
- ✓ Consultant: GE Healthcare
- ✓ Consultant: Medtronic Digital Surgery

Why is it a question?

Image fusion advanced guidance



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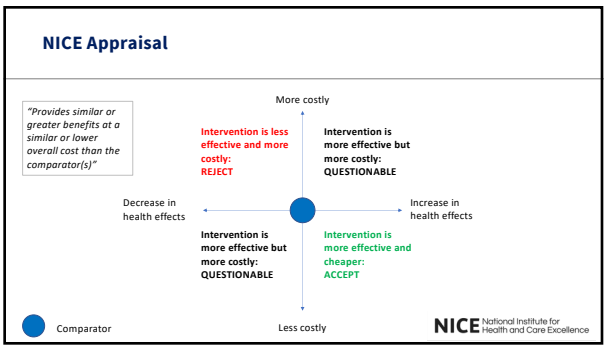
About
NICE helps practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer.
We do this by:
producing useful and usable guidance for health and care practitioners
providing rigorous, independent assessment of complex evidence for new health technologies
developing recommendations that focus on what matters most and drive innovation into the hands of health and care practitioners
encouraging the uptake of best practice to improve outcomes for everyone.
Who we are
The history, structure and key responsibilities of NICE. Contains governance information, up-to-date policies, procedures and publications.
What we do
Our guidance, advice, quality standards and information services for health, public health and social care. Contains resources to help maximise use of evidence and guidance.
Communities
Essential information for key groups including GPs, local government, public health professionals, social care professionals and members of the public.


NICE Appraisal
"Provides similar or greater benefits at a similar or lower overall cost than the comparator(s)"
More costly
Intervention is less effective and more costly: REJECT
Intervention is more effective but more costly: QUESTIONABLE
Decrease in health effects
Increase in health effects
Intervention is more effective but more costly: QUESTIONABLE
Intervention is more effective and cheaper: ACCEPT
Comparator
Less costly
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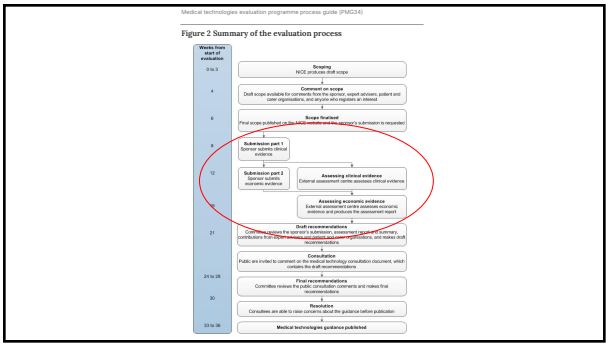
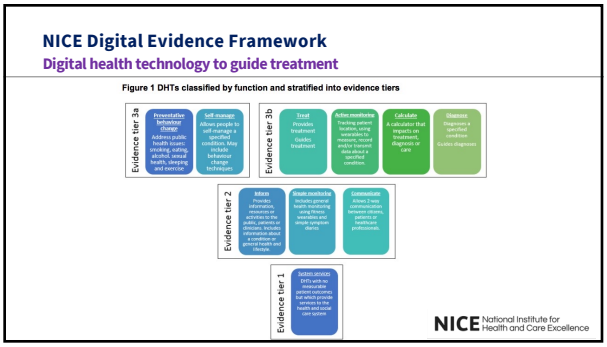

Medical technologies evaluation programme process guide (PMG34)
Figure 2 Summary of the evaluation process
Weeks from start of evaluation
Scoping
NICE produces draft scope
Comment on scope
Draft scope available for comments from the sponsor, expert advisers, patient and carer organisations, and anyone who registers an interest
Scope finalised
Final scope published on the NICE website and the sponsor's submission is requested
Submission part 1
Sponsor submits clinical evidence
Submission part 2
Sponsor submits economic evidence
Assessing clinical evidence
External assessment centre assesses clinical evidence
Assessing economic evidence
External assessment centre assesses economic evidence and produces the assessment report
Draft recommendations
Committee reviews the sponsor's submission, assessment reports and (if necessary) contributions from stakeholders and patient and carer organisations, and makes draft recommendations
Consultation
Public are invited to comment on the medical technology consultation document, which contains the draft recommendations
Final recommendations
Committee reviews the public consultation comments and makes final recommendations
Resolution
Consultees are able to raise concerns about the guidance before publication
Medical technologies guidance published


NICE Digital Evidence Framework
Digital health technology to guide treatment
Figure 1 DHTs classified by function and stratified into evidence tiers
Evidence tier 3a
Preventative behaviour change
Address public health issues: smoking, eating, alcohol, sexual health, sleeping and exercise
Self-manage
Allows people to self-manage a specified condition. May include behaviour change techniques
Evidence tier 3b
Treat
Provides treatment
Guides treatment
Active monitoring
Tracking patient location, using wearables to measure, record and/or transmit data about a specified condition.
Calculate
A calculator that impacts on treatment, diagnosis or care
Diagnose
Diagnoses a specified condition
Guides diagnosis
Evidence tier 2
Inform
Provides information, resources or activities to the public, patients or clinicians, includes information about a condition or general health and lifestyle.
Simple monitoring
Includes general health monitoring using fitness wearables and simple symptom diaries.
Communicate
Allows 2-way communication between citizens, patients or healthcare professionals.
Evidence tier 1
System services
DHTs with no immediate patient outcomes, but which provide services to the health and social care system
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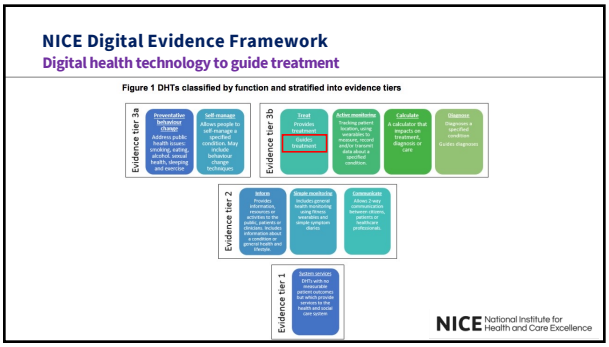
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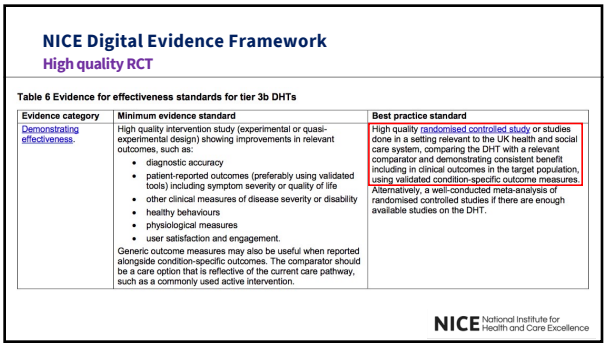
NICE Digital Evidence Framework
High quality RCT
Table 6 Evidence for effectiveness standards for tier 3b DHTs
Evidence category
Minimum evidence standard
Best practice standard
Demonstrating effectiveness.
High quality intervention study (experimental or quasi-experimental design) showing improvements in relevant outcomes, such as:
diagnostic accuracy
patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life
other clinical measures of disease severity or disability
healthy behaviours
physiological measures
user satisfaction and engagement.
Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.
High quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the DHT with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures.
Alternatively, a well-conducted meta-analysis of randomised controlled studies if there are enough available studies on the DHT.
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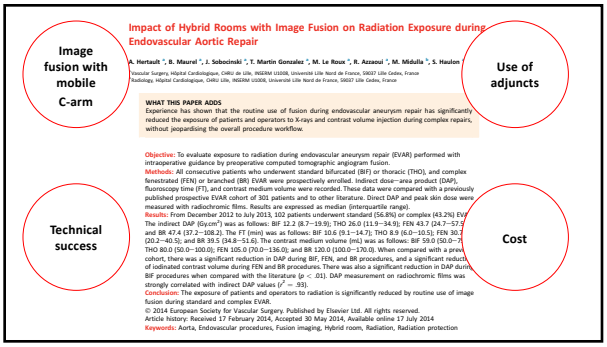
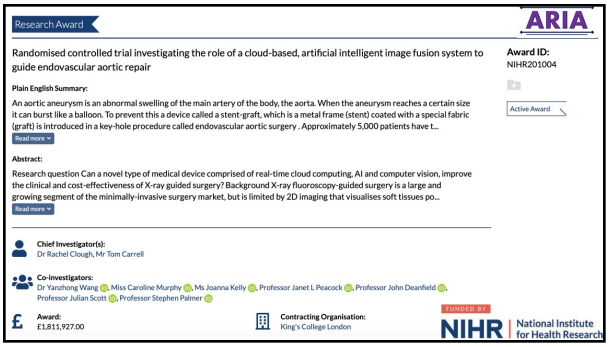
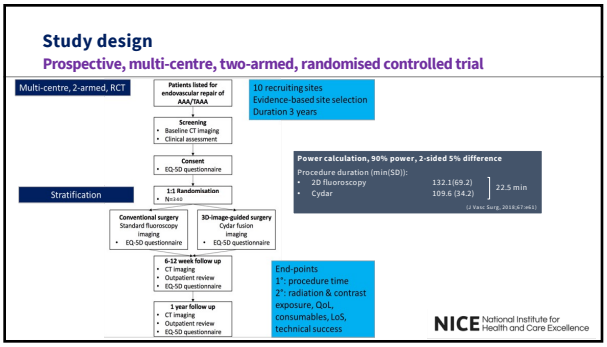
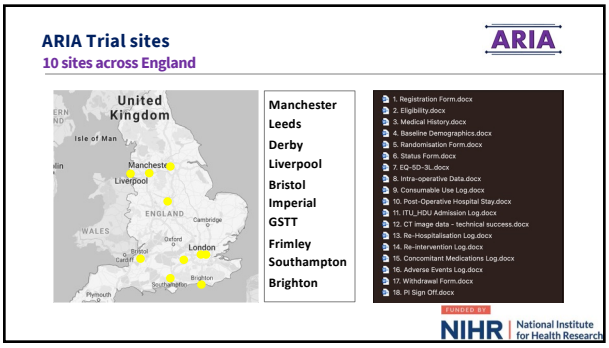
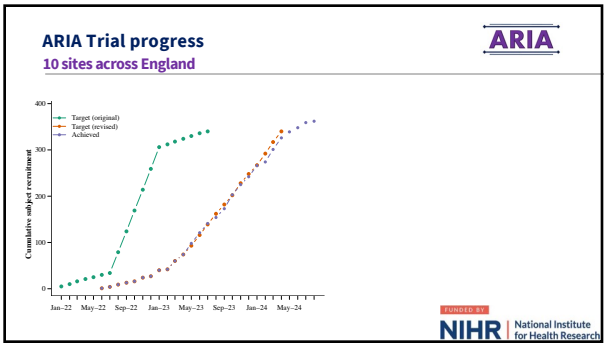
Why do we need a trial?





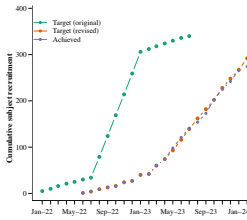






ARIA Trial progress

10 sites across England



Site	Recruited
Brighton	55
Derby	62
Frimley	23
Guys	23
Imperial	12
Leeds	34
Liverpool	30
Manchester	43
North Bristol	33
Southampton	32
Taunton	8
Total	**355**

Statistic	Time between			
	Screening-Randomisation	Randomisation-Surgery	Surgery-Visit1	Surgery-Visit2
N*	349	333	308	147
Range	0-1096	0-142	4-217	247-469
Mean (SD)	12.8 (62.3)	9 (20)	65 (37.8)	373.3 (51)
Median (IQR)	1 (0-8)	1 (0-8)	57 (42-79)	373 (366-387)

* number of participants with available data

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Conclusion

- Image fusion advanced guidance has widespread uptake but it is expensive and further data is needed to inform purchasing decisions
- In the UK, to support adoption of this technology a RCT is required
- The ARIA trial has completed recruitment and will be reporting early clinical and technical outcomes shortly