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A practical approach to diagnostic appraisals

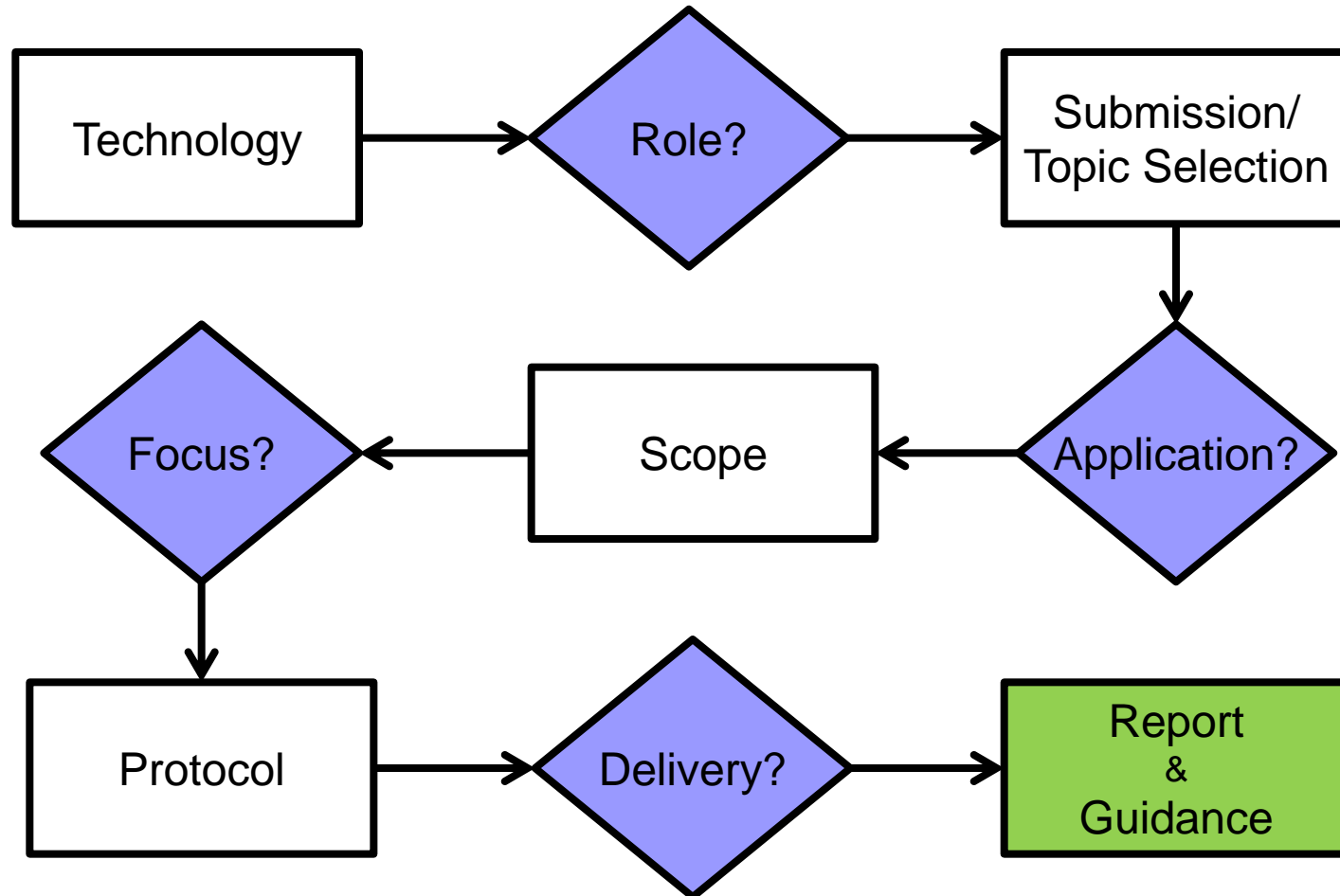
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A diagnostic appraisal pathway



What is the aim of a diagnostic appraisal?

Role?



Does the test have a potential role in the NHS?

- What does the test add to what is already being provided?

Accuracy versus clinical benefit

- Does the test result in benefits perceived by the patient?

Clinical benefit

- Improved health outcomes
- Changes to management
- Reassurance?



Topic selected – SonoVue ✓

Potential position in the care pathway



Replacement of an existing test

- Improved discriminatory value
- Better patient experience/fewer adverse effects
- Quicker
- Cheaper

Addition to an existing test

- Improved discriminatory value
- Improved coverage

Triage

- Sensitive test which could be used to rapidly rule-out further investigation with more invasive/expensive tests

Scoping and question setting



Contrast enhanced ultrasound of the liver using SonoVue[®] (sulphur hexafluoride microbubbles)

- Target group – adults who require liver imaging by ultrasound techniques
- Other indications – echocardiography, Doppler of the macrovasculature, Doppler of the microvasculature (including breast and liver lesions)
- Existing treatments and comparators:
US, CT and MRI (all with and without contrast), biopsy and first generation microbubble contrast agents.



Final scope published ✓

Research question



To compare the clinical and cost-effectiveness of contrast enhanced ultrasound (CEUS) using the contrast agent SonoVue[®] with contrast-enhanced CT and contrast-enhanced MRI for the assessment of adults with focal liver lesions (FLL), in whom previous liver imaging has been inconclusive.

- Cirrhosis surveillance
- Detection of liver metastases from colorectal cancer
- Incidentally detected focal liver lesions



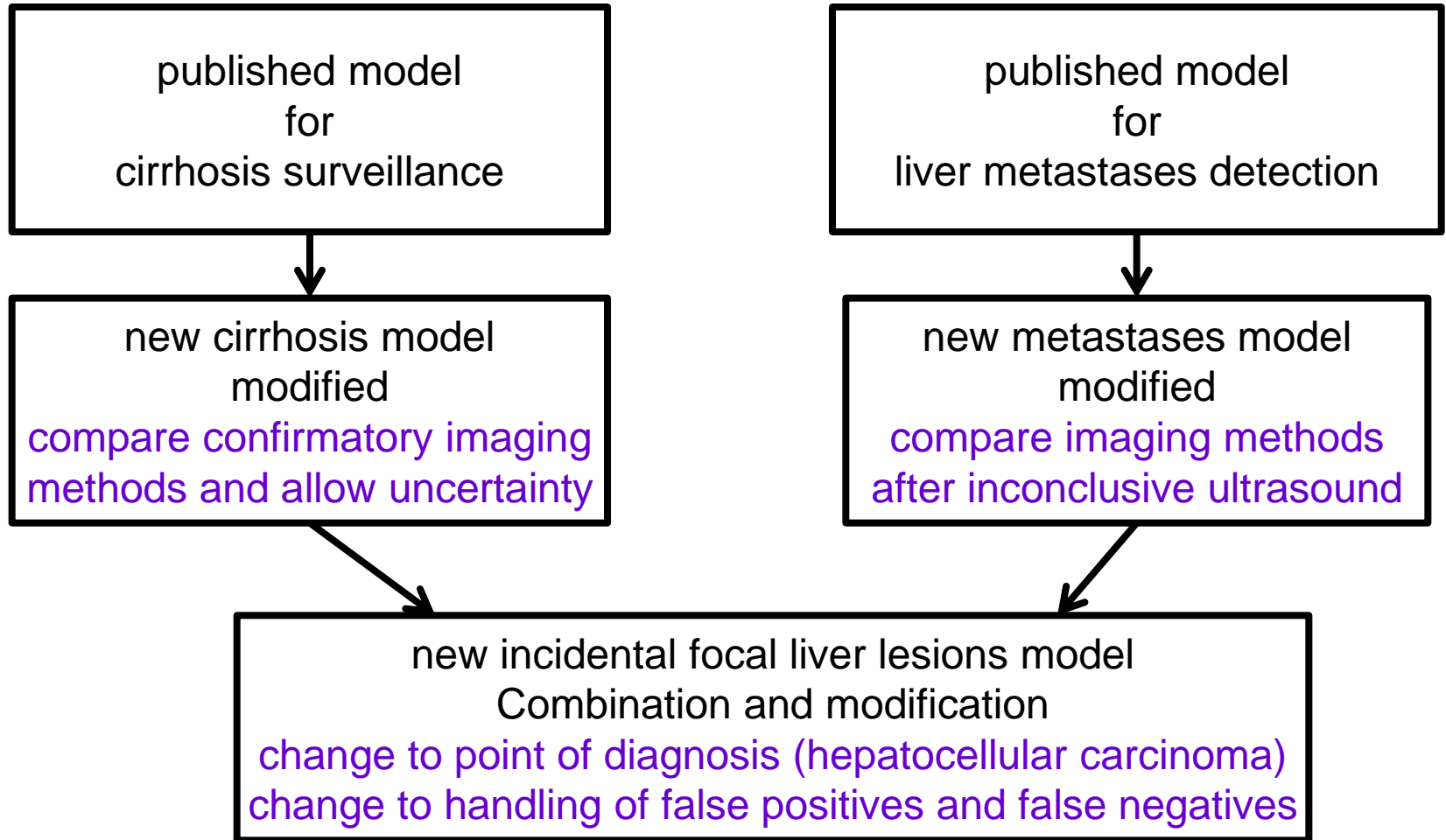
Final protocol published ✓

Direct vs. 'linked-evidence' approach



- Trial data to address the question: do patients who undergo the diagnostic test have better health outcomes than those who do not?
- Accuracy + prognostic link between the target condition and morbidity/mortality + effective intervention
- SonoVue[®] – three clinical applications = three cost-effectiveness models
- Comparators – other contrast-enhanced imaging modalities

Modelling approach



Conclusion of the SonoVue® assessment



Systematic review

- SonoVue® could provide similar diagnostic performance to other imaging modalities (CECT and CEMRI) for the three main clinical applications considered

Cost-effectiveness analyses

- SonoVue® instead of CEMRI was cost-effective. SonoVue® instead of CECT was considered cost-effective in the surveillance of cirrhosis and characterisation of incidentally detected focal liver lesions, with similar costs and effects for the detection of CRC liver metastases



Report submitted ✓

NICE guidance DG5



“SonoVue® is recommended for use with ultrasound for examining abnormal-looking areas in the liver that are noticed, but **cannot be properly identified, using normal ultrasound**. These areas may have been **noticed during routine scanning**. If they were noticed **when looking for cancer that has spread** from another part of the body, SonoVue® is recommended if the person **cannot have or does not want a CT** (computed tomography) scan. If they were noticed in **someone with cirrhosis who is having their liver checked**, SonoVue® is recommended if the person **cannot have or does not want an MRI** (magnetic resonance imaging) scan.”

The future – companion diagnostics



- Trial data are generally available for test and treatment
- Different trials may use different tests, but trials do not usually compare tests
- No reference standard test – tests may select different populations

Possible approaches

- Compare accuracy of test(s) to predict response to treatment
- Compare treatment effects obtained when participants are selected using different tests

Problem

- Other variables may effect these measures

References



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