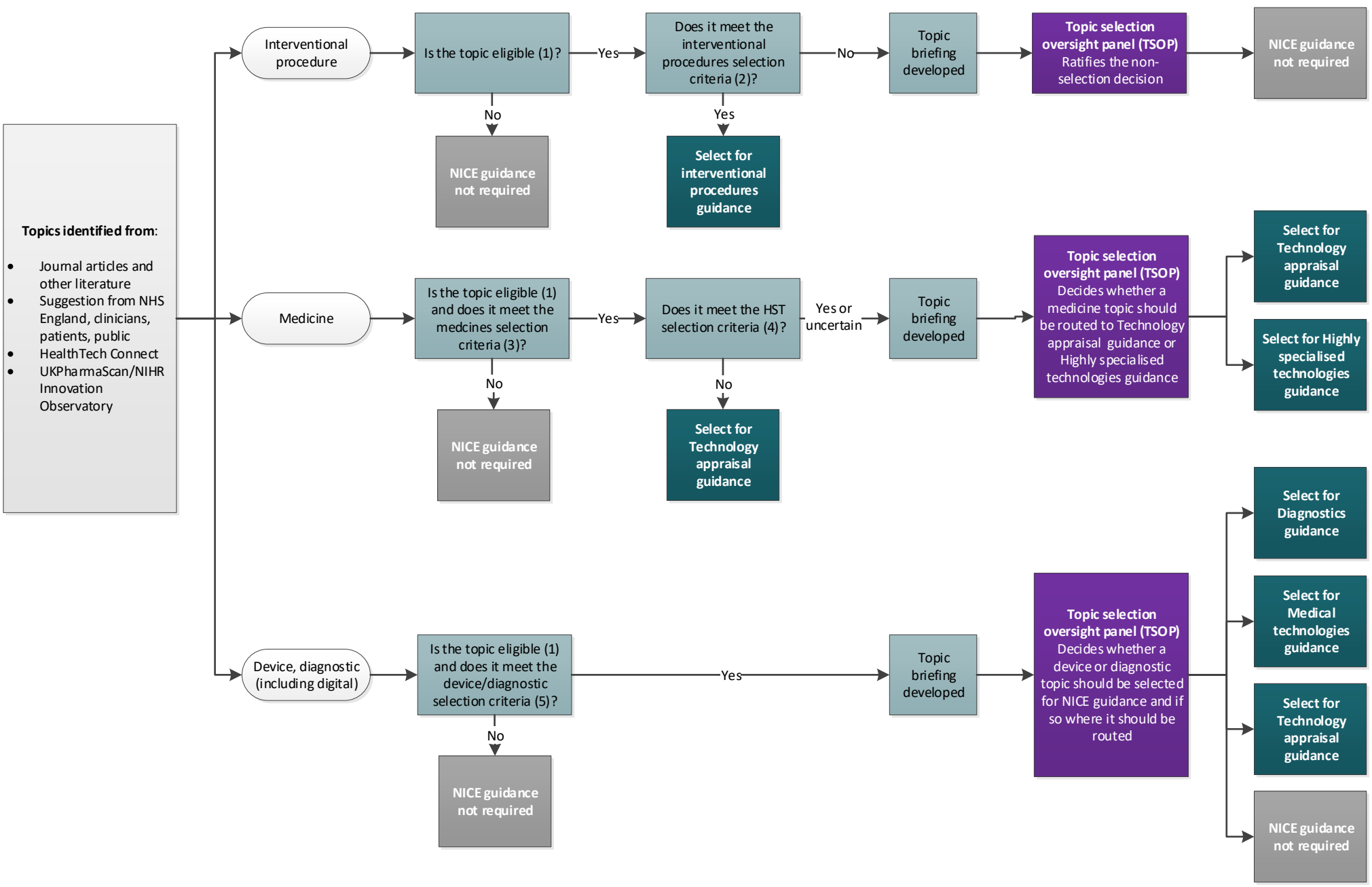
CHTE Topic Selection Process



1) Eligibility

The following topics are not usually eligible:

- will not be available in the UK within 24 months
- Involve use of an unlicensed technology *Unlicensed technologies cannot be considered in NICE guidance because there is no UK regulatory assessment of safety and efficacy to support their use. Unlicensed medicine topics may be passed on for consideration in a NICE Evidence Summary (NICE advice)*
- Involve use of an off-label technology *Off-label topics cannot be routinely considered in NICE guidance, unless it's use is common practice in the UK, there is good evidence for it's use, and there is no other alternative for the indication. Off-label medicine topics may be passed on for consideration in a NICE Evidence Summary (NICE advice).*
- digital health technologies in tiers 1, 2, or 3a of the Evidence Standards Framework
- have been used widely by the target population in the UK and have a well-known safety, efficacy and cost profile, unless:
  - there is new information that brings their safety, efficacy, or cost into question or
  - there is a new variation that might have a different safety, efficacy, or cost profile to the established topic.
- are intended to be used for population-based screening because this use is in the remit of the UK National Screening Committee and is not eligible to be considered by NICE.
- are prophylactic vaccinations because these are in the remit of the Joint Committee on Vaccination and Immunisation and are not eligible to be considered by NICE (therapeutic vaccines are eligible to be considered by NICE).
- do not involve a technology or interventional procedure because these are best considered by NICE guidelines. For example, exercise on prescription, rehabilitation programmes, care pathways.

2) Selection criteria for interventional procedures

- All new or significantly modified interventional procedures will be selected, if they are available to the NHS or independent sector, or about to be used outside of formal research.

3) Selection criteria for medicines

- All new active substances will be selected, except where there is a clear rationale not to do so. For example, if the topic is a duplicate or has a significant overlap with an existing topic.

4) Selection criteria for Highly specialised technologies

To be selected for Highly Specialised technologies guidance all of the following criteria must apply:

- The target patient group for the technology in its licensed indication is so small that treatment will usually be concentrated in very few centres in the NHS;
- The target patient group is distinct for clinical reasons;
- The condition is chronic and severely disabling;
- The technology is expected to be used exclusively in the context of a
- highly specialised service;
- The technology is likely to have a very high acquisition cost;
- The technology has the potential for life long use;
- The need for national commissioning of the technology is significant.

5) Selection criteria for devices and diagnostics (including digital)

- A device or diagnostic is likely to be selected if:
- it has benefits that are likely to be highly disruptive or lead to a stepwise change to an established care pathway in the UK; and
- a systematic assessment of the cost and system impacts is needed. For example, because there is uncertainty about the likely cost or system impact, or because the costs and impacts are expected to be significantly cost incurring or cost saving; and
- the benefits are supported by:
  - evidence of effectiveness (such as RCT, before/ after studies, cohort studies, diagnostic test accuracy studies) that compares the technology to current practice in the UK health and care system or to an appropriate reference standard and
  - information about the expected resource impact of adopting the technology that is directly applicable to the UK health and care system such as reports or studies describing the cost and system impact of implementing the technology, or an economic model and
  - advice from experts (such as patients, carers, clinicians and commissioners) that confirms the benefits are desirable and are likely to be realised when adopted in the UK health and care system.