DO'S & DON'TS OF MEDTECH HTA SUBMISSIONS TO UK'S NICE (NATIONAL INSTITUTE OF HEALTH AND CARE EXCELLENCE)

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ANDREW ADAMS OF WMC AND MARK CAMPBELL (EX-NICE Associate/Programme Director, 2010-2019) discussed what MedTech companies hoping for NICE Guidance for the UK National Health Service (NHS) should and shouldn't do.

One of NICE's roles is that of evaluation of medical technologies (devices, diagnostics and digital). NICE reviews products for their relevance to NHS priorities and appraises those selected to determine the extent of the benefit their use will bring to patients and the health and care system. Its guidance may recommend adoption of the device for particular clinical indications, may conclude that more research is needed and no recommendation can be made, or advise that the device does not offer sufficient benefit for it to replace current practice.

AA: *What are some of the common mistakes you have seen applicants for guidance make?*

MC: Insufficient research into NHS priorities, care pathways, organisation and context of care.

A series of errors can flow from this.

1) The medical device put forward does not actually address a high priority unmet need in the NHS, or offer a significant improvement in outcomes, or was developed in a specific care setting, such as hospital in-patient care, which does not take account of typical NHS patient flow, where most management may be delivered in primary and community care.

2) Choosing the wrong comparator. The alternative products and therapies used as benchmarks to show the device's superiority do not represent standard care (such as defined by a NICE clinical guideline) or current practice in the NHS.

3) Clinical and economic evidence generated outside of the NHS in non-UK health systems may be generalisable to UK HTA based on NHS practice. NICE will scrutinise this closely in judging the relevance of the evidence by considering whether the way patients are managed in the particular health system can be generalised to NHS care, and whether the patient characteristics and pathway stage are representative of NHS management.

Not engaging early enough with clinical and technical specialists and those commissioning services in the UK

No health technologies have a perfect evidence base for HTA, so NICE and its evidence assessment partners will seek expert advice from UK-based specialists (clinicians and other experts) to cover the gaps. This might, for example, be whether the benefits shown in the evidence for 1 patient sub-group can be extrapolated to others. Companies should therefore ensure Key Opinion Leaders, commissioners and frontline clinicians are familiar with their technology and have sought their views on it in preparation for guidance development.

Basing the Health Economic modelling on highly selective data and not considering alternative datasets.

Due diligence needs to be done on the quality/credibility of the data on which the assumptions in the health economic modelling are based. As far as possible, real world evidence for care outcomes beyond the time horizon of clinical studies needs to be used but in wound care this is very hard to find. Where there is insufficient evidence available on the outcomes of current practice, the applicant may need to conduct surveys or clinical audits of that practice, ideally in partnership with the relevant professional associations.

Underestimating the resources needed.

Applying for any health technology assessment is a big project. Companies which try to do it all in-house can underestimate the extent of the diversion of company resources and the budget and expertise required.

MUST DO'S.

- ✓ **PLAN AHEAD**- be prepared. Plan your engagement with NICE (or any HTA) in the same detailed way you would plan work for Regulatory approval.
- ✓ **FIND THE RIGHT EXPERTISE** – think of the partners you will need; in-house as well as externally – Project management, Statistics, Health Economic modelling, Clinical Insights, Technical-Scientific expertise.
- ✓ **BE REALISTIC ABOUT TIME** – from first engagement with NICE to publication of a Guidance can be 2- 4 years.
- ✓ **UNDERSTAND THE HTA PROCESS**. Commit a serious amount of time to understanding the process. Look at examples of Guidances and MedTech briefings (MIB) published by NICE which may be relevant to your product.
- ✓ **SENSE CHECK THE VALUE PROPOSITION** – have the Value Proposition thoroughly checked by practising clinicians before submitting it. Engage with NICE's META Tool to assess the eligibility of your technology for adoption.
- ✓ **CAR** – **C**lear and plausible claims based on the product performance and meaningful outcomes, **A**ble to be evaluated/reproducible, **R**elevant, high-quality evidence.