Evaluation of Medical Device

12.1 INTRODUCTION

Every medical device must not only be entirely safe, but it must also work as it was meant to. Moreover, when new medical technology becomes available, we should be able to assume that it is at least as good as what the market already offers, and that it also costs less if at all possible. That is no unnecessary luxury if we remember that there are already approximately 500,000 types of medical devices in circulation, from thermometers to surgical robots.

It is quite difficult to evaluate whether a new medical device offers any advantages, and what those advantages are. After all, there is more involved than technical quality and safety. Any evaluation also has to consider the varying usage and user requirements, sector-specific guidelines and legislation. But all the 'ifs, ands and buts' should never throw up insurmountable barriers to the introduction of new medical devices.

The aim is to provide explicit guidance for research suitable for assessing and inferring the benefits and performance of medical devices, tailored to the various types of devices, their specifics, and the intended contexts, indications and individuals for which they are used.

Establishing the benefits of medical devices poses specific challenges because they are intrinsically diverse in terms of use, users, sector and regulation. All this makes it a complex matter to design and conduct valid research into the merits of medical devices and their use. In light of this diversity, this report considers:

- why there is no one-size-fits-all approach to evaluating the risks, performance and benefits of devices;

- why and how research on the benefits and performance of devices differs between 'therapeutic' devices (e.g. pacemakers, nerve stimulators, prostheses) and 'non-therapeutic' devices (e.g. diagnostic, monitoring, screening or prognostic tests);
- the key principles of device evaluations;
- the optimal approach for evaluating the benefits of devices;
- alternative research approaches, in view of the specifications and the targeted context, users and individuals/patients of a device;
- why and how device evaluations are enhanced when device developers, manufacturers and end-users (e.g. professionals and targeted individuals/patients) collaborate and describe at an early stage the potential mechanisms/pathways through
- which, and in whom, device use leads to intended (i.e. benefits) and unintended (i.e. risks) effects on health or health care;
- how knowledge of these 'working mechanisms' helps to place evidence taken from multiple studies on a device – e.g. technical, safety and clinical studies – into a 'linked' or 'network of evidence' perspective;
- why a linked or network of evidence approach is better suited to device evaluations than a 'hierarchy of evidence' approach.

12.2 Evaluation principle

The overarching principle that actually drives the evaluation and regulation of any health care intervention:

To generate and accumulate evidence that the use of an intervention, including a medical device, is not only safe but also has benefits, preferably added benefits beyond existing care, for the health or health

care of the intended individuals, patients, professionals or for society at large.

12.3 Aim and target readership

The aims of the evaluation programme are:

- to promote faster uptake of new medical technologies.
- to encourage collaborative research, in both industry, to generate evidence on the **clinical utility** and/or healthcare system benefits of selected technologies.

The Academy aims to respond to the EU's request that its Member States '*take into account that improved research frameworks and criteria are needed to enhance reliability, predictability, speed and transparency in the decision-making on the introduction (and reimbursement) of medical devices*'

12.3.1 Definition

The committee adopted the European Commission definition of a medical device: '*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings' (Directive 93/42/EC).*

12.3.2 Variety of medical devices

There are many different types of devices in different classes, ranging from medical implants and medical aids to *in vitro* diagnostic tests and medical imaging, to mention only a few. Of the almost 500,000 different medical devices, the majority are relatively simple, e.g. a disposable syringe or an ear thermometer. Various devices are complex, however, and reflect the latest advances in medical

technology, for example new imaging equipment, various heart, vessel, bone and joint implants, and advanced pointof- care lab tests. Medical devices are thus intrinsically diverse: their lifespan varies widely, with extremes ranging from a few seconds for disposable devices to several decades for some implantable devices and medical equipment. Some medical devices have expiration dates, whereas other long-lived individual equipment may undergo replacement of components.

12.3.3 Variety in medical device use

Medical devices are used for a variety of diagnostic, prognostic, screening, monitoring and therapeutic indications. Consequently, there are differences in the level of risk and in the regulatory systems used to manage those risks; in the manufacturing costs and sale prices; in the standards and in the nomenclature systems; and in the various approaches used to determine their safety, performance, and benefits. The devices market stretches far beyond the professional care relationship. Devices are also sold over the counter. They may be developed for use in laboratories, in first aid kits, in kindergartens and in homes for the elderly. In the coming years, the market for medical devices will become even more crowded. Companies are preparing a range of self-testing devices, and major European multinationals such as DSM, Philips and Siemens are also investing a great deal of effort in health care devices and other types of medical support, often intended for primary and home care and for patient self-management.

The question is how to deal with the wide variety of existing medical devices, which is set to increase, perhaps in ways that we cannot anticipate.

12.3.4 Characteristics of medical devices

Medical technologies are different from other medical interventions because:

- Technologies may be modified over time in ways that change their effectiveness.
- The clinical outcomes resulting from the use of technologies often depend on the training, competence and experience of the user (sometimes referred to as the 'learning curve').
- Clinical evidence on technologies, in particular new technologies, is often limited, especially comparative studies against appropriate alternative treatments or methods of diagnosis.
- The healthcare system benefits of adopting medical technologies often depend on organisational factors, such as the setting in which the technology is used or the staff who use it, in addition to the benefits directly related to the technology.
- When the technology is a diagnostic test, improved clinical outcomes depend on the subsequent delivery of appropriate healthcare interventions.
- Evidence of the effect of diagnostic tests on clinical outcomes may not be available because improved diagnostic accuracy may not be reflected in improved clinical or quality-of-life outcomes.
- Some technologies are indicated in managing or investigating a number of different medical conditions and may be used by different healthcare professionals and in a variety of healthcare settings.
- Costs of medical technologies often comprise both procurement costs (including associated infrastructure) and running costs (including maintenance and consumables).
- A new technology may influence costs by its effect on various aspects of the care pathway, in addition to costs directly related to the use of the technology.
- In general, medical technology pricing is more dynamic than that of other types of medical interventions.

12.4 Regulatory bodies

The variety of medical devices available and the growing number of technological innovations are also having a significant impact on the methodologies and types of study needed to collect evidence in order to ensure the introduction not only of 'safe' but also of 'useful' and 'beneficial' devices in health care.

Clinical evaluation is, moreover, not needed for all medical devices. The variety of different devices makes it difficult if not impossible to define a common (one-size-fits-all) framework for clinical investigations evaluating the risks and performance of a device (and its use), let alone to define its benefits or added benefits for health care.

- to take a comparative effectiveness approach, with current practice or management in the NHS usually being used as comparator(s)
- to evaluate the impact of the technology on the healthcare system, alongside its clinical benefits for individual patients
- to use appropriate health economic approaches to support decision-making
- to priorities questions for future research to help reduce any uncertainty in the evidence as quickly and efficiently as possible.
- information about the disease, condition or clinical problem relevant to the technology
    - the regulatory status of the technology
    - the Committee's rationale for developing medical technologies guidance, which can include any relevant equality considerations
    - the **decision problem** to be addressed by the evaluation of the technology
    - a list of the professional and patient organisations involved in providing comments on the technology

- a list of the societies or organisations to be invited to comment on the scope.

The scope may also include technical questions raised by the Committee or the Programme team at selection stage, which may relate to the technology's ease of use or ability to generate the claimed patient or healthcare system benefits. The technical questions do not extend to a full technical evaluation of the device.

12.5 Types of evidence and advice presented to the Committee

In developing its draft recommendations, the Committee considers the following:

- the submission from the sponsor: a clinical and economic evidence submission, based on the scope, which includes relevant cost modelling; the sponsor is responsible for ensuring that the submission contains all relevant data required to evaluate whether the case for adoption is supported
- evidence presented by the External Assessment Centre: a detailed analysis and critical appraisal of the submission in the form of an **assessment report**
- evidence from the Programme team or other relevant organisations or working groups
- contributions from expert advisers
- contributions from patient and carer organisations
- information about ongoing or future research.

The Medical Technologies Evaluation Programme identifies medical technologies that have the potential to offer substantial benefit to patients.

12.5.1 Key activities

The key activities of the evaluation programme are:

- Identifying and selecting appropriate medical technologies that would benefit from national evaluation.
- Routing these medical technologies to guidance programme for evaluation.
- Evaluating medical technologies routed to the Committee, which involves:
- developing and publishing guidance for use by the NHS in England and its social care partners, including recommendations for further research
- developing and publishing implementation tools
- reviewing and updating guidance when required.

12.5.2 Principles for developing medical devices guidance

The principles for developing medical technologies guidance are:

- to evaluate a single medical technology based on the claimed patient and healthcare system benefits and not comparing it with similar technologies in a broader class
- to evaluate the case for adoption in the NHS, with particular emphasis on technologies that have the potential either to provide additional benefit to patients at the same or lower cost to the NHS, or to provide equivalent benefit to patients at lower cost to the NHS

12.5.3 Analysis of indirect and intermediate clinical and system outcomes

The available evidence may not always provide information on all clinical and system outcomes, particularly those that occur at some point in the future, or that are not directly linked to immediate use of the technology. If this is the case, the sponsor's submission should include appropriate modelling of outcomes and these should be reflected in the **cost analysis**.

12.5.3Analysis of costs and consequences

As part of the sponsor's submission, analysis may be needed to quantify the resources and expected outcomes associated with the technology under consideration compared with current comparators and healthcare pathways defined in the scope. Such analysis may not be needed if relevant high-quality economic evaluations are already available. Given the remit of the Programme, the approach expected to be appropriate for most technologies is **cost-consequence analysis**.

Cost-consequence analysis considers the costs and **resource consequences** resulting from, or associated with, the use of the technology under evaluation and comparator technologies, as well as considering relevant clinical benefits (for example, effectiveness outcomes) alongside the cost analysis.

The range of costs and resource consequences to be included in the analysis depends on the clinical characteristics of individual medical technologies and their comparators. Generally, the following apply:

- Typically, cost-consequence analysis frameworks include calculating and presenting estimates of resource use and of clinical benefits as separate domains of the evaluation.
- Estimates of resource use should include comparative costs of technology (and infrastructure) acquisition, use and maintenance. Focusing on these costs may be particularly applicable when the clinical effects of the technology can be assumed to be almost the same as those of comparator technologies.
- Estimates of resource use may also include the comparative value of healthcare service use outcomes (such as length of hospital stay, or number of hospitalisations, outpatient or primary care consultations) associated with the use of the technology or its comparators.

12.6 Main considerations in decision-making

The Committee's main considerations when making its decisions are:

- Benefit to patients: whether the medical technology has measurable benefit to patients over currently available NHS technologies, measured by relevant outcome indicators.
- Benefit to the NHS: whether the impact of the medical technology is likely to reduce the burden on NHS staff or reduce resource use (for example staff or facilities) compared with current management.

The Committee makes its recommendations based on the clinical and economic evidence and informed by contributions from expert advisers and patient and carer organisations. The Committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations. If there are any uncertainties the Committee makes informed judgements and describes their uncertainties in the 'Committee considerations' section of the guidance.

The Committee considers how medical technologies guidance may potentially impact on equality at specific stages of guidance development, including topic selection, scoping, and when the Committee produces draft and final recommendations. Any potential equality issues raised and considered for a topic are recorded in an equality impact assessment, which is completed in accordance with the Medical Technologies Evaluation Programme equality impact assessment procedure. The equality impact assessment is approved by the programme or centre director and published with the scope and the final guidance. Any relevant equality issues that relate directly to the guidance topic and recommendations are also accounted for in the final guidance itself. In developing its recommendations, the Committee considers relevant legislation

on human rights, eliminating unlawful discrimination and promoting equality. It also takes into account advice from NICE on making scientific and social value judgments. This advice is informed by the work of the **Citizens Council**. The Committee considers the social value judgements provided in 'Social value judgments.

12.6.1 Recommendation for use of a technology

The Committee usually produces a recommendation for use of a technology when it considers that:

- there is sufficient certainty that the technology produces at least equivalent clinical and/or healthcare system benefits compared with current management options and with a net reduction in resources required **or**
- there is sufficient certainty that the technology produces significantly greater clinical and/or healthcare system benefits compared with current management options for similar investment of resources.

The Committee may make recommendations for use of the technology in specific circumstances only, such as for patients with a particular condition, by staff with certain training or in a particular care setting.

12.6.2 Recommendation for development of further evidence

When technologies are not supported by adequate evidence of clinical utility to allow a comprehensive evaluation, or to produce recommendations covering the sponsor's entire case for adoption, the Committee may recommend use in specific circumstances, and may also recommend development of further evidence.

The aim of recommending the development of further evidence is to reduce uncertainty about specific issues, such as whether particular benefits suggested in the evidence submission can be realised in normal clinical settings. When

recommending the development of further evidence the Committee follows the framework outlined in section 8.3.

12.6.3 Recommendations for use in a research context

The Committee usually produces recommendations for use in a research context when it considers that:

- the technology has the potential to provide substantial benefits to patients and/or of releasing significant resources.