

A framework for the evaluation of new interventional procedures.

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Abstract

Objectives: The introduction of new interventional procedures is less regulated than for other health technologies such as pharmaceuticals. Decisions are often taken on evidence of efficacy and short-term safety from small-scale usually observational studies. This reflects the particular challenges of evaluating interventional procedures – the extra facets of skill and training and the difficulty defining a ‘new’ technology. Currently, there is no framework to evaluate new interventional procedures before they become available in clinical practice as opposed to new pharmaceuticals. This paper proposes a framework to guide the evaluation of a new interventional procedure.

Proposed framework: A framework was developed consisting of a four-stage progressive evaluation for a new interventional procedure: Stage 1: Development; Stage 2: Efficacy and short-term safety; Stage 3: Effectiveness and cost-effectiveness; and Stage 4: Implementation. The framework also suggests the types of studies or data collection methods that can be used to satisfy each stage.

Conclusions: This paper makes a first step on a framework for generating evidence on new interventional procedures. The difficulties and limitations of applying such a framework are discussed.

A framework for the evaluation of new interventional procedures

Introduction

The introduction of new technologies into health care should reflect a judgement that benefits outweigh any harm. Those making such decisions should be guided by evidence that is both reliable and timely and thereby avoid erroneous decisions that put patients at unnecessary risk or delay the introduction of helpful treatments. Interventional procedures are health technologies that can be used “for diagnosis or treatment involving an incision, puncture, entry into a body cavity or the use of electromagnetic radiation.”[1] Many interventional procedures also involve the use of medical devices. A medical device is defined as ‘any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, 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 for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease..’[2] Compared with other types of health technology, new interventional procedures including medical devices are subject to relatively little regulation, often entering clinical practice without a thorough assessment of safety and efficacy.[3-5] This contrasts with pharmaceuticals, which are subjected to rigorous assessment before they are routinely used in patients.[6-8];

In the United Kingdom, the evaluation of pharmaceuticals follows a framework made up of four distinct progressive phases[9] (Box 1).

Currently, there is no formal framework for the evaluation of interventional procedures and the framework used for the evaluation of medical devices is suboptimal[5]. The lack of a defined set of steps for the approval of interventional procedures may lead to patients being offered

treatments without access to adequate information on the nature and likelihood of benefits and harms and clinicians being uncertain which new treatments they should adopt. Furthermore, health systems have difficulty in managing the risks associated with new procedures and hospitals do not want to be taken by surprise by unexpected consequences arising from treatments.[3,10] Typically, the evaluation of interventional procedures stops at studies assessing safety and efficacy in small groups of patients.[11] For example, in the late 1980's optic nerve decompression surgery for nonarteritic anterior ischaemic optic neuropathy, a condition that is associated with a sudden and painless loss of vision, was performed very frequently with supporting data coming from small short-term case-series.[11] Years later, findings from a pragmatic[12] randomised controlled trial (RCT) indicated that this surgical treatment is both ineffective and potentially harmful as patients receiving surgery had a significantly greater risk of losing visual acuity.[11] Based on these findings the investigators recommended that its use should be abandoned.[11] Another example where early data was misleading is electronic fetal heart rate monitoring during labour. This procedure was used for two decades based on evidence from case-series and comparative studies using historical or non-randomised concurrent controls. When results from RCTs became available, these showed no evidence of benefit to the fetus and that electronic fetal heart rate monitoring was potentially harmful to the mother by increasing the caesarean section rate two to three fold.[13] Box 2 shows examples of other interventional health technologies that were widely used in routine clinical practice before they were found to be ineffective or harmful.[14]

In this paper we therefore argue that the evaluation of interventional procedures including or not a medical device (from this point onwards we refer to this as “interventional procedures”) should also be regarded as a progressive process rather than a discrete event focusing on short-term data on efficacy and safety by proposing a framework for their evaluation, and this echoes

arguments of Ergina and colleagues[15] on the need for a framework for generating evidence on interventional procedures.

Why is the regulation of interventional procedures different?

Table 1 summarises the main differences between pharmaceuticals and interventional procedures. A key difference is that the safety and efficacy of pharmaceuticals is mainly dependent upon the effect on the body, whereas the performance of interventional procedures depends not only on the technology itself, but also on operator skill. All new interventional procedures are likely to be affected by a learning curve;[16] for example, in a large multicentre RCT comparing open surgery with laparoscopic surgery for the treatment of colorectal cancer, the outcomes for the laparoscopic arm were seen to improve over time as surgical skill improved.[17] There are very few evaluations that have clearly demonstrated what the learning curve is for a new intervention. The key issue is the speed at which learning occurs and the ability of practitioners to see sufficient cases and learn quickly. This therefore increases complexity in evaluating interventional procedures in comparison to pharmaceuticals.

Another difference is related to the types of studies available. RCTs provide the most reliable evidence to determine the value of a health technology.[18] For a long time, evaluation of pharmaceuticals through RCTs has been a widely accepted method to inform their introduction into the market and into national health systems. However, for interventional procedures, particularly surgical interventions, only 3% to 9% of the published literature comprises studies using an RCT design,[19] with the majority of data coming from case-series. The history of RCTs of surgical interventions is tainted with major flaws in their design and conduct (e.g. difficulties in recruitment and randomisation, measurement of outcomes, and the standardisation of surgical procedures) and poor reporting. It has therefore proved difficult to obtain valid conclusions. There has been an improvement to this problem in recent years partly

due to initiatives like the CONSORT[†] statement in 1996 with guidelines for reporting which are regularly updated to reflect methodological developments in the design and conduct of RCTs,[20,21] advances in trial methodology, design, and the Medical Research Council framework for complex interventions.[22] The differences between pharmaceuticals and interventional procedures pose major challenges in the interpretation of formal technology assessments, particularly the greater consideration of observational data, despite increased levels of sophistication in the statistical methods employed to summarise the evidence.[23]

An example of how much challenging the evaluation of interventional procedures can be, was well illustrated in a recent study by Tarricone and Drummond[24] where they analyse the challenges of evaluating a health technology for the treatment of aortic stenosis called transcatheter aortic valve implantation (TAVI). TAVI appears to be a promising health technology to manage patients with this condition, however, the data available is slim, patient selection is variable making up a very heterogeneous study population, and the level of expertise of practitioners have been proven to be an important determinant of outcomes for TAVI.[24] Another aspect are the wider implications regarding reorganisation of services as a TAVI procedure requires a multidisciplinary team and is logistically more challenging.[24] Also, the investment decision for TAVI, as for other devices, might be harder to reverse. TAVI has already been modified and there are two types of devices that are currently being marketed. This means that we cannot assume that devices have equal effectiveness.[24] Moreover, buying an expensive technology to carry out a clinical study when there are so many factors that might pose problems is risky since after completion of the study, the hospital is 'stuck' with the new technology if results are not favourable. All these aspects pose greater challenges in the evaluation of interventional procedures than the evaluation of pharmaceuticals.

[†] CONSORT: Consolidated Standards for Reporting Trials

Nevertheless, how challenging an evaluation of a new technology will be, regardless of it being a pharmaceutical or an interventional procedure, will ultimately depend upon the context and the scale of the change in practice that will be required. A new medication that requires the addition of frequent monitoring may be more problematic than replacing one surgical technique with another.

A framework for the evaluation of a new interventional procedure

The framework is illustrated in Figure 1. It has four stages: 'development', 'efficacy and short-term safety', 'effectiveness and cost-effectiveness' and 'implementation'. Details of each of these stages are presented in the Figure and in the text below.

Procedures at *Stage 1 ('development')* are those that have been recently developed, in which most of the available information comes from the 'innovators' or device manufacturers, as well as occasional case reports.

Procedures at *Stage 2 ('efficacy and short-term safety')* are represented by evidence based on surrogate measures of effect and short-term safety outcomes. Evidence is produced under tightly controlled conditions typically arising from case-series, and explanatory trials, where patients are highly selected and interventions delivered under 'optimal' clinical conditions (sometimes an expert centre) with a single or a few skilled operators.[25] While information about safety and efficacy of new interventional procedures is important for decision-makers, it is unlikely that it will be sufficient, because there are wider considerations when deciding whether or not to introduce a new procedure. A study exploring perceptions of UK National Health Service decision-makers regarding national guidance on the safety and efficacy of new interventional procedures showed that additional information over and above safety and efficacy

would be useful to help decide whether or not the new technology should be offered to patients in routine care.[26]

Procedures at *Stage 3 ('effectiveness and cost-effectiveness')* are characterised by evidence that is typically generated from pragmatic RCTs and longer-term data from registries. At this stage, it is expected that the information about effects should be based on patient relevant outcomes, such as serious morbidity and quality of life outcomes. Also, at this stage it is expected that information regarding the cost-effectiveness of the new procedure in comparison to the current standard of care is available. Evidence at this level is particularly relevant to national healthcare systems where treatments compete with each other within a limited budget.

At *Stage 4 ('implementation')*, the interventional procedure has already been judged to be safe and efficacious, with evidence that the procedure is effective and cost-effective. At this stage, regular monitoring might be performed through the conduct of surveys or cohort studies and the analysis of registry data, to ensure the quality and safety of widespread use of the procedure.

Although this framework is suggesting that the evaluation of an interventional procedure should be made up of four discrete stages, the generation of evidence about them can be expected to overlap. Nevertheless, the balance between the different types of evidence does change progressively over time.

When should we not use the four staged framework?

In suggesting a framework for the evaluation of interventional procedures, we are not trying to imply that this should be used unquestioningly. There might be situations in which waiting for an interventional procedure to reach stage four of the framework may be inappropriate or unethical. An interventional procedure that has not been fully evaluated in the terms of this framework

could be offered in situations: (1) where the patient suffers from a rare condition with no treatment with proven effectiveness; (2) where all other available treatments have failed; and (3) arising within the operating room, in which the plan might have been to deliver one procedure, but in the event, given certain unexpected patient characteristics or response to treatment, a new procedure was undertaken. This implies therefore that there are occasions when common sense, taking into account the clinical context, determines whether a practitioner decides to offer a new interventional procedure. We would like to highlight that the options that we described above are rules of rescue. It is possible that there are other exceptions for the use of such framework and therefore more consideration is required.

Discussion

This proposed framework encourages a progressive approach of evidence generation for interventional procedures. The importance of a staged approach to the evaluation of other health technologies, such as pharmaceuticals, is well established. Here it is advocated that this should be extended to interventional procedures to include not only assessments of safety, efficacy and effectiveness but also consider economic implications. Below we discuss the implications for policy and challenges associated with the application of this framework.

Implications for policy

- Pre-market considerations

Currently, interventional procedures may be widely adopted before reliable information about their likely effects and resource use becomes available. The regulatory arrangements for the introduction of interventional procedures are fragmented. As discussed above many interventional procedures also involve the use of a medical device and although there is an European Directive by which the biomedical industry must comply,[27] the process of approving medical devices in Europe is considered flawed, lacks information, lacks transparency and

patient safety may be put at risk.[28] The approval process of high risk (category III) medical devices in Europe now includes an assessment and analysis of clinical data to verify the clinical safety (absence of unacceptable clinical risks) and the performance (ability to achieve intended purpose) of the device when used as intended by the manufacturer.[28] Such clinical investigations do not, however, evaluate efficacy or effectiveness. The current approval process of medical devices in Europe implies that the benefit is estimated before clinical effectiveness is confirmed[29] and it dangerously assumes that the benefit for the rapid availability of the medical device outweighs the consequences. Putting our framework in this context, the evaluation mandated by European authorities halts at *Stage 1*, where safety is considered, but lacks any attempts to evaluate clinical benefit. So, an increased pre-market evaluation of high risk devices at least up to *Stage 2* should be considered with post-market mandatory data collection to fulfill *Stages 3 and 4*.

- Post-market and other policy considerations

The European Directive[27] stipulates that manufacturers must implement a “medical device monitoring system’ to monitor their products once on the market, but how they do this is not mandated, so reporting is generally low.[30] Therefore, it takes even longer for the risks and benefits associated with the use of the medical device to surface. Evaluating interventional procedures further into *Stage 3 and 4*, especially those that include a medical device, helps identifying whether any risks are associated with surgical skill, or the device itself.

Considering the proposed framework and the current situation in the UK,[31] where the National Institute for Health and Clinical Excellence (NICE) has a programme that issues guidance on the safety and efficacy of interventional procedures, it appears that their evaluation typically consists of *Stage 1* and *Stage 2*. For many procedures, evaluation may halt at *Stage 1* as

relatively few procedures are considered by the NICE Interventional Procedures Programme and therefore may be introduced into practice on the basis of *Stage 1* evaluation only.

Although there is a body in the UK that evaluates interventional procedures, only occasionally do interventional procedures undergo formal assessment of effectiveness and cost-effectiveness. Also, interventional procedures guidance is not mandatory and there is no direct mechanism to control diffusion, however, 'negative findings' normally stop a procedure. It is the responsibility of each organisation to implement the guidance and therefore the success of this Programme is dependent on appropriate engagement from the NHS.[1] This means that patients may be receiving suboptimal care, clinicians may be unsure about which procedures to adopt and may lack appropriate training, and health systems struggle to manage any unexpected harm that new treatments may cause.[3] The problem relates to how a health service should react to judgments of safety and efficacy. In this sense, the NICE Interventional Procedures Programme is not helping to further structure the diffusion of the technology. We argue that formal use of the four-stage approach would help to address this. NICE has partially tackled this gap by launching a new programme called the Medical Technologies Evaluation Programme, aiming at promoting a faster uptake of new medical technologies in the NHS and to encourage collaborative research, in both industry and the NHS, to generate evidence on the clinical utility and/or healthcare system benefits of selected technologies.[32] For the small number of interventional procedures that NICE will consider, evaluation will go through *Stages 1* to *3*. NICE will consider only select procedures and for these, given that the burden of evidence has been put on the manufacturer it might be expected that further good quality primary research will be conducted for these technologies. Nevertheless, the impact on research of this recent change are unclear and it is likely that many eligible interventional procedures will not be formally considered. Furthermore, the development of methods for the early evaluation of interventional is required especially given the belief that interventional procedures are harder to

evaluate than new pharmaceutical intervention.[24] The framework outlined in this paper can however help guide the stage of evaluation in which a particular health technology is in regard to the current available evidence.

This framework can also be used for existing technologies. It can be used to identify where in the cycle of evidence generation a technology is and make recommendations about what further research is needed and about how the health service should treat the technology. It can also be used to further demonstrate the limitations of current practices. For example, to highlight that actions to adopt or reject a technology at a point in time were reasonable based upon the evidence available at the time.

Challenges for the application of the framework

There are some difficulties in applying this theoretical approach of progression in the evaluation of an interventional procedure. One is the fact that it is unusual for research to be strictly linear or compartmentalised. This is because (1) individual studies may have elements of more than one stage; (2) where more than one evaluation has been performed on a technology, the emphasis may vary between the demonstration of efficacy and effectiveness; and (3) the concepts of efficacy and effectiveness are not uniformly accepted and the terms are often used interchangeably. This causes confusion regarding what the results of studies actually mean in practice and a framework addressing this difference would be useful.

Another difficulty associated with the use of a possible framework that can be used for the evaluation of an interventional procedure concerns the lack of a standard definition for when a procedure should be considered “new”. Due to the nature of interventional procedures, it can sometimes be difficult to judge whether an interventional procedure is a new or an established procedure. This is because some ‘new’ procedures are adaptations of existing practice or used

to treat conditions other than that for which they were initially conceived. Health technology innovation can be viewed in terms of a spectrum.[33] At one end of the spectrum are major innovations. These are mainly novel therapies that are in general only allowed to enter routine clinical practice after several clinical trials have been carried out to test the value of the treatment. At the other end of the spectrum, are those therapies that represent minor changes of existent therapies that are deemed 'appropriate' for clinical practice. In between those two extremes are those new technologies characterised as 'moderate' changes. These have undergone little or no evaluation, and are adopted in routine practice because they are believed to be adaptations or improvements of established procedures, therefore 'not requiring' a strict evaluation of their safety and efficacy. It is therefore with this latter type of health technology innovation that most problems are likely to arise.

One such concern is the potential to cause unintended harm to patients. For example, laparoscopic cholecystectomy is a treatment that involved the merging of two well-established technologies:[34] open cholecystectomy, performed for over 100 years, and laparoscopic surgery, which was originally developed to diagnose and treat conditions in gynaecology. It appeared later, after the technology was already being routinely offered to patients, that the combination of these two procedures was not as safe as had been assumed, with laparoscopic surgery increasing the risk of serious biliary injuries that were difficult and costly to treat.[33]

The criteria for an interventional procedure to be considered as 'new' have therefore been the subject of much debate[35] and there is no standard definition. In the UK, for example, the Scottish Government states that an interventional procedure should be considered as 'new' if a doctor no longer in a training post is using it for the first time in his or her NHS clinical practice.[35] In Australia, the definition is more stringent, where a new interventional procedure is defined as 'one either not previously carried out in the facility in question or not previously

carried out within that facility by the practitioner requesting privileges to do so'.[36] Stirrat adopted a more flexible definition, and defined a new procedure as one that is innovative or significantly different from those currently practiced.[37]

Conclusion

A framework for the evaluation of interventional procedures should not be regarded as a barrier to innovation and should not lead to a lack of access of beneficial technologies to patients. Instead, the objective is to promote good practice guidelines regarding the evaluation and the introduction of new interventional procedures into routine care. Although health technologies in many cases are a driver for better health outcomes, they are also a major driver for increased healthcare expenditure. Therefore, their appropriate evaluation is warranted so that not only the best care is provided to patients, but also healthcare resources are used in the most efficient manner. Many new health technologies are costly and take years to develop. However, as soon as the technology is developed, its dissemination can be rapid due to the media and to, perhaps most importantly, the multinational nature of the biomedical industry. To control the speed of this dissemination, many countries, including the UK, regulate the introduction of new technologies into routine clinical practice. This regulation is aimed to control which technologies should be offered to patients, in terms of demonstrated safety and benefits, and help health policy-makers manage the risks and resources that new technologies might pose.

The current regulatory arrangements for interventional procedures are fragmented making the introduction of this type of health technologies inconsistent and difficult to control. Due to the complex nature of most interventional procedures, it is not surprising that there is not a framework yet, as there is for pharmaceuticals. This paper aims to inform further discussion about how to improve the evaluation of interventional procedures.

Conflicts of interest

None

Ethics Committee Approval

Not applicable

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None

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