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What is an invasive procedure? A definition to inform study design, evidence synthesis and research tracking

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ABSTRACT

Worldwide, there are at least 230 million invasive procedures performed annually and most of us will undergo several in our lifetime. There is therefore a need for high-quality evidence to underpin this clinical area. Currently, however, there is no widely accepted definition of an invasive procedure and the terms ‘surgery’ and ‘interventional procedure’ are characterised inconsistently. We propose a definition for invasive procedures which addresses the limitations of those currently available. Our definition was developed from an analysis of the 3946 papers from the last decade. A preliminary definition was created based on existing definitions and applied to a variety of papers reporting all types of procedures. This definition was continuously updated and applied iteratively to all articles. The definition has three key components: (1) method of access to the body, (2) instrumentation and (3) requirement for operator skill. It therefore encapsulates all types of invasive procedure regardless of the method of access to the body (incision, natural orifice or percutaneous access), and is relevant whatever the clinical discipline (eg, obstetric, cardiac, dental, interventional cardiology or radiology). Crucially, the definition excludes medicinal products, except where their administration occurs within an invasive procedure (and thereby involves operator skill). The application of a universal definition of an invasive procedure will (1) inform the selection of relevant methods for study design, (2) streamline evidence synthesis and (3) improve research tracking, helping to identify evidence gaps and direct research funds.

INTRODUCTION

Invasive procedures, including surgery, are fundamental to healthcare. Worldwide, there are at least 230 million procedures performed annually and numbers are likely to increase due to the widening application of minimally invasive and image guided techniques. Despite the volume of invasive procedures undertaken, the number and quality of randomised controlled trials (RCTs) in this area has historically been poor. Papers examining the quality of surgical RCTs have repeatedly demonstrated limitations in study design and conduct, such as recruitment, quality assurance of interventions and the blinding of trial personnel. In the absence of evidence from well designed and conducted RCTs, clinical practice has been largely driven by personal preference, experience and anecdote. This results in variations and inequalities between surgeons, centres and regions with respect to the indications for, and types of, invasive procedures performed.

Cultivating research in invasive procedures

In the UK, the situation has begun to improve. The number and quality of funded RCTs in surgery is increasing, which has been facilitated by methodological advances and a marked shift in research culture. The Royal College of Surgeons of England has invested in surgical trials centres and networks of research-active surgeons have been established. These activities have resulted in 50 new surgical RCTs in the last 5 years and over 150 new chief and principal investigators. As a result, the number of patients entering surgical RCTs has doubled. Although these improvements have largely centred around surgery, the underlying principles are common to invasive procedures undertaken in other clinical disciplines such as cardiology, gastroenterology and radiology. To maximise the opportunities afforded by these initiatives, it is now necessary to understand exactly what is meant by an invasive procedure by developing a transparent and practical definition.

Why is it important to define invasive procedures?

A clear definition of invasive procedures has several benefits. It would, (1) inform the selection of relevant methods for study design, (2) streamline evidence synthesis and (3) improve the accuracy of categorisation and tracking of research activity.

Designing studies to evaluate invasive procedures

Evaluation of invasive procedures requires the application of specific methods to optimise trial design and conduct. These differ...
from those required in pharmaceutical studies. One main
difference is that invasive procedures are complex inter-
ventions, with multiple interacting parts that can act inde-
pendently or interdependently to influence outcomes. Specific design features include the need for iterative
development work in early phase studies before under-
taking a main trial. This may involve establishing the
parameters of intervention standardisation, methods for
blinding trial personnel and participants, and assessing
adherence to treatment protocols. Challenges during
later phase studies (ie, RCTs) include recruitment and the
need to account for operator skill and expertise at either
the individual and/or centre level. These features are
common to studies evaluating all types of invasive pro-
cedures, regardless of anatomical area or clinical discipline,
and recognition of this would optimise study design and
conduct, and clarify governance requirements.

Streamlining evidence synthesis
Developing and applying a common definition for inva-
sive procedures has the potential to make systematic
literature searching more efficient and sensitive. This
is especially relevant for reviews investigating groups of
procedures. For example, a review synthesising evidence
regarding surgical interventions for a particular condi-
tion may draw different conclusions depending on the
definition of surgery used. Similar problems are apparent
for methodological reviews investigating surgical pro-
cedures as a whole.

Another problem is that it is currently not possible to
search for studies of invasive procedures without devel-
oping extensive keyword lists, because terms such as
‘surgery’ and ‘invasive procedure’ do not consistently
identify relevant papers. Searches can then be difficult
to reproduce because authors define surgery in different
ways using different strategies and Medical Subject
Headings (MeSH). A common definition for inva-
sive procedures linked to a working search strategy and
MeSH term would facilitate these reviews by minimising
the number of irrelevant papers retrieved and reducing
the risk of missing relevant papers.

Research tracking
Accurate tracking of research involving invasive pro-
cedures is vital for the strategic prioritisation of future
RCTs. Tracking can help demonstrate output to funding
bodies, identify evidence gaps, provide funds for under-re-
searched areas and to reduce research waste. A common
definition for invasive procedures would provide trans-
parent information about research activities and promote
the accurate categorisation of studies.

Existing definitions
Currently, there is no widely accepted definition of an
invasive procedure and the terms surgery and ‘interven-
tional procedure’ are characterised inconsistently. Some
definitions include only procedures that physically change
the anatomy, involve making a cut, are undertaken in a
sterile environment or use anaesthesia. Each of these has
limitations. For example, requiring that procedures phys-
ically change anatomy will exclude invasive diagnostic
procedures (eg, laparoscopy, arthroscopy). Definitions
specifying that procedures should involve a cut will miss
those undertaken via natural orifices (eg, endoscopy)
or using percutaneous techniques (eg, cardiac catheter-
isation), which are also invasive. The need for a sterile
environment and/or anaesthetic would also potentially
exclude these types of procedures from the definition.

Further definitions of surgery are based on the
personnel involved in the study regardless of the nature
of the intervention, such that any research involving
surgeons is labelled surgical. This poses problems as
studies of pharmaceutical interventions delivered to
surgical patients will be deemed ‘surgical’, whereas they
actually require research methods and governance appro-
priate for the evaluation of pharmaceutical interventions
rather than invasive surgical procedures.

Proposal for a comprehensive definition of invasive
procedures
We propose a definition for invasive procedures that
addresses the limitations of those currently available. Our
definition was developed from an analysis of the 3946
papers from the last decade. Initially, a preliminary defini-
tion was created based on existing definitions and applied
to a variety of papers reporting all types of procedures.
The preliminary definition was continuously updated and
applied iteratively to all articles, thereby verifying that the
final definition could be applied to the entire spectrum
of invasive procedures (box 1). The definition has three
key components: (1) method of access to the body, (2)
instrumentation and (3) requirement for operator skill.
This definition encapsulates all types of invasive pro-
cedure regardless of the method of access to the body (inci-
sion, natural orifice or percutaneous access) or clinical

Box 1 Proposed definition of an invasive procedure

► An invasive procedure is one where purposeful/deliberate
access to the body is gained via an incision, percutaneous
puncture, where instrumentation is used in addition to the
puncture needle, or instrumentation via a natural orifice.
It begins when entry to the body is gained and ends when
the instrument is removed, and/or the skin is
closed. Invasive procedures are performed by trained health-
care professionals using instruments, which include, but
are not limited to, endoscopes, catheters, scalpels, scissors,
deVICES and tubes.

► Where invasive procedures also involve the administration of a
medicinal product, these could be categorised as being part of an ‘inva-
sive procedure’ when operator skill is required for its
administration within the body, that is, when an internal action is
performed to administer the product or the product is
administered to a targeted anatomical area, for example, Zhu
et al. There are also procedures
which involve operator skill to target something inside the body
(eg, electromagnetic radiation in the eye) without an incision, percuta-
neous puncture or instrumentation via a natural orifice. These
types of procedures do not fall within the definition of an invasive
procedure.

discipline (eg, obstetric, cardiac, dental, intervention radiology and so on). Crucially, the definition excludes medicinal products, except where their administration occurs within an invasive procedure (and thereby involves operator skill).

**Patient perspectives**

Three patients who had previously undergone an invasive procedure provided feedback on the proposed definition of invasive procedures. The patients expressed that their view of invasive procedures was not centred on how access to the body was obtained, but rather that ‘it’s not about a cut, it’s about something entering your body’. One patient stated, ‘surgery is not all about cutting… I think that’s quite an old-fashioned view. There are more procedures around now that may not involve cutting and a definition needs to include those’. Furthermore, the purpose of the invasive procedure, whether diagnostic or therapeutic, was not expressed as being an important criterion in whether a procedure is defined as invasive, and thus has not been included in the proposed definition.

**CONCLUSION**

We propose a comprehensive way of defining invasive procedures. Agreeing and applying a definition to this fundamental aspect of healthcare is crucial, to optimise study design and conduct, facilitate evidence synthesis and improve the tracking of research activity.

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