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Regulating Risk in Surgical Innovation? A UK perspective

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Disclaimer

The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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  - Prof Jane Blazeby
  - Prof Richard Huxtable
  - Dr Teresa Swift
  - The Bristol BRC Surgical Innovation workstream

- This talk broadly represents our collective thinking, but with my own spin and emphasis. Any mistakes are my own.

Outline

- Case outline - Robotic assisted heart surgery
- Surgical innovation regulation in the UK
- Three key challenges:
  - Defining innovation
  - Consent and unknown risk
  - The learning curve
- An eliminativist approach to regulating surgical innovation

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The case

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The case (1)

- Stephen Pettitt, 69 year old retired music teacher.
- Underwent ‘pioneering’ (Dyer, C. BMJ, 2018.) robotic heart surgery using the ‘Da Vinci’ robot at Newcastle Hospitals NHS Foundation Trust.
- Problems:
  - Ambient noise from robot inferred with surgeon communication;
  - Robot knocked theatre assistant’s arm and made disorderly stitches which needed replacing;
  - Patient developed a bleed that blinded the camera;
  - Moved to open heart surgery but heart tissue already irreparably damaged.

The case (2)

- Death occurred as a “direct consequence of the operation and its complications.” “Mr Pettitt died due to complications of an operation to treat mitral valve disease and, in part, because the operation was undertaken with robotic assistance.” (Karen Dilks, coroner. Reported in Dyer 2018).

- Mr Nair, the surgeon:
  - Had observed the robot’s use and practiced on simulator, but declined one-on-one training.
  - Did not tell the patient he would be the first in the UK to undergo this robotic surgery, and that it may therefore carry more risk than conventional surgery.

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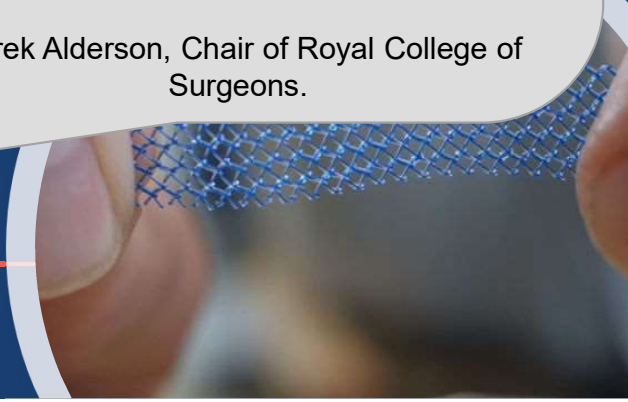
UK regulatory context

This one is easy…

- There really isn't regulation of new surgical practice.
- A surgeon in the UK is free to use whatever technique they wish, whether there is an evidence base or not.
- This can range from minor modifications through to newly invented procedures, using new or repurposed devices.
- A successful new idea can be reported at conferences etc. and adopted by others, without any testing or regulation.
- A failed new idea will generally not be reported, meaning failures are not learned from.

"In contrast to drugs, many surgical innovations are introduced without clinical trial data or centrally held evidence. This is a risk to patient safety and public confidence."

Derek Alderson, Chair of Royal College of Surgeons.



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How could this death have been prevented?

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Better regulation of surgical innovation?

"fragmentary and non-standardized oversight mechanisms leave surgeon- innovators and patients open to significant risk of breaching the ethical principles at the core of surgical practice. A systematized approach that mitigates these risks while maintaining the independence and dignity of the surgical profession is necessary"

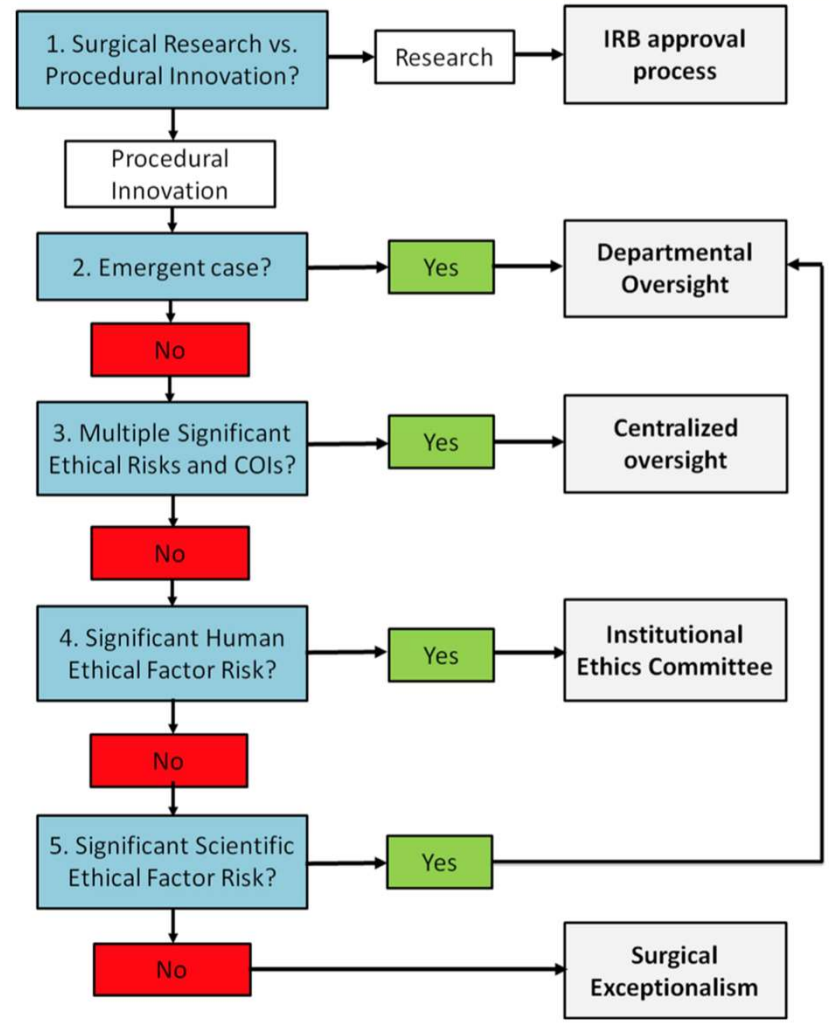
Gupta S. et al. 2018. World Journal of Surgery, 42:2773–2780

How do we know if we are doing surgical innovation?

How can we identify and communicate uncertain risk?

How does the surgeon's learning curve impact on the above?

Fig. 1 Framework for the determination of appropriate level of oversight



From (Gupta S. et al. 2018. World Journal of Surgery, 42:2773–2780)

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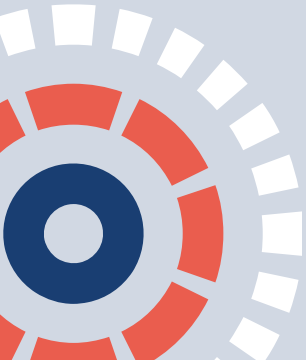
Defining surgical innovation



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Unclear definition

- In order to regulate surgical innovation, we have to be able to define it so that we can identify it. But it is not clear:
  - “a novel procedure, a significant modification of a standard technique, a new application of or new indication for an established technique, or an alternative combination of an established technique with another therapeutic modality that was developed and tested for the first time”

    (Reitsma, A. M., & Moreno, J. D. *2002)*
  - “departures from standard surgical practices that are both nonvalidated and major”

    (Meyerson, D. 2013)
  - “a dynamic and continuous process involving the introduction of a new technology or technique that initiates a change in clinical practice.”

    (Hughes-Hallett, A.et al. 2014)

Unclear definition

- In ca… cal i… be… t cle…
  - sig… a standa… nique, a new indic… d technique, … an alternative abli… other therapeutic modality that w… eloped and tested

(Reitsma, A. M., & Moreno, J. D. *2002)*

  - "departures from standard su… l practices that are both nonvalidated and major"

(Meyerson, D. 2013)

  - "a dynamic and continuous process involving the introduction of a new technology or technique that initiates a change in clinical practice."

(Hughes-Hallett, A.et al. 2014)

Define: standard; major.

Changing the colour of surgical instruments for easier recognition?

Is it innovation?

Define: continuous; initiating change in clinical practice.

Trainee surgeon learns new way of doing established technique from other surgeon and starts to use it.

Is it innovation?

Define: new; significant; modification; standard; established; first time.

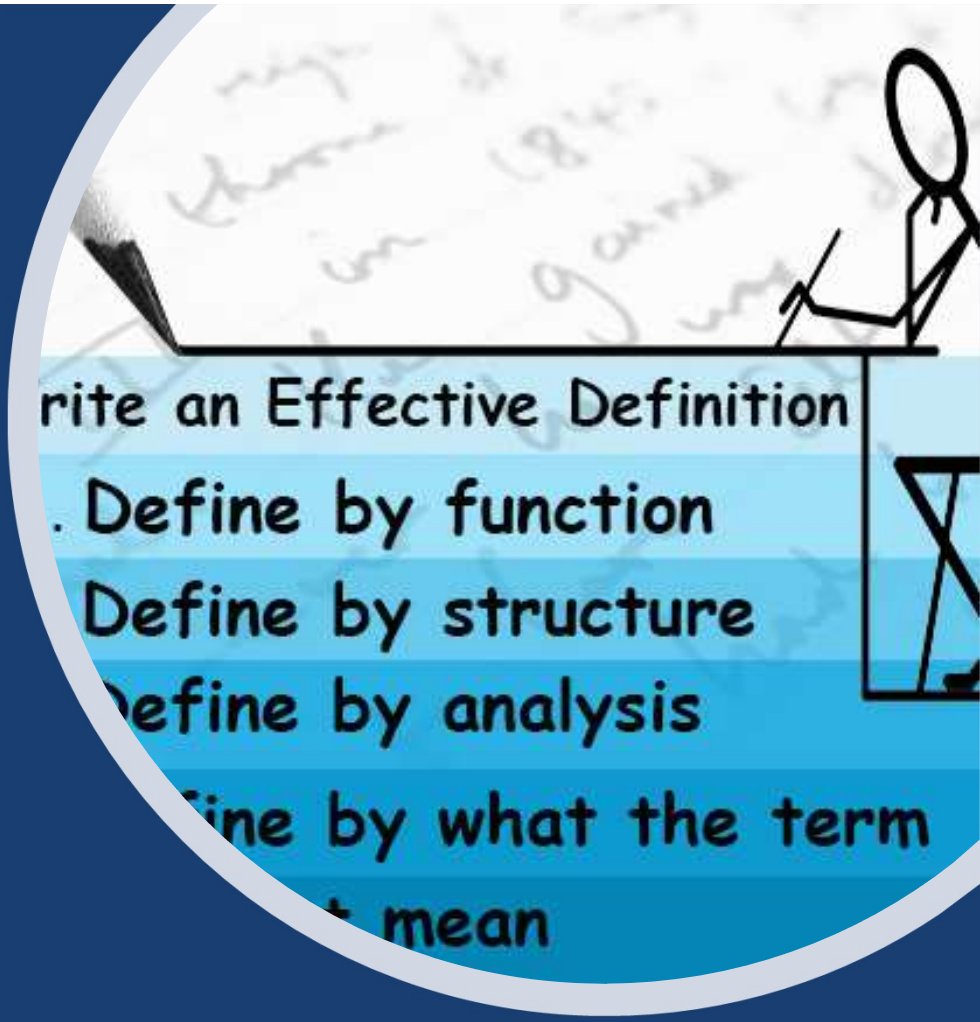
Surgeon 'invents' and uses novel technique which, unknown to them, is already being used in another country.

Is it innovation?

Our work on defining Surgical innovation

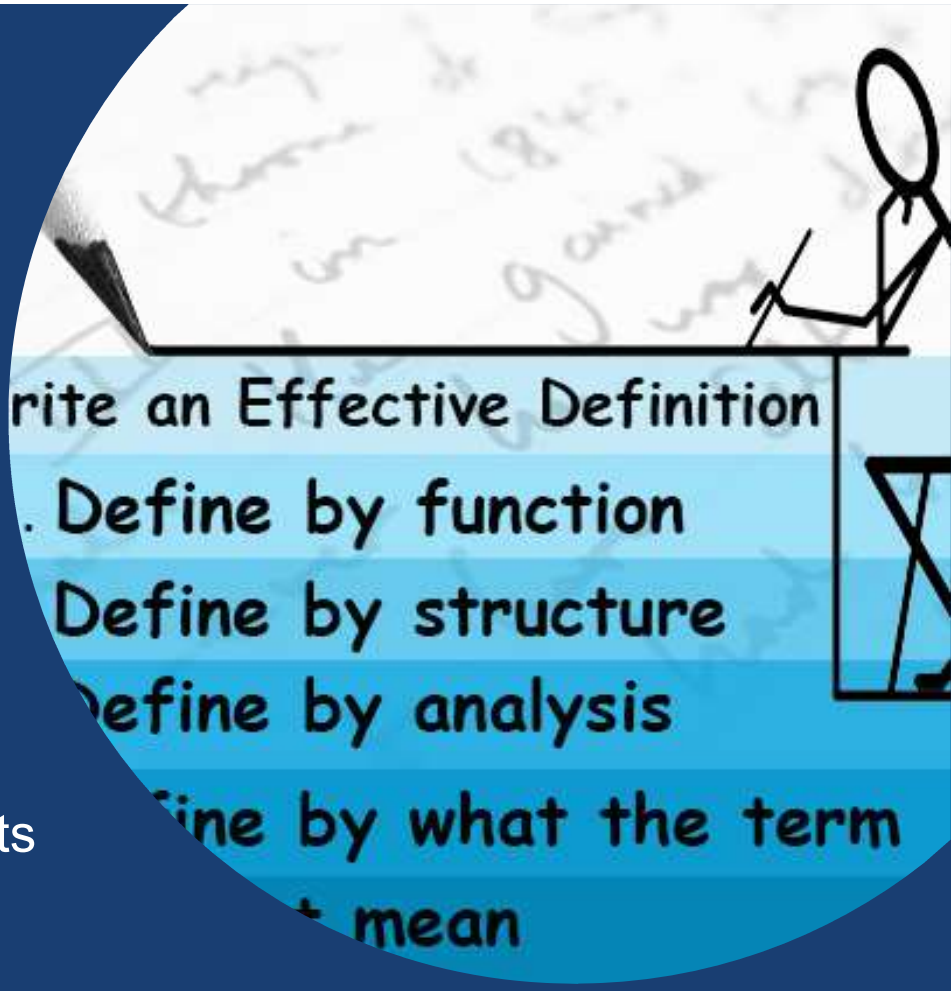
- Definitions vs concepts:
  - A definition is always purposive - it is a definition *for something.*
  - A conceptualisation attempts to capture the underpinnings of a concept divorced from a specific agenda.

- We started with a conceptualization study (Birchley *et al*, accepted), which identified 5 conceptual elements of surgical innovation that any definition of SI might want to attend to:



Our work on defining Surgical innovation

- **Purpose** – what is driving the practice?
- **Place** – what is the geographical location and/or context of the practice?
- **Process** – how is the practice developed?
- **Product** - what are the consequences/outputs
- **Person** – who is practicing?



Our conclusion?

- Defining surgical innovation, in a way that avoids high risk of false positives and false negatives, is pretty much impossible.
- The concept of innovation is cluttered with elements that may be unhelpful and obfuscating when attempting to define innovation for governance purposes.
- Our various working hypotheses tended to fail because they did not capture practices that we felt needed regulation, or did capture practices that we felt did not.
- The common feature of failed definitions is a failure to properly capture the most important element – the introduction of risk – and used proxies to tangentially refer to risk (such as new, novel, untested) etc.

Our conclusion?

In light of this, why do we need a definition of ‘surgical innovation’ in order to regulate the practices we are concerned about?

If our concern (our purpose) is to facilitate the safe translation of surgical techniques and devices into practice, we don’t need to talk about innovation. We only need to talk about safety and risk.

Surgical innovation is simply a term of art standardly used to refer to an ambiguous collection of activities loosely related to ‘newness’ (as usefully captured by the Macquarie definition: Hutchinson et al).

But arguably it is not necessary, or even that useful, when thinking about regulation and governance.

- The common feature of failed definitions is a failure to properly capture the most important element – the introduction of risk – and used proxies to tangentially refer to risk (such as new, novel, untested) etc.

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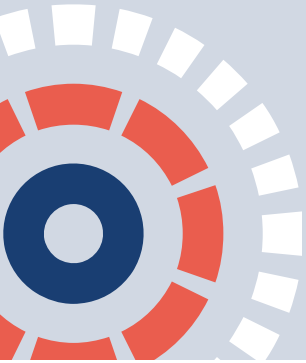
Communicating unknown risk



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The introduction of unknown/uncertain risk

- Our concern is with techniques/devices being introduced into clinical practice that may not be safe or effective.
- Regulation may help ensure patients/surgeons can benefit, but avoid harms as far as possible.
- The proper focus is not on ‘innovation’, but on changes that introduce uncertainty about the risk/benefit profile of a surgeon’s practice.
- The Newcastle case is a prime example:
  - Whether it was ‘innovative doesn’t matter.
  - What matters is the surgery performed had a different and uncertain risk/benefit profile to the standard surgery.

Calculating, Communicating and Consenting

- **Calculating** the precise risks/benefits introduced by a change in a surgeon's practice is challenging. Much will be uncertain.
- Not all changes introduce uncertain risk/benefit, but any change has the potential to.
- Not all changes to risk/benefit profile will be large or significant.
- But **communicating** a risk that is uncertain makes **consenting** difficult.
- **Communication** is key, and terminology matters. People may associate 'innovation', 'new' and 'novel' with 'good' and 'beneficial'.
- Calling something 'innovative' likely implies it is good, and can led to poor **consent** that fails to properly **communicate** the uncertain risk/benefit profile.

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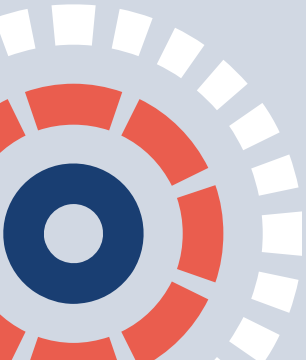
The learning curve



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Learning curve and risk

- A new drug either works or not for a given indication. It makes no difference who prescribes it or whether it is the first time the prescriber has used it.

- But it matters who the surgeon is.
    - Even established techniques can be performed well or poorly.
    - Much depends on the learning curve of the surgeon.

- Unclear whether a surgeon has a duty disclose their performance record or point on the learning curve in general (Oakley, 2007; Ives, 2007).

- But, arguably, when a surgeon plans a change in practice that adds uncertainty to the risk/benefit profile of the planned procedure, this must be communicated to, and understood by, the patient.

Learning curve and risk

This was not done in the Newcastle da Vinci case.

The surgeon was at the very start of his learning curve with this robotic procedure, and did not disclose this to the patient.

The risk/benefit profile was significantly different to – and much more uncertain than - the standard procedure, both because of the newness of the technology and the learning curve of the surgeon.

- But, arguably, when a surgeon plans a change in practice that adds uncertainty to the risk/benefit profile of the planned procedure, this must be communicated to, and understood by, the patient.

Risk assessment > identifying innovation

- Dealing with this this does not seem to require a definition of innovation.
- It requires an risk assessment of the effects of a surgeon's learning curve on the likely safety and efficacy of the planned procedure.
- If our focus is safety and efficacy, it doesn't matter if:
  - It is established but the first time used by the surgeon.
  - It is brand new and never been done before.
  - This surgeon has done it 15 times but no-one else has adopted it.
- The language of innovation ("this is the first time I'll be using this innovative procedure") is likely to obfuscate rather than clarify the risk/benefit profile.

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The redundancy of innovation

Defining innovation is not necessary…

- We should focus instead on:
  - to what extent an intervention presents a substantially new risk profile because of its difference from existing interventions;
  - to what extent a risk profile can be anticipated because components of the intervention are tried and tested interventions;
  - what new risks arise from any hitherto untried combination of these components.

- Regulation should therefore focus on assessing risk, appropriate methods for studying changes to surgical practice according to its risk profile, and the appropriate reporting of outcomes.

(Birchley et al)

…and can be actively unhelpful

- None of this requires the language of innovation – which actually makes understanding risk/benefit profile more difficult because of it's positive bias.
- The ambiguity of 'innovation' provides cover for both misunderstanding and wilful avoidance of scrutiny.
- Our focus should be on regulation for the reporting and monitoring of any planned or unplanned changes to invasive surgical procedures that result in an uncertain risk profile.

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Back to the case

What went wrong

- The Newcastle Da Vinci robot surgery case was likely a catalogue of errors.
- Arguably, the following problems were key:
  - The technology was relatively new, the surgeon did not have adequate training, and was early in the learning curve.
  - This newness, and the surgeon's learning curve, changed the risk/benefit profile, making it uncertain compared to standard surgery, if not certainly higher risk.
  - The consenting process did not adequately convey the risk/benefit profile of the procedure.
- Risk assessment of the change to practice was inadequate (if undertaken at all).

Could regulation help?

- Possibly…
- Regulation may have helped if it focused on a requirement to conduct and register risk assessment of any planned change to a surgeon's practice.
- Relying on regulation of *innovation* to regulate such practices may have failed because:
    - The surgeon may not have identified what he was doing as innovation (genuinely or to avoid scrutiny).
    - The positive bias associated with 'innovation' may impair consent, whether full known/unknown risks are disclosed or not.

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Conclusion

- Regulation for monitoring, evaluating and reporting surgical practice, including the process of informed consent, should avoid the language of innovation.

- It should focus instead on what matters:
  - Changes to a surgeon's practice that introduce uncertainties into the risk/benefit profile of the planned procedure.

- Generally, this would require undertaking and logging a risk assessment, reporting the outcomes, and evaluating the change.

- Depending on the risk identified there could be a range of different and proportionate regulatory/governance responses.

- Whether or not it is 'innovation' is simply irrelevant.

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Thank you.