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Rise of the machines: does evidence support the use of negative pressure wound therapy for complex wounds?

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Overview

Consider relatively high cost **wound care devices** for **complex wounds** in terms of:

- Use
- Evidence
- Further research

Academy of Medical Royal Colleges

Forty treatments that bring little or no benefit to patients.

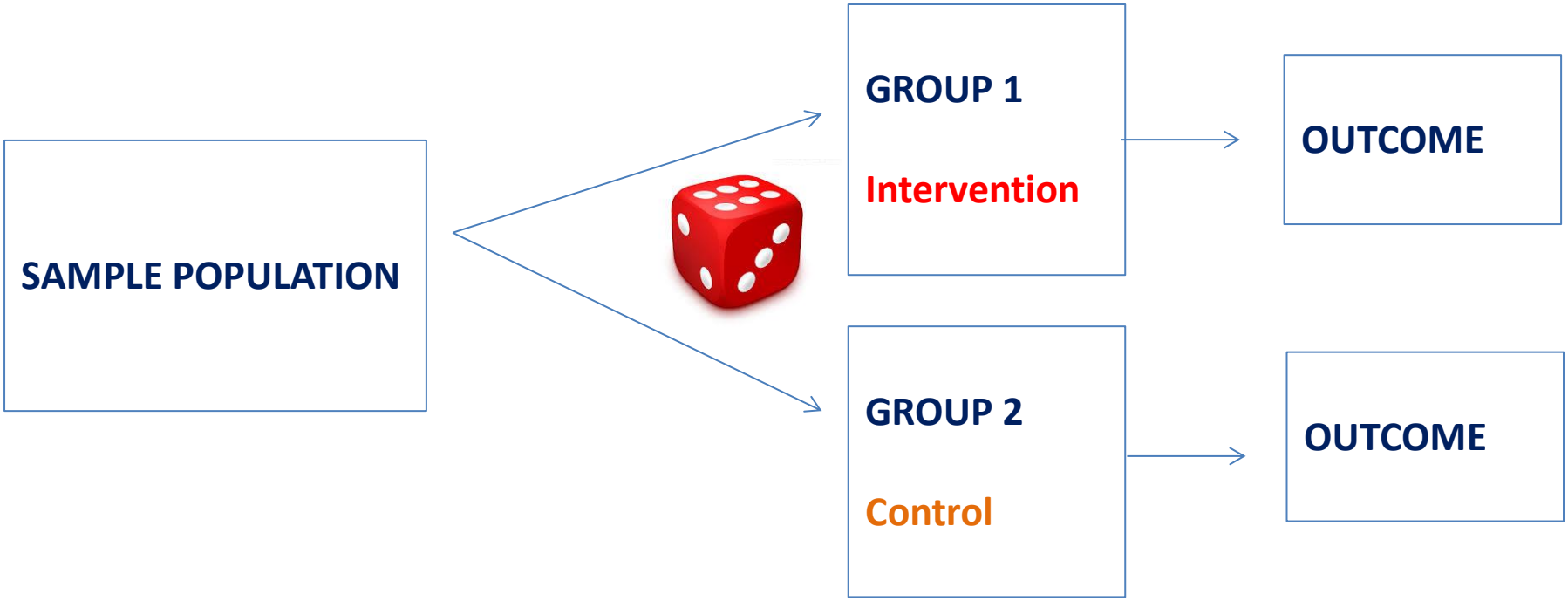
Press Release – Strictly embargoed until:
00:01 Monday 24th October 2016

The Academy of Medical Royal colleges is today (Monday 24th October) launching its Choosing Wisely campaign, with a list of forty treatments and procedures that are of little or no benefit to patients. The list, which has been drawn up by the Academy's member royal colleges and faculties includes advice to both patients and doctors for treating health related issues such as:

- Cuts and grazes – Tap water is just as good for cleaning them as saline solution
- Lower back pain – X-rays are of little benefit if there are no other concerning features
- Terminal cancer – Chemotherapy may be used to relieve symptoms but can also be painful, cannot cure the disease and may well bring further distress in the final months of life
- Prostate conditions – Routine screening using a test known as a Prostate Specific Antigen, or PSA test does not lead to longer life and can bring unnecessary anxiety
- Small wrist fractures or 'buckle fractures' in children – Do not normally need a plaster cast, and will heal just as quickly with a removable splint.

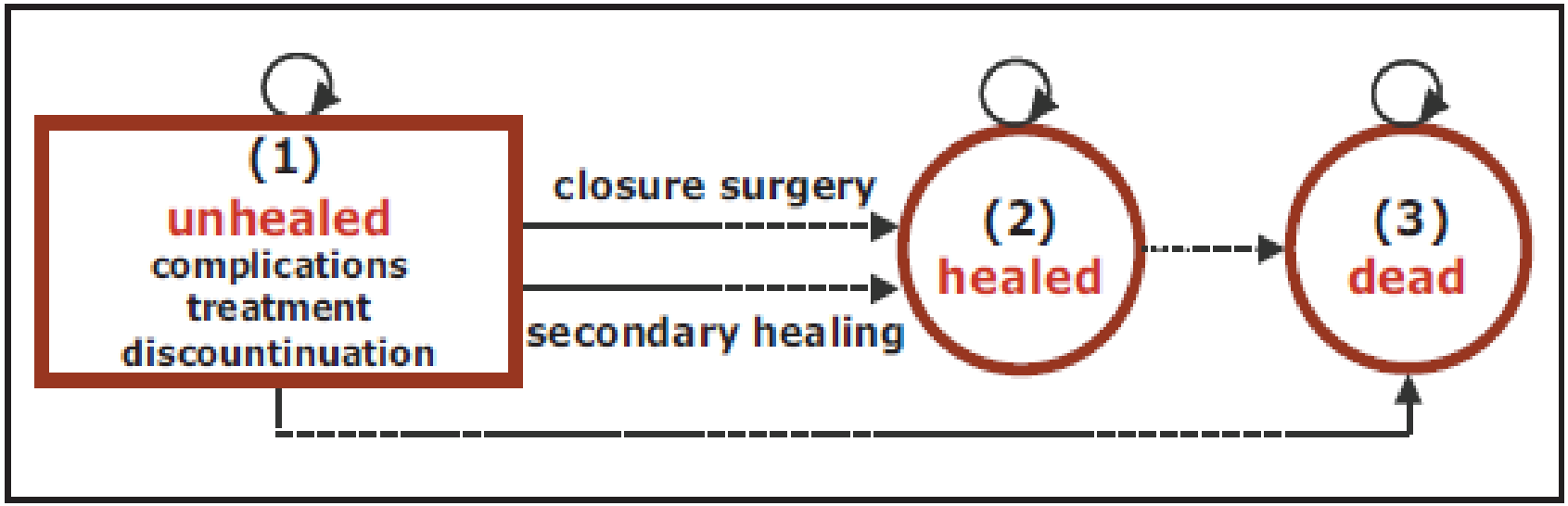
Academy of Medical Royal Colleges
10 Dallington Street

Assessing effectiveness



The randomised controlled trial

Cost effectiveness



Soares MO et al. Medical Decision Making, 2013 33:415-36.

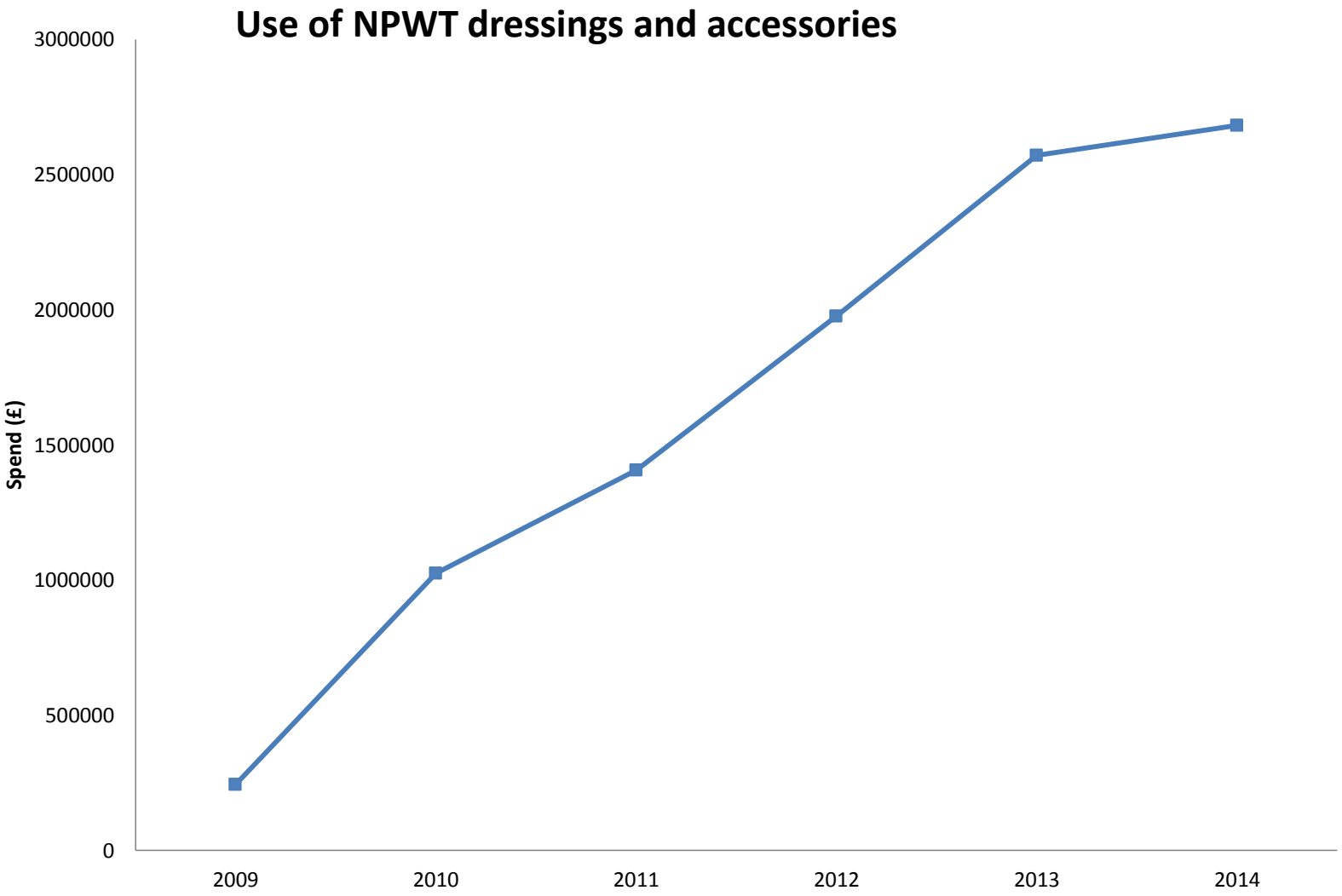
Bring medical device to market

CE

Negative pressure wound therapy (NPWT)

Silver dressings

Use of NPWT: Community use in England

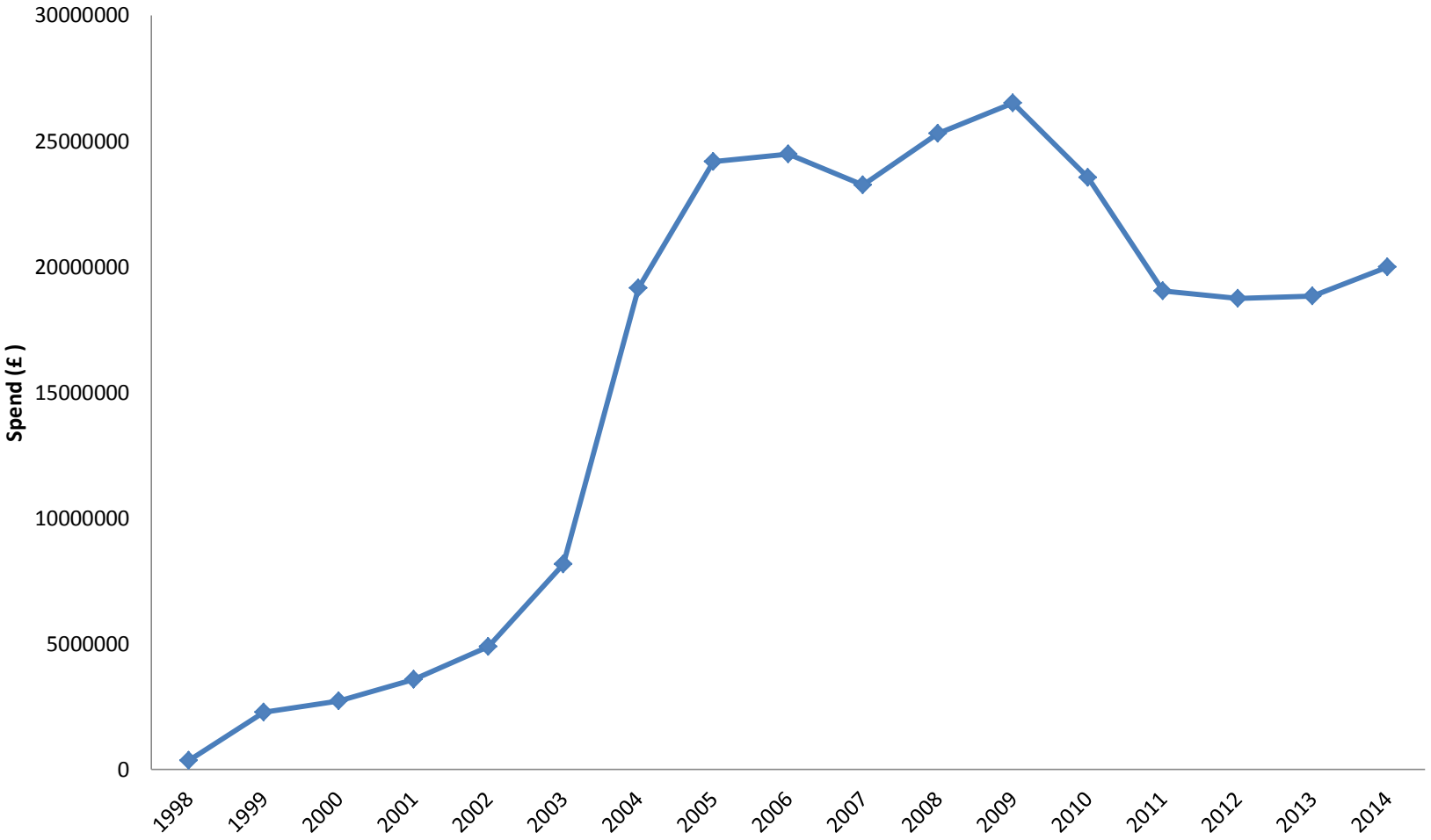


- Between 2001 and 2007, Medicare Payments for NPWT pumps increased by 538% (from $24 million to $164 million)

- Recent study of people with open wounds in Leeds and Hull

- Change and choice

Use of silver dressings: Community use In England



Other data

- 263 health professionals in Scotland asked about AWD use and 96% said would use for an infected wound.

- When asked which AWD was used most frequently of 255 respondents 55% said silver dressings (iodine containing was most frequent).

- Variation

What is the evidence: Silver dressings

NICE National Institute for Health and Care Excellence

NICE advice

Healthcare Improvement Scotland

Chronic wounds: advanced wound dressings and antimicrobial dressings

Evidence summary
Published: 30 March 2016
nice.org.uk/guidance/esmpb2

Key points from the evidence

Overall summary

This evidence summary discusses the best available evidence for advanced wound dressings and antimicrobial dressings for managing common chronic wounds (diabetic foot ulcers, pressure ulcers, venous leg ulcers and infected wounds). It includes evidence and recommendations from national guidance (if available) and the most up-to-date systematic reviews and meta-analyses (search date July 2015).

Health technology assessment report 13

V0.14 July 2015

Antimicrobial wound dressings (AWDs) for chronic wounds

Authors: Kelly J, Clifton E, Fearns N, Harbour J, Heller-Murphy S, Herbert P, Macpherson K, Myles S, Santo V, Wilson L.

Clinical effectiveness

Several good quality systematic reviews were identified, but the studies that they included were generally methodologically weak.

The main outcomes of interest for this HTA related to localised wound infection. However, studies on AWDs in chronic wounds mostly report on outcomes related to wound healing. Conclusions for both outcomes are presented.

Based on a systematic review of the clinical evidence:

- For treating localised wound infection in chronic wounds, the evidence is insufficient in terms of quality and quantity to draw conclusions on the use of AWDs.
- For the healing of chronic wounds, the evidence either:
  - does not support the routine use of AWDs; or
  - is insufficient in terms of quality and/or quantity to draw conclusions on the routine use of AWDs.

Cost effectiveness

A systematic review of the economic evidence highlighted a small number of relevant studies. However, taken together there is insufficient evidence in terms of quality and quantity to determine the cost effectiveness of AWDs relative to non-AWDs for the treatment of localised wound infection and healing of chronic wounds.

Recommendations

- Guideline recommendations

- Other

What is the evidence: NPWT

Evidence based medicine

- Research evidence
- Clinical experience
- Available resources
- Patient views and preference

For rapid cost-effective wound debridement, one product leads the field*.....

*The speed of maggot debridement compared with conventional materials was described in a review published previously.
Thomas, S. and McCubbin, P.,
Use of maggots in the care of wounds,
Hospital Pharmacy, 2002, 9(9): p. 267-271.

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Identifying the causes of increased wound pain: The role of the Tissue Viability Nurse

A leg ulcer that had stopped healing was causing a patient increased pain. Heavy infection was identified as the cause, and found to be exacerbated by a range of factors. An assessment resulted in treatment changes, leading to complete healing

leg ulcer; wound pain; infection; MRSA; oedema

Joan Ferguson was in hospital for a routine blood transfusion for asymptomatic normochromic-normocytic anaemia, caused by chronic leg ulceration on the lower left leg, when she had a cerebrovascular accident. Some weeks later, after she had been moved to a rehabilitation unit, staff had noted that her ulcer appeared to be regressing: it was sloughy, malodourous and was causing increasing pain.

The ulcer, which had started off as three smaller ones, had been improving slowly, but the results of bacterial swabs, taken when infection was suspected, showed a heavy growth of methicillin-resistant *Staphylococcus aureus* (MRSA), as well as a heavy growth of other mixed flora in the ulcer bed.

Medical and social history

Following hip surgery in 1994, Mrs Ferguson had developed deep-vein thrombosis and shortly afterwards a leg ulcer of mixed aetiology. She had peripheral vascular disease affecting both legs, which lead to exploration of left common femoral artery, angioplasty and left saphenofemoral ligation in May 2000. This was followed by a bypass graft three months later.

She was able to walk about 45m only and was an ex smoker, with a long history of pain associated with her leg ulcer. This was normally controlled with 1g paracetamol six-hourly as necessary.

When Mrs Ferguson was admitted to the ward, her pain was assessed using a five-point descriptive scale.[1] Increased wound pain can indicate the presence of problems. While most wounds heal without problems, chronic or complex wounds can be slow or fail to heal, increasing the risk of infection.

General appearance

I reviewed the patient's records and went to see her. She had left-sided facial weakness and was unable to move her left arm or hand; she could verbalise and make herself understood. Both legs felt warm and were red in appearance. The right was oedematous to the calf, while the left was oedematous to the knee. There was hyperpigmentation and discolouration around the left ankle area. Calf circumference measurements were 39cm (right) and 47cm (left). The re-perfusion rate was below two seconds in both feet, but the patient's foot pulses were not palpable owing to oedema. Documented ankle brachial pressure index was 0.5.

The treatment aim was to reduce analgesia by using appropriate wound care interventions and by addressing contributing factors. The wound was dressed according to the original treatment plan.

Wound management

The ward team continued to use paraffin gauze and non-adhesive foam dressing (Allevyn, Smith and Nephew), which was held in place with a wool conforming bandage. These were sodden with exudate and there was an offensive odour. The skin edges were macerated and the wound bed looked wet. Removal of the dressings caused the patient a great deal of pain. Accordingly, morphine sulphate tablets (MST) 40mg twice a day were prescribed.

The ulcer

The leg ulcer was of irregular appearance on the outer aspect of the left lower leg, starting at the fibular head prominence and ending just above lateral malleolus. Using a transparent grid I traced the outline: it measured 17cm in length and was 10cm at its widest point; it was 1cm deep.

It appeared to be healing at the superior end, as there were clear signs of epithelialisation for the first 5cm. The next 5cm showed signs of granulation, with some islands of slough near the distal portion. The distal part of the wound was covered in slough, which was thick and tenacious. The wound edges were painful to the touch, and beyond the macerated rim of the wound the skin looked inflamed and was warmer to the touch.

To manage Mrs Ferguson's wound effectively we considered a range of factors that can affect healing,

More research needed!

IDEAL-D: a rational framework for evaluating and regulating the use of medical devices

High profile device failures have highlighted the inadequacies of current regulation. **Art Sedrakyan and colleagues** call for a move to a graduated model of approval and suggest a framework to achieve this goal

Art Sedrakyan *professor*[1], Bruce Campbell *professor*[2], Jose G Merino *clinical research editor*[3], Richard Kuntz *chief scientific, clinical, and regulatory officer*[4], Allison Hirst *researcher*[5], Peter McCulloch *professor*[5]

[1]Department of Healthcare Policy and Research and Medical Device Epidemiology Network (MDEpiNet) Science and Infrastructure Center, Weill Medical College of Cornell University, New York, NY, USA; [2]Interventional Procedures Programme, National Institute for Health and Care Excellence, London, UK; [3]*The BMJ* and Johns Hopkins Community Physicians, Bethesda, MD, USA; [4]Medtronic, Minneapolis, MN, USA; [5]Nuffield Department of Surgical Science, University of Oxford, Oxford, UK

Implantable devices such as pacemakers and hip implants have transformed many lives, but there have also been high profile instances of harm.[1-5] Unlike the system for drugs, marketing approval for devices in the European Union and the United States has historically focused on proof of safety as a minimum requirement, and approval could be granted based on preclinical evidence alone, with no randomised clinical trials (fig 1⇓). In both jurisdictions, recent years have seen some tightening of requirements. In the US, more invasive devices now generally require a rigorous "pivotal" clinical trial either through the

procedures. We discuss IDEAL's potential to provide a structure for evaluation and regulation of devices and how a partnership between surgeons, academics, and regulators could facilitate such a move without major new resources.

What is IDEAL?

The IDEAL framework was developed by an expert consensus group to describe what types of studies and reporting should be used for new surgical procedures, from first use through to adoption in practice (table 1⇓).[9] The initial idea stage focuses

Tables

Table 1| IDEAL framework and recommendations for surgical innovation. More details are available at http://www.ideal-collaboration.net/

	1 Idea	2a Development	2b Exploration	3 Assessment	4 Long term study
Question	Can the procedure or device achieve a specific physical or physiological goal?	What is the optimal technique or design, and for which patients does it work best?	What are the outcomes of more widespread use? Can consensus equipoise be reached on a trial question?	How well does the procedure work compared with current standards of care?	What are the long term effects and outcomes of the procedure?
Key outcome	Proof of concept	Safety, efficacy	Efficacy	Comparative effectiveness	Quality assurance
Patient base	Single to few (<10)	10s	100s	100s+	100s+
Recommendations for study design and reporting	First-in-human study; case report (structured): confidential registration of all first-in-human procedures	Prospective development study—cohort study with sequential reporting of cases and modifications	Prospective exploratory study—a collaborative cohort study with learning curve evaluation or feasibility RCT	Randomised controlled trial	Comprehensive disease based registry or database
Example of procedure at this stage	Uterine transplant with successful live birth[1]	Peroral endoscopic myotomy for oesophageal achalasia[2]	Complex endovascular stenting, such as in complex aortic aneurysms[3]	Minimally invasive oesophagectomy[4]	Banding and bypass for morbid obesity[5]

On the other hand

A Use of **pentoxifylline** *(400 mg three times daily for up to six months)* **to improve healing** should be considered in patients with venous leg ulcers.

Questions

- How big is this issue?
- Does it matter?
- How can we ensure better value health care in wound?
- Should there be disinvestment?
- Can we disinvest?