

## *Exploring Histories and Futures of Innovation in Advanced Wound Care*

### **Welcome**

AHRC Cross-Disciplinary  
Wounds Research Network

#woundhistsoc

@woundinnovation

wounds.leeds.ac.uk

Thackray Wireless 1, 2 or 3

WiFi code 'conference55'



Workshop 3: marketing, regulation and  
the evidence base in wound care



- Lots of products
- Lots of marketing
- Clinical guidelines state that clinical judgement must be used in selection of appropriate product
- Scant good quality evidence to support choice
- Most wound care interventions classified as devices rather than medicinal products
- Devices not automatically subject to clinical trial
- European regulatory focus - CE marking, Medicines and Healthcare products Regulatory Agency (MHRA) - is on safety assessment, viability, competitiveness not population effectiveness (health outcomes for patients)
- Many of the current ideas in wound care haven't been tested thoroughly (JL)
- More clinical trials add costs to industry – “cost-evidence-risks-profits conundrum”

THE GENERATION OF  
**EVIDENCE...**






The screenshot shows the BioMed Central website interface. At the top, the BioMed Central logo is visible. Below it is the 'Trials' logo. A navigation bar contains links for HOME, ABOUT, ARTICLES, and SUBMISSION GUIDELINES. A banner below the navigation bar reads: 'We'd like your opinion about BioMed Central, help us by [answering 3 questions](#)'. The main content area features the article title 'Funding source and the quality of reports of chronic wounds trials: 2004 to 2011'. Below the title is the author list: 'Robert Hodgson, Richard Allen, Ellen Broderick, J Martin Bland, Jo C Dumville, Rebecca Ashby, Sally Bell-Syer, Ruth Foxlee, Jill Hall, Karen Lamb, Mary Madden, Susan O'Meara, Nikki Stubbs and Nicky Cullum'. At the bottom of the article header, it says: 'Trials 2014 15:19 | DOI: 10.1186/1745-6215-15-19 | © Hodgson et al.; licensee BioMed Central Ltd. 2014. Received: 3 September 2013 | Accepted: 23 December 2013 | Published: 14 January 2014'.

- Systematic search RCTs of treatments for chronic wounds 2004-2011 (incl.) - 67 met inclusion criteria.
- Findings: poorly reported with many methodological flaws  
often short durations of follow-up (median 12 weeks), small sample sizes (median 63), failure to define a primary outcome (41%), and those that do use surrogate measures of healing (40%). Only 40% of trials used appropriate methods of randomisation, 25% concealed allocation and 34% blinded outcome assessors.
- Funding: 41% of included trials wholly or partially funded by industry, 33% declared non-commercial funding, 26% did not report a funding source. Industry funding was not statistically significantly associated with any measure of methodological quality - analysis was probably underpowered.



 OPEN ACCESS

ESSAY

## Why Most Clinical Research Is Not Useful

John P. A. Ioannidis 

Published: June 21, 2016 • <http://dx.doi.org/10.1371/journal.pmed.1002049>

- High quality of evidence for medical and other health-related interventions uncommon in Cochrane systematic reviews
- Certain conditions get lots of research attention, other (more common conditions) get little
- Huge nuisance of significant results. Discoveries that go nowhere. Glacial pace of clinical translation
- Most studies ignore patient centred outcomes – (service-user voice notably absent in wound care PURSUN UK, JLAPUP)
- Problems of novelty and optimism. Always getting the 'right results' yet re-analysis finds something new/different
- Barriers to transparency and reproducibility
- Conflicts of interest and market pressure (finance based medicine) - more medicine not necessarily leading to more health. E.g. each company generates a clinical research agenda strongly focused on its own products and commercial return – c.f. useful comparisons of different interventions from different companies

WOUND CARE HAS A VERY  
**LOW PRIORITY**  
OVERALL



- Lots of industry sponsorship. Company paid speakers and 'educational' materials. Clinical brand preference.
- In order to keep products moving, industry must negotiate the barriers that divide conventions in medical research and practice from marketing objectives (Applbaum, 2009) – JL's provocative:
  - **"most dangerous meme"**
    - That we don't need to worry about RCT absences and failures
    - That clinicians can see for themselves what works
    - That Evidence Based Woundcare is "Facism"
    - That the Cochrane Org have got it all wrong
- Research from the USA indicates that nurses view the marketing activities they experience as educational and beneficial. They perceive other providers, but not themselves as being susceptible to influence (Crigger et al 2009).

WOUND CARE HAS  
BECOME A PARTNERSHIP  
BETWEEN

