




National Institute for Health Research

Collaborating the Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester

Towards Evidence Based Wound Management

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Wounds By Numbers

- Complex wounds are difficult to prevent and difficult to heal
- Include bed sores, leg and foot ulcers, surgical wounds that break down
- 1 to 2 people per 1000 being treated for a *complex* wound (pressure ulcers, leg and foot ulcers) at any time (126,460 people in UK)
- Annual of wounds to NHS estimated at £2 to £3 Billion pa.



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Back to 1990...



Thatcher resigns!



Simpsons broadcast



Baywatch was big!




1990 FIFA World Cup Winners
West Germany
Third title



Nelson Mandela released

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The Nursing Management of Leg Ulcers in the Community: A Critical Review of Research

- Objectives:
 - to critically review the research underpinning the nursing management of leg ulcers in the community and
 - develop a research agenda to inform and improve nursing practice


The first systematic review in wound care and one of the first in nursing

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Questions Addressed

Question	Answer?
What is the underlying pathology?	X/✓
How many people affected?	X
What are the risk factors/early warning signs?	X/✓
(How) can we prevent them?	X
(How) can we reduce recurrence?	X
Which treatments are used?	X/✓
Which treatments are effective?	X
What are the adverse effects of treatments? Can they be reduced?	X/✓
How should nurses assess people with leg ulcers?	X
How and where is care currently delivered?	X/✓
Contribution to nursing workload?	X
Impact on the patient of having a leg ulcer?	X
Important outcomes?	X

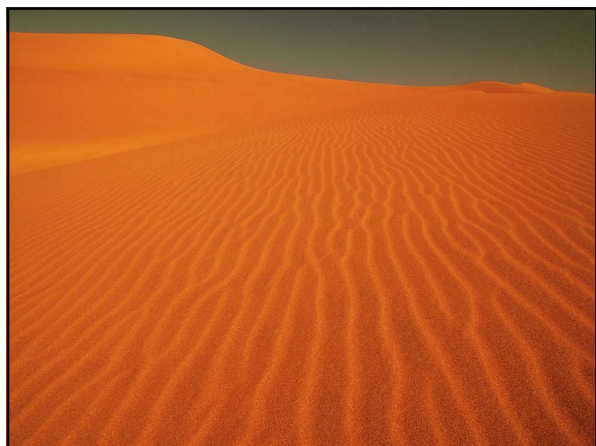
Pressure Ulcer Systematic Review



Effective Health Care
 The Prevention and Treatment of Pressure Sores:
 How could we use the evidence for setting people's risk of developing pressure sores?

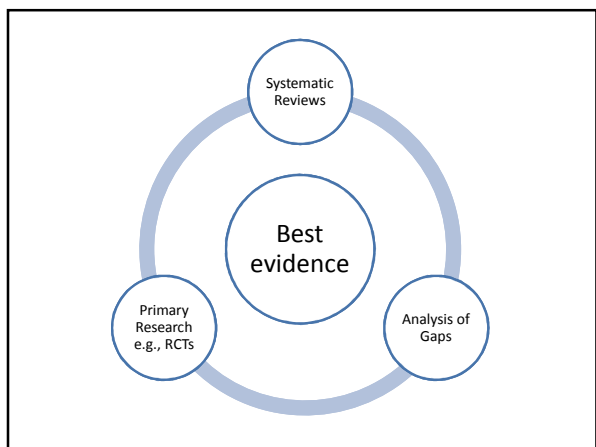
DH funded (NHS Centre for Reviews and Dissemination at the University of York)

- Evidence for the accuracy of risk prediction scales is confusing; not clear whether better than clinical judgement
- Effects of manual repositioning not adequately studied
- Most available equipment not reliably evaluated
- More RCTs and economic evaluations required



NHS HTA Programme

- Funded a suite of systematic reviews in wound care beginning around 1995



Systematic Reviews

- Address a focused, answerable question (clear objectives)
- Scientific method (pre-specified protocol, systematic and transparent approach, minimisation of bias, reproducible)
- Comprehensive (try to find ALL eligible studies)
- Systematic assessment of validity of primary study findings
- Systematic presentation and synthesis of included studies
- May include meta-analysis

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Advantages

- More precise estimates
- More likely to be true
- Can investigate consistency and explore differences; yields better understanding

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Cochrane Wounds Group

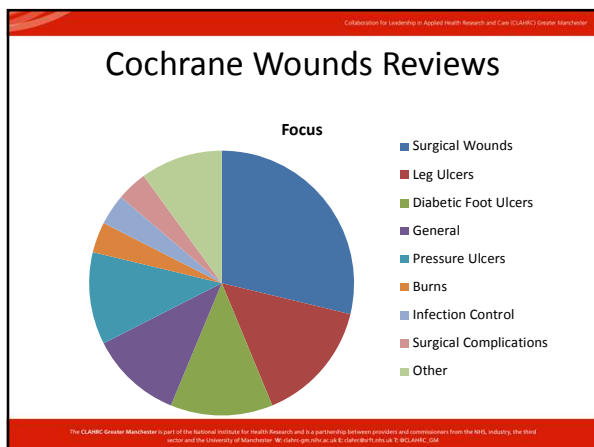
- Cochrane Collaboration was established 1993; the Wounds Group in 1995
 - 14 Editors
 - 560 Authors
 - 105 Referees
 - >100 systematic reviews published to date with many more in production

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Scope of Wounds Group Reviews

- Systematic reviews of the effects of interventions to prevent and treat wounds and their complications
- includes
 - prevention of pressure ulcers, leg and foot ulcers;
 - prevention of wound complications, e.g. surgical site infection, scarring;
 - treatment of wounds including burns, e.g. dressings, bandages, support surfaces;
 - infection control
- Systematic reviews of diagnostic test accuracy studies relevant to wounds

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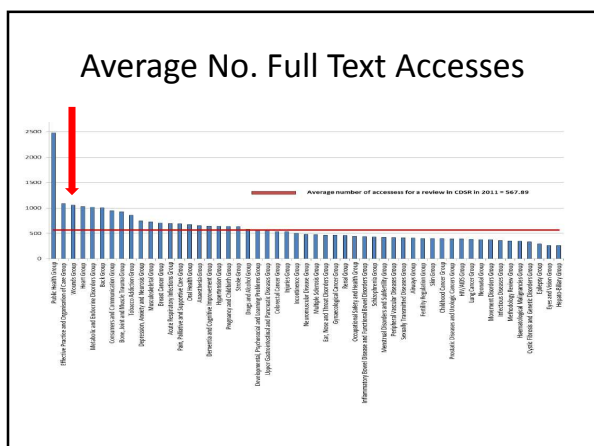
SEARCH THE COCHRANE LIBRARY
Title, Abstract, Keywords

COCHRANE DATABASE OF SYSTEMATIC REVIEWS
Issue 10 of 12, October 2013 (Updated Daily) Contents

BROWSE BY TOPICS
Anesthesia & pain control (203)
Blood disorders (192)
Cancer (573)
Child health (1475)
Complementary & alternative medicine (584)
Consumer & communication strategies (73)

SPECIAL COLLECTIONS
Hospital-acquired infection
World day for Safety and Health at Work 2013
Tuberculosis
Cochrane Evidence Add: resources for therapists

EDITORIALS
Rotator cuff tears and shoulder management: a tale of two diagnostic test accuracy reviews
Screening for prostate cancer: sharing the debate on benefits and harms
Mossquito larval source management: evaluating evidence in the context of practice and policy



Top 10 Accessed Reviews 2012

CD Number	Review Title	Full Text Accesses
CD001735	Support surfaces for pressure ulcer prevention	9,379
CD003861	Water for wound cleansing	5,501
CD000265	Compression for venous leg ulcers	5,241
CD005083	Honey as a topical treatment for wounds	4,558
CD006471	Risk assessment tools for the prevention of pressure ulcers	4,475
CD004423	Preoperative fasting for adults to prevent perioperative complications	3,675
CD006898	Repositioning for treating pressure ulcers	3,469
CD003216	Nutritional interventions for preventing and treating pressure ulcers	3,357
CD001488	Patient education for preventing diabetic foot ulceration	3,329
CD006354	Infection control strategies for preventing the transmission of methicillin-resistant Staphylococcus aureus (MRSA) in nursing homes for older people	3,091

Key Findings

Review	Findings
Support surfaces	High specification foam better than standard hospital mattresses Relative merits of AP and CLP unclear Operating table overlays can reduce pressure ulcers Medical sheepskins prevent pressure ulcers
Water for wound cleansing	No evidence that cleansing with sterile saline superior to cleansing with tap water
Compression for VLU	Compression better than no compression Multi-component systems better than single component systems 4LB better than SSB
Honey for wounds	Honey doesn't increase healing of VLU Honey may delay burn healing cf. grafting
Risk assessment for PU prevention	No evidence that structured risk assessment better than unstructured risk assessment



Impact on the Research Agenda

Dressings for Venous Leg Ulcers
Antibiotics and antiseptics for VLU

• Michaels et al. A prospective randomised controlled trial and economic modelling of antimicrobial silver dressings versus non-adherent control dressings for venous leg ulcers: the VULCAN trial. *Health Technol Assess* 2009;13(56).

Compression for Venous Leg Ulcers

• Iglesias C, Nelson EA, Cullum NA, Torgerson DJ on behalf of the VenUS Team. VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers. *Health Technol Assess* 2004;8(29).



• VenUS IV

Support Surfaces for Pressure Ulcer Prevention

• Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA, et al. Pressure relieving support surfaces: a randomised evaluation. *Health Technol Assess* 2006;10(22).



PRESSURE Trial

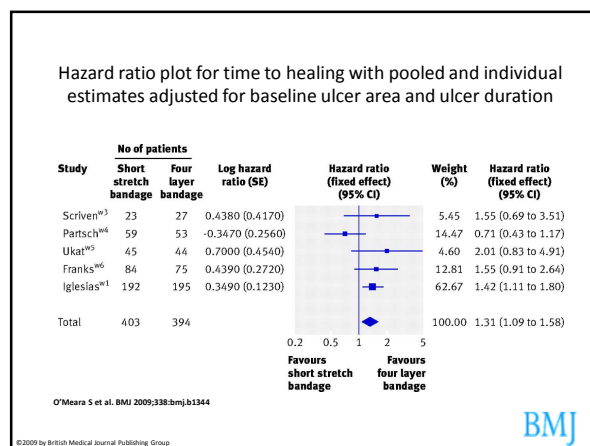
- NIHR HTA (£1,012,641)
- Alternating pressure (AP) mattresses (c.£4k) vs. AP overlays (c. £1k)
- 11 centres, 1972 participants
- More costly mattress replacements more likely to be cost saving (delay to pressure ulceration and lower costs)

VenUS I

- Funded by NIHR HTA Programme (£378,388)
- 387 participants
- 4-layer vs. short stretch bandaging
- 4-layer more clinically and cost effective



VenUS IV

- Funded by NIHR HTA Programme (£976,422)
- A pragmatic randomised controlled trial comparing the clinical and cost-effectiveness of two-layer hosiery with the four layer bandage in terms of time to healing of venous leg ulcers
- Primary Outcome: Time to healing of the reference ulcer

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Results

Median time to healing:

Hosiery: 99 days (95% CI 84 to 126)
Four layer: 98 days (95% CI 85 to 112)

After adjustment for ulcer area, duration, and mobility with shared centre frailty

Hazard ratio:

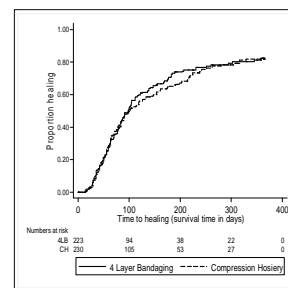
0.99 (95% CI 0.79 to 1.25; p=0.96)

Ulcer Recurrence:

Hosiery: 14.4% (24/167)
Four layer: 23.3% (41/176)

Time to recurrence:

Hazard ratio = 0.56 (95% CI: 0.33 to 0.94, p=0.026)



Conclusions

- **Two layer hosiery:**
 - as effective as the four layer bandage for healing venous leg ulcers
 - more cost effective, probably as a result of reducing the frequency of nurse consultations and enhancing self-management
 - was associated with a reduced risk of ulcer recurrence after healing

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Hodgson et al. *Trials* 2014, **15**:19
<http://www.trialsjournal.com/content/15/1/19>



RESEARCH

Open Access

Funding source and the quality of reports of chronic wounds trials: 2004 to 2011

Robert Hodgson¹, Richard Allen², Ellen Broderick¹, J Martin Bland¹, Jo C Dunville³, Rebecca Ashby¹, Sally Bell-Syer¹, Ruth Foxlee¹, Jill Hall¹, Karen Lamb¹, Mary Madden¹, Susan O'Meara⁴, Nikki Stubbs² and Nicky Cullum²

Quality of RCTs of Treatments for Complex Wounds

- 167 RCTs published 2004 – 2011 in English
 - 63 leg ulcers
 - 57 foot ulcers
 - 31 pressure ulcers
 - 16 mixed wounds
 - 42 wound dressings/topical agents
 - 33 drugs
 - 16 growth factors
 - 16 bandages/stockings
 - 11 tissue grafts
 - 23 miscellaneous

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Funding of Complex Wound Trials

- 35% reported as commercially funded (58/167)
- 33% not commercially funded (55/167)
- 26% (44/167) did not report funder or nature of funder unclear
- 6% (10/167) mix of commercial and non-commercial

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Study Conduct and Reporting Quality

- Median total sample size 60 or 28 per arm
- Median duration of follow up 12 weeks
- Only 59% reports identified a primary outcome
 - Of which 48% were intermediate measures of healing and 11% unrelated to healing
- 40% adequate random sequence generation (59% unclear)
- 25% adequate allocation concealment (74% unclear)
- 54% blinded outcome assessment

30% high/60% unclear/15% of bias

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Lockyer et al. *Trials* 2013, **14**:371
<http://www.trialsjournal.com/content/14/1/371>

 TRIALS

RESEARCH Open Access

"Spin" in wound care research: the reporting and interpretation of randomized controlled trials with statistically non-significant primary outcome results or unspecified primary outcomes

Suzanne Lockyer¹, Rob Hodgson¹, Jo C Dumville^{2*} and Nicky Cullum²

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"Spin" in Wound Care Research

- Authors' use of language and emphasis on results for particular outcomes potentially misleads readers (as per Boutron et al¹)
- May "result from ignorance... Unconscious bias, or wilful intent to deceive"
- Set out to determine the prevalence of spin in wound care studies with no statistically significant treatment effect AND the prevalence of wound care studies with no specified primary outcome
- Excluded Phase I trials and equivalence/non-inferiority/pilot trials and conference abstracts

¹JAMA 2010; 303:2058-2064.

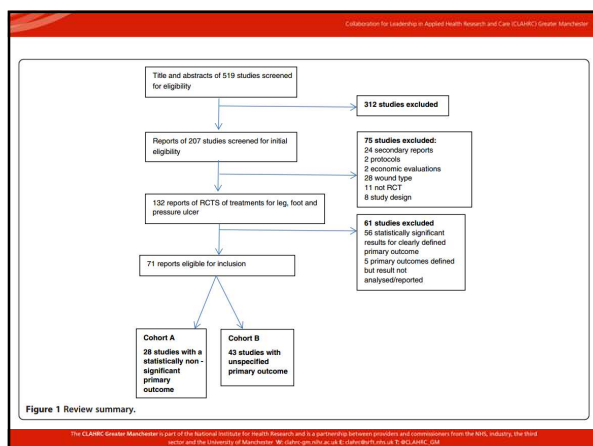
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Sample

- 71 eligible RCTs of interventions for leg, foot, pressure ulcers published 2004 to 2009
 - 28 had a clear primary outcome for which there was a statistically non-significant result (**Cohort A**)
 - 43/132 studies (33%) had no clear primary outcome specified (**Cohort B**)

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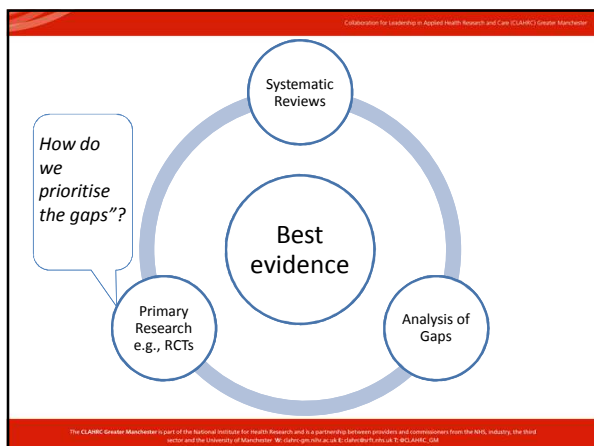


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Results

- 20/28 studies in Cohort A contained spin (71%)
- 63% of Cohort A abstracts contained spin (30% claimed effectiveness)
- 43/132 (33%) of reports did not specify the primary outcome (Cohort B) but reported a median of 9 outcomes and 86% claimed a favourable treatment effect in the abstract.

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James Lind Pressure Ulcer Priority Setting Partnership

- Collaboration with partners such as Spinal Injuries Association, MS Society
- Paper and electronic surveys
 - Nearly 1000 “raw” uncertainties in pressure ulcer prevention and treatment (patients, carers, clinicians)
 - Prioritisation survey collapsed these down (voting)
 - Final top 12 priorities released in May 2013

JLA Pressure Ulcer Priorities

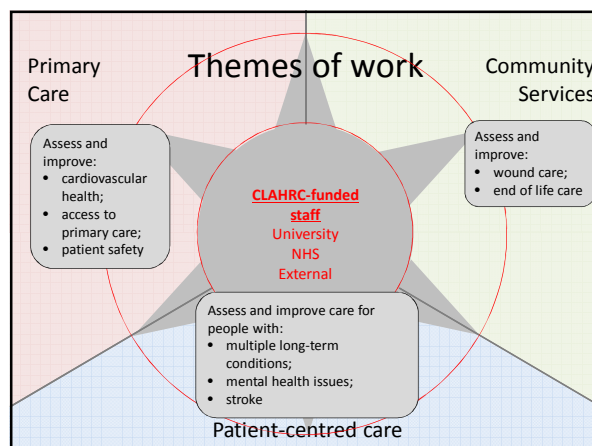
1. How effective is **repositioning** in the prevention of pressure ulcers?
2. How effective at preventing pressure ulcers is **involving patients, family and lay carers** in patient care?
3. Does the **education of health and social care staff** on prevention lead to a reduction in the incidence of pressure ulcers and, if so, which are the most effective education programmes (at organisational and health/social care level)?
4. What is the relative effectiveness of the different types of **pressure relieving beds, mattresses, overlays, heel protectors and cushions** (including cushions for electric and self-propelling wheelchairs) in preventing pressure ulcers?
5. What impact do different **service models** have on the incidence of pressure ulcers including staffing levels, continuity of care [an on-going relationship with same staff members] and the current organisation of nursing care in hospitals?

6. What are the best **service models** (and are they sufficiently accessible) to ensure that patients with pressure ulcers receive the best treatment outcomes (including whether getting people with pressure ulcers and their carers more involved in their own pressure ulcer management improves ulcer healing and if so, the most effective models of engagement)?
7. For wheelchair users sitting on a pressure ulcer, how effective is **bed rest** in promoting pressure ulcer healing?
8. How effective are **wound dressings** in the promotion of pressure ulcer healing?
9. Does **regular turning of patients in bed** promote healing of pressure ulcers?
10. Does **improving diet (eating) and hydration (drinking)** promote pressure ulcer healing?
10. How effective are **surgical operations** to close pressure ulcers?
12. How effective are topical **skin care** products and skin care regimes at preventing pressure ulcers?

CLAHRC GM vision and objectives

Create true and enduring partnerships that deliver high quality research, which improves health care and has impact in Greater Manchester and beyond

- Innovating through research
- Getting evidence into practice
- Showing the difference it makes
- Developing people and organisations



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CLAHRC-GM: Wound Care Objectives Years 1-2

Overall goal is to build a network for collaboration in wounds research and implementation

- Identify key stakeholders and map activity
- Identify and develop research areas/priorities for implementation
- Research project set up and conduct (including implementation projects)

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Reflections on Developing an Evidence Base in Wound Care

- Strategic approach to summarising evidence, prioritising primary research questions, updating evidence summaries
- Importance of identifying areas of clinical and patient need (NHS priorities) and asking the right research questions ... clearly!
- Collaboration with high quality methodologists essential (ideally leading edge); importance of methodological research
- Collaborations between researchers and clinicians essential to getting the questions and the impact right
- Importance of epidemiological approaches

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