

Wounds research for patient benefit: a 5-year programme of research

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Scientific summary

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Background

Complex wounds are those that heal by secondary intention, that is, they are open wounds that heal from the base upwards. Typically, complex wounds are a consequence of acute or long-term conditions including diabetes, vascular disease and neurological conditions. The most common types of complex wounds are ulcers of the lower limb and pressure ulcers. Community nurses deliver most of the care for people with complex wounds and there is no routine clinical data collection. The cost of delivering care for people with complex wounds has not been accurately estimated but will be high. Community prescribing costs alone for wound dressings were £184M in 2012; however, staff time and hospitalisation are the greatest cost elements. The high cost of wound care and large patient and family impact of complex wounds are served by a weak evidence base and low-quality research. The overall aim of the programme was to undertake research that would optimise the quality of care and outcomes for people with, or at risk of, complex wounds.

The objectives for each workstream were as follows:

- workstream 1 – undertake a high-quality point prevalence survey and care audit of people with complex wounds; pilot a prospective complex wounds register suitable for both health care and research to assess how high-quality data about complex wounds can be captured effectively for use in both service planning and research while ensuring integration with current clinical data collection systems and minimal impact on staff time and investigate whether or not a clinical register of people with complex wounds could give valid estimates of treatment effects, thus reducing dependence on large-scale randomised controlled trials (RCTs).
- workstream 2 – explore people’s experiences of complex wound care; identify which outcomes matter most to people with complex wounds, their carers and health-care professionals and compare these with those reported in wounds research; derive a prioritised list of research questions in the area of pressure ulcer prevention and treatment.
- workstream 3 – in collaboration with NHS colleagues, identify areas of high decision uncertainty and summarise the best available evidence in those areas using appropriate systematic review methods; evaluate the potential contributions of individual patient data meta-analysis and mixed treatment comparison meta-analysis.

Workstream 1

Objectives

Our objectives were to undertake a high-quality point prevalence survey and care audit of complex wounds and pilot a prospective complex wounds register suitable for both health care and research.

Methods

We undertook a systematic review of complex wounds prevalence studies and a point prevalence survey and audit of people receiving care for a complex wound in Leeds. We designed and piloted a new complex wounds register.

Results

There were no previous high-quality prevalence surveys that focused on people with all kinds of complex wounds and most previous studies were weak in terms of design and reporting. Our own prevalence survey in Leeds estimated the point prevalence of all complex wounds to be 1.47 per 1000 people [95% confidence interval (CI) 1.38 to 1.56 per 1000 people]. The point prevalence of complex wounds in former or current injecting drug users was 5.64 per 1000 people (95% CI 3.97 to 7.99 per 1000 people). Pressure ulcers and venous leg ulcers were the most common type of complex wound.

A total of 195 people with a complex wound were recruited to a complex wounds register pilot by the Leeds Community Wound Prevention and Management Service and community nurses (a 26% consent rate). We established the feasibility of correctly identifying, extracting and transferring routine NHS data into the register; however, participant recruitment, data collection and tracking individual wounds in people with multiple wounds were challenging. Staff feedback highlighted the need for further developments to facilitate routine data collection along with consideration of new information technology (IT) and devices. A possible method of electronic data collection, that is, smart pens, had severe limitations as a data collection tool in the context of community wound management.

Conclusions

A complex wounds register that serves both clinical care and research would be valuable. Such a register proved impossible to implement comprehensively. Challenges included an absence of existing electronic data collection tools, lack of routine clinical data collection in the community nursing service, limited IT infrastructure, a requirement for individual participant consent and the difficulty of accurately tracking multiple wounds on the same patient.

Workstream 2

Objectives

Our objectives were to explore the experiences of people with complex wounds, their carers and health professionals, identify which outcomes matter most to them, compare these with the outcomes reported in wounds research and derive a prioritised list of research questions in the area of pressure ulcer prevention and treatment.

Methods

We undertook semistructured interviews with people affected by complex wounds, carers and health professionals regarding their experiences of complex wound care and desirable treatment outcomes; a systematic review of the design and conduct of RCTs of complex wound treatments; and a consultative and deliberative research agenda setting involving patients, carers and clinicians in the area of pressure ulcer prevention and treatment.

Results

Most patients and health professionals viewed healing of the complex wound as the primary treatment goal. Patients were greatly troubled by the socially inhibiting consequences of their complex wound, but wound care services did not focus on the psychological or social impacts. The treatment model was geared to *healing*, not *'living with'* a long-term condition with potentially negative consequences. In total, 167 RCTs of complex wound treatments were analysed, of which 69 (41%) did not specify a primary outcome; only 40 (24%) had complete healing as the primary outcome, 47 (28%) used a surrogate measure of wound healing and 11 (7%) reported only outcomes unrelated to healing. A total of 960 treatment uncertainties were elicited and a top 12 list of research priorities was developed by patients, carers and health professionals.

Conclusions

There is a mismatch between the nature and quality of RCTs in complex wounds and the kind of research evidence desired by patients, carers and clinicians. It was possible to work with patients, carers and health professionals to identify and prioritise for research the uncertainties in pressure ulcer prevention and treatment. Community nursing management of people with complex wounds may be improved by adopting an approach aimed at helping patients live with a long-term condition.

Workstream 3

Objectives

Our objectives were to identify, in collaboration with NHS colleagues, areas of high decision uncertainty in complex wound management and summarise the best available evidence in those areas and to evaluate the potential contributions to decision-making of evidence synthesis using individual patient data and mixed-treatment comparisons.

Methods

Stakeholder consultation was carried out to identify decision uncertainties; a scoping review of the evidence for silver-containing wound dressings for treating venous leg ulcers was performed; Cochrane methods of systematic review were applied to 11 complex wound topics; and mixed-treatment comparison meta-analyses of dressings for diabetic foot ulcers and venous leg ulcers were carried out.

Results

Techniques involving facilitated face-to-face contact with health professionals performed best in generating clinical uncertainties as topics for evidence synthesis. Research-based information regarding the relative effectiveness of different wound dressings for different wound types had high priority. There was no evidence that silver dressings were more effective than non-antimicrobial dressings for healing venous ulcers; however, the limited availability of time-to-healing data in the existing trials hugely reduced the potential value of meta-analysis using individual patient data. A series of Cochrane reviews in prioritised topics identified several wound treatments that may be more effective than others in different wound types but the quality of the evidence was low and much uncertainty remains. The matrix hydrocolloid dressing was associated with the highest probability (70%) of being the best dressing for diabetic foot ulcers, whereas a hyaluronan fleece dressing had the highest probability (35%) of being the best dressing for venous ulcers; however, in both cases there was high uncertainty and the quality of the evidence was poor.

Conclusions

A range of approaches to evidence synthesis was applied to complex wound treatments across a broad range of topics that had been prioritised by health-care professionals. This approach identified some treatments associated with the highest probability of effectiveness.

Overall conclusions

We estimated a point prevalence of approximately 1.5 cases of complex wounds per 1000 population; 20% of these wounds were pressure ulcers, 28% were leg ulcers of various aetiologies and 14% were foot ulcers. Most people with complex wounds were aged > 70 years and they often had other conditions, incontinence and immobility. The planning and delivery of good-quality care for people with complex wounds is hampered by an absence of good research evidence in terms of both basic epidemiological data (e.g. prognostic information to facilitate realistic treatment goals and expectations) and evidence about which treatments are effective and for whom. Most complex wounds are the manifestation of underlying systemic disease; however, treatment is typically focused on trying to find the magic dressing that will heal the wound. There is much scope for considering (and evaluating) more psychological approaches to helping people *live with* their complex wound.

Most patients with complex wounds are managed in the community by nurses (patients received an average of two to three visits or consultations per week, each lasting nearly half an hour). Clinical practice, as measured in the prevalence survey, generally compared well with current evidence-based guidelines; areas for further implementation of best practice included hosiery and pentoxifylline for the treatment of venous leg ulcers. There was little routine collection of clinical data in the community nursing service and a lack of IT infrastructure. Current information systems are not geared towards supporting clinical decisions, communicating between clinicians or collection of data for research. Although it is possible to adapt and improve the collection of routine data to improve its suitability for clinical care and research, comprehensive implementation of a complex wounds register is not currently possible.

Clinical decision-making and commissioning are themselves not served well by the evidence base in wound care; our analysis of the quality of RCTs of complex wound treatments showed that 41% of trials did not specify a primary outcome and most had a very short duration of follow-up and were at high risk of bias (because of poor trial design and conduct) or the risk of bias was unclear (because of poor reporting).

The James Lind Alliance Pressure Ulcer Partnership (JLAPUP), involving extended consultation and collaboration with patients, carers and clinicians, yielded a diverse top 12 list of research priorities about pressure ulcer prevention and management. It was difficult to engage the population of people most affected by pressure ulcers in this process (the frail elderly with comorbidities).

In undertaking mixed-treatment comparison meta-analysis to identify the dressings for venous leg ulcers and diabetic foot ulcers that were most likely to be best for healing, we were struck by the importance of incorporating an assessment of the quality of the evidence in the process. We developed and implemented the iGRADE tool as a first attempt to do this. These evidence syntheses concluded that matrix hydrocolloid dressings had the highest probability (70%) of being the most effective dressing for diabetic foot ulcers, whereas a hyaluronan fleece dressing had the highest probability (35%) of being the most effective dressing for venous ulcers; however, in both cases the quality of the evidence was low and uncertainty was high.

Recommendations for future research

The JLAPUP prioritised a further 12 genuine uncertainties that can be taken forward by the research community. These were, in reducing order of priority:

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 the 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 ongoing relationship with the 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 or not 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?
11. How effective are surgical operations to close pressure ulcers?
12. How effective are topical skincare products and skincare regimens at preventing pressure ulcers?

Other research areas emerging from this work include (in no particular order):

- The importance of prognostic research for common types of complex wound (pressure ulcers, leg ulcers, foot ulcers, etc.). This research would begin with systematic reviews of the current evidence and then move to targeted primary research including prognostic modelling. Such research would inform patient and clinical expectations, shared decision-making and assessment of the cost-effectiveness of treatments as well as the planning of new RCTs. Such data could be collected within a complex wounds register that served both clinical practice and research although support for data collection would have to be properly costed.
- Mixed treatment comparison meta-analysis, using individual patient data when available, of trials of silver-containing dressings for venous ulcers to further explore if there is an incremental effect of silver on wound outcomes.
- The relative cost-effectiveness of negative pressure wound therapy compared with usual care for the treatment of foot wounds in people with diabetes.
- The relative cost-effectiveness of 0.5% chlorhexidine compared with povidone iodine in alcohol for preoperative skin antisepsis in clean surgery.
- The cost-effectiveness of ibuprofen-containing dressings for reducing pain in people with painful skin ulcers.
- The cost-effectiveness of different dressings for healing after toenail surgery.
- The cost-effectiveness of alternative postoperative strategies for managing pilonidal sinus.

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