Complexities of conducting dressing selection research for malodourous fungating wounds

Malignant fungating wounds are a complication of cancer and develop in patients with advanced onset of the disease, typically within 6–12 months before death (Alexander, 2009). They can present in one of three different ways: as primary skin neoplasms, as local extension and integumentary erosion from primary tumours or malignancy recurrence, or as metastatic cutaneous lesions (Alexander, 2009). Malignant fungating wounds can develop from any type of malignancy but are mainly associated with breast cancer (66%) and head and neck tumours (24%). They can also develop in the groin, genitals and back (3%) or other sites (8%) (Tilley et al, 2021).

Fania Pagnamenta
Clinical Academic Nurse Consultant (Tissue Viability); The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK/ Northumbria University, Newcastle upon Tyne, UK

Dr Victoria Michaels Lopez
Clinical Research and Scientific Communication Manager, CEMAG Care, Paris, France

Dr Clémence Desjardin
Director of Operations and Business Development, CEMAG Care, Paris, france

Professor Monique Lhussier
Northumbria University, Newcastle upon Tyne, UK

Key words
- Dressing selection
- Fungating wounds
- Malignant wounds
- Palliative wound care

Malignant fungating wounds are not expected to heal, therefore, treatment is centred on symptom control and improving quality of life. Malodour, bleeding, pain and exudate are all symptoms associated with these wounds and have a significant impact not only on patients and their families, but also on nurses and other healthcare professionals (Ousey and Roberts, 2016).

The intensity, discomfort and perception associated with malodour may be different from person to person. A malodorous ulcer can have negative social and psychological repercussions with shame and loss of self-esteem which may lead to isolation, depression or loss of appetite (Gethin et al, 2023). Malodour is a real concern to patients and their families, with research indicating that it is the most distressing and socially isolating wound-related symptom (Gethin et al, 2014). It also affects healthcare professional involved in their care (Alexander, 2009; Ousey and Roberts, 2016; Gethin et al, 2023).

Palliative wound care aims to alleviate symptoms and enhance overall wellbeing at the end of life. Patients with malodourous malignant fungating wounds should be offered appropriate wound care that may include dressings to alleviate malodour.

Challenges in wound care research

It is generally accepted that research on the effectiveness of dressings is limited for a number of reasons that have been documented in the literature (Pagnamenta, 2017; Welsh, 2017; World Union of Wound Healing Societies, 2020). Indeed, the challenges are multifactorial. Legally, in the UK dressings are listed as medical devices, thus limiting the need for evidence generation. From a methodological point of view, generating evidence using trial methodologies has proven challenging for a number of technical reasons. Randomised controlled trials (RCTs) are difficult to undertake for dressings used in wound care because of lack of funding, difficulties in study design, a narrow focus and limited inclusion criteria (Brouwers et al, 2016). Additionally, results are not generalisable to daily practice because a high proportion of patients have comorbidities that are typically excluded from trials, as they are considered to present confounding factors.

While highly desirable for the patient, measuring a healed wound as an outcome in dressing selection research does not reflect the requirement to use a variety of dressings during the healing continuum (Bull et al, 2022; Raepsaet et al, 2023) or, in the case of fungating malignant wounds, in which healing is unlikely to ever occur.

Within the field of palliative care, conducting research is met with additional challenges, related to ethical, emotional and methodological considerations (Higginson, 2016).

Ethical considerations

Risks and benefits have to be delicately balanced in this patient population, as by virtue of their prognosis, they are likely to experience significant physical and emotional distress. Indeed, obtaining informed consent from seriously ill patients can be complex, requiring clear and compassionate communication (Ecarnot et al, 2017). Palliative care patients may be particularly vulnerable and researchers must take steps to protect their rights and wellbeing. This includes considering factors such as cognitive impairment, language

Declaration

FP and ML have no affiliation with any organisation with a direct or indirect financial interest in the subject matter discussed in the manuscript.

VML, CD are employed by Cemag Care (Paris, France) who produce a cinnamon-based dressing used in the care of malodourous fungating wounds.

barriers and cultural differences. DeCamp et al (2022) identified further ethical challenges in this context, such as facilitating the participation of patients with serious illness and recommending working with patients and carers to identify the best setting for the research to take place (i.e. patient's home or virtually; ensuring they can park at the facility and so forth). Researchers may be required to respond to difficult questions surrounding death, illness and the progression of disease. DeCamp et al (2022) also recommend that the patient be engaged in the research process before they become too sick. Research burdens must be minimised, for example, by reducing the number of interviews or questions asked without losing the depth and breadth of the data collected.

Researchers must avoid paternalistic attitudes while also questioning potential gatekeeping from well-meaning relatives and/or healthcare professionals. Participants need to be recruited sensitively and unobtrusively. They have to be approached skilfully at the right time, which can be difficult within stretched health care settings. Finally, relatives/care givers might at times have conflicting opinions with the patient and it is, therefore, important to make time to have open conversations with all parties during these highly emotional times.

Emotional labour

Emotional labour in research refers to the effort a researcher exerts to manage their own emotions while engaging with participants. This can involve controlling or suppressing emotions, expressing desired emotions or simply experiencing the emotional strain of being exposed to sensitive or traumatic information (Alias, 2022). Emotional labour can be a source of stress and can lead to burnout particularly when researchers are exposed to high levels of emotional intensity or have to consistently suppress their own feelings (Rogers-Shaw et al, 2021). Emotional labour in palliative and end-of-life care is driven by a desire to put the patient's needs first (Brighton et al, 2018). Malignant fungating wounds can be significantly distressing for nurses to dress, not only because of their malodour but also due to their visual appearance (Ousey and Roberts, 2016). Nurses are not always able to recognise and acknowledge feelings of disgust or to mitigate them at every patient contact, resulting in further emotional labour. Researchers may not be familiar with the realities of malignant fungating wounds and the strong feelings that such sights and malodour can engender.

Methodological challenges

Research that is considered to provide the highest quality of evidence requires large sample sizes of wounds that are homogenous in presentation to minimise confounding factors and maximise statistical significance (WUWHS, 2020). Studies focussing on symptom control and quality of life, rather than cure, in malignant fungating wounds are needed to provide evidence for practice but are currently under-researched. One of the reasons for this is the small population size available, as only 5–14% of advanced cancer patients may present with such wounds (Vardhan et al, 2019).

Measuring outcomes in palliative care can be challenging due to the multifaceted nature of patient needs, the fact that their symptoms and cognition can be variable and the rapid progression of disease. As the endpoint is unlikely to be healing, patient-reported outcomes are crucial for understanding their perspective on their health and the impact of treatment (Klassen et al, 2021).

In dressing selection research, these challenges are amplified for the methodological reasons explained above, as well as when working with industry partners that might have an innovative product but a small budget for research, as our experience demonstrates below.

Our experience

When a new cinnamon-containing dressing indicated for malodourous wounds came to market, we endeavoured to conduct research rather than a simple evaluation based on a few case studies. The local research office suggested that a commercial study was the best way forward so that the full cost of the research would be absorbed by industry. The NHS charges industry sponsors a fee to cover the costs of conducting a research study that has commercial value to ensure that the NHS is fully reimbursed for the resources it provides for the study (The Association of the British Pharmaceutical Industry, 2024). The NHS may also set a margin on top of the full cost, which can be used to support other research activities, develop new initiatives or improve existing services (National Institute for Health and Care Research, 2021). Our study aimed to undertake an observational study on 30 patients, recruited over a 12-month period in the Northeast of England with fungating malignant wounds. The aim of the study was to seek patients' and staff opinions on the ability of the dressing to control malodour.

The NIHR (2021) suggests that the ability to generate income from commercial research can provide incentives for NHS staff and departments to get involved in research. For clarity to those who are not research-active,

the process to set up a study is complex and time-consuming. A number of documents had to be prepared before submission to NHS Ethics. All procedures were performed in compliance with relevant laws and institutional guidelines, and that the work was approved by the Health Research Authority – Cambridge East REC. (REC reference 22/EE/0210; IRAS project id 316042). Once ethics approval had been granted, the study had to be established within a specific research delivery department, involving another round of bureaucracy. From the inception of the study idea to being ready to start, the process took over 22 months.

Once the study was finally ready to start, it became very clear that the research delivery team (registered nurses) had limited wound care experience and found it very difficult to cope with the severity of the fungating wounds. Most of their clinical experience within research involved administering trial cytotoxic drugs. Despite a huge effort to communicate the study details to as many healthcare professionals as possible, recruitment was slow to start. Having recruited three patients over a period of four months, the funder took the difficult decision to terminate the study as it was unlikely that we were going to recruit sufficient patients to provide credibility to the findings. These three patients, who all died within 2 months of taking part in the study, offered valuable insight and their efforts were not futile; they resulted in a case-cohort study presented at an international conference (Pagnamenta et al, 2024). The findings added to a body of knowledge but did not provide commercial value to the company that set out to provide robust evidence for their innovative product.

From an NHS point of view, the intensity of the process did not make the income worthwhile. Furthermore, the costs can be prohibitive for a small company.

Most dressing selection research does not conform to the traditional pathway to develop evidence, especially where small numbers of patients with significant comorbidities develop wounds that are unlikely to ever heal.

Using pragmatic methodology

Addressing the challenges of dressing selection research requires a paradigm shift. Traditional evidence-based practice models, heavily reliant on RCTs (considered the gold standard), must evolve to accommodate the nuances of palliative contexts. Pragmatic studies should be designed to mirror everyday clinical practice and should combine qualitative data collection techniques (e.g. interviews, focus groups) with quantitative data (e.g. short questionnaires such as Quality of Life measures). By integrating mixed methods and focussing on meaningful, patient-centred outcomes, research studies can generate actionable evidence without compromising ethical or practical considerations. The administrative process to set up a study must be curtailed and simplified, with pre- and post-award teams, finance and research delivery teams working seamlessly and in a more timely way.

Evidence acceptance

Pragmatic studies will generate a different type of evidence. The findings of these studies are most likely to be based on small numbers of patients. If rigour and trustworthiness are applied to the process and the process is described clearly, the findings of such studies should be accepted by healthcare professionals and by healthcare authorities not just in the UK but also in countries where healthcare is based on reimbursement (i.e. France) and be triangulated with their experience and expertise. The focus for these studies should be on patient-centred outcomes such as comfort, dignity and symptom management. Qualitative feedback from patients, caregivers and clinicians should be incorporated into the findings and given equal value.

Effective communication and collaboration between researchers, clinicians and patients are essential to conduct meaningful research in this field. By understanding the complex interplay of physical, psychological and social factors, researchers can develop evidence-based interventions to optimise palliative wound care and improve patient outcomes.

Our next move

Having regrouped from the limited success of the commercial study, we embarked on a new revised research project, aiming to recruit 10 patients over a 12-month period. The study is of a mixed-method design and data will be collected by a Tissue Viability Nurse, new to research delivery, but very experienced in looking after malignant fungating wounds. We successfully gained a modest grant from NIHR Research Capacity Funding to pay for her time. The same dressing will be used but without industry support. The dressings are listed on the local Wound Formulary and, therefore, will be purchased as per standard care.

Conclusion

Undertaking research can be complex and time-consuming especially for staff who have clinical commitments but who are determined to develop robust evidence for their practice.

Research in dressing selection is even more challenging. Within the field of palliative and end-of-life care it is often unfeasible to ask patients to participate in long and in-depth interviews as they often do not have the cognitive ability to concentrate for any length of time. In this field small pragmatic studies can deliver actionable evidence. The process to set up such studies needs to be simplified to encourage clinicians to undertake research without sponsorship from industry.

References

Alexander S (2009) Malignant fungating wounds: managing malodour and exudate. *J Wound Care* 18(9): 374-382

Alias R (2022) *Emotional labour and stress. In*: *Handbook of Research on the Complexities and Strategies of Occupational Stress* pp184-199

Association of British Pharmaceutical Industry (2024) *The Value of Industry Clinical Trials to the UK*. London: The Association of the British Pharmaceutical Industry

Brighton LJ, Selman LE, Bristowe K et al (2019) Emotional labour in palliative and end-of-life care communication: A qualitative study with generalist palliative care providers. *Patient Educ Couns* 102(3): 494-502

Brouwers MC, Kerkvliet K and Spithoff K (2016) The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ* 352: i1152

Bull RH, Staines KL, Collarte AJ et al (2022) Measuring progress to healing: A challenge and an opportunity. *Int Wound J* 19(4): 734-40

DeCamp M, Alasmar A, Fischer S et al (2022) Meeting ethical challenges with authenticity when engaging patients and families in end-of-life and palliative care research: a qualitative study. *BMC Palliat Care* 21(1): 74

Ecarnot F, Quenot JP, Besch Get al (2017) Ethical challenges involved in obtaining consent for research from patients hospitalized in the intensive care unit. *Ann Transl Med* 5(Suppl 4): S41

Gethin G, Vellinga A, McIntosh C et al (2023)Systematic review of topical interventions for the management of odour in patients with chronic or malignant fungating wounds. *J Tissue Viability* 32(1): 151-7

Higginson IJ (2016) Research challenges in palliative and end of life care. *BMJ Support Palliat Care* 6(1): 2-4

Klassen AF, van Haren ELWG, van Alphen TC et al (2021) International study to develop the WOUND-Q patient-reported outcome measure for all types of chronic wounds. *Int Wound J* 18(4): 487-509

National Institute for Health Research (2021) *Income distribution from NIHR RDN Industry Portfolio Studies*. Available at: https://www.nihr.ac.uk/income-distribution-nihr-rdn-industry-portfolio-studies (accessed 10.09.2025)

Ousey K, Roberts D (2016)Exploring nurses' and patients' feelings of disgust associated with malodorous wounds: a rapid review. *J Wound Care* 25(8): 438-42

Pagnamenta F (2017) Evidence generation for wound care dressing selection: reviewing the issues. J Wound Care26(9): 545-550

Pagnamenta F, Jones S, Tait K et al (2024) Measuring the impact of a cinnamon-based dressing in malodorous malignant fungating wounds: a case series. [Poster] EWMA, 1-3 May, London

Raepsaet C, Alves P, Cullen B et al (2023) The development of a core outcome set for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds. *J Tissue Viability* 32(3): 430-6

Rogers-Shaw C, Choi J, Carr-Chellman D (2021) Understanding and Managing the Emotional Labor of Qualitative Research. *Qualitative Social Research* 22(3)

Tilley CP, Fu MR, Qiu JM et al (2021) The microbiome and metabolome of malignant fungating wounds: a systematic review of the literature from 1995 to 2020. *J Wound Ostomy Continence Nurs* 48(2): 124-135

Vardhan M, Flaminio Z, Sapru S et al (2019) The Microbiome, Malignant Fungating Wounds, and Palliative Care. *Front Cell Infect Microbiol* 9: 373

Welsh L (2018) Wound care evidence, knowledge and education amongst nurses: a semi-systematic literature review. *Int Wound J* 15(1): 53-61

World Union of Wound Healing Societies (2020) *Evidence in Wound Care*. London: Wounds International. Available at: https://woundsinternational.com/wp-content/uploads/2023/02/a882ee7838966645a4840208171f256e.pdf (accessed 10.09.2025)