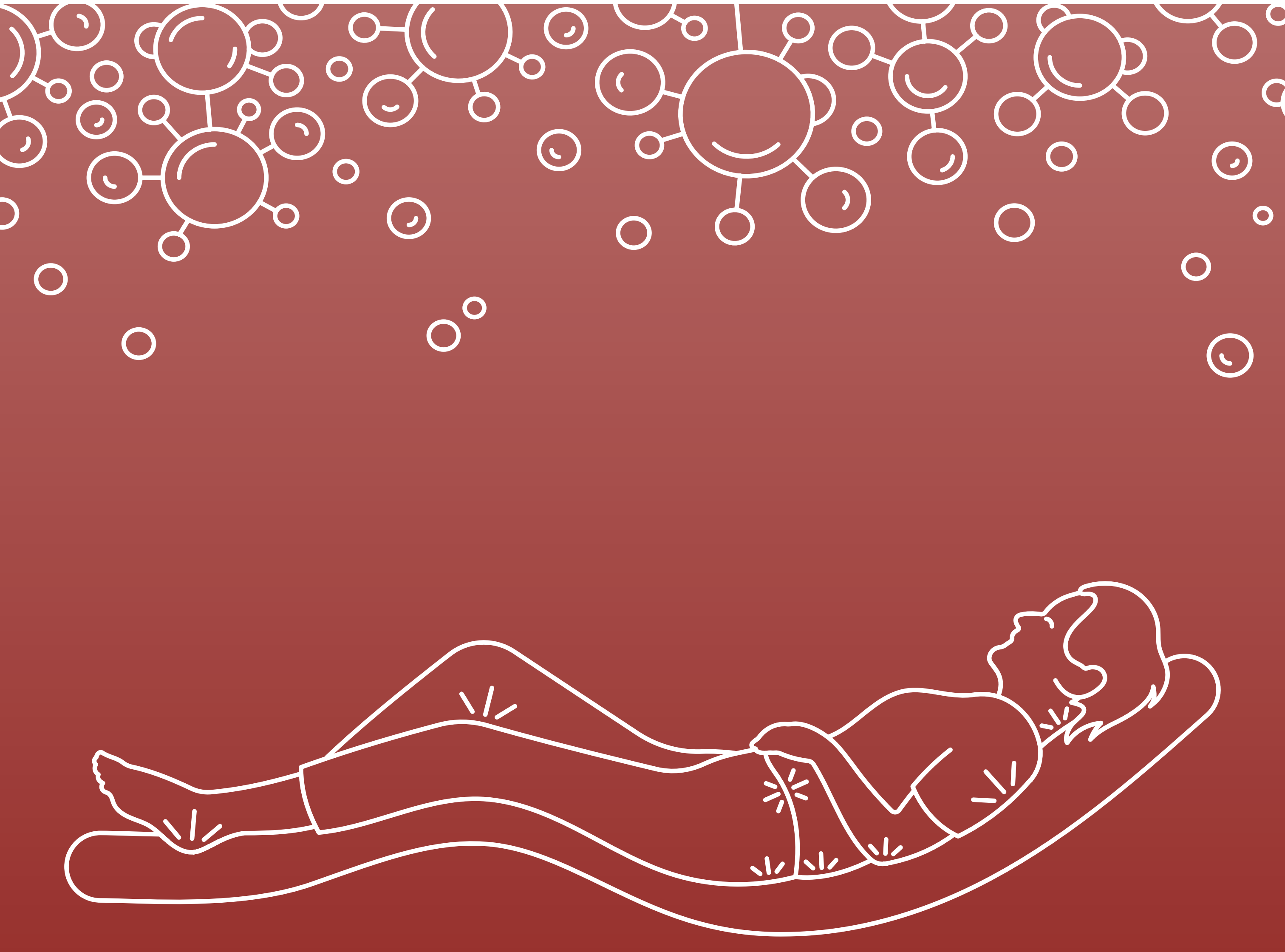
JWC International Consensus Document



CELLULAR, ACELLULAR AND MATRIX-LIKE PRODUCTS (CAMPS) IN PRESSURE INJURIES

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CELLULAR, ACELLULAR AND MATRIX-LIKE PRODUCTS (CAMPS) IN PRESSURE INJURIES

Executive summary

- The high prevalence and recurrence of pressure injuries (PIs) require new treatment strategies.
- The goals of PI treatment and research should be holistic, encompassing quality of life, symptom control, patient-directed goals of care and survival, as well as cure.
- Cellular, acellular and matrix-like products (CAMPs) are advanced wound-care tools that promote innate healing processes, such as stimulating fibroblast activity, granulation tissue formation and keratinocyte migration.
- CAMPs have been shown to be safe and effective in full-thickness PIs and other hard-to-heal wounds.
- Indications for CAMPs should include early application in complex wounds, multiple comorbidities or impaired healing capacity, with or without exposed deep structures.
- Patient selection should consider absolute and relative contraindications for CAMPs, as well as differential diagnoses for PIs, such as skin failure and malignant or atypical wounds.
- Patients treated with CAMPs require optimisation of offloading, mobility and tissue perfusion, along with addressing nicotine use and polypharmacy, as well as skin protection, nutrition and psychosocial support.
- Application of CAMPs must be preceded by wound-bed preparation encompassing tissue debridement, inflammation/infection control, moisture management and optimisation of patient and social factors.
- CAMPs should be applied in a clean environment following instructions for use, potentially supported by negative pressure wound therapy.
- Use of CAMPs requires ongoing documentation and re-assessment of treatment efficacy and quality of life, with onward referral for osteomyelitis, fistulas or other arterial disease.
- CAMPs use should be based in multidisciplinary collaboration and supported by patient and professional education.
- The appropriate use of CAMPs in PIs should be applied across all payors and relevant sites of service.
- Research on CAMPs in PIs should make wider use of real-world data to support the limited number and narrow scope of randomised control trials.

Wounds can be an indicator of general health, and pressure injuries (PIs) are often associated with wider underlying systemic problems, such as immobility, malnutrition and vascular disease. People with PIs are often debilitated and medically fragile, facing diminished mobility and frequent or prolonged hospitalisation. Moreover, care may be complicated by social marginalisation, inadequate caregiver support and dependence on health systems that are ill equipped to address patients' layered needs.[1–3]

Like wounds of all aetiologies, PIs do not exist in isolation, and patients require more than just specialist wound treatment to support healing. Technical skills such as debridement must be part of a comprehensive, holistic and compassionate approach to care of the whole person that engages with their lived experiences, upholds their dignity and can unravel the web of physiological and psychosocial factors contributing to the wound. As no one specialty receives training broad enough to address all these complex multifaceted needs, the management of PIs requires a multidisciplinary approach. This may integrate the coordinated efforts, shared knowledge and diverse clinical expertise of physicians, surgeons and advanced practice providers, as well as nurses, dietitians, social workers, clinical psychologists and physical and occupational therapists. As a result, the care of patients with PIs should be collaborative, consistent and guided by proactive treatment plans. However, in the authors' experience, care is often fragmented or compartmentalised.

PIs are initiated by pressure, so initial management focuses on offloading. If this is not implemented immediately, the wound can become hard-to-heal, often necessitating the use of a cellular, acellular or matrix-like product (CAMP) for stimulation of metabolic processes and protective covering. Much of the literature on the use of CAMPs on hard-to-heal wounds focuses on their use for lower-extremity diabetic ulcers (LEDUs) and venous leg ulcers (VLUs) and therefore does not account for the distinct complexities of other hard-to-heal wounds, including PIs.[4] Despite limited high-level evidence, clinical experience supports the potential for CAMPs to accelerate healing and save costs in full-thickness PIs.

This international consensus document presents clinical best-practice recommendations for the use of CAMPs in adults with full-thickness PIs. The document presents the outcomes of a multidisciplinary expert panel discussion on this topic held in Florida, US, in March 2025. The panel comprised seven key opinion leaders representing disciplines including plastic surgery, internal medicine, advanced care provision, infectious disease, wound care nursing, physician assistance and physical therapy. Panel members were not compensated for participating.

The recommendations in this document are based on a critical appraisal of scientific and real-world clinical evidence where possible and supplemented with expert opinion when necessary. For the purposes of this consensus document, PIs are discussed in terms of tissue depth, such as partial- or full-thickness, rather than using traditional staging terminology. This decision reflects the variability in grading/staging systems and classification frameworks used in different countries, which can introduce inconsistency in clinical interpretation and management.[5,6] The scope of this document does not extend to palliative care, which rarely requires regenerative interventions such as CAMPs.

This document recommends the use of CAMPs within a collaborative multidisciplinary approach to care and as part of a care framework that is flexible enough for personalisation. The document is a call to action to unite practitioners of different disciplines working across the continuum of care to elevate the standard of PI care, reduce disparities and improve patient outcomes.

The case for CAMPs

Burden of pressure injuries

PIs are highly prevalent, representing a significant portion of hard-to-heal wounds managed by wound-care specialists. PIs have reached epidemic proportions globally, posing a clinical crisis to patient health and financially encumbering healthcare systems. Among hospitalised adults worldwide, the prevalence of PIs is approximately 12.8%, with an incidence rate of 5.4 per 10 000 hospital patient-days.[7] In the US alone, over 2.5 million individuals develop PIs each year,[8] with particularly alarming rates among older people. Recent US data from the National Pressure Injury Advisory Panel (NPIAP) reveal a staggering 20–30% incidence of PIs in skilled nursing facilities,[9] highlighting the disproportionate impact on patients discharged from acute care to post-care settings, such as home care, assisted living and nursing facilities. However, a systematic review and meta-analysis, whose exclusion criteria did not restrict by country, found the burden of PIs among older people in nursing homes was comparable to that for inpatients.[10] In terms of the health-economic burden, the annual cost of treating PIs in the US is estimated at $26.8 billion.[11] In Australia, the annual cost of PIs in public hospitals has been estimated at $9.11 billion.[12] In the UK, the NHS incurs roughly £3.8 million every day on the treatment of these injuries.[13] These overwhelming figures reflect the immense burden on national healthcare systems and the urgent need for systematic prevention and early intervention.

Consensus statement: Without robust and novel strategies to curb the development of PIs, healthcare systems worldwide will continue to bear escalating human and economic costs.

Patients who develop PIs have a 3.6-fold increase in mortality over age-matched peers,[14] associated with comorbidities and high-risk status. PIs with subcutaneous tissue involvement are linked to an approximate 50% increase in mortality,[15] and mortality in PIs involving deeper structures have been reported to be as high as 70% at 180 days, depending on the patient's comorbidities.[16]

Patients with PIs often have a long history of such injuries, being caught in a cycle of healing and recurrence. In the US, the relapse rate of PIs is highly variable, with reported recurrence rates ranging from around 7% to over 80%.[17–19] In many countries, the US especially, comprehensive infrastructure reform is needed to manage the influx of the ageing population and address the gaps in their care. To meet these needs, wound medicine and surgery providers in the US have started targeting PIs in untraditional and other previously often overlooked point-of-care settings, such as home and post-acute settings.

Holistic treatment objectives

Despite their association with serious comorbidities and high mortality rates, clinical management of full-thickness PIs is often narrowly focused on full wound closure. However, there is no currently available data demonstrating that healing or closing a PI influences mortality in this patient population. Therefore, care should instead aim to achieve a wider range of common treatment goals, embracing the broader implications of the patient's overall health and functional status and prioritising quality of life (QoL).

Care of hard-to-heal wounds should learn from the holistic approaches common to treatment goals in oncology, where therapeutic success is frequently measured in terms of survival, symptom control and QoL, rather than complete disease eradication. This holistic paradigm acknowledges the chronic and sometimes incurable nature of certain conditions, while still emphasising the need for proactive management and specialist care. This approach also embraces the frailty of these patients and recognises the overall condition of the host.

A comparable framework for hard-to-heal wounds would reframe metrics of treatment success from full epithelialisation alone to include pain reduction, infection prevention (including osteomyelitis) and extended survival, as well as improvement in ambulation and QoL (*Box 1*). Hard-to-heal wounds would no longer be seen solely as localised defects, but as a systemic and multifactorial condition that requires comprehensive, ongoing management akin to that of other complex chronic diseases. Holistic care goals would allow for more patient-centred care, and they would likely encourage consideration of advanced therapies such as hyperbaric oxygen, topical oxygen, cold plasma and CAMPs, as well as surgical referral and interdisciplinary collaboration.

Consensus statement: Treatment of hard-to-heal PIs should aim to decrease the impact of the wound on the individual patient's quality of life, rather than exclusively focusing on full wound healing.

Box 1. Holistic care goals for people with pressure injuries

- Better quality of life
- Coverage of deep or critical structures
- Decreased wound size (potentially as a bridge to surgery)
- Epithelialisation
- Extended survival
- Fewer hospitalisations
- Improved mobility and ambulation
- Infection prevention
- Minimal morbidity
- Pain reduction
- Reduced caretaker burden
- Full wound closure
- Prevention of osteomyelitis

CAMPs and the healing trajectory

Mitigating the epidemic of full-thickness PIs requires novel advanced wound-care strategies that harness the innate wound-healing process.

Wound healing depends on the human body's ability to progress in an orderly manner through the phases of wound healing: haemostasis, inflammation, proliferation and maturation. When wounds fail to progress through these phases despite standard-of-care wound management, they are considered hard to heal. Despite efforts to stimulate wound progression through proven methodologies, hard-to-heal wounds sometimes fail to improve and require advanced therapies, such as a CAMP, to reset the biological pathway into one that facilitates progression towards healing.

Wounds heal through connective tissue matrix deposition, contraction and epithelialisation. A delicate balance of cytokines, growth factors, hormones and proteases is essential to promote mitogenic activity, tissue regeneration and, therefore, wound healing. Unlike wounds progressing through the healing process in a timely fashion, hard-to-heal wounds typically become stalled in a persistent inflammatory state. This disruption of normal healing progression can be driven by one or multiple factors that prevent appropriate cellular signalling and tissue regeneration (*Box 2*).[20–22]

CAMPs function by mimicking or replacing damaged extracellular matrix components, offering structural scaffolding and barrier protection that supports cellular adhesion, migration and proliferation. In addition, CAMPs

Box 2. Factors that can disrupt wound healing[21,22]

- Degraded extracellular matrix
- Elevated levels of proteases such as matrix metalloproteinases
- Excessive pro-inflammatory cytokines (e.g., TNF-α, interleukin-1β, interleukin-6)
- Excessive reactive oxygen species
- Impaired macrophage transition (M1 to M2)
- Poor fibroblasts response to platelet-derived growth factor and transforming growth factor-beta

contribute to angiogenesis, re-epithelialisation and immune modulation, all hallmarks of effective wound healing. Many CAMPs provide a reservoir of bioactive molecules, such as vascular endothelial growth factor, platelet-derived growth factor and transforming growth factor-beta, which are integral to stimulating fibroblast activity, granulation tissue formation and keratinocyte migration.[23,24] These growth factors are often deficient in hard-to-heal wounds, and their reintroduction through CAMPs has been shown to reactivate stalled cellular responses, thereby transitioning the wound back into a regenerative trajectory. Furthermore, most CAMPs act as a temporary biologic cover that protects the wound from environmental insults while actively reducing local inflammation and rebalancing proteolytic activity.[24] This dual role, as both a passive barrier and an active biological modulator, enables CAMPs to shift the wound from a hard-to-heal to an acute-like healing state, allowing for the restoration of normal tissue structure and function.[25]

Consensus statement: CAMPs are considered one of the most effective solutions for achieving favourable outcomes in patients with PI who have not responded to standard of care. They also present an opportunity to avoid surgery, which is often a key treatment goal in this high-risk population.

Moreover, CAMPs have demonstrated a favourable safety profile in a large randomised controlled trial and other clinical studies across diverse patient populations, in PIs[26] and other comparable wounds.[27–31] These findings are consistent with broader systematic reviews and retrospective analyses that highlight the overall safety and biocompatibility of CAMPs in the management of non-PI hard-to-heal wounds.[32–38]

Consensus statement: CAMPs have the potential to disrupt the trajectory of hard-to-heal wounds, and to withhold this modality would be unjustifiable.

Patient selection

Consensus statement: The use of CAMPs is justified in selected patients with full-thickness PIs, where they can act as a protective covering, reset the normal wound healing trajectory and accelerate the natural process of wound closure, with minimal risk to the patient.

CAMPs can be considered in patients with full-thickness PIs that have failed to respond to standard of care after comorbidities and other risk factors have been addressed. Use of CAMPs should be strategically integrated into individualised treatment plans, following standardised clinical protocols as part of a bundle approach. This should be supplemented with audit and feedback systems.

Differential diagnoses

Effective use of CAMPs requires accurate diagnosis and patient selection. The wound's aetiology should be confirmed with a thorough assessment (*Figure 1*), alongside an evaluation of the pressure-support surfaces provided.

A thorough clinical evaluation, including history and examination, is required to differentiate PIs from other disease states. Care must be taken to avoid misdiagnoses of malignant and atypical wounds that may mimic PIs. Likewise, hard-to-heal ulceration should be distinguished from skin failure, as this is a key indicator of impending death, and the use of CAMPs is not warranted at the end of life.[39] In the absence of a definitive confirmatory test, skin failure is typically diagnosed by exclusion, and the patient's history must be checked for a hypoperfusion event, COVID-19 infection or transition to end-of-life care.

Similarly, the patient work-up must be thorough enough to identify other underlying aetiologies that could contribute to the failure of CAMPs, such as osteomyelitis. Diagnosis of osteomyelitis can be supported by palpation of bone in sinus tracts and confirmatory testing, often in the form of magnetic resonance imaging. Definitive diagnosis and targeted treatment decisions should be made following tissue biopsy, as well as culture and sensitivity when possible. Those with osteomyelitis should be promptly diagnosed and treated. Referral to infectious disease and/or plastic surgery is often beneficial.

Contraindications

Consensus statement: Safe and effective use of CAMPs must be preceded by a thorough assessment of both absolute and relative contraindications, underscoring the importance of comprehensive patient evaluation, interdisciplinary collaboration and shared decision making in determining the suitability of CAMPs for managing hard-to-heal wounds.

Absolute contraindications represent conditions under which the use of CAMPs is strictly inadvisable due to the high risk of adverse outcomes or treatment failure (*Box 3*). For example, cellular therapies may be futile in the presence of active malignancy at the wound site. Likewise, CAMPs should not be applied in cases of active, ongoing or inadequately treated infections. They also should not be used in PIs where the wound margins have not been clearly established and fully demarcated, such as evolving deep-tissue injuries. Untreated osteomyelitis is contraindicated, and deep-seated bone infections require definitive surgical and antimicrobial management before advanced therapies can be considered. Any necrotic or other non-viable tissue must be completely debrided before CAMP application, as necrosis impairs graft integration and may harbour infection. Use of CAMPs is contraindicated in patients who are moribund or at the end of life, as regenerative therapies are not aligned with the goals of comfort-focused, palliative care. Lastly, known allergies or hypersensitivity to any component of the CAMP, such as bovine, porcine or human-derived materials, present an absolute barrier to treatment. Application of CAMPs is not contraindicated by the use of systemic antibiotics, provided they are used as prophylaxis or as a treatment for other aetiologies (e.g., urinary tract infection), and the wound is not actively infected. In addition, CAMP application cannot work

Figure 1. Assessment of suspected pressure injuries

PRESENTATION

Patient and wound assessment

Medical history
- Comorbidities
- Pharmacotherapy
- Smoking status

Wound examination
- Wound location
- Size (length, width and depth)
- Devitalised (sloughy or necrotic) tissue
- Exposed hardware or structures
- Exudate (quantity and consistency)
- Periwound skin (e.g., maceration, redness or swelling)
- Wound-related pain

Psychosocial factors
- Accessibility
- Adherence
- Competence

Immediate consideration
- Vascular status
- Need for surgery
- Nutrition
- Oxygenation

SUSPECTED AETIOLOGY

Aetiology-specific assessment

Diabetes
- Blood glucose
- Monofilament testing (neuropathy)
- Vascular assessment

Peripheral arterial disease
- Perfusion studies (e.g., ankle brachial index)
- Magnetic-resonance arteriogram
- Near-infrared spectroscopy

Pressure
- Exclusion of other diseases (e.g., malignancy or pyoderma gangrenosum)
- Offloading provision

Venous insufficiency
- Venous reflux
- Compression provision

DIAGNOSIS

Box 3. Absolute contraindications for CAMPs
- Active malignancy in the wound site
- Active, ongoing or untreated infection
- Moribund or actively dying patient
- Patient allergy/sensitivity to CAMPs components
- Non-demarcated wound margins
- Presence of any necrotic tissue
- Untreated osteomyelitis

Box 4. Relative contraindications for CAMPs
- Active chemotherapy or immunosuppression
- Compromised perfusion
- Cultural, religious, societal or personal objections
- Inability to offload
- Inability to maintain adequate cleanliness
- Patient non-adherence
- Social considerations concerning access to care

in patients with significant malnutrition, nor in wounds that cannot be kept free of outside contamination.

Some conditions are relative contraindications that do not necessarily preclude use of CAMPs but do present risks and require caution and consideration (*Box 4*). In lower-limb PIs, an ankle–brachial index (ABI) below 0.6 indicates the presence of moderate-to-severe peripheral artery disease, where CAMPs can be considered for limb salvage or as a last resort for treatment. The efficacy of CAMPs has not been studied in patients with an ABI <0.6, and at least one study shows decreased efficacy in patients with ABI <0.9 vs >0.9.[40] Patients receiving active chemotherapy or immunosuppressive therapies may exhibit delayed wound healing and an altered immune response, requiring individualised risk–benefit assessment before proceeding with treatment. Cultural, religious, societal or personal beliefs may influence patient acceptance of CAMPs, particularly those derived from human or animal tissues. Additionally, social determinants of health, including transportation barriers, caregiver support and limited access to follow-up care, can impact a patient's ability to receive and adhere to appropriate wound care protocols, thereby influencing treatment success.[39,41]

Indications

CAMPs should be considered in patients with full-thickness PIs that have not responded to standard of care. Emerging evidence supports early use of CAMPs to optimise outcomes in patients with complex wounds, multiple comorbidities or impaired healing capacity with or without exposed deep structures.[42,43] Early intervention with CAMPs can restore the disrupted molecular and cellular pathways necessary for orderly tissue regeneration in these patients. This can mitigate the risk of local and systemic infections, including osteomyelitis; prevent the downward spiral of wound deterioration; and accelerate the progression toward granulation tissue formation and wound closure.[27,43]

The biological properties of CAMPs, including their ability to promote granulation tissue formation and protect underlying structures, make them a viable alternative when surgery is not feasible or desired. This could include patients with PIs for whom general anaesthesia is contraindicated by comorbidities or poor functional status. The presence of chronic osteomyelitis is the caveat here. It is proposed early application of CAMPs could help prevent further wound deterioration and reduce the risk of osteomyelitis and systemic complications such as sepsis.[44]

Consensus statement: The indications for CAMPs should be re-evaluated and extended to include early application in patients with complex wounds, multiple comorbidities or impaired healing capacity, with or without exposed deep structures.

In selected cases, CAMPs may also be used preoperatively to reduce the size and complexity of full-thickness PIs prior to definitive surgical closure. Early application can stimulate robust granulation tissue formation and epithelial advancement, allowing for partial reduction of wound dimensions. This may, in turn, decrease the extent of flap coverage required, preserve donor tissue for potential future reconstructive procedures, and ultimately render the operation less invasive. Such a staged biologic–surgical approach can improve surgical outcomes and facilitate more conservative reconstruction while maintaining durable closure potential.

A potential new application for CAMPs is as an adjunctive to surgery in patients with complex PIs, where integration of CAMPs into multimodal surgical reconstruction plans can improve healing outcomes. This combined approach has synergistic benefits, with the regenerative capacity of CAMPs complementing surgical techniques to promote durable wound closure, reduce recurrence and enhance the overall trajectory of recovery. To date, there is mainly low-level evidence to support the use of CAMPs in surgical reconstruction of full-thickness PIs,[45,46] so more research is needed. However, the widespread use of CAMPs in soft-tissue reconstruction in acute surgical and traumatic wounds was the subject of a recent *Journal of Wound Care* consensus document.[47] Similarly, there is evidence to support the use of CAMPs on exposed tendon or bone in diabetic foot ulcers.[48,49] Surgical intervention is often necessary in PIs with exposed critical deep anatomical structures, such as bone, tendon, ligament or muscle, where surgical consultation is strongly advised to evaluate the need for flap reconstruction, resection or surgical debridement.[40]

Consensus statement: Surgical pathways should be in place for patients with complex PIs who are surgical candidates.

CAMP selection

Selection of a specific CAMP should be based on clinical judgement, with reference to treatment goals, wound characteristics and patient preferences (including cultural and religious perspectives). The selection process should include thorough pre-planning and review of the manufacturer's instructions for use, as specified with the product packaging. The results of current prospective trials may enhance future ability to make informed decisions in this area.

Patient optimisation

The trajectory of healing is determined by more than a wound's aetiology and stage of progression. There is substantial evidence that wound-healing mechanisms are fundamentally determined by local and systemic comorbidities, such as infection, compromised perfusion and unmanaged vascular disease.[23,50–52] Other concomitant modifiable factors that present a barrier to healing include malnutrition, polypharmacy and offloading noncompliance, as well as psychosocial and socioeconomic stressors. Whatever the wound type, addressing these factors should improve the potential for healing.

Patients with PIs typically present with multiple modifiable risk factors that have not been adequately or fully controlled. Therefore, holistic patient optimisation is foundational to PI care (*Box 5*). Strategies to address these concomitant factors are an essential prerequisite to use of CAMPs and other advanced therapies, which cannot correct the underlying pathophysiology alone. The biological reset facilitated by CAMPs must occur within an optimised systemic environment to realise its full therapeutic potential.

Consensus statement: Use of CAMPs must be preceded by holistic optimisation of modifiable patient factors that could present a barrier to healing.

Holistic patient optimisation is widely supported in the literature:

- A 2005 paper demonstrated how diabetes-associated metabolic derangements impair wound healing and how glycaemic control and treatment of infection/inflammation support healing progression.[53]

Box 5. Aspects of holistic patient optimisation

- Comorbidity management
- Encouragement of nicotine reduction or cessation
- Microclimate management
- Offloading and special considerations by location
- Optimisation of nutritional or hydration deficits
- Patient and caregiver education
- Promotion of patient ambulation and mobility
- Psychological support for adherence, as appropriate
- Reduction or elimination of medications that may delay wound healing
- Strategy for dealing with the socioeconomic burden facing patients and/or caregivers
- Urine and faecal management

- A comprehensive review described how wounds progress through healing phases, and how failure typically results from persistent hypoxia, bioburden, or chronic inflammation—all modifiable factors.[23]
- A specialised wound-healing centre concept demonstrates superior healing outcomes when wounds are managed in multidisciplinary environments that address comorbidities systematically.[54]
- International best practice guidelines on wound management in diabetic foot ulcers explicitly state that ulcers heal predictably when ischemia, infection and pressure are addressed.[55]

Offloading

Offloading is the gold standard treatment for PIs, as it addresses the primary aetiology (pressure) of these wounds. Offloading must be included in any PI treatment plan, as it is critical to healing. Hard-to-heal PIs typically do not resolve if it is not implemented, even with the use of advanced therapies. Selection of offloading devices and support surfaces should reflect the anatomical location of the wound (*Box 6*).[6,56–58] This includes using boots to offload the heel,[59] and low-air-loss or alternating pressure mattresses and air flotation technology to protect sacral or coccygeal PIs. If available, pressure mapping or near-infrared spectroscopy can help identify anatomical locations subject to pressure (*Figure 2*). To promote concordance, education should be provided to patients and caregivers on positioning, re-positioning and pressure-relieving manoeuvres, and as well as the need for regular monitoring when skin care is provided.

Box 6. Key considerations for tailoring offloading by location[6,56–58]

Trochanter
- Turning/repositioning in place, with adequate caregiver training
- Risk of sheer injuries from wheelchair or toilet seat
- Need for transfer boards

Sacral/coccygeal
- Turning/repositioning in place, with adequate caregiver training
- Need for appropriate pressure-support surface based on individual needs
- Moisture/microclimate management in place
- Urine/faecal management in place
- Head of bed <30 degrees if not contraindicated[57]
- Patients on enteral nutrition or ventilation may require additional considerations for proper safe positioning

Heels
- Potential for poor vascularity
- Mattress support surfaces may be insufficient for offloading
- Heels should be 'floated' whenever possible
- Appropriate redistribution along posterior calf is essential to prevent Achilles injury[6]
- Patients with contractures may require additional considerations for proper offloading[58]

Cartilage
- Need to ensure appropriate placement and size of medical devices (i.e., nasogastric tubes, oxygen tubing or positive-pressure breathing devices)[56]
- Need to pay special attention when patient is in prone position or ventilated

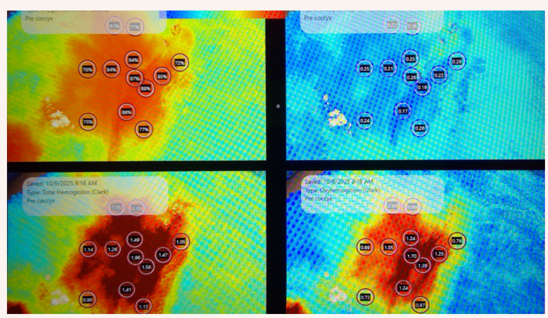
Ischium
- Turning/repositioning in place, with adequate caregiver training
- Risk of shear injuries from wheelchair or toilet seat
- Pressure-redistribution cushion in place on bed and seated surface
- Pressure-relief and offloading interventions in place

Mobility

It is essential to enhance patient mobility. Referral to physical therapy should be considered to promote ambulation and optimise functional independence. The therapist can recommend specialised equipment or treatment programs to address any underlying issues.

Figure 2. Near-infrared spectroscopy (NIRS) for assessing offloading

NIRS shows varying total haemoglobin values, indicating areas with higher or lower pressure.



Insufficient offloading on the coccyx
Tissue is inflamed and not adequately perfused due to pressure preventing perfusion and blood flow circulation. Perfusion is reduced well into the periwound space due to inadequate offloading.

Sufficient offloading on left ischial tuberosity
Inflammation is reduced after appropriate offloading, and perfusion is extended into the periwound space.

Wound Care Plus, LLC

NIRS can be used to provide objective confirmation of the effectiveness of patient repositioning, offloading and pressure redistribution in improving tissue perfusion by measuring oxygen saturation (StO2) before and after these interventions. The findings can be used to determine the optimal intervals between interventions and the most appropriate technique for an individual patient. It can identify the perfusion status in high-risk areas such as the sacrum and heels.[60]

Nicotine
Clinicians should encourage cessation or reduction of nicotine use, given its well-documented negative impact on wound healing.[61] Cigarettes disrupt oxygen delivery to the wound bed by various mechanisms including vasoconstriction, reduced angiogenesis and weakened collagen remodelling through carbon monoxide, nicotine and tar inhalation. However, other modalities, such as vaping[62] and nicotine transdermal-patch delivery systems, may also impede wound healing and need ongoing investigation. Therefore, vaping and use of e-cigarettes should be discouraged, along with traditional smoking.

Nutritional support
Nutritional support is often needed to stimulate wound healing. Therefore, it is vital to assess for elemental or vitamin deficiencies and protein-calorie malnutrition, and if required refer to a registered dietitian for identification of nutritional deficiencies and supplementation recommendations.

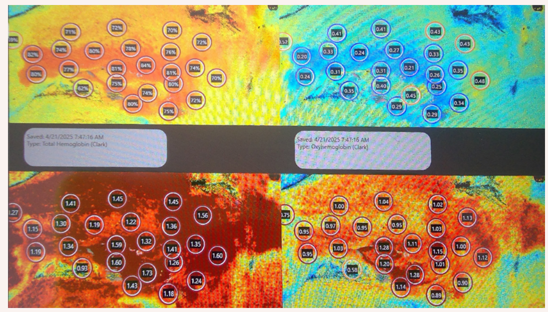
Polypharmacy
Medications may impede healing or contribute to adverse effects, especially when combined.[63,64] Ideally, medications should be managed by a pharmacist with a doctoral qualification. Vitamin A is frequently used to counteract the negative impact of corticosteroids on wound healing.[65]

Tissue perfusion
In PIs, tissue perfusion is primarily optimised through effective offloading. However, PIs may develop as a result of peripheral arterial disease, for example in lower limbs lacking three-vessel arterial flow.[66] Therefore, for lower limb ulcers, the patient's vascular status should be assessed with an ABI, supported by other diagnostic tests if ABIs may be falsely elevated, such as in Mönckeberg sclerosis and chronic calcification in diabetes.[67] If poor perfusion is suspected, further imaging, such as arterial duplex or computerised tomographic arteriograms, should be obtained to confirm the diagnosis. If a patient's vascular status is compromised, especially in the lower extremities prompt vascular referral is recommended for potential surgical intervention.

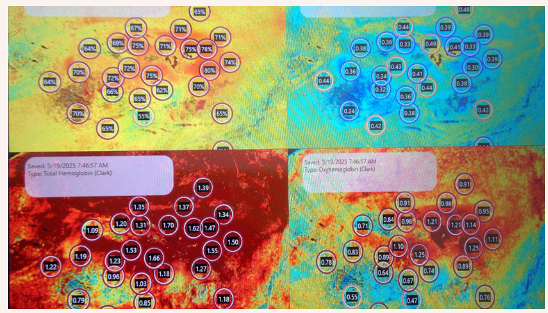
NIRS can be used in conjunction with a vascular occlusion test to assess microcirculatory function and autoregulatory reserve. This will help determine if underlying vascular issues are contributing to the pressure wound (*Figure 3*).[60]

Figure 3. Near-infrared spectroscopy (NIRS) for assessing perfusion

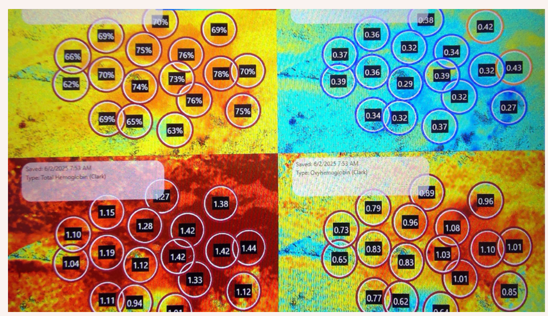
Sequence of NIRS images taken over time, showing change in oxygen saturation, deoxyhaemoglobin, total haemoglobin and oxyghaemoglobin values



Baseline



Day 28



Day 42

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Skin protection
Hard-to-heal PIs on the sacrum or coccyx can be associated with the risk of faecal or urinary soilage and contamination. Urinary and faecal management may involve moisture management or a more aggressive surgical plan, such as faecal or urinary diversion, to maintain a clean wound microenvironment.

Psychosocial support
A patient's ability to modify their behaviour plays an essential role in the healing process. Psychological support may be required to address any mental health challenges affecting the patient and enhance adherence to treatment. Regular follow-up, regardless of setting, will provide an opportunity for ongoing psychosocial support. Similarly, referral to speech therapy and occupational therapy can provide the additional support needed to optimise outcomes.

Strategies might be needed to address potential socioeconomic barriers facing patients and caregivers, such as financial constraints resulting in limited access to medical supplies and transport. CAMPs should not be considered until these elements are addressed.[6]

Wound bed preparation

In hard-to-heal wounds of all types, there are usually several modifiable factors local to the wound itself that can be optimised to facilitate healing. Wound bed preparation should be based on a thorough assessment of the wound bed, edges and periwound skin, and it should follow best-practice recommendations from the TIMERS framework.[68] The aim is to optimise moisture balance, disrupt biofilm and remove excess cytokines and proteases that help prolong the inflammatory state and delay healing.

> **Consensus statement:** Use of CAMPs must be preceded by thorough wound bed preparation to ensure readiness for application.

Tissue

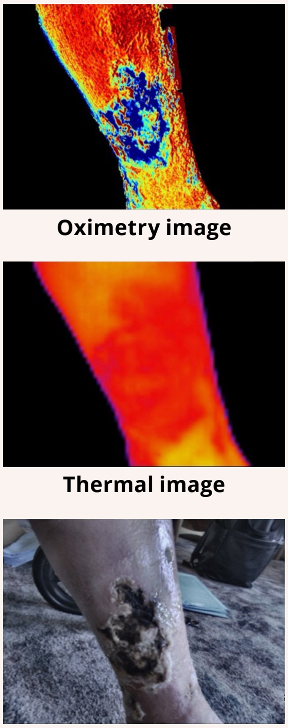
Tissue management involves removing devitalised tissue (slough and necrotic tissue) and biofilm via debridement. This can be achieved with sharp, surgical, mechanical, hydrosurgical, larval, ultrasound or laser CO_2 methods of debridement.[69]

Regular debridement plays a critical role in the management of hard-to-heal wounds by disrupting biofilm and removing devitalised tissue, cytokines and proteases. In this way, it modifies the wound microenvironment, effectively signalling the body to interpret the wound as being in the acute haemostasis phase.[68,69] To be effective, debridement must be ongoing, to maintain the wound in this 'acute' state. It also needs to be sufficiently aggressive, while also safe. To promote healing, less invasive methods of debridement, such as oxidative, autolytic, osmotic and enzymatic, can be used as an adjunct with more aggressive approaches, such as mechanical or sharp.[69] This approach has been termed integral debridement.

The effectiveness of debridement can be monitored with available technologies such as NIRS or singular biofluorescent devices (*Figure 4*). NIRS can also provide guidance on when it is safe to debride; for example, if low saturations are indicated via a blue hue (indicative of reduced or absent vascular supply) in the perimeter of the wound bed on the NIRS image, then debridement might not be advisable. It can also be used to determine when debridement is effective, as the image will reveal if the remaining tissue has adequate oxygenation.[60]

Figure 4. Imaging technologies for assessing debridement effectiveness

Oximetry and thermal imaging compared to a normal photograph of the same wound



Oximetry image

Thermal image

Visual light image

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Inflammation and infection

Debridement should be preceded and followed by wound cleansing of the wound bed and surrounding skin to reduce bioburden and disrupt biofilm. Cleansing is preferably performed with concentrated antimicrobial surfactants. Bioburden, inflammation and infection can also be controlled with bacterial-binding wound dressings, fluorescence biomodulation and cold plasma, as well as hyperbaric or topical oxygen therapy.

Moisture

A balanced moisture level in a wound creates an environment conducive to healing. Excess exudate can be corrected with negative pressure wound therapy (NPWT), compression if indicated and selection of appropriate absorbent dressings.

Maintaining an appropriate microclimate, characterised by optimal temperature and moisture balance, at the wound interface is essential for effective healing. A well-regulated microclimate supports cellular activity; minimises dehydration and maceration; reduces the risk of infection; and facilitates the removal of devitalised tissue. Achieving the right balance is critical, as excessive heat or moisture can contribute to skin breakdown and delayed healing, while insufficient moisture may impede the repair process. PIs are more likely to develop in areas prone to candidal overgrowth, such as the sacrum, when excess moisture is present, underscoring the need for careful management.[70] Along with individual patient characteristics, the properties of support surfaces and dressings will determine whether they enhance or hinder the microclimate.

Edge

Wound edges showing rolling, epibole or callus are linked to poor epithelial advancement. Interventions include refashioning[71] and excision of sclerosed margins and undermining, as well as cyanoacrylate periwound protectants, fluorescence biomodulation and wound fillers, such as collagen.

Repair

Even with optimal foundational care, some wounds remain stagnant and ultimately require a therapeutic reset. Wounds that fail to heal with conservative therapy may require advanced interventions to promote repair.[68] Regenerative interventions range from growth factors, platelet-rich plasma and NPWT to hyperbaric or topical oxygen therapy, cold plasma and CAMPs.[68]

Social and patient factors

Wound healing can be influenced by the patient education, understanding, beliefs and health literacy, as well as their social situation and systemic barriers. Interventions include education (and psychoeducation) for patients and their family and caregivers, as well as active listening and understanding of the patient's own goals. This should promote patient adherence, choice and engagement with the care plan.

Use of CAMPs

Application

CAMPs should only be applied in a controlled environment where a clean technique can be maintained. The frequency of CAMPs application will depend on the product used and the setting, as well as patient need. In the US, it will also have to comply with the requirements of local reimbursement policy, and each application and reapplication of a CAMP should independently meet medical necessity.

The application process generally involves securing the CAMP using an adhesive contact layer, which may be affixed with wound-closure strips, sutures or staples. This is followed by a bolstered secondary dressing, tailored to the wound's exudate and moisture levels. The specific CAMP's instructions for use should be checked for contraindicated wound dressings, which should be avoided.

Detailed guidance on product-specific handling, storage and administration protocols, as well as considerations of cost-effectiveness and formulary management, are beyond the scope of this document but have been comprehensively addressed in prior consensus statements on CAMP best practice.[24]

NPWT is increasingly used concomitantly with CAMPs to support granulation tissue formation, stabilise the graft and improve patient outcomes. NPWT is used in deeper wounds and/or exposed deeper structures, as well as in post-surgical wounds not being closed by primary intention and to integrate split-thickness skin grafts.[72,73]

Documentation

It is essential to accurately document the plan of care, all clinical practices (including dressings used) and patient adherence to offloading and other provider recommendations. This is essential not only for effective care coordination, but also for legal purposes, as well as for billing, coding and adherence to applicable payor coverage policies.

Ongoing re-assessment

Initiation of CAMPs must be followed by regular holistic re-assessment of the wound and patient to determine treatment effectiveness and overall quality of life. This should be conducted at least weekly, with more frequent evaluations as clinically indicated. If nutritional markers are a concern, these should be reassessed every 60–90 days.

Following adequate wound bed preparation and CAMPs application, signs of stagnation or deterioration should prompt a thorough re-evaluation of the wound environment and the patient's overall clinical condition. This should aim to identify and address any underlying patient- and wound-specific factors that might be compromising the outcome. When available, point-of-care imaging and other technologies can support clinical decision-making.[60,74,75]

In cases of recurrent pressure injuries, a biopsy may be necessary to exclude alternative aetiologies. Reassessment should also cover patient behaviours, especially their adherence and offloading. Reinforcement of patient education may be required. If the wound is stagnant, a step-down/step-up approach can be implemented, whereby a full reassessment is undertaken, the need for patient optimisation and wound bed preparation re-evaluated and the care pathway repeated (*Figure 5*).[68]

Onward referral

Failure to improve may be caused by an underlying comorbidity, such as osteomyelitis, fistulas, aortoiliac disease or arterial disease. Untreated gastro-cutaneous fistulas are associated with high morbidity and mortality, and so suspected fistulas should be assessed with a fistulogram for potential surgical intervention.[76] Aortoiliac disease affecting the pelvis can inhibit flow to ischial, sacral and coccygeal wounds.

Suspected or confirmed presence of osteomyelitis, sinus or fistula require prompt referral to general surgery, while major-vessel arterial disease warrants referral to vascular surgery.

Collaboration and education

Patient education

Key components of supportive multidisciplinary care include thorough patient and caregiver education to ensure understanding of the wound care plan and the importance of adherence. Consent must be obtained to detail risks and benefits of the application of CAMPs, and the level of patient understanding documented. Education must be provided on use of CAMPs, including application, post-application wound care and potential reactions.

Figure 5. Step-down/step-up wound-healing strategy based on early multimodal intervention

AROUND DAYS 1–4

Initiate multiple therapies in combination

- Aggressive debridement
- Empirical topical antiseptics and systemic antibiotics
- Management of underlying aetiology (offloading, compression, diabetes, nutrition)
- DNA identification of microorganisms and point-of-care diagnostics

AROUND DAYS 5–7

Optimise therapy according to healing status

- Assessment of inflammation and healing status
- Appropriate debridement
- Optimised topical antiseptics and systemic antibiotics
- Ongoing management of underlying aetiology

AROUND WEEKS 1–4

De-escalate treatment as wound improves

- Assessment of inflammation and healing status
- Maintenance debridement
- Re-evaluation of need for topical antiseptics and systemic antibiotics
- Ongoing management of underlying aetiology

UNTIL WOUND HEALS

Continue standard care, evaluate healing and consider advanced therapies

- Growth factors
- Cellular, acellular and tissue-based products (CAMPs)
- Surgical grafts and flaps
- Negative pressure wound therapy

Multidisciplinary collaboration

Given the complex interplay of factors in patients with full-thickness PIs, management requires a multidisciplinary approach. Effective delivery of integrated care requires mutual respect between healthcare professionals and a commitment to honour each patient's unique perspectives. The healing journey of full-thickness PIs is rarely linear and is often shaped by a complex interplay of medical, environmental and personal factors. To deliver patient-focused care and achieve a good outcome, the multidisciplinary team must be able to identify these factors and coordinate well to address them. To ensure effective communication, all multidisciplinary team members need to understand the fundamentals of good wound management and the medical literacy level of the patient and their caregivers.

Professional education

Wound care providers enter the field from a diverse experiential background, and standardisation of practices and knowledge base is crucial to deliver high-quality care. Therefore, education on wound management should be incorporated into the core training of all medical professionals involved in the care of people living with PIs. To promote appropriate use, those involved in the application of CAMPs should obtain relevant credentials. In the US, this could be certification from an accredited entity, such as the American Board of Wound Management, American Board of Wound Medicine and Surgery or American Board of Wound Healing, or a board certification in general or plastic surgery.

Consensus statement: Health professionals caring for people with PIs should receive credentialled training on wound care and use of CAMPs.

Case for reimbursement

Consensus statement: A uniform policy of reimbursement for the appropriate use of CAMPs in PIs should be applied across all payors and relevant sites of service.

The alarmingly high incidence and severity of full-thickness PIs, particularly in acute and post-acute settings, cause a significant health economic burden and are devastating for patients. CAMPs can play a key role in addressing this. However, in the US usage is currently limited by variations in reimbursement, restrictions on access in various point-of-care settings, a lack of experienced wound providers and financial barriers. Larger wounds (e.g., >25 cm^2) may also exceed the bundled payment limit in hospital-based wound clinics.

Meanwhile, outside the US, many CAMPs are not even accessible, restricting this valuable tool from many of those in need of more advanced and novel therapies.

In the US, billing and coding of CAMPs are complex, with regional and carrier-specific details that are often entangled. This process requires careful documentation that must be checked with plan-specific documentation, in addition to Local Coverage Determination guidance. Secondary or tertiary carriers often do not cover the additional costs of CAMPs. Healthcare providers are overwhelmed with excessive pre-authorisations and denials in obtaining these necessary therapies. To secure access to this essential treatment, providers must navigate numerous burdensome administrative and procedural barriers, such as the typical example given in *Box 7*. These requirements often involve complex documentation, multiple layers of prior authorisation and varying interpretations of coverage criteria, all of which contribute to delays in care and potential adverse outcomes for patients in need.[77] This raises important questions about the cost of failing to reimburse society. In the US alone, $26 billion is spent treating hard-to-heal PIs.[11] PIs are common among patients discharged from acute to long-term care, who suffer unnecessarily in situations beyond their control.[78] The US PI population has reached a level that presents significant challenges for the current healthcare system, highlighting the need for expanded capacity and improved resources. Building a robust infrastructure to address the influx of the aging population is imperative for reformation.

Box 7. Email exchange

Sample inquiry
Please advise: Could you please confirm coverage of [CAMP] in POS 32 and 12? I can verify coverage for POS 11 for NGS but not for 32 or 12. I was able to confirm coverage for 11 and 12 for CGS, First Coast, Novitas and WPS, but for some reason I can't locate for NGS. If it is not currently covered in POS 32 or 12, I would request that this product code be added to POS 32. Thank you for everything! I appreciate all you do!

Response 1
Hello, POS 12 and 32 are payable for biologic products. System updates are pending on these POS, so I would suggest holding claims for 10 days. Thanks.

Response 2
Thank you for your inquiry. XXX is currently set to allow in POS 32.

In the US, a key part of the solution to this epidemic may be a uniform national reimbursement policy, potentially via a National Coverage Determination (NCD) or other approach that ensures CAMPs availability for those who need them without undue delay or burden.[79] Outside the US, access to CAMPs is determined by local reimbursement systems and national policy. These payors should also consider expanding access and reimbursement for CAMPs for PIs.

Evidence

Despite the high prevalence of PIs, obtaining comprehensive and meaningful data remains a significant challenge. The development of standardised treatment guidelines is hindered by variations in clinical practices and access to advanced wound care providers, as well as concurrent ongoing comorbidities and uncontrollable environmental factors, such as transportation or geographical barriers.

To date, few prospective clinical trials have evaluated the utility of CAMPS in PIs. There are two randomised controlled trials (RCTs): one on full-thickness PIs only[26] and the other on stage 2 and stage 3 PIs,[80] both at or slightly below their study power target. They showed that the CAMPs were associated with accelerated healing. This is supported by a third RCT, which involved full-thickness PIs and compared CAMPs plus NPWT with NPWT alone.[81] A multicentre RCT is currently underway.[82]

Double-blinded RCTs provide valuable insights. However, RCTs not only remain limited in number, but they often do not adequately encompass the PI population by excluding typical patients with PIs due to comorbidities, which limits the relevance of the findings to real-world settings. Comparative studies with a control group may raise ethical dilemmas of withholding treatment options to a population already at high risk of morbidity. Additionally, most RCTs are costly and, therefore, usually sponsored by companies manufacturing or distributing CAMPs.

Real-world data can provide a more inclusive, practical and applicable foundation for supporting the use of CAMPs in PIs and other hard-to-heal wounds.[83,84] Real-world data is the evidence generated from real-world business and clinical processes, and generally not part of formal study a priori. Clinical practice often relies on inference from observed real-world data to guide decision making. Use of real-world data can provide timely evidence on chronically ill patients who do not always meet criteria for a larger RCT, which can help inform best practices and accelerate innovation to improve care quality and outcomes for patients in need.

Real-world data tends to have comparatively stronger external validity than RCTs, although RCTs have strong internal validity. However, the internal validity of real-world data can be increased with analytic methods including propensity score matching, inverse probability weighting, marginal structural modelling and G-computation. National registries could also play a crucial role in analysing real-world data on a large scale.

Real-world clinical experience and growing literature support the efficacy of CAMPs in a wide variety of hard-to-heal wound types, especially when used in conjunction with wound bed preparation and systemic optimisation. Insights from other hard-to-heal wounds are particularly relevant, as the underlying biology and mechanisms of wound healing are shared. With strong pathways on the mechanism of action of wound repair, real-world data affirms the role of CAMPs in re-establishing the core biological processes necessary for tissue repair.[85] Once comorbidities are managed, the body's innate healing response has the potential to initiate recovery across any wound type, regardless of the cause.

Consensus statement: Research on CAMPs in PIs should make greater use of real-world data, as well as widen outcomes to include QoL and survival rather than disease resolution alone.

Conclusion

PIs represent a profound and growing public health challenge across all care settings. This challenge extends beyond the confines of wound care to encompass systemic failures in healthcare infrastructure, resource allocation and equitable patient support. In countries such as the US, as the population ages and healthcare systems become increasingly strained, the burden of PIs will continue to escalate, demanding urgent innovation in prevention, diagnosis and treatment. The current standard of care, while essential, is insufficient for many patients with full-thickness, hard-to-heal PIs, particularly when healing is inhibited by underlying factors such as comorbidities, limited mobility and social determinants of health. In this context, the appropriate and timely application of CAMPs offers a promising solution, supported by both physiological rationale and growing real-world evidence.

Beyond the immediate clinical application of CAMPs, this consensus document underscores a necessary paradigm shift in hard-to-heal wound care, one that moves from symptom management to root-cause resolution. In particular, the treatment of pressure injuries must evolve beyond a narrow focus on local wound metrics to embrace a more comprehensive model that addresses the systemic drivers of wound chronicity. CAMPs are powerful reparative tools, but their success depends on correcting the physiological, psychosocial and structural impediments to healing. As wound healing is inherently a systemic process, the use of CAMPs must be embedded within a broader strategy aimed at restoring the body's natural regenerative potential.

This international consensus represents a critical step forward in standardising the use of CAMPs in the management of PIs. Through multidisciplinary collaboration, it distils expert knowledge, clinical best practices and evidence-informed strategies into a unified framework that can guide clinicians across various care settings. These guidelines reflect not only what is known, but also what must be strived toward. The aim is to offer a roadmap that encompasses the complexity of hard-to-heal wounds, demonstrating pathways to optimise the effectiveness of CAMPs and minimise risk for patients. These guidelines are intended to inform clinical decision making but should not be interpreted as definitive standards of care. They may evolve when the results of real-world and prospective RCTs currently in progress are published.

Crucially, this document challenges the traditional notion that complete wound closure must be the singular endpoint of treatment. Instead, it advocates for a broader, outcomes-driven philosophy that emphasises functional improvements, QoL and pain reduction, as well as prevention of complications such as osteomyelitis and sepsis. This reframing aligns PI care with the approach seen in oncology and other chronic disease models where cure is elusive and so survival, comfort and dignity take precedence. In the same vein, early application of CAMPs, even in the presence of exposed critical structures, should be viewed not as exceptional but as essential in select cases to reset the stalled wound environment and promote biological recovery.

The successful implementation of these practices depends not only on clinical expertise but also on systemic support. In the US, an NCD for appropriate and timely CAMP usage is urgently needed to eliminate reimbursement barriers, standardise access across care settings and payors and mitigate the growing economic and societal costs of hard-to-heal wounds. Without equitable access to advanced therapies, millions of patients will continue to experience preventable complications, prolonged hospitalisations and diminished QoL.

While RCTs remain the gold standard for generating evidence, they are often too narrow to capture the reality of PI care. The increased use of real-world evidence allows researchers to assess the effectiveness of CAMPs and other therapies in complex, comorbid populations typically excluded from trials. National registries and collaborative databases can provide the robust, inclusive evidence base needed to refine best practices, inform policy and accelerate innovation. Embracing the judicious use of CAMPs, advancing clinical education, removing systemic barriers and grounding decisions in real-world evidence all present opportunities to elevate the standard of care for highly vulnerable patients. Doing so reaffirms a shared commitment to healing not only wounds, but the systems that have long failed to support those who bear them. **JWC**

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