The Development and Content Validation of a Multidisciplinary, Evidence-based Wound Infection Prevention and Treatment Guideline

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Abstract

Acute and chronic wound infections create clinical, economic, and patient-centered challenges best met by multidisciplinary wound care teams providing consistent, valid, clinically relevant, safe, evidence-based management across settings. To develop an evidence-based wound infection guideline, PubMed, Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature databases were searched from inception through August 1, 2017 using the terms (or synonyms) wound infection and risk factor, significant, diagnosis, prevention, treatment, or surveillance. Studies on parasitic infections, in vitro studies, and non-English publications were excluded. The 19-member International Consolidated Wound Infection Guideline Task Force (ICWIG TF), hosted by the Association for the Advancement of Wound Care (AAWC), reviewed publications/assessed levels of evidence, developed recommendations, and verified representation of all major recommendations from 27 multidisciplinary wound infection documents. Using a web-based survey, practitioners were invited to assess the clinical relevance and strength of each recommendation using standardized scores. Survey responses from 42 practitioners, including registered nurses (RNs), Wound Care Certified and advanced practice RNs, physical therapists, physicians, podiatrists, and scientists from 6 countries were returned to AAWC staff, tabulated in a spreadsheet, and analyzed for content validity. Respondents had a median of >15 years of military or civilian practice and managed an average of 15.9 ± 23 patients with infected wounds per week. Recommendations supported by strong evidence and/or content validated as relevant by at least 75% of respondents gualified for guideline inclusion. Most (159, 88.8%) of the 179 ICWIG recommendations met these criteria and were summarized as a checklist to harmonize team wound infection management across specialties and settings. Most of the 20 recommendations found not to be valid were related to the use of antibiotics and antiseptics. After final ICWIG TF review of best evidence supporting each recommendation, the guideline will be published on the AAWC website.

Keywords: practice guideline, validation study, wound infection, checklist, interdisciplinary communication

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Although these statistics are alarming and merit the rigorous efforts (underway) to reduce SSI, they are only part of the wound infection story. Infections are just as likely in nonsurgical wounds, with rates increasing with population age. Estimates of wound infection incidence vary among settings and countries that use differing criteria and reporting systems, highlighting the need for increased consistency of infection diagnosis, definitions, and surveillance recording tools.9-12 A prospective SSI surveillance survey, standardized to CDC criteria,13 reported that 28% of SSIs occurred during the hospital stay for 1324 patients undergoing coronary artery bypass grafts; the remaining 72% of SSIs were reported when SSI surveillance was extended to 30 days post-discharge.14 This finding suggests the need for community-based surveillance for all acute and chronic wounds across all care settings. To explore this issue, focused literature searches were conducted of the MEDLINE database from inception to June, 2017, addressing the topic wound infection incidence for each wound type listed in Table 1. Example studies cited included registries, meta-analyses, or clinical trials reporting 100 or more patients.¹⁴⁻²⁸ Diabetic foot ulcers, burns, and pressure ulcers all have higher reported infection incidence than clean/contaminated surgical wounds. However, the only chronic wound subject to CDC NHSN standardized infection surveillance⁴ is the "decubitus ulcer" (ie, pressure injury). It remains to be explored whether parallel standardized surveillance and feedback programs for nonsurgical wound infections may improve chronic wound, burn wound, or trauma wound infection outcomes.

Acute and chronic wound infection similarities. Most definitions of chronic or acute surgical, trauma, or burn wound infection include 2 or more of the classic clinical signs and symptoms of infection (ie, increased tenderness or pain, local heat, erythema, edema, or purulent or excessive drainage^{4,29-32}), although wound infection is not recognized as a primary outcome for clinical trials.^{30,33} Also, the wording of the SSI criterion "dehiscence and separation of surgical wound edges"³⁴ is applied to chronic wounds when stated as, "unexplained chronic wound breakdown despite addressing all causative host or environmental factors."³⁵ These criteria demonstrate potential for harmonizing acute and chronic wound infection measurement.

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Key Points

- Although many wound infection prevention, diagnosis, and treatment guidelines are available, content and application inconsistencies remain.
- Using evidence from the literature, 179 recommendations were developed by the International Consolidated Wound Infection Guideline Task Force (hosted by the Association for the Advancement of Wound Care), verified against 27 wound infection guidance/guideline documents, and validated by 42 interdisciplinary health care professionals.
- Content and strength of recommendation ratings showed most recommendations (88.8%) were valid.

Infection depth classification differs somewhat between chronic and acute wounds. SSI is classified by depth of infected tissue and noted as superficial incisional, deep incisional, and organ space.4 Chronic wound infections may use these criteria or report the level of tissue involvement as partialthickness or full-thickness or involving underlying tendon, joint, or bone.9 To support risk-adjusted SSI surveillance in its National Nosocomial Infection Surveillance Risk Index,⁴ the CDC classifies surgeries according to wound contamination level, severity of patient systemic disease, and duration of surgery, adding 1 risk point on a 0 to 3 scale for each of the following: 1) the wound is contaminated or dirty-infected, 2) the patient has severe systemic disease, and 3) the surgery lasted longer than 75% of the average duration for that surgical procedure.³⁶ Margolis et al³⁷ have validated a risk scale for chronic venous ulcer delayed healing based on "wound duration >6 months" that parallels the third qualification for wound infection risk, but parallels between chronic and acute wound infection risk classification remain unclear.

Acute and chronic wound parallel management strategies. Preventing and treating wound infection requires management of patient, environmental, and microbial infection risk factors.^{38,39} Typically, wound infection, identified using clinical signs, is confirmed by microbial culture and sensitivity testing and leukocytosis.40,41 Although these signs vary subtly with wound etiology,40,41 chronic and acute surgical, burn, or trauma wounds typically are diagnosed by at least 2 of the 5 common signs and symptoms of wound infection.41-43 Life-threatening situations are exceptions to the "culture only if infected" rule. These include necrotizing fasciitis, for which standard therapy involves immediate, high-dosage, broad-spectrum antibiotics followed by life-saving surgery and subsequent narrow-spectrum antibiotics focused on microbes identified from appropriately cultured involved tissue. Similar procedures are followed for patients with large burn wounds because of the elevated infection/sepsis risk and resulting need for preventing potentially lethal infection.^{38,39}

Table 1. Examples of chronic or acute wound infections incidence and costs					
Category of injury	Type of wound ^a (Total number of patients)	Incidence of wound infections ^b (number per 100 patients subject to >30-day surveillance)	Incidence/Den- sity of wound infections (num- ber per 1000 patient-days)	Health system cost added by a wound infection ^c (currency, year)	
Surgical wounds	Cardiac (1500) ¹⁷ (1988) ¹⁸	3.32-6.53 (5.6/1.3) ^b	1.11–12.18	\$1 642 780 US (2010)	
	Hip prosthesis (30 491) ¹⁹ (2204) ¹⁸	0.45-0.51 (2.6/1.3) ^b	0.015-0.17	\$228 855 US (2010)	
	Ambulatory surgery (284 098) ¹	0.46	0.15		
	Pediatric neurosurgery (9296) ²⁰ (743) ¹⁸	2.7-4.99	0.90–2.70	\$415 281 US (2010)	
	Colon surgery (318) ¹⁸	1.88 (9.4/5.6) ^b	0.63	\$117 849 US (2010)	
Burns, trauma	Burns patients >55 years of age (187) ²¹	44.39	22.76		
	Burns pediatric (100) ²² (11 days)	8.00	7.27		
	Combat wounds (17 726) ²³ (first 2 weeks)	3.9	9.68		
Chronic	Diabetic foot ulcers (1127) ²⁴	57.85	1.59	\$11 290 US (2016) ²⁵	
	Pressure ulcers (United Kingdom, long-term care) (412 000) ²⁶	22.50	1.45		
	Pressure ulcers Grade 2	5.00	0.53	8737 £ (2004)	
	Pressure ulcers Grade 3	10.00	0.79	9192 £ (2004)	
	Pressure ulcers Grade 4	30.00	1.95	9192 £ (2004)	
	Venous ulcers ²⁷	8.65	2.88		
³ Surveillance is 30 days unless stated (many wound infections occur after nationt discharge) ^{14, b} Data from example registry, trial, or reported ^{15,16} :					

^aSurveillance is 30 days unless stated (many wound infections occur after patient discharge)¹⁴; ^bData from example registry, trial, or reported^{15,16}; ^cExcludes costs of readmission

Although validating research is needed, the parallels noted in chronic and acute wound infection burdens, definitions, risk classification schema, and outcome measures signal opportunities to harmonize diagnostic language, practice, and outcome measures by multidisciplinary wound care teams as they manage patients with various acute or chronic wound infections across settings. The purpose of this work was to describe derivation from published literature and content validation of a set of wound infection diagnosis, prevention, and treatment recommendations to serve multidisciplinary wound care teams as they manage patients with acute or chronic wounds across settings.

Methods

To identify evidence-based wound infection management recommendations from structured systematic literature searches, 19 multidisciplinary wound care professional members of the Association for the Advancement of Wound Care (AAWC, the host society), the Wound Healing Society, the Canadian Association for Enterostomal Therapy, and the Mexican Wound Healing Society (AM-CICHAC) collaborating as part of the International Consolidated Wound Infection Guideline Task Force (ICWIG TF) explored barriers to evidence-based wound infection practice; conducted structured literature searches to identify evidence supporting recommendations for wound infection diagnosis, prevention, and treatment; evaluated each recommendation's multidisciplinary construct validity; and content-validated clinical relevance and strength of recommendation (SOR), described as benefit-to-harm derived from implementing the recommendation.

Exploring evidence-based practice barriers. Many simple, low-cost techniques have been known for decades to prevent SSIs.¹ These include hand washing,^{7,8} preoperative clipping rather than shaving hair from the surgical site,^{8,44} using a sterile swab to remove subincision fluid postoperatively until drainage subsides,⁴⁵ and avoiding gauze-type topical acute or chronic wound dressings.⁴⁶⁻⁴⁸ Despite ample evidence, research that includes a review of microbiologic diagnostic procedures for chronic wounds in Germany,⁴⁹ a 7-week observational study of elective pediatric surgical cases at a US hospital,⁵⁰ and a qualitative thematic analysis of institutional tools and protocols and transcripts of interviews with infection control supervisors at 7 Canadian hospitals⁵¹ shows guideline interventions for reducing chances of wound infection are inconsistently used.

To address this inconsistency of use, ICWIG TF members used brainstorming based on their experience to identify reasons for gaps between science and practice. In the course of their discussions, they realized that reducing wound infections would

Table 2. Recommendation metrics

Clinical relevance ratings of each recommendation

1 = Not relevant

- 2 = Confusing/unable to assess relevance without more information
- 3 = Relevant but needs minor improvements
- 4 = Very relevant and succinct

Strength of recommendation ratings of patient benefit versus harm

0 = Risks, costs, or harms clearly outweigh benefits

1 = Benefits clearly outweigh costs, risks, and/or harms

Strength of evidence supporting each recommendation

A. Results of a meta-analysis or 2 or more clinical wound infection-related randomized controlled trials (RCT) on humans provide support (or for diagnostics or risk assessment: prospective cohort [CO] studies and/or controlled studies reporting recognized diagnostic or predictive validity measures)

B. Results of 1 clinical wound infection-related RCT in humans plus 2 or more similar historically controlled trials (HCT) or convenience controlled trials (CCT) or 1 HCT and 1 CCT provide support or when appropriate; results of 2 or more animal model RCTs validated as clinically relevant to human wound infection provide indirect support. For diagnostics or risk assessment: 1 clinical wound infection-related prospective CO study and/or a controlled study reporting recognized diagnostic or predictive validity measures

C. This rating requires 1 or more of the following:

• C1: Results of 1 controlled trial on clinical wound infection prevention or treatment – eg, RCT, CCT, or HCT (or for diagnostics or risk prediction: 1 prospective CO study may be substituted for a controlled trial)

• C2: Results of at least 2 series (CS) or descriptive studies or a CO study in humans with or at risk of clinical wound infection

• C3: Expert opinion (EO)

be feasible only if concerns and practices of each professional specialty involved in managing wound infection across settings were adequately served. As such, the ICWIG TF resolved to examine the construct validity of all evidence-based wound infection recommendations found in structured literature searches to ensure each final recommendation also was congruent with wound infection guidelines previously developed by individual specialties, such as infectious disease, dermatology, surgical, advanced practice nursing, or other specialists or by organizations devoted to specialized settings, such as acute care, home care, or military settings.

Literature review. Using recognized guideline development processes,^{52,53} the 19 members (ie, physicians, nursing professionals, and related doctoral candidates) of the ICWIG TF searched PubMed, Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases from inception through November 30, 2013, including up to 400 of the most recent English publications using the search term *wound infection* combined with the search terms or synonyms *risk factor, significant, diagnosis, prevention, treatment*, or *surveillance*. Auxiliary related searches were conducted in Google Scholar to obtain full text and to expand evidence on specific recommendations as needed. Studies on parasitic infections or *in vitro* studies were excluded. The final step of selecting best available evidence from these and added searches supporting each ICWIG recommendation according to standardized criteria (listed in Table 2) was ongoing at the time of this publication.

Interdisciplinary relevance and construct validity. To ensure interdisciplinary ICWIG relevance for all specialties managing wound infection across all settings, ICWIG TF members verified that all unique major recommendations from 21 post-2000, interdisciplinary wound infection reviews, position papers, or guidelines were addressed by IC-WIG recommendations identified by evidence found in the literature searches. Additionally, they evaluated each ICWIG recommendation's construct validity by checking "Yes" if it was included in at least 1 interdisciplinary post-2000 wound infection guideline or review or "No" if not. Ensuring consistency with published interdisciplinary guidelines, reviews, and position papers of all ICWIG wound infection recommendations addressed Institute of Medicine (IOM) criteria⁵² for developing trustworthy guidelines while supporting each ICWIG recommendation's capacity to harmonize wound infection practices for all members of interdisciplinary wound care teams across settings and specialties.

Content validation. ICWIG developers abstracted recommendations from evidence found in the initial literature searches, removed redundancy, and condensed all recommendations into a comprehensive list of 179 actionable recommendations. To ensure interdisciplinary clinical relevance of these recommendations, formal content validity^{54,55} was established by voluntary respondents to an online survey using judgment quantification to rate each recommendation's clinical relevance on the 4-point scale shown in Table 2. Safety was estimated as SOR by each respondent rating the recommendation as "1" if more benefit than harm would be derived by implementing the recommendation or "0" if not as recommended by the IOM.52 Private ratings avoided potential bias from social pressures associated with consensus discussions. The content validation survey of recommendations compiled through November 30, 2013 was accessible online from December 1, 2013 through December 31, 2014. Invitations to complete the survey were published in major wound journals serving >40 000 readers and sent as eblasts to >5000 members of wound care societies in the United States, Europe, Asia, Australia, Canada, and Mexico.

Respondents downloaded the survey, completed it on their computers, then emailed the completed survey to an AAWC staff member who compiled all surveys into an Excel file for later analysis by an ICWIG TF member. In addition to the ratings described, the survey requested respondent credentials and practice demographics, along with their suggested changes or additions to the recommendations.

Updated literature searches. After the survey, the IC-WIG TF conducted updated literature searches of PubMed and Google Scholar databases from December 31, 2014 through August 1, 2017, for the term *wound infection* combined with synonyms or derivatives of the terms *reliable*, *valid*, and *significant*, plus appropriate key words in each recommendation. Best available evidence from these and the prior searches currently is being reviewed, evaluated according to criteria in Table 2, added as appropriate supporting evidence to corresponding ICWIG recommendations, and abstracted into ICWIG evidence tables describing study patients, interventions, comparators, design, and outcomes of each of up to 5 best references supporting an ICWIG recommendation.

Updated interdisciplinary relevance and construct validity. The power of interdisciplinary teamwork in improving wound outcomes has been affirmed by expert consensus,9 randomized clinical trials,56 and longitudinal cohort studies.^{57,58} To ensure ICWIG interdisciplinary currency in empowering wound care team members to speak and act in harmony, ICWIG TF members evaluated a total of 27 interdisciplinary publications (literature reviews, position documents, or guidelines) to ensure 1) that each ICWIG recommendation was represented in at least 1 prior evidence-based published summary of wound infection recommendations, and 2) that every recommendation in these published summaries was addressed appropriately in the ICWIG. The construct validity check had been performed before the content validity survey for 21 publications⁵⁹⁻⁸⁰ and was repeated for 6 more recent publications accessed after completion of the last content validation survey.8,78,81-84

Data analysis and statistical methods. Relevance and benefit (SOR) content validity indexes (CVI) were calculated for each recommendation from all surveys returned as the percent of respondents rating that recommendation as 3 (relevant but needs minor improvement) or 4 (relevant and succinct) to their own clinical practice. A CVI of at least 0.75 is considered as having content validity,⁵⁵ calculated as follows:

Relevance CVI = (number of 3 ratings + number of 4 ratings)/total N responding for the recommendation.

Benefit (SOR) validity was the percentage of respondents rating the recommendation's implementation as 1 (beneficial) = (number of 1 ratings)/total N responding with a rating of 0 or 1 for the recommendation.

A 1-page ICWIG Checklist was compiled of the guideline recommendations with the highest CVI and SOR ratings (>0.75) for patient and wound assessment to diagnose and manage wound infection risk factors, wound infection prevention, and treatment.

In the final guideline (accessible at aawconline.org once best evidence is summarized and aligned with each recommendation), each recommendation will be displayed with its evidence rating from Table 2, up to its 5 best supporting references, CVI, and SOR.

Results

Barriers to evidence-based management. Current guidelines reviewed differed in clarity, stated professional roles and accountability, and criteria for SOR, resulting in credibility gaps between specialties and across settings. Team members agreed with prior research⁴⁹⁻⁵¹ that evidence-based guideline interventions are inconsistently followed due to limited communication between specialties or across settings; confused perceptions about safety and efficacy of interventions such as timing of antibiotic use; and inadequate training, resources, or reimbursement. Patient and wound outcomes are not consistently measured and rarely tracked across settings, so wound professionals are rarely held accountable or receive feedback about the outcomes of their wound care.⁵¹

It was concluded that an adequately developed,⁵³ evidence-based wound infection guideline (ICWIG) meeting IOM standards for a trustworthy guideline⁵² designed to unify and serve all wound care team members and the patient with an acute or chronic wound would help resolve many barriers and subsequently enhance the consistency of care and outcomes for those at risk of or with a wound infection.

Interdisciplinary validation. All ICWIG recommendations were represented in at least 1 prior publication of evidence-based wound infection recommendations and, conversely, all evidence-based recommendations in the 27 reviews or guidelines evaluated^{8,59-84} with different wound, specialty, or setting focus were represented in the ICWIG. Although these documents differed from each other in their recommendations (often due to their focus on a specific specialty or acute or chronic wound etiology), many

Table 3. Highest rated 20 of 82 recommendations for respondent ratings of clinical relevance and strength of recommendation (SOR)			
Highest rated 20 guideline recommendations with content validity index (CVI) for clinical relevance and clear benefit, both at least 0.95	CVI for clinical relevance	Percent that rated beneficial (SOR)	
Monitor wound area regularly to ensure that a wound is on a path to healing	1.00	0.98	
Document medical history of diabetes and address related issues that may increase likelihood of wound infection	1.00	0.95	
Debride devitalized tissue	0.98	0.98	
Offload diabetic foot ulcers with total contact cast or other nonremovable offloading device to reduce healing time and likelihood of infection	0.98	0.98	
Redistribute pressure with appropriate surface(s) and frequency to prevent pressure ulcers	0.98	0.98	
Qualified staff or interdisciplinary wound care team member conducts wound and skin infection assessments as appropriate and consistent with facility protocols and communicates to all responsible for the patient's care	0.98	0.98	
Prevent or manage gross contamination of wounds from urine, stool, and environ- mental contaminants	0.98	0.98	
Suspect infection if there is an increase in wound pain or drainage for any chronic or acute wound	0.98	0.98	
Communicate chronic wound area and infection signs to wound care providers to improve healing outcomes	0.98	0.98	
Between patients, meticulously clean and steam-sterilize instruments and scopes that enter body parts	0.98	0.98	
Assess wound and surrounding skin for increase in wound size or devitalized tissue; assess for local and systemic signs of infection (edema, erythema, warmth, foul odor, and pain or tenderness) to rule out infection	0.98	0.97	
Evaluate and address all wound burden factors (duration, edema, contaminants, inflammation, innervation, nutrition, oxygenation, trauma, metabolism) regularly	0.98	0.97	
Prevent tissue breakdown and reduce susceptibility to infection of a chronic wound by alleviating its primary cause	0.97	0.97	
Educate patients, caregivers, and families as appropriate throughout all stages of care about actions they can take to reduce morbidity, mortality, and likelihood of infection	0.95	0.98	
Employ effective postoperative care standards	0.96	0.97	
Provide adequate sustained compression for venous ulcers	0.95	0.98	
Inform patient or appropriate family of antibiotics and other medications planned and/or given and check patient allergies	0.95	0.98	
Measure wound volume (length, width, depth) consistently within and across institu- tions to assess and address risks of delayed healing	0.95	0.98	
Instruct patients or their caregivers to seek professional care quickly if they see signs of chronic wound infection (increased pain, redness, swelling, heat, odor, fluid or wound area)	0.95	0.98	
Determine presence and antibiotic susceptibility of invasive pathogens by culture and sensitivity testing of deep tissue sample or quantitative swab only if clinical signs of infection are present	0.95	0.98	
Debride foreign matter or devitalized tissue that can harbor biofilms unresponsive to topical antimicrobials and potentiate infection	0.95	0.98	

Table 4. Recommendations with lowest rated content validity index (CVI) (N=20)Lowest rated recommendations with CVI <75% ^a	for clinical relo CVI for relevance ^b	evance and benefit Strength of recommendation (SOR)°
Use 10 to 100 times higher doses of topical antimicrobial agents for bactericidal efficacy for biofilms than for ordinary planktonic bacteria	0.34	0.32
Use 2 weeks of topical antibiotics for nonhealing pressure ulcers	0.39	0.35
Add daily topical application of gentamicin collagen sponge to standard protocol of care for moderately infected diabetic foot ulcers, including appropriate systemic antibiotics and offloading to help abolish infection	0.33	0.45
Avoid nasal decontamination with antimicrobial agents. This is ineffective	0.51	0.52
Use tap water for wound cleansing after 48 hours if the surgical wound has separated or has been surgically opened to drain pus	0.50	0.58
Avoid use of mechanical bowel preparation	0.47	0.62
Use single implanted application of gentamicin collagen sponge with caution as there is insufficient evidence of efficacy in reducing surgical site infection (SSI) incidence	0.59	0.54
Document circulatory or respiratory insufficiency to surgical or wound site and ad- dress as feasible, patient-appropriate, and consistent with institutional protocols, using increased standardized validated score such as EuroSCORE II, National Nosocomial Infection Surveillance, or American Society of Anesthesiologists score	0.60	0.59
Avoid povidone-iodine surgical drapes, which are associated with increased SSI compared to no incise drape, while insufficient evidence supports use of incise drapes as compared to no incise drapes	0.69	0.68
Recognize that platelet-rich plasma does not prevent infection	0.69	0.69
No evidence supports superiority of 1 topical antimicrobial agent over the others	0.68	0.71
If appropriate for the patient, close wound surgically if it does not heal with optimal wound care to limit fluid and protein loss, infection, or malignancy	0.68	0.71
Drain or reduce excess fluid trapped inside wounds using sterile applicator probe daily or safe levels of negative pressure	0.66	0.74
Debride confirmed osteomyelitis and cover with flap containing muscle or fascia with 3-week antibiotic choice guided by culture results	0.68	0.73
Left ventricular dysfunction is a risk factor for coronary artery bypass graft SSI	0.68	0.74
Recognize there is insufficient evidence supporting the need for chronic wound cleansing or superiority of any specific chronic wound cleansing agent over any other	0.68	0.73
Advise patients that they may shower safely 48 hours after surgery with tap water	0.68	0.74
Avoid use of iodophor-impregnated incise drapes shown to increase SSI risk and recognize that those without antimicrobials do not affect SSI incidence	0.70	0.72
Use sterile saline for wound cleansing up to 48 hours after surgery	0.68	0.74
Prolonged exposure to cold temperatures during immediate postop period adds infection risk	0.72	0.71

^a CVI of 0.75 for clinical relevance and strength of recommendation; <0.75 indicates that using the recommendation was rated neither relevant nor beneficial by at least 75% of survey respondents; ^b CVI=percent of respondents rating use of recommendation as clinically relevant (3 or 4); ^c SOR=percent of respondents rating use of recommendation as clearly beneficial

commonalities were observed among recommendations for wound infection diagnosis, prevention, and treatment.

Content validation. Forty-two (42) clinicians with a median of >15 years of military or civilian practice on wounds completed and returned the content validation survey. They included 12 registered nurses (RNs); 10 RNs certified in wound ostomy continence (WOC) care; 8 physical therapists; 7 advanced practice nurses; 4 physicians specializing in surgical, dermatologic, or endocrinological care; 4 doctors of podiatric medicine (DPMs); 3 (2 RNs and one MD) Certified Wound Specialists; 3 specialists with PhDs in microbiology or authors of peer-reviewed continuing medical education literature reviews on wound infection; and 1 PhD patient advocate. Several respondents had more than one credential.

These participants managed an average of ~16 wound infections per week. Participant practice settings included acute

DEVELOPING A WOUND INFECTION GUIDELINE

Wound Infection Checklist



Improve Patient Outcomes

ASSESS	PREVENT	HEAL
Trained professional or interdisciplinary tea	m + Patient, family and all care providers	= Unified wound infection team
Outpatient/Inpatient and Wound initial Evaluation	Prevent Acute or Chronic Wound Infections	Wound Management All Settings as Patient-appropriate
 □ Document patient history, comorbidities and related issues that may increase likelihood of wound infection including: • Diabetes, COPD, ischemia, nicotine use, obesity, nutritional deficiencies, anemia, impaired renal function, BMI > 25, serum albumin < 2.5 g/dl □ Perform valid peripheral neuropathy test, e.g. Semmes Weinstein monofilament or tuning fork. □ Assess medications/therapy that may decrease immune response (>7 day corticosteroid use, chemotherapy, radiotherapy, etc.). □ Document abnormal anatomy or gait that may cause skin injury. □ Document pre-operative extended hospital stay or nursing home residence. □ Obtain ABI or TBI to assess peripheral vascular disease, oxygenation of lower extremity wounds. □ Document wound infection signs, impaired blood flow and risk factors for delayed healing: • Loration > 6 months, area > 5 cm² full-thickness • Increased pain, edema, erythema, heat, dor, drainage or wound-related leucocytosis • Contamination or foreign matter in wound • Lack of protective sensation • Repeated or prolonged trauma or pressure □ Take wound cultures using a validated technique only if signs of infection are present. □ Use narrow-spectrum antimicrobial agents when 	 To extent feasible alleviate all causes of delayed wound healing before prescribing antibiotics. Maintain a moist wound environment. Maintain homeostasis of patient before, during, and after all procedures, including surgery. Stop nicotine use at least 4 weeks before surgery or initiate nicotine cessation therapy for patients with chronic wounds or impending emergency surgery. Avoid blood transfusion before surgery unless required to improve patient outcomes. Maintain normal body temperature (36-38 C). Maintain normal body temperature (36-38 C). Maintain normal body temperature (36-38 C). Maintain blood oxygen saturation >95%. Manage patient to achieve normal blood glucose, hemoglobin, serum creatinine and platelet count. Prepare staff, patient and operating room per CDC standards (gowns, shoe covers, hair covers, and surgical gloves. Change gloves if penetrated). Clip, don't shave sites of required hair removal. Use pressure redistribution under bony prominences. Decontaminate all surgical equipment between patients in accordance with facility protocols. Start prophylactic antibiotics 24 hours before surgery. Stop within 48 hours postoperatively. Apply CDC contact precautions to all patients with known multi-drug resistant organisms. Minimize duration of surgical procedures and of patient's institutional stav. 	 Apply effective post-operative care standards including wound infection management and surveillance with feedback to all care providers per institutional or CDC standards. Avoid stress on incision lines to reduce likelihood of dehiscence by instructing patients on appropriate activities and weight bearing techniques. Apply a sterile non-gauze dressing to surgical wounds for 24-48 hours after surgery. Instruct patient on proper wound care and how to shower safely with or without cleansing their wound. Cleanse and debride wound to remove contamination, nonviable tissue and foreign matter using proper technique for wound size, severity and contamination level. Instruct patient to seek professional care quickly if they see signs of infection (increased pain, redness, swelling, heat, odor, drainage, or unexplained increase in wound area). Manage acute or chronic wound infections per institutional or CDC standards. Moisturize and protect wounds if site is dry or damaged Use patient-appropriate causes of chronic wound breakdown: Off-load / protect wounds on sites of reduced sensation. Redistribute pressure on bony prominences during 2 or more hour intervals of limited mobility. In patients with venous insufficiency, provide adequate compression sufficient to reduce dema unless contraindicated.

- feasible for non-severe infections to avoid development of antibiotic-resistant pathogens.
- П Avoid use of toxic agents either systemically or topically on wounds if feasible.
- other conditions identified on evaluation, when feasible.
- Assure adequate hydration, nutrient intake and environment to support wound healing and homeostasis.

Figure 1. Wound Infection Checklist. All recommendations in this Checklist had a content validity index >0.75 and a strength of recommendation >0.075.

(inpatient) care (43%), separate wound clinic (25%), acute (outpatient) care (21%), long-term acute care (17%), skilled nursing facility (17%), office practice (15%), medical school (11%), subacute care (7%), home care (3%), or extended care (2%), with <1% of respondents in a group practice organization or government agency. Most of the participants' practice time was devoted to surgical wounds (29%), pressure ulcers (27%), diabetic foot ulcers (23%), venous ulcers (15%), burn/trauma or other acute open wounds healing by secondary intention (10%), mixed etiology wounds (eg, venous and arterial ulcers) (9%), dermatologic conditions (5%), or other wounds (3%) such as cancer, fungating, or lymphedema wounds or other unusual wounds. Respondents practiced in Australia, Canada, Slovenia, Sweden, Switzerland, the United Kingdom, and 13 of the United States, representing all regions except Hawaii.

Of the 179 recommendations, 159 (88%) were rated as relevant and recommended (CVI >0.75). Among the 179 recommendations, 82 (45.8%) had robust content validity with high relevance (CVI >0.90) and SOR >0.75. The 20 recommendations with the highest ratings focused mainly on consistent wound monitoring with feedback to care providers, avoiding contamination, and preventing tissue damage (see Table 3). Twenty (20) recommendations were judged to be of questionable relevance (CVI <0.75) and low SOR or not clearly beneficial in ratings from >75% of respondents (see Table 4). These recommendations mainly addressed the use of antibiotics or topical antimicrobial agents.

Wound Infection Checklist. A Wound Infection Checklist containing ICWIG recommendations with CVI and SOR >0.75 was developed as an implementation tool to simplify ICWIG use by interdisciplinary wound care teams, including patients, families, and all care providers across settings (see Figure 1). The Checklist organized recommendations into 3 columns. The first column lists actions recommended to identify wound infection risk factors during patient and wound assessment and evaluation. The second column lists actions recommended to prevent acute or chronic wound infection. The third column lists actions recommended to manage patients with wounds until wound healing occurs.

Discussion

To be useful and trustworthy for health care providers, a guideline requires clear, evidence-based, actionable recommendations with consistently defined parameters and measurable outcomes.^{52,53} Specialty-, setting-, or wound-related discrepancies among wound infection definitions, assessment, or diagnostic parameters and prevention or treatment interventions can confuse professional caregivers and reduce the consistency of management and quality of outcomes. For example, a provider with mainly acute wound experience may assume increased pain, erythema, and discharge of a venous ulcer signals infection and prescribe unneeded antibiotics. The same patient receiving care designed to harmonize multidisciplinary team members in addressing all host, environmental, and organism risk factors would receive prompt, appropriate referral(s) to identify and address more likely needs for improved compression, nourishment, or vascular perfusion to resolve the problem without increasing patient risk of developing antibiotic-resistant microbes. Using trustworthy, content-validated guidelines that harmonize wound care team communications and actions may avoid costly errors and improve patient outcomes.

The literature reviewed documented an array of contradictions in wound infection management recommendations. Wound infection diagnostic criteria were varied and included clinical signs such as pain or increased discharge³⁴ and deep tissue biopsy harboring >10⁵ colony forming units.³¹ Despite commonalities in the evidence-generated recommendations, discrepancies were noted on how to diagnose, prevent, and treat wound infection.^{9,34,36,38} These differences signaled the need for a wound infection guideline that could unify interdisciplinary wound care teams. Until communication and actions related to wound infections are seamless across specialties and settings, patients with or at risk of developing a wound infection are unlikely to receive recognized benefits of consistent care and outcomes derived from interdisciplinary teams adhering to evidence-based practice and sharing information about wound progress.56,57

Two (2) European Wound Management Association publications addressed multidisciplinary wound infection management,^{9,83} but the ICWIG literature review found no structured guidelines developed to meet IOM standards that fulfill that purpose. The ICWIG is designed to fill this void. Generally high CVI values for most recommendations' relevance and SOR values reflecting safety supported the feasibility of developing such a guideline to harmonize wound infection management. This is underscored by the ICWIG's congruence with prior guidelines for individual specialties and verifies its interdisciplinary functionality for acute and chronic wound infection diagnosis, risk management, prevention, and treatment.

However, sufficient commonality was found among acute and chronic wound infection diagnosis, prevention, treatment, and published risk factors to enable development of many relevant, beneficial recommendations supporting most aspects of managing chronic and acute wound infections, such as those in the Checklist (see Figure 1). Highly relevant and beneficial recommendations spanned wound etiology, professional specialties, and settings. Wound experts from a variety of professions, settings, and countries almost universally agreed that increased wound pain and discharge are key signals of infection for both acute and chronic wounds and that consistently monitoring and measuring wound area would help multidisciplinary wound care teams improve the consistency and quality of care and outcomes for their patients with acute and/or chronic wounds across care settings.

Acute and chronic wound infections share most of the common signs and symptoms and arise from the same interacting host, environmental, and organism risk factors. Microorganisms invade healthy tissue only when compromised host and environmental factors favor infection.^{9,38} Optimizing patient and wound infection outcomes takes a multidisciplinary team reinforcing each other's work to manage all these risk factors for acute or chronic wounds across all settings.⁸⁵

Implications for Practice

The ICWIG Checklist (see Figure 1) summarizes the content-validated ICWIG recommendations with high SOR, and Table 5 illustrates measureable aspects of adherence to and outcomes derived from example recommendations. Researchers are continuing to compile newly published evidence to verify if all 179 recommendations represent good clinical practice and to identify which need more research. Twenty (20, 11.2%) recommendations were rated neither relevant nor beneficial by >75% of respondents and as such failed to meet acceptable standards of content validity (see Table 4), thus requiring careful consideration of available evidence and/or further research before use in clinical practice.

Resolving barriers to evidence-based wound infection practice. Infection-related costs and reimbursement vary across settings, states, regions, or provinces and may drive care decisions toward least expensive gauze wound dressings despite RCT evidence that their use doubles infection rates.⁴⁶⁻⁴⁸ Encouraging use of or adequately reimbursing clearly defined,⁸⁶ moisture-retentive dressings could encourage their timely and appropriate use, preventing costly wound infections.

Highly relevant and beneficial guideline recommendations described in the ICWIG Checklist (see Figure 1) merit consistent use with reporting of adherence measures, documenting that the recommendation was followed, and measures of expected outcomes if the recommendation is followed, as illustrated in Table 5. These illustrate how to customize ICWIG recommendations for use in institutional protocols, practice settings, or as quality measures for wound registries,⁸⁷ informing all collaborating wound care team members what action was taken, when, and with what related outcomes.

Table 5. Example implementation metrics for adhering to validated wound infection diagnosis, prevention, and treatment recommendations with expected outcome measures if the recommendation is implemented				
Qualified staff or interdisciplinary wound care team members consis- tently assess, diagnose, document, prevent, or manage patient and wound infection or delayed healing risk factors regularly per institu- tional protocols (adherence measure)	Corresponding example (outcome measures related to wound infection or delayed healing)			
Document patient medical history before surgery and address related is- sues that may increase likelihood of surgical site infection (SSI) (eg, percent of surgical patients examined for a standardized patient-appropriate list of risk factors including elevated blood glucose HbA1c >6.4 %, renal dialy- sis, chronic obstructive pulmonary disease, anemia, body mass index >25, peripheral vascular disease, nicotine use, serum albumin <2.5 g/dL, che- motherapy, chronic steroid use, immunosuppression, or long preoperative hospital or nursing home stay)	Percent of patients whose identified risk factors were addressed or managed as feasible (eg, serum albumin >2.5g/ dL, HbA1c <6.4%, and nicotine use stopped at least 2 weeks before surgery or permanently for those with a chronic wound)			
 Reduce chronic wound susceptibility to infection by alleviating its primary cause and preventing tissue breakdown as follows (percent of patients admitted to care who were routinely examined for the following conditions): Diabetic foot ulcers or areas with abnormal anatomy, neuropathy, or circulation or sites without protective sensation Pressure ulcers or bony prominences exposed to prolonged intervals of anesthesia or immobility (eg, during prolonged surgery or neurologic impairment) Venous ulcers on lower limbs of those with venous insufficiency 	 Percent of patients with the indicated condition who received the indicated care below: Offload or protect with total contact cast or other nonremovable offloading device Redistribute pressure away from affected site with effective pressure redistribution device Providing sustained, graduated, multilayer compression adequate to reduce edema 			
To the extent feasible, recognize and minimize procedure-related risk factors for SSI including: inadequate hand washing or glove use, use of razor to remove hair, surgery longer than its 75th percentile in duration, hypother- mia, blood transfusions, dual antiplatelet therapy, high-tension closure or inappropriately placed incision, surgical drains, inappropriately timed or no prophylactic antibiotics, tissue trauma, excessive dissection, undermining areas, or dead space (percent of surgical patients free of all listed risk fac- tors)	Percent of risk-adjusted SSI incidence compared to local and national stan- dards (percent of surgeons regularly informed of their risk-adjusted SSI incidence for each type of surgery performed)			
Prevent or manage gross contamination of all wounds from urine, stool, personnel, or environmental sources (percent incidence of wound contamination episodes per month)	Percent incidence per month of all wound infections associated with an episode of documented chronic or acute wound contamination			
Debride foreign matter or devitalized tissue from all wounds (percent per month of all wounds containing foreign matter that were debrided)	Percent incidence per month of all wound infections associated with a chronic or acute wound containing for- eign matter or devitalized tissue			
Between patients, best standard procedure is to meticulously clean and steam-sterilize instruments or scopes that enter body parts. If not feasible,	Percent of patients undergoing a pro- cedure, including surgical debridement,			

steam-sterilize instruments or scopes that enter body parts. If not feasible, utilize Centers for Disease Control and Prevention (CDC)-recommended, high-level disinfectants per package insert instructions (percent of patients undergoing procedures that require instruments or scopes to enter body parts for whom these are steam-sterilized or sterilized per CDC recommendations)

Employ effective postoperative care standards including discharge planning, routine assessment of infection signs, discontinuing prophylactic antibiotics, showering, and wound protection/cleansing/dressing (percent of surgical patients who received all these elements of postoperative care)

Percent of patients undergoing a procedure, including surgical debridement, in which an instrument or scope enters a body part, who experience a wound infection

Percent of patients who experience a SSI within 30 days after nonimplant surgery or within 90 days after implant surgery and percent of patients expressing adequate or optimal satisfaction with care on a valid rating scale

continued on next page

Table 5. Example implementation metrics for adhering to validated wound infection diagnosis, prevention, and treatment recommendations with expected outcome measures if the recommendation is implemented *continued*

Educate patients, caregivers, and families throughout all stages of their care about actions they can take to reduce morbidity, mortality, and likelihood of infection. Instruct them to seek professional care quickly if they see signs of wound infection (increased pain, redness, swelling, heat, odor, drainage) (percent of hospital inpatients and appropriate others educated before surgery, before discharge, and on admission to and before discharge from other health care setting)

Regularly evaluate, document, and address all wound infection risk factors (duration, area, depth, local edema, trauma, contaminants, inflammation, innervation, nutrition, oxygenation, circulation, and metabolism) (percent of patients with a wound with these risk factors documented)

Debride foreign matter or devitalized tissue that can harbor biofilms⁸⁸ unresponsive to topical antimicrobials and potentiate infection (percent of all patients with foreign matter in their wounds [eg, fabric, sutures, devitalized tissue] documented at least once weekly)

Premedicate for topical pain management before debriding the wound or removing painful dressings (percent of patients receiving patient-appropriate topical or systemic anesthesia prior to wound debridement or painful dressing removal)

Reevaluate patients with a history of healed osteomyelitis every 3 to 6 months or according to institutional protocol for recurrence (percent of patients with healed osteomyelitis reevaluated with a documented valid test for osteomyelitis within 3 months after the episode)

Monitor and manage wound-related pain, fever, white blood cell count >11 000 cells/µL, bacteremia, bleeding, odor, pruritus, drainage, and psychosocial distress in all settings including acute care, home, community care, palliative care, and long-term care (percent of patients in any setting receiving at least once weekly patient- and surgery-appropriate surveillance and documentation of these adverse events)

Percent of patients who experience a SSI within 30 days after nonimplant surgery or within 90 days after implant surgery

Percent of patients with a measured improvement of at least 1 risk factor within 2 weeks after documentation (eg, reduced wound area or depth, local edema, serum albumin, glycemic control, nicotine use)

Percent of all patients with foreign matter or >25% of devitalized tissue debrided, if still needed, from their wounds within 1 week after its first documentation

Percent of patients reporting scores <3 on validated Universal Pain Assessment Tool during wound debridement or dressing removal

Percent of patients experiencing recurrent osteomyelitis who receive patientappropriate treatment for it within 24 hours after the episode is documented

Percent of patients with any of these documented wound-related adverse events who receive patient- and woundappropriate effective treatment for it within 24 hours after documentation

Ready access to evidence-based ICWIG recommendations embedded in implementation tools or electronic health records could alert a primary provider to the need for specialist referral or help a patient understand importance of adhering to the plan of care. Hierarchical medical structure may obstruct team approaches to guideline use by promoting disputes instead of supporting team synergy and by limiting the authority of evidence users. Just as implementing wound infection prevention "bundles" has reduced SSI rates and costs,⁴⁴ embedding key ICWIG recommendations in protocols and medical records could support a cost effective, mutually respectful team approach, reducing delays between assessments and interventions. Developing a wound infection guideline to harmonize multidisciplinary teams is a small first step. Only consistent ICWIG use and documentation can measure and find ways to enhance its potential to improve clinical and economic outcomes.

It was not surprising that all recommendations in the 27 interdisciplinary guidelines and evidence-based position documents tested already were addressed in the ICWIG. All were based on the same evidence found in the ICWIG searches. This result supported the ICWIG's comprehensive and interdisciplinary qualities. Ensuring that a guideline serves all wound care team members encourages a harmonized, teambased approach with timely referrals for wound infection diagnosis, prevention, or treatment by appropriate specialists applying their more detailed specialty evidence-based guidelines in time to optimize patient outcomes and reduce costs.

The literature reviewed clarified what is known and not known about wound infection. The implication for practice is that it benefits patients to avoid infection harm and costs (reported in Table 1) by rigorously managing host and environmental factors to prevent wound infection; doing so before surgery or developing a chronic wound also can limit unnecessary use of antibiotics to address inflamed or nonhealing wounds.

Future ICWIG steps. The best 5 or fewer publications supporting each recommendation are currently being selected according to criteria listed in Table 2. The final IC-WIG will feature each recommendation, CVI for clinical

relevance and benefit, and up to 5 best available supporting references, plus an ICWIG Evidence Table summarizing those references and patient and professional implementation tools will be accessible at: aawconline.org/professional resources after ICWIG completion.

Future ICWIG updates will continuously improve its capacity to inform clinical decisions related to wound infection and identify related research and education gaps. For now, need is evident for research and clarification of the recommendations in Table 4. Methods are needed to differentiate wound infection from other causes of inflammation with improved diagnostic and screening validity.88 It is time to answer questions regarding if/when to extract sutures or dressing fibers embedded in wounds⁸⁹ and whether CDC rules for antibiotic prophylaxis apply to surgical debridement of chronic wounds and if so, how to avoid proliferation of drug-resistant microorganisms⁹⁰ or delayed healing associated with prophylactic administration of antibiotics to uninfected chronic wounds.⁹¹ Harmonized care and collaborative research across specialties and settings should help answer these questions and improve consistency and quality of wound infection surveillance and outcomes as aging patients traverse settings with increasing frequency.

Among the strengths of this method of content-validating recommendation relevance and safety is that it replaces the social interactions of group consensus with independently expressed standardized ratings as a measure of the strength of opinion supporting the recommendation. Each professional with his/her own patients in mind contributes equally to the CVI, expressing the capacity of each recommendation to benefit (or harm) patients. This leaves little opportunity for the personal opinions of guideline developers to distort recommendations.

Limitations

This report's focus on harmonizing acute and chronic wound infection management is not intended to minimize the vital importance of emergency management of severe burns, trauma, necrotizing fasciitis, or other serious conditions that threaten immunologic competence or homeostasis. These require immediate, appropriate referral to and management by experts in life and limb salvage and wound infection management. Additional resources provide more information regarding management of these wounds.^{70,92}

The sample of 42 respondents to the ICWIG content validation survey appears small but is ample in comparison to the 5 or more independent reviewers required to establish formal content validity of a practice recommendation.⁵⁵Independence of respondents, the breadth and duration of their wound care practices, and the variety of civilian and military practice settings and wounds they managed support this survey as a robust content validation process with broad relevance.

The ICWIG still needs best available evidence supporting the efficacy and safety of each recommendation before it becomes an evidence-based guideline. This vital step, currently being completed, will allow assessment of research and educational gaps, while placing it among the ICGTF guidelines accessible at aawconline.com later this year as a multidisciplinary resource supporting content-validated science-based practice.

Conclusion

Multidisciplinary wound care teams improve the consistency and quality of care and outcomes for patients with wounds. Multinational ICWIG guideline developers searched wound infection literature, confirming the need to develop an interdisciplinary wound infection guideline to harmonize team wound infection management across specialties and settings. Literature reviews found 179 ICWIG recommendations informing decisions about acute and chronic wound infection risk factors, diagnostic criteria, and prevention and treatment interventions. Standardized independent ratings by 42 multidisciplinary online survey respondents supported content validity and SOR of 159 (88.8%) of the recommendations for clinical relevance and patient benefit. These were condensed into a Wound Infection Checklist designed to harmonize interdisciplinary teams practicing across settings to improve the consistency and quality of care and outcomes for patients with or at risk of chronic or acute wound infection.

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