

Methodology for the World Council of Enterostomal Therapists® International Ostomy Guideline third edition

ABSTRACT

Introduction The International Ostomy Guideline (IOG) developed by the World Council of Enterostomal Therapists (WCET®) is currently being updated with the newest evidence to produce the third edition. The IOG presents clinical guidance to promote access to holistic stomal care, reduce stoma-associated complications, improve knowledge of health professionals regarding stomal care, and to optimise quality of life of individuals living with a stoma.

Methods The guideline development process is being undertaken by a Guideline Development Panel consisting of representatives of WCET® and its collaborative partner, the International Society of University Colon and Rectal Surgery (ISUCRS). The development methods are underpinned by the Joanna Briggs Institute's (JBI) theoretical framework of evidence-based care. The methodology embeds a rigorous process that includes generation of relevant clinical questions, evidence identification, critical appraisal of the research and use of adapted Evidence-to-Decision frameworks to reach evidence-based recommendations and good practice statements agreed on by an expert panel through a Delphi process. The methods include engagement from international stomal therapists, colorectal surgeons and individuals living with a stoma. The guideline development process addresses the key components of the JBI evidence-based model: global health, evidence generation, evidence synthesis, evidence transfer and evidence implementation.

Results The guideline will present evidence-based recommendations and good practice statements providing practical clinical guidance for the care of individuals who are to undergo, or who have undergone, ostomy surgery. Input from the WCET® Executive Board, WCET® Education Committee, Norma N Gill Foundation® WCET® International Delegates (IDs), the ISUCRS Education Committee, individuals living with an ostomy and broad stakeholder feedback will enhance the guideline recommendations.

Conclusion Developed using a rigorous methodology and with input from international experts and individuals living with a stoma, the WCET® IOG third edition embraces the JBI aim of healthcare that is globally-relevant, feasible, appropriate, meaningful and effective.

Keywords guideline, ostomy, enterostomal therapy nurses, methodology

For referencing Haesler E et al. Methodology for the World Council of Enterostomal Therapists® International Ostomy Guideline third edition. WCET® Journal 2025;45(2):13-21.

DOI <https://doi.org/10.33235/wcet.45.2.13-21>

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BACKGROUND

The World Council of Enterostomal Therapists® (WCET®) was founded in 1978. The WCET's® vision is to support the care of individuals living with stomas, wounds or continence needs by leading the global advancement of professional nursing care through the provision of specialised education. Holism and co-participatory care are essential guiding principles underpinning the care of individuals with a stoma and form the foundation for high quality assessment, care planning and care delivery. Quality care includes awareness of the personal, societal and cultural implications of living with an ostomy.

The WCET® defines an ostomy as a “surgically created opening in the abdomen for the purpose of passing stool waste or urine”¹. The word ostomy is often used interchangeably with the word stoma. Throughout this paper, and the IOG, the terms ostomy and stoma are used interchangeably, and in this context, are used to specifically refer to abdominal (intestinal and urinary) stomas. We also use the terms stomal care, care of an ostomy or stoma and enterostomal care interchangeably.

To support its vision and enhance the quality of care for individuals who are to undergo, or who have undergone, surgery that results in the formation of an abdominal stoma, the WCET® produced its first International Ostomy Guideline (IOG) in 2014, followed by a second edition in 2020. The IOG summarises the available evidence to positively influence the knowledge, skills and quality of life of individuals living with a stoma and their caregivers. The IOG provides guidance to inform the decision making and clinical practice of health professionals involved in delivering enterostomal care, and offers education to health professionals, individuals managing their own stoma, and their informal carers who assist in that care. The IOG also seeks to address cultural, religious and ethnic considerations across a wide range of geographic and clinical contexts. This will enable nurses and other health professionals to appropriately adapt care for individuals from diverse socio-cultural and religious backgrounds, ensuring individuals worldwide receive enterostomal care consistent with the available resources in their local communities.

To ensure their relevance and alignment with the most recent evidence, clinical guidelines require regular update. Preliminary searches in health databases identified over 17,800 publications related to enterostomal therapy since the release of the IOG (second edition) in 2020. Therefore, the WCET® has commenced the process to develop a third edition of the IOG. The aim of this paper is to outline the methods that are being used to undertake this update.

METHODS FOR DEVELOPMENT OF THE IOG (THIRD EDITION)

The methodology for the IOG (third edition) outlines the process being used to identify, evaluate and synthesise the evidence to develop practice recommendations and, in the absence of research of sufficient levels, good practice statements. The methodology draws on evidence synthesis

methods developed by the Joanna Briggs Institute, the Australian National Health and Medical Research Council (NHMRC) and Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).²⁻⁵ The methods have been selected with consideration to the clinical questions relevant to the IOG, the type of evidence available to address these clinical questions, and the resources available for the project. The process includes:

- developing clinical questions,
- identifying, appraising and synthesising the evidence,
- evaluating the body of evidence, and
- translating the body of evidence into recommendations and good practice statements.

Purpose and audience

The purpose of the IOG update is to:

- promote access to holistic stomal care,
- reduce stomal, peristomal and parastomal complications,
- improve knowledge related to the formation and care of a stoma (including the management of complications),
- support the education and training of health professionals involved in providing stoma care, and
- optimise care participation, self-management, and health-related quality of life of individuals living with a stoma.

The IOG (third edition) is intended to apply to individuals living with a stoma in all care settings and all countries, with a primary focus on adults. As the most common ostomies formed are colostomy, ileostomy and urostomy, either permanent or temporary, the care of these ostomies will be the primary focus of the IOG.

The IOG will provide recommendations and implementation considerations intended as a general guide for clinical practice implemented by health professionals. Numerous terms are used to describe health professionals (usually nurses) who specialise in or are qualified to provide ostomy care, including enterostomal therapy (ET) nurses, stomal therapy nurses, stoma nurses, ostomy nurses and wound ostomy continence nurses.¹ In the IOG, the term ET nurses will be used to encapsulate these titles and roles. However, as the practice guidance seeks to be inclusive of non-specialised nurses and health professionals from different disciplines who are providing enterostomal care, the preferred term used in the guideline is ET/stoma/ostomy nurses/clinicians.

Guideline Development Panel

The IOG (third edition) is being overseen by a Guideline Development Panel. The Panel includes experts from the WCET® and the International Society of University Colon and Rectal Surgeons (ISUCRS). This collaboration reflects the shared missions and goals of these organisations to facilitate international collaboration, exchange scientific knowledge, and to promote quality outcomes for all individuals living with a stoma.^{6,7} The Guideline Development Panel also consists of a guideline methodologist to oversee the development

process, as well as individuals living with a stoma who can provide input from their lived experience of managing a stoma, and negotiating the health care system. Throughout the development process, input will be sought from other WCET® and the ISUCRS representatives to enhance the recommendations with implementation guidance, ensuring that the guideline addresses global issues and is appropriate to diverse global cultural, religious and social contexts.

Clinical questions

The Guideline Development Panel has identified *a-priori* clinical questions to address in the IOG (third edition). The initial clinical questions (see Table 1) are based on topics identified through an audit of the IOG (second edition) and the Guideline Development Panel's expert knowledge, as well as feedback from users of the second edition IOG. These clinical questions will be reviewed by the WCET® Executive Board, the WCET® Education Committee, the WCET® Norma N Gill Foundation® Committee, WCET® International Delegates and the ISUCRS Education Committee to ensure they address relevant topics and areas of guidance for the target audiences.

Identifying the evidence

A literature search has been undertaken to identify published evidence relevant to each clinical question. The search strategy is designed to identify relevant literature to each of the clinical questions, building on the evidence used in previous editions of the IOG. Searches will be conducted in the following databases:

- Ovid MEDLINE®,
- Cumulated Index to Nursing and Allied Health Literature (CINAHL),
- Excerpta Medica Database (Embase),
- Allied and Complementary Medicine (AMED),
- The Cochrane Review Library, and
- Google Scholar.

For each clinical question, a search is being conducted for evidence published since the previous edition of the guideline (01 January 2020 to 30 March 2025) in English that meets the broad inclusion and exclusion criteria in Table 2. Limiting the search date recognises that earlier research has already been identified in previous editions of the IOG, and provides a balanced approach between accuracy and workload.⁸ Additional articles identified as sentinel either within the included literature or by the Guideline Development Panel will also be eligible for consideration.

Search terms will focus on identifying evidence relevant to each of the clinical questions (see Table 3). First, a broad search will be conducted for publications related to ostomy care using MESH terms and keywords combined with Boolean operators. For each clinical question, the ostomy-specific literature search will be combined with search terms that address the key conceptual components of each clinical question.

Appraising the evidence

All evidence meeting the inclusion criteria that addresses a clinical question will be assigned a level based on the study design/type of evidence (see Table 4). Levels of evidence provide a basis on which guideline developers and users can evaluate the strength and reliability of research findings. The levels of evidence that will be used for the IOG (third edition) are based on the levels of evidence identified by the Joanna Briggs Institute (JBI) for studies of effectiveness (i.e. intervention studies) and studies focused on meaningfulness (qualitative evidence).⁹ Noting the lack of a recognised hierarchy of evidence for psychometric studies, levels were assigned by the Guideline Development Panel based on criteria considered most important in exploring the psychometric properties of an assessment tool.

After assigning a level of evidence to a study, the risk of bias will be evaluated by the Guideline Development Panel using recognised tools that facilitate the appraisal of internal and external validity^{4, 10} (see Table 5). Risk of bias tools to evaluate synthesised evidence focus on the literature selection, evidence assessment, synthesis and interpretation of results and publication bias. Tools for appraising intervention studies typically evaluate the risk of bias arising from selection, performance, attrition, detection and reporting. Appraisal of descriptive studies incorporates a consideration of confounding factors, and tools for evaluating qualitative studies consider the congruity, influence of researcher and reflection of the participant voice. The risk of bias assessment will be conducted by one reviewer and a sample of 75% the evaluations will be verified by a second reviewer. Should substantial discrepancy arise, the Guideline Development Panel will discuss differences of opinion and reach agreement on interpretation of the risk of bias tools.

Synthesising the evidence

Key details from the evidence sources relating to each of the clinical questions will be extracted to a question-specific evidence data table by one reviewer and verified by a second reviewer. The purpose of data extraction is to provide an overview of the evidence that is available to inform each of the clinical questions.¹¹ Data extraction will include the study design/level of evidence, risk of bias, participants and their clinical context, interventions and comparators and findings/results. When there is a larger volume of high-level evidence with consistent findings to address a clinical question, the lower-level evidence may not be included in the data extraction process, particularly where it supports the evidence already presented. All research excluded from the data extraction will be listed.

After summarising the research directly addressing the clinical question, a strength will be assigned to the body of evidence using a hierarchy adapted from NHMRC guideline development methods² (see Table 5). The strength of the body of evidence to support a specific clinical choice will be based on the study designs, their risk of bias, the volume of evidence and the consistency of results. For example, if there is a risk of bias

Table 1. Initial clinical questions

Quality of life, mental health and sexuality	<ol style="list-style-type: none"> 1. What is the impact of having an ostomy have on quality of life? 2. What is the impact of having an ostomy have on sexuality? 3. What factors impact how an individual adapts to having an abdominal ostomy? 4. What factors should be included in an assessment of the holistic psychosocial needs of an individual with an ostomy (including their families/carers)? 5. What are valid and reliable tools to guide holistic psychosocial assessment of an individual with an ostomy (including their families/carers)? 6. Is a targeted patient/consumer intervention/education effective in improving the quality of life of a person with an abdominal ostomy? 7. What are effective strategies to manage an abdominal stoma during sexual activity (and other physical activity such as sports)?
Knowledge, skills and ability to self-care	<ol style="list-style-type: none"> 8. What is the level of knowledge of individuals (including their families/carers) regarding how to manage their ostomy? Where do people source information? 9. What factors influence the self-care ability of an individual living with an abdominal ostomy (including their families/carers)? 10. What are valid and reliable tools to guide assessment of an individual living with an ostomy's self care ability? 11. Is a targeted patient/consumer support intervention/education effective in improving the knowledge, confidence, attitude/beliefs and self-care ability of an individual with an abdominal ostomy?
Health professional attitudes and beliefs	<ol style="list-style-type: none"> 12. What are the attitudes and beliefs of health professionals related to care of an individual with an abdominal ostomy? 13. Is a targeted intervention/education effective in improving health professionals' attitudes and beliefs regarding ostomy care?
Interprofessional practice	<ol style="list-style-type: none"> 14. Who should be involved in managing the care of an individual who is preparing for abdominal ostomy surgery? 15. Who should be involved in managing the care of an individual who has had abdominal ostomy surgery? 16. Is an interprofessional practice model more effective compared to other care models in improving outcomes for an individual with an abdominal ostomy?
Pre-operative care needs	<ol style="list-style-type: none"> 17. What are valid and reliable tools to facilitate a pre-operative clinical assessment of an individual undergoing abdominal ostomy surgery? 18. What pre-operative clinical care should be implemented for an individual undergoing abdominal ostomy surgery? 19. What factors should be considered when performing stomal site marking prior to abdominal ostomy surgery? 20. What components should be included in education, mental health and preparation for an individual prior to undergoing abdominal ostomy surgery?
Post-operative care needs	<ol style="list-style-type: none"> 21. What are valid and reliable tools for post-operative clinical assessment of an individual who has undergone abdominal ostomy surgery? 22. What factors should be considered when performing a post-operative assessment of the abdominal stoma? 23. What factors should be considered in a post-operative care management plan? 24. What post-operative peristomal skin care practices are effective in preventing abdominal stomal/peristomal complications? 25. What factors should be considered when preparing an individual for discharge and rehabilitation? 26. What components should be included in education, mental health and preparation for an individual following abdominal ostomy surgery? (e.g. colostomy irrigation).
Device/product selection	<ol style="list-style-type: none"> 27. What tools are available to assist in fitting ostomy barriers and abdominal containment devices? 28. What factors should be considered when fitting ostomy barriers and abdominal containment devices? 29. What devices/products are effective to manage a retracted stoma?
Ongoing care/long term of the person with an ostomy	<ol style="list-style-type: none"> 30. What are effective strategies for managing a stoma when traveling? 31. What are effective strategies for nutrition and hydration for an individual living with an abdominal ostomy? 32. What are effective strategies for high output ileostomy? 33. What are effective strategies for medication administration for an individual living with an abdominal ostomy?
Prevention and management of stomal complications	<ol style="list-style-type: none"> 34. What is the prevalence and incidence of abdominal stomal complications, emergencies and re-admission rates? 35. What are risk factors for abdominal stomal complications, emergencies and re-admission? 36. What are valid and reliable tools to identify and/or assess stomal and peristomal complications? 37. What are effective strategies to prevent common abdominal stomal complications? 38. Are there effective strategies to prevent stomal hernia? 39. What are effective strategies to treat common abdominal stomal complications/emergencies?
Considerations in populations with varying needs	<ol style="list-style-type: none"> 40. What cultural and religious/spiritual considerations should be made for an individual with an ostomy? 41. What are additional considerations for the following populations: <ul style="list-style-type: none"> • Individuals living with multiple stomas • An ostomy during pregnancy • Individuals living with a stoma who are overweight/obese, underweight or who have significant weight change • Individuals living with a stoma who have a spinal cord injury • Individuals living with a stoma who have physical disabilities and/or sensory impairments • Individuals living with a stoma who have a cognitive impairment • Considerations for individuals living with a stoma who are receiving end of life care

Table 2. Inclusion and exclusion criteria for new evidence sources

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> Published 01 January 2020 to 30 March 2025 English language Synthesized research: meta-analyses, systematic reviews and other evidence-based or consensus guidelines Primary research: analytical designs (e.g. randomized controlled trials and comparative study designs), observational designs (e.g. cross-sectional studies and case reports with >5 cases) and qualitative research Population: individuals undergoing abdominal stoma siting or surgery, or those with an abdominal stoma Context/setting: all clinical settings, all geographic settings Additional: When insufficient synthesised or primary evidence is identified, scoping reviews and narrative literature reviews will be considered 	<ul style="list-style-type: none"> Published prior to 01 January 2020 (excluding sentinel evidence) or not published by 30 March 2025 Languages other than English Non-peer reviewed research sources: non-peer reviewed case studies, conference abstracts and posters Commentary: opinion articles, editorials, letters to the editor, computational modelling, animal and bench research, reports Population: healthy volunteers or populations not directly relevant to individuals with a stoma, case reports with ≤5 participants

Table 3. Indicative search terms

Primary search	Key conceptual areas determined by the clinical question
Colostomy, enterostomy, enterostomal therapy, ileostomy, ileal conduit, peristomal, stoma, stomal therapy, ostomy, urostomy	<p>Management: appliances; accessories; barrier, base plate, flange, bag (pouch), stomal complications, skin integrity</p> <p>Patient values and experiences: body image, culture, holistic care, sexuality, quality of life, religion</p> <p>Surgical management: preoperative care, postoperative care, surgical stoma, stoma siting</p> <p>Holistic care: diet, discharge planning, telehealth, travel, education, assessment tools</p>

or low consistency across studies, the strength of evidence may be downgraded, even when the study designs are of the highest level.

When the body of evidence underpinning a clinical choice is insufficient to achieve a strength of A-C (see Table 6), the Guideline Development Panel may choose to make a good practice statement based on consensus. A good practice statement describes clinical practice considered by the Guideline Development Panel with a high level of confidence to be associated with achieving more good than harm for most people living with an ostomy.¹² A good practice statement is appropriate for providing clinical guidance when there is no high-level research related to the clinical question, the evidence base is not high enough, and/or for issues that are not appropriate for clinical research (e.g. for ethical reasons).

Next, the body of evidence addressing each clinical question will be synthesised in a narrative summary. An adapted Evidence to Decision (EtD) framework will be used to summarise the key information related to each clinical question. An EtD framework is designed to structure and inform the different considerations that contribute to

making a clinical recommendation.¹³ The framework is used to summarise not only the body of evidence (including its level and strength) on health benefits and risks associated with a clinical choice, but also information on the values and priorities of stakeholders, resources and feasibility, all of which are important considerations when deciding if a clinical choice should be recommended.^{4, 13, 14}

The EtD frameworks will be reviewed by the Guideline Development Panel and by the WCET® Executive Board, Committees and Delegates, the ISUCRS Education Committee and individuals living with stomas to ensure that the diverse perspectives of stakeholders across geographic and cultural contexts are represented, and to provide implementation considerations to support the recommendations (see below).

Making recommendations

The data included on the framework will be used by the Guideline Development Panel to determine a final recommendation, implementation considerations (i.e., practice points and initiatives to assist in implementing a recommendation), any considerations for specific sub-populations (e.g. individuals living in various geographic,

Table 4. Levels of evidence for individual studies

Level	Evidence for effectiveness	Evidence for meaningfulness	Evidence for psychometric properties
1	<ul style="list-style-type: none"> Systematic review and/or meta-analysis of randomised, controlled trials (RCTs) reporting risk of bias assessments for primary research Evidence-based guideline based on RCTs and reporting risk of bias assessments for primary research RCTs 	Qualitative or mixed-methods systematic review reporting risk of bias assessments for primary research	Systematic review of psychometric studies reporting risk of bias assessments for primary research
2	<ul style="list-style-type: none"> Systematic review of non-randomised studies reporting risk of bias assessments for primary research Evidence-based guideline based on non-randomised studies and reporting risk of bias assessments for primary research Quasi-experimental studies with prospective control Pretest/posttest design and retrospective control cohort study 	Synthesis of qualitative or mixed-methods studies with no risk of bias assessment	Psychometric studies with a population size appropriate to the tool and the analysis
3	<ul style="list-style-type: none"> Observational, analytical studies (e.g., single group cohort study, case-controlled study or observational study with no control) Repeated measures study with at least two data points (before and after the intervention) 	Single qualitative study	Psychometric studies with an inadequate population size for the tool and analysis
4	<ul style="list-style-type: none"> Cross sectional studies Case series/case study reports with >5 participants 	Cross sectional studies	
5	<ul style="list-style-type: none"> Narrative literature review and scoping review Bench research 	Systematic review of expert opinion	

Table 5. Risk of bias appraisal tools

Study design	Tool
Meta-analyses and systematic reviews	AMSTAR 2 ^{18, 19}
Clinical guidelines	AGREE II ^{3, 20}
Randomised controlled trials (RCTs)	Joanna Briggs Institute Critical Appraisal Tool for RCTs ²¹
Non-randomised comparative studies	Joanna Briggs Institute Critical Appraisal Tool for Quasi-experimental Studies ²²
Cohort studies	Joanna Briggs Institute Critical Appraisal Tool for Cohort Studies
Case series	JBI Critical Appraisal Checklist for Case Series ²³
Cross-sectional studies	JBI Checklist for Analytical Cross Sectional Studies ²⁴
Qualitative research	JBI Critical Appraisal Checklist For Qualitative Research ^{25, 26}
Psychometric studies	COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist Psychometric and Pragmatic Evidence Rating Scale (PAPERS) will be used to describe the psychometric strength of reported measures ²⁷

cultural or religious locations), and related priorities for future research. Recommendations addressing each clinical question will be reached with consideration to all elements on the EtD framework. The Guideline Development Panel will reach agreement on the strength of each recommendation it makes using the guidance in Table 7.

Reaching agreement

The Guideline Development Panel, together with selected WCET® experts, will undertake a formal Delphi process to reach a final agreement on recommendations. This will be undertaken using the RAND Appropriateness Method, a

nominal group voting methodology published by Research and Development/University of California at Los Angeles (RAND/UCLA) that can be used by a panel to reach agreement on topics.¹⁵ The consensus voting process will be conducted online using an interface that allows the panel members to share their opinions on each topic until agreement has been reached.¹⁵ Using the RAND Appropriateness Method, panel members vote on their level of agreement using a nine-point Likert Scale that represents three tertiles of agreement, uncertainty or disagreement. At the end of each voting round, a software system calculates the voting outcomes. The median agreement score on the Likert scale will be taken as the result for the voting round. Whether or not consensus has been reached will be determined using the RAND Appropriateness Method.¹⁵ The 30% to 70% interpercentile range (IPR) is calculated, along with the IPR adjustment for symmetry (IPRAS). If the IPRAS is greater than, or equal to, the magnitude of the IPR, then agreement will be considered to have been reached. Conversely, if the IPRAS is less than the magnitude of the IPR, then it is considered that there is no agreement.¹⁵ The recommendation will then either be accepted, discarded or adapted based on expert comments and voted on in the next consensus round. The full process will consist of a maximum of three consensus votes, with the results of each vote informing the next cycle, allowing consensus to be converged upon. Where consensus in agreement with a recommendation is not reached within three votes, the statement will be considered rejected.

Implementation considerations and culturally specific clinical guidance

Subsequent statements (implementation considerations) that support a recommendation and provide additional information (e.g., how, when, how often or who) will be developed to guide how recommendations and good practice statements are implemented in practice. Implementation considerations

may describe practical information or core principles considered pertinent to the recommendation. Implementation considerations and culturally specific clinical guidance will be supported by the available evidence as summarised in the data extraction tables and based on the expert opinion from WCET® and ISUCRS representatives, and individuals living with a stoma.

Stakeholder input and review

As outlined above, expert opinion from the WCET® Executive Board, Committees and International Delegates, the ISUCRS Education Committee and individuals living with stomas will be sought throughout the guideline development. Stakeholder input will also be sought through a formal review process inviting feedback from individuals living with a stoma and their caregivers, ET/stoma/ostomy nurses/clinicians, surgeons performing ostomy siting, academics, researchers, educators and industry representatives/companies. Feedback provided by stakeholders will be considered by the Guideline Development Panel, and when appropriate any additional evidence raised by stakeholders will be reviewed and incorporated into the final IOG (third edition).

DISCUSSION

Clinical guidelines and their development must embody the principles of evidence-based healthcare, because they establish expectations for the highest quality of care. The JBI outlines an evidence-based healthcare process that is relevant to the mission of WCET® and summarises the holistic process of guideline development adopted by the Guideline Development Panel.^{16, 17} The JBI's FAME model¹⁶ (see Figure 1) suggests that evidence-based healthcare must be practised within the context of feasibility, appropriateness, meaningfulness and effectiveness (FAME). These same principles are fundamental to the IOG (third edition) development methods.

Table 6. Strength of body of evidence underpinning a clinical choice

A	B	C	Consensus
Level 1 synthesized evidence at low risk of bias Multiple sources of level 1 primary research at low risk of bias	Level 1 evidence at moderate risk of bias Level 2 evidence at low risk of bias	Level 2 studies at moderate risk of bias Level 3 evidence at low or moderate risk of bias	Body of evidence not reaching the level required for a Strength of Evidence of A-C, but the choice is important for clinical practice
Consistent body of evidence	Most studies consistent and any inconsistencies may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	

Table 7. Strength of recommendation

Strong	Conditional	No recommendation
Indicates a judgment that most well-informed people would make	Indicates a judgment that a majority of well-informed people would make, but a substantial minority would not	Either no recommendation, or a recommendation indicating multiple options are equivalent

The FAME model¹⁶ highlights five key components that are fundamental to universal evidence-based healthcare: global health, evidence generation, evidence synthesis, evidence transfer and evidence implementation. Clinical guidelines themselves are one source of synthesised evidence (blue sector in Figure 1). However, the process of the IOG (third edition) development incorporates all the key components in the FAME model, highlighting how the guideline update process epitomises the key concepts of evidence-based healthcare.

The IOG (third edition) guideline development promotes global health. Sustainability in healthcare is more likely when research questions are derived from the knowledge needs of the target community and a collaborative approach, as prescribed in the guideline methods. Engagement of individuals living with a stoma, WCET® Board, Committees and International Delegates and other stakeholders will promote the global relevance of the guideline. Knowledge needs of individuals living with a stoma, ET/stoma/ostomy nurses/clinicians and surgeons performing ostomy siting underpin the clinical questions the guideline will address.

The FAME model highlights that generation of evidence is based on the three pillars of evidence-based healthcare: well-designed research studies, expertise of health professionals and the health consumers, and discourse and debate.^{16, 17} Throughout the IOG (third edition) development process, the Guideline Development Panel plays a role in research generation through its discourse and generation of new practice guidance. This process is facilitated by incorporation into the methods of a formal consensus process for reaching agreement on recommendations. Additionally, the evidence review process will identify and highlight evidence gaps to address in future research.



Figure 1: Joanna Briggs Institute Model of Evidence-Based Healthcare (FAME model)¹⁶ (used with permission)

As noted in the methods above, evidence synthesis is a key component of the guideline development process. Guideline development focuses on identification, evaluation and synthesis of evidence into evidence summaries from which clinical recommendations can be made. The methodology designed to promote transparency for guideline users, clearly identifying the level and strength of the underpinning evidence.

Within the FAME model, evidence transfer refers to active, participatory processes designed to promote access to and application of evidence within local (geographic and clinical) contexts.¹⁶ The IOG (third edition) plays a role in evidence transfer by providing recommendations for incorporation into local health systems, education for ET/stoma/ostomy nurses/clinicians and individuals living with a stoma, and active dissemination of the evidence.

Finally, the IOG (third edition) methods address the evidence implementation component of the FAME model. By engaging stakeholders across the world, the development process seeks to incorporate and support best practice in diverse local contexts. The production of international clinical guidelines seeks to facilitate change by incorporating the most contemporary evidence, considering facilitators and barriers to implementing recommendations, and consulting with key opinion leaders to prompt guideline uptake.

CONCLUSIONS

This article outlines the guideline methodology for the development of the IOG (third edition) being undertaken by the WCET® and ISUCRS. The methodology incorporates contemporary clinical guideline development methods that reflect the fundamental principles of evidence-based healthcare, ensuring the third edition IOG has a higher scientific quality and produces meaningful, positive impacts on clinical decision making. Most importantly, the methods highlight the values of WCET®, ISUCRS and the Guideline Development Panel to promote the holistic nature of enterostomal care, by incorporating the experiences of individuals living with a stoma and the expertise of ET/stoma/ostomy nurses/clinicians into the guideline, promoting best practice in ostomy care worldwide for all individuals with a stoma.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

GRANT ACKNOWLEDGEMENT

The World Council of Enterostomal Therapists® gratefully acknowledges the unrestricted educational grant from Hollister which will be used to support the development of the IOG 3rd Edition.

The IOG 3rd Edition is the sole independent work of the WCET® and partner organisation IUSCRS and in no way will be influenced by the company who provided the unrestricted education grant.

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