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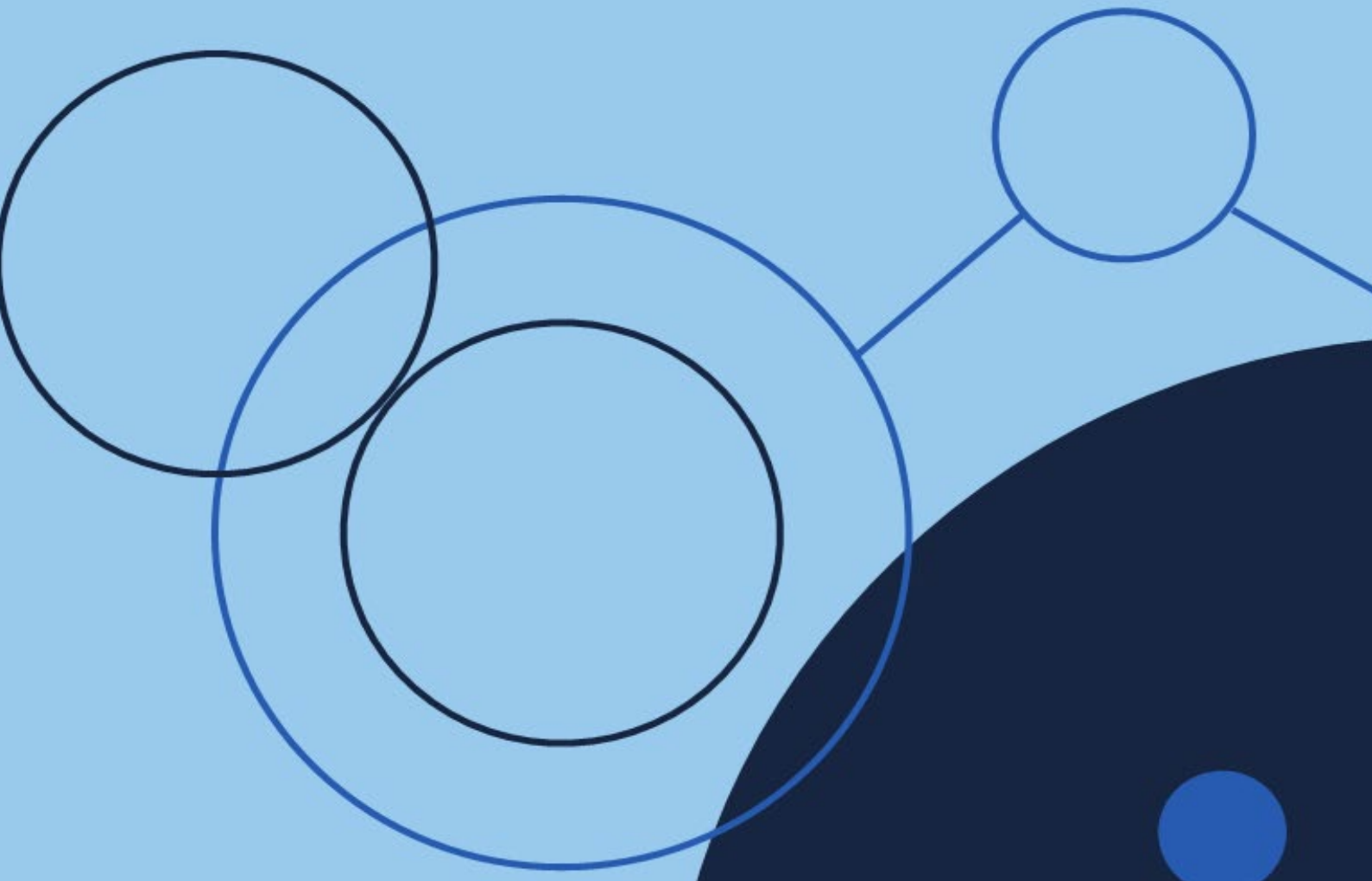
Developing a sustainable HIV,
viral hepatitis & sexual health workforce

ASHM Guideline Framework

Framework 1 - Creating and Updating ASHM Guidelines



Version Control

- **Version number:** V1
- **Date of issue:** August 2025
- **Prepared by:** Joel Paparello, ASHM Senior Project Officer
- **Approved by:** Zoe Sever, ASHM HIV Program Manager
- **Next review date:** August 2026

Acknowledgements

ASHM acknowledges the many individuals and organisations whose expertise, commitment, and lived experience contributed to the development of this Framework.

We wish to pay special tribute to Dr Nick Medland, who was the core driver of this Framework in its early stages. His vision, leadership, and dedication laid the foundations for this work, and his legacy continues to shape our commitment to evidence-based, inclusive, and impactful guidelines.

HIV Guidelines Strategic Subcommittee

We extend our thanks to the members of the HIV Guidelines Strategic Subcommittee for their strategic direction, clinical expertise, and commitment to ensuring that the Framework reflects best practice: Adam Bartlett, Liz Crock, Vincent Cornelisse, James McMahon, Louise Owen, Mary Poynten, Darren Russell, Janine Trevillyan, Rick Varma, Arthur Wong, and Edwina Wright.

Guideline Committee Members

We also acknowledge all Guideline Committee members who generously reviewed and provided feedback on the Framework, ensuring it meets the needs of both healthcare professionals and the communities we serve.

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Executive Summary

Purpose and Principles

Framework 1 provides ASHM with a standardised process for developing and updating evidence-based clinical guidelines in HIV, viral hepatitis, and sexual and reproductive health. It ensures transparency, methodological rigour, equity, and meaningful inclusion of diverse stakeholders by:

Being evidence-based and transparent – Recommendations are underpinned by systematic review or, where evidence is limited, clearly labelled Good Practice Points (GPPs), documented through the Evidence to Decision (EtD) process.

Placing equity at the core – Equality Impact Assessments and inclusive language standards ensure recommendations address accessibility and the needs of priority and marginalised groups.

Maintaining quality through engagement – Public consultation, documented feedback, and a two-year review cycle keep guidance current, relevant, and responsive.

Roles and Responsibilities

The Guideline Oversight Committee (GOC) oversees process quality, approves the scope, conducts AGREE II appraisals, appoints GOC Representatives, and grants final approval of the guideline.

The GOC Representative (GOC Rep) acts as a liaison between the GOC and the Guideline Committee, supporting the selection of committee members, reviewing draft content, ensuring adherence to methodological standards, and facilitating communication between the two groups.

The Guideline Committee drafts and finalises content, reviews the evidence, develops recommendations, and ensures equity and stakeholder inclusion throughout the process.

The Guideline Chair coordinates the development process, manages timelines, integrates feedback, and ensures all work adheres to the framework's requirements.

Development Process

The framework follows a six-step process to ensure methodological rigour, transparency, and stakeholder engagement:

1. Identify Gaps & Develop PICO Questions – Conduct a structured gap analysis using stakeholder feedback (clinicians, policymakers, community members). Formulate

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clinical questions using the PICO framework (Population, Intervention, Comparison, Outcome) and secure a minimum of 75% consensus from both the GOC and Guideline Committee before progressing.

2. Conduct Systematic Review – Commission an external review team to ensure an unbiased, high-quality evidence base. The Guideline Chair and GOC Rep oversee the confirmation of scope, methodology, and alignment with international standards.

3. Develop Recommendations – Review evidence and document decisions in an EtD table, outlining rationale, benefits, harms, feasibility, equity, and resource implications. Where robust evidence is unavailable, develop GPPs based on expert consensus, clearly labelled as such. Conduct an Equality Impact Assessment to ensure recommendations address equity and accessibility for priority and marginalised groups.

4. Internal Quality Review – Compile the draft guideline, including key recommendations, methodology, and review schedule. Apply the AGREE II Appraisal Tool to assess rigour, clarity, applicability, and editorial independence before consultation.

5. Public Consultation (4–6 weeks) – Engage clinical experts, community representatives, and professional bodies. Document all feedback, integrate where appropriate, and secure 75% committee consensus on substantive changes.

6. Final Approval & Publication – GOC formally approves, sets the next review date, and publishes the guideline on the ASHM website. Optional submission to a peer-reviewed journal. Ongoing monitoring every six months, with interim or rapid updates issued as required.

Key Methodological Tools

- Evidence to Decision (EtD) Tables – Used during drafting to transparently show how evidence is translated into recommendations, considering benefits, harms, feasibility, and equity.

- Good Practice Points (GPPs) – Recommendations based on expert consensus when high-quality evidence is lacking, always clearly labelled.

- AGREE II Appraisal Tool – Internationally recognised tool for assessing guideline quality across scope, rigour, clarity, applicability, and editorial independence.

Outputs

Guidelines that are clear, actionable, equitable, and evidence-informed, enabling healthcare professionals to deliver best-practice care, with all decisions traceable through transparent documentation.

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Glossary of Terms

Term	Definition
AGREE II (Appraisal of Guidelines for Research and Evaluation II)	A validated tool for assessing guideline quality across seven key domains, including scope and purpose, stakeholder involvement, rigour of development, clarity, applicability, and editorial independence.
Consensus Recommendation Tool	A structured tool guiding the development and review of recommendations, addressing rationale, stakeholder input, feasibility, equity considerations, potential harms, and resource implications.
Consensus Statement	A document reflecting expert agreement on a specific clinical or public health topic. Developed through structured expert consensus methods, these statements provide guidance but do not constitute formal guidelines.
Equality Impact Assessment (EIA)	A structured assessment ensuring recommendations consider equity, access, and inclusion, highlighting potential impacts on diverse population groups to mitigate unintended inequalities and maximise equitable outcomes.
Evidence to Decision (EtD)	A structured framework supporting guideline development groups in systematically translating research evidence into clinical or public health recommendations, considering criteria such as benefits, harms, resource use, equity, acceptability, and feasibility.
Good Practice Point (GPP)	Expert consensus recommendations are intended to guide clinical practice when direct research evidence is limited or unavailable, but the perceived benefits outweigh potential harms or risks.
GRADE (Grading of Recommendations Assessment, Development and Evaluation)	An internationally recognised systematic approach for assessing the quality of evidence and strength of clinical recommendations. Provides transparent and structured guidance for translating evidence into recommendations. Clarification on GRADE relating to this framework: ASHM guidelines do not currently adopt the complete GRADE system. Instead, ASHM elements of the GRADE system, such as systematic reviews, structured Evidence to Decision (EtD) tables, and clearly labelled Good Practice Points (GPPs). This approach aligns with ASHM's practical needs, providing flexibility and clarity, especially in scenarios where evidence may be limited or indirect.
Guide / Guidance Document	Consensus-based resources providing clinical or practical advice, distinct from formal guidelines. Developed using structured consensus

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	methods (Consensus Recommendation Tool), guides offer recommendations where comprehensive systematic reviews may not be feasible or practical.
Guide Writing Group	A team appointed to develop consensus-based guidance documents using structured expert consensus methods. This multidisciplinary group may include healthcare providers, relevant professionals, and end-user representatives (e.g., individuals with lived experience, peer navigators, community advocates, or consumer representatives).
Guideline	A systematically developed, comprehensive, evidence-based document providing clinical recommendations to assist healthcare practitioners in decision-making for specific clinical circumstances. Guidelines follow rigorous systematic review methodologies and align with the ASHM Guideline Framework.
Guideline Chair	The individual responsible for coordinating activities of the Guideline Committee, chairing meetings, managing project timelines, compiling contributions, integrating stakeholder feedback, and ensuring adherence to ASHM's methodological and editorial standards.
Guideline Commentary	Documents produced by ASHM that contextualise and interpret international guidelines for the Australian healthcare environment, considering local clinical practices, regulatory frameworks, and healthcare system specifics. Generally, commentaries do not introduce new recommendations unless clearly justified and transparently documented.
Guideline Committee	A Multidisciplinary group responsible for drafting and finalising guideline content based on systematic evidence reviews. It includes clinical experts, healthcare professionals from relevant disciplines, and at least two end-user representatives (e.g., individuals with lived experience, peer navigators, community advocates, or consumer representatives).
Guideline Oversight Committee (GOC)	A standing committee established for each ASHM health area (such as HIV, Viral Hepatitis, and Sexual Health) that oversees ASHM guidelines, guides, and commentaries. Responsibilities include ensuring methodological quality and consistency, conducting AGREE II appraisals, overseeing development processes, appointing guideline committee representatives (GOC Reps), and approving final outputs. The GOC also provides oversight and input, where relevant, on scope, priorities, and processes whenever new guideline development, updates, or rapid guidance is required. Members include diverse experts such as clinicians, basic scientists, social scientists, epidemiologists, clinical researchers, policy experts, and community representatives.

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GOC Representative (GOC Rep)	A member of the Guideline Oversight Committee who acts as a liaison within the Guideline Committee, supporting the selection of guideline committee members, reviewing draft content, ensuring adherence to methodological standards, and facilitating communication between the committee and the GOC.
Inclusive Language and Terminology	ASHM's standards for respectful, person-centred, and inclusive language in all guidelines, guides, and commentaries, aiming to avoid stigma, respect identity and preferences, and support clear communication in diverse healthcare contexts.
Population, Intervention, Comparison, Outcome (PICO)	A structured framework used for formulating clinical questions to guide systematic evidence reviews, clearly defining the Population, Intervention, Comparison, and Outcome of interest.
Resource	Supporting materials developed to enhance clinical practice, education, or patient care by translating recommendations into practical formats (e.g., clinical tools, decision aids, educational materials).
Systematic Review	A comprehensive, structured synthesis of research evidence addressing specific clinical or public health questions using transparent, reproducible methods designed to minimise bias.

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ASHM Guideline Framework V1

ASHM has developed this framework to guide the creation and updating of guidelines, which enable the healthcare workforce to deliver the best possible care in the areas of HIV, viral hepatitis, and sexual and reproductive health.

Selection and Composition Processes for ASHM Guideline Committees

Guideline Oversight Committee (GOC)

GOC Purpose

The Guideline Oversight Committee (GOC) provides oversight and governance of ASHM guidelines, ensuring methodological rigour, consistency, transparency, and alignment with international best practice.

GOC Selection Process

The GOC selection follows a structured, transparent approach:

Step-by-step Selection:

- Identification of Required Expertise: The ASHM Senior Project Officer or Program Manager, in consultation with senior ASHM leadership and stakeholders, identifies the broad range of expertise needed for effective oversight within each ASHM health area (e.g., HIV, Viral Hepatitis, Sexual Health).

- Expressions of Interest (EOI): ASHM circulates an open call for EOIs through existing guideline committees, professional networks, stakeholder communications, ASHM announcements, and relevant professional bodies. Applicants submit structured EOIs detailing their appropriate experience, expertise, leadership capabilities, availability, and disclosure of any potential conflicts of interest.

- Shortlisting and Approval: EOIs are reviewed by the ASHM Senior Project Officer or Program Manager.

Shortlisted candidates are formally presented to existing GOC members or, if no existing GOC members are available, ASHM senior management for review, endorsement, and final approval.

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GOC Composition

GOC membership typically includes senior clinicians and healthcare professionals (e.g., physicians, nurses, pharmacists, allied health professionals)

- Epidemiologists, social scientists, and clinical researchers
- Policy experts and public health specialists
- Community representatives and patient advocates
- Experts experienced in guideline methodology and appraisal

Typically, these individuals have previous experience with guidelines or have participated in ASHM guideline committees. ASHM ensures diverse representation across professional backgrounds, geographical locations, gender, and cultural experiences. All GOC members complete and submit a Disclosure of Interest form before appointment.

Guideline Committee

Guideline Committee Purpose

The Guideline Committee drafts and finalises guideline content, translating systematic reviews, expert clinical judgment, and stakeholder insights into clear, actionable clinical recommendations.

The selection process is structured, transparent, and involves collaboration between the GOC Representative (GOC Rep), Guideline Chair, and ASHM Senior Project Officer or Program Manager:

Guideline Committee step-by-step Selection:

- Identification of Required Expertise: The GOC Representative, Guideline Chair and ASHM Senior Project Officer or Program Manager, who collaboratively determine the specific expertise required based on the defined guideline scope, gap analysis findings, and clinical priorities.

- Expressions of Interest (EOI): ASHM issues a public call for EOIs through targeted stakeholder communications, ASHM website, professional networks, and community channels. Referrals or recommendations from stakeholders or current committee members are acceptable and encouraged; however, all referred candidates must undergo the identical structured EOI submission, review, and approval process to maintain rigour and transparency.

- Review and Shortlisting: EOIs, including referred candidates, are reviewed by the ASHM Senior Project Officer or Program Manager and the Guideline Chair, and or the GOC Representative. Candidates are shortlisted for consideration based on relevant clinical

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expertise, professional experience, diversity considerations, and committee balance.

- Final Selection and Approval: The shortlist is reviewed and formally approved by the GOC. If neither a formal meeting nor email approval from GOC members is feasible, final approval will be provided by the current Guideline Committee Chair and the GOC Representative (GOC Rep). Suppose the Guideline Chair or GOC Rep has not yet been appointed or is unavailable. In that case, the ASHM Senior Project Officer or Program Manager will liaise directly with the GOC to obtain approval. This ensures the final selection aligns with the required expertise, diversity, and methodological rigour standards.

Guideline Committee Composition

The Guideline Committee consists of a multidisciplinary group that may include:

- Clinical experts (physicians, nurses, pharmacists, allied health professionals)
- Epidemiologists and clinical researchers
- Social scientists and policy experts
- Jurisdictional representatives
- At least two community or consumer representatives with lived experience
- Additional stakeholders such as health promotion specialists, program managers, or health policy experts

ASHM ensures diverse representation across professional backgrounds, geographical locations, gender, and cultural experiences. All Guideline Committee members complete and submit a Disclosure of Interest form before appointment.

Publication of Committee Membership

For transparency and acknowledgment of committee member contributions, all members of ASHM Guideline Committees, including the Guideline Oversight Committee (GOC), will have their details formally published on the official ASHM Guideline website (unless explicitly advised otherwise).

Published details will include:

- Full name and professional photograph
- Brief professional biography
- Place of work and affiliation
- Specific position or role on the committee
- Name(s) of the guideline(s) they are contributing to

This information supports accountability, demonstrates transparency in the guideline development process, and formally recognises the expertise and contributions of each committee member.

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Framework 1: Creating and Updating Guidelines

This framework outlines the process for creating and updating guidelines to ensure they are evidence-based, clear, and practical. It supports healthcare decision-making by summarising current evidence into clinical recommendations, developed systematically, transparently, and with input from healthcare professionals, researchers, and people with lived experience.

Roles of Guideline Oversight Committee, Guideline Oversight Committee Rep, Guideline Committee, Guideline Chair and Writing Group

The Guideline Oversight Committee (GOC) operates independently of the Guideline Committee and writing group. It oversees the entire suite of guidelines in the relevant health area, guideline development process, formally endorses the scope and methods for each guideline, and ensures that recommendations meet standards for transparency, equity, methodological rigour, and quality. The GOC also provides final approval before guidelines are published, ensuring consistency with ASHM standards and international best practice.

Guideline Oversight Committee Representative (GOC Rep) is a member of the Guideline Oversight Committee who acts as a liaison within the Guideline Committee, supporting the selection of guideline committee members, reviewing draft content, ensuring adherence to methodological standards, and facilitating communication between the committee and the GOC.

The Guideline Committee is the primary group responsible for developing and overseeing guideline content. Members are selected to ensure broad geographic and stakeholder representation from across Australia. The Committee's key responsibilities include reviewing systematic evidence, formulating clinical recommendations, ensuring equity considerations, and maintaining methodological rigour throughout the guideline development process. The choice of term—Guideline Committee or Reference Group—depends on established preference or practice for a specific guideline, but their roles and responsibilities remain consistent.

Writing Group is an optional group that can be established by the Guideline Committee, depending on the complexity, size, or specific requirements of each guideline. A smaller subgroup, referred to as a Writing Group, may be drawn directly from the members of the Guideline Committee. The writing group performs similar tasks, including drafting guideline recommendations, synthesising evidence, preparing Evidence to Decision (EtD) tables, developing Good Practice Points (GPPs), and conducting the Equality Impact Assessment.

The Guideline Chair coordinates the overall guideline development process, facilitates meetings, manages timelines, and ensures the process adheres strictly to ASHM's methodological framework. Working closely with the ASHM Program Manager or the Senior Project Officer and the GOC rep, the chair will elect members for the Writing Group. The Chair integrates contributions from the Guideline Committee, Writing Group, and Reference Group, ensuring recommendations are clear, evidence-based, equitable, and practical. The Chair is also responsible for clearly documenting decision-making processes and for escalating any unresolved issues to the Guideline Oversight Committee.

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Methodological Tools in ASHM Guidelines

ASHM uses three primary methodological tools to ensure rigour, transparency, and clarity when developing and updating guidelines:

1. Evidence to Decision (EtD) Tables

   When used: During guideline drafting to transparently document how the committee translates systematic review findings into clear, evidence-based recommendations.

   Purpose: To systematically illustrate the development of recommendations by clearly assessing the quality of evidence, weighing benefits and harms, considering the feasibility of implementation, equity impacts, and resource implications.

   Who uses it: The Guideline Committee and or Writing Group during initial drafting stages (Step 2: Systematic Review – Step 3: Drafting Recommendations).

2. Good Practice Points (GPPs)

   When used: Clearly and explicitly used when high-quality, direct evidence is unavailable or insufficient for a strong evidence-based recommendation.

   Purpose: Facilitates the formulation of recommendations based primarily on expert clinical judgment, consensus, and practical experience, rather than solely relying on direct research evidence.

   Who uses it: The Guideline Committee and or Writing Group during recommendation drafting, clearly documented in the EtD tables (Step 3, Drafting Recommendations).

3. AGREE II Appraisal Tool

   When used: During internal and final quality review stages, to assess the methodological rigour, transparency, clarity, and usability of the guidelines.

   Purpose: Ensures the draft guideline meets international standards across key domains (scope, stakeholder involvement, methodological rigour, clarity, applicability, editorial independence).

   Who uses it: Members of the Guideline Oversight Committee (GOC) during internal quality review (Step 4, Internal Quality Review) and again during final review post-consultation, only if recommendations change following public consultation (Step 5, Final Quality Review).

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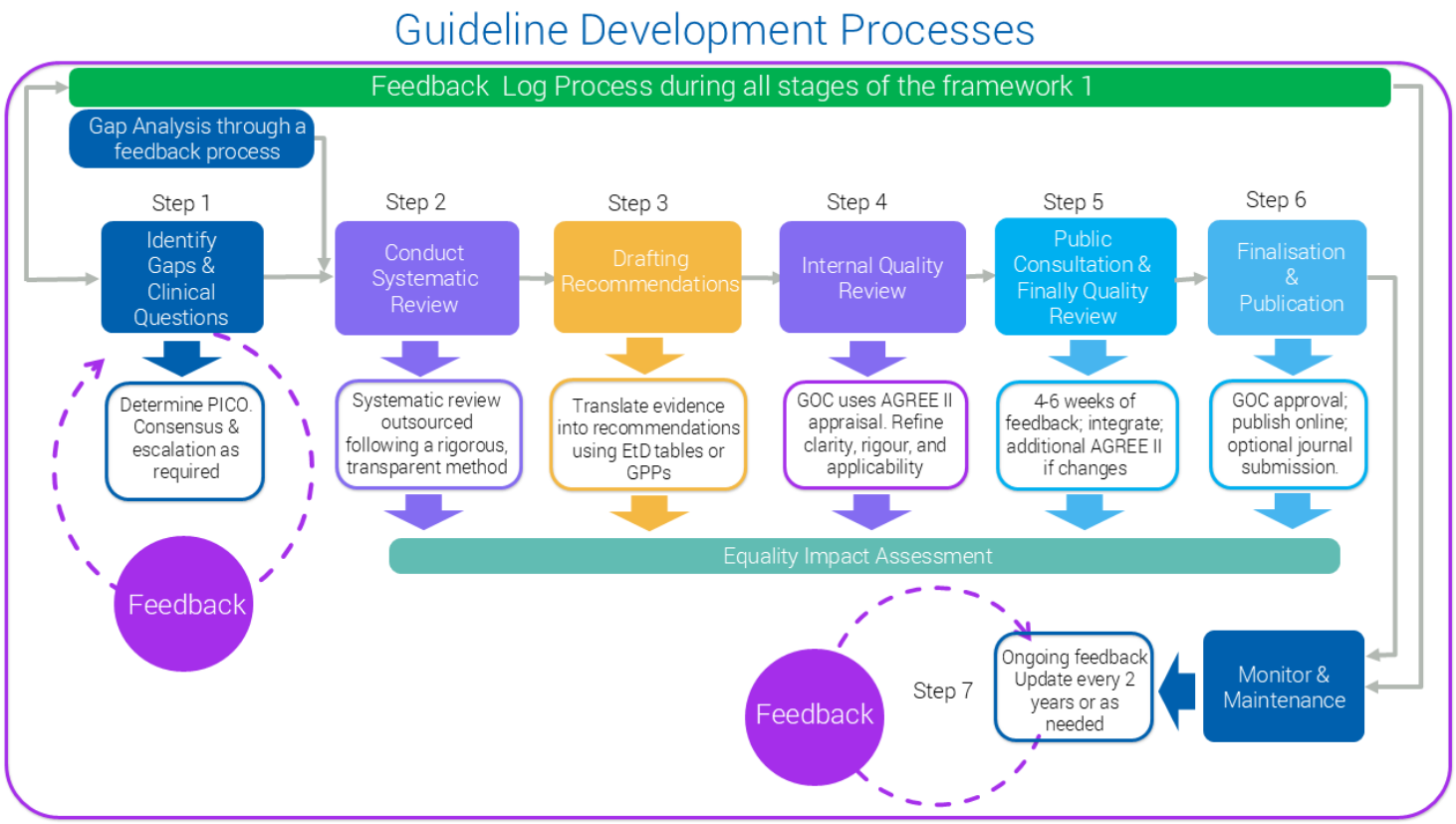

Guideline Development Process

Step 1: Identify Gaps and Clinical Questions (PICO)

Feedback and Gap Analysis Process

ASHM, with the support of the GOC rep and Guideline Chair, conduct a gap analysis based on feedback collected from stakeholders, including clinicians, community members, program managers, policymakers, and guideline users. Feedback may be gathered through online feedback, website analytics, webinar Q&A sessions, evaluation data, post-guideline implementation surveys, and direct consultations with advisory and program committees. This structured input helps ASHM identify outdated content, emerging clinical priorities, implementation challenges, and areas requiring new evidence or clarification.

Note: These feedback collection processes represent best-practice methods. ASHM may selectively use some or all methods based on guideline requirements, stakeholder engagement needs, timelines, and available resources. All feedback is systematically logged, categorised, and reviewed regularly. Only complex, contentious, or high-impact issues are escalated to the full GOC for formal discussion and decision-making.

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Determining and Developing PICO Questions

Based on the comprehensive gap analysis, the GOC rep, Guideline Chair and ASHM Senior Project Officer or Program Manager collaboratively identify priority areas requiring new or revised clinical guidance. This is then shared with the Guideline Committee for their review and input.

- Typically, 4–6 PICO questions are developed per guideline update cycle. However, the precise number is collaboratively decided, considering:
- Urgency and clinical significance of identified gaps: Priority is given to questions addressing immediate clinical needs, significant uncertainties, or gaps directly impacting patient care and outcomes.
- Scope and feasibility of conducting systematic reviews: Questions are selected to ensure systematic reviews remain manageable, practical, and methodologically robust within given resources.
- Available project timelines and resources: ASHM ensures a realistic workload and timeline, balancing methodological rigour with available staffing, expertise, and funding resources.

Define exactly what the guideline covers and clearly outline key clinical questions using the PICO framework:

Population: Who is affected?
Intervention: What treatment or action?
Comparison: Alternatives?
Outcome: What results or impacts are measured?

Consensus Requirement for PICO Questions

A minimum of 75% agreement from both the Guideline Oversight Committee (GOC) and the Guideline Committee is required to endorse PICO questions for further progression.

For a detailed explanation of the consensus process, please refer to the "Consensus Decision-Making Process" section below.

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Consensus Decision-Making Process

Purpose:

ASHM employs a structured consensus decision-making process to ensure transparency, rigour, and fairness in guideline development. This process primarily applies to approving clinical questions (PICO), recommendations, and key methodological decisions.

Achieving Consensus (75% Agreement) is required from both the Guideline Committee and the Guideline Oversight Committee (GOC) for formal endorsement. Voting is recorded and conducted either through open voting during committee meetings—documented in the official minutes—or via online survey voting or email confirmation. In all cases, each committee member's vote is recorded and reported by the ASHM Senior Project Officer or Program Manager.

Documentation and Transparency

All voting outcomes are formally documented in meeting minutes or official decision records, indicating individual votes, overall percentages, and final outcomes. This documentation is securely stored on ASHM's internal systems and remains accessible to relevant committee members to ensure complete transparency.

Process if Consensus is Not Initially Reached

If the required 75% consensus is not achieved, the issue is discussed in greater detail either during the same meeting or at a subsequent scheduled meeting. Additional supporting evidence or alternative proposals may be requested or presented. If initial agreement remains out of reach, revised proposals, further data, or alternative options are presented clearly to the committee. Following these discussions, a second formal vote is conducted using the same structured method as the initial vote.

Escalation Process for Persistent Disagreement or <75% Agreement

When consensus remains below 75% after thorough discussion, revision, and additional votes, the unresolved matter is formally escalated to the ASHM Senior Project Officer or Program Manager, the Guideline Committee Chair, and the GOC Representative (GOC Rep). These senior representatives review the issue in detail, provide additional strategic or methodological guidance, facilitate targeted discussions if required, and make a clear and transparent final decision to resolve the matter. The final decision and its rationale are documented and communicated transparently to the full Guideline Committee and the GOC.

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Step 2: Conduct Systematic Review (outsourced to external researchers)

An external group conducts a systematic review to provide clear, comprehensive, and unbiased evidence to inform guideline recommendations.

ASHM engages external researchers to conduct systematic reviews. The GOC rep and Guideline Chair confirm that the scope and clinical questions are appropriate and that the review method aligns with international standards. While the Guideline Chair and GOC representative typically oversee the review process, in cases where their direct involvement is not feasible, a qualified ASHM-appointed reviewer may assume this role.

Note: During the review, the appointed reviewer monitors progress, ensures the use of appropriate databases and inclusion criteria, and determines—where applicable—if advanced evidence synthesis methods such as meta-analysis should be considered.

The Systematic Review Outsourced Team presents its findings in a structured and transparent format. Results are communicated clearly to the Guideline Chair, GOC Representative (GOC Rep), and the ASHM Senior Project Officer or Program Manager, including detailed documentation of search strategies, databases used, inclusion and exclusion criteria, data extraction methods, quality assessment procedures, and justification for conducting or not conducting a meta-analysis.

Step 3: Develop Guideline Recommendations

Process overview

After receiving the systematic review findings from external reviewers, the Guideline Committee and/or writing group follows a structured process to develop the recommendations.

The first stage involves a careful review of the evidence to confirm the relevance, quality, and completeness of the findings from the systematic review. Once the evidence review is complete, the committee drafts each recommendation using a structured Evidence to Decision (EtD) table. This EtD table outlines the rationale for the recommendation, implementation considerations, potential risks, and resource implications. Recommendations that are evidence-based draw on robust and sufficient evidence from the systematic review. In contrast, recommendations developed primarily through expert consensus—when robust direct

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evidence is not available—are clearly labelled as Good Practice Points (see GPP information in Step 3: Develop Guideline Recommendations).

> Additional clarification on Good Practice Points (GPPs): Good Practice Points (GPPs) are recommendations developed by the Guideline Committee and/or writing group based on their clinical expertise and experience, primarily used when high-quality research evidence isn't available or sufficient. GPPs assist healthcare providers by providing practical guidance based on the most current expert knowledge and clinical consensus. For example, a GPP might recommend regular clinical monitoring intervals when specific evidence-based timing hasn't yet been established by research.

Equality Impact Assessment

After drafting recommendations or GPPs, the community representatives from the Guideline Committee complete an Equality Impact Assessment to systematically ensure that recommendations consider and address equity, accessibility, and potential impacts on marginalised groups (e.g., Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse communities, LGBTQIA+ individuals, and people with lived experience).

Step 4: Draft Guideline

Purpose

The Guideline Chair systematically compiles the guideline draft to ensure it is practical, precise, methodologically rigorous, and directly beneficial for healthcare providers and stakeholders. The draft guideline explicitly includes the following key components:

- Key Recommendations Upfront: A concise, clearly articulated summary of actionable recommendations at the beginning of the document. This placement enables quick reference for healthcare providers and stakeholders.

- Introduction and purpose: A clear statement of the guideline's purpose, objectives, intended audience, clinical context, and overall scope of practice.

- Definitions and Methods: Explicit definitions for critical terms, concepts, and acronyms used within the guideline. It also transparently documents the methodologies employed in conducting systematic reviews, developing and drafting recommendations (including Good Practice Points), and evidence synthesis and decision-making processes.

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- Clinical Guidance: Structured, clearly organised sections dedicated to specific clinical areas such as screening, diagnosis, and management. Each section explicitly provides practical, evidence-informed, and easily implementable guidance tailored specifically to clinical practice.

- References: A full, clearly cited references for all evidence sources used throughout the guideline, formatted consistently under the Vancouver referencing style.

- Next Review Date: A clearly stated schedule for the guideline's future review and update, explicitly indicating timelines and processes for future evidence assessment and revisions.

Internal GOC review:

The GOC rep circulates the drafted guideline and completed assessments to the GOC, which will undergo an internal quality review using Agree II appraisal. This review ensures that the GOC verifies methodological rigour, equity considerations, and the overall appropriateness of the recommendations.

- Recommendations align with the evidence from the systematic review or appropriately justify expert consensus (GPPs).
- The methodology used in formulating recommendations (EtD tables and Equality Impact Assessments) has been correctly followed and transparently documented.
- Recommendations adequately consider equity, feasibility, and practicality for end-users.
- Language used is inclusive and suitable for the intended clinical audience.
- Any disagreements or unresolved issues are explicitly documented and addressed.

Additional Quality Assurance Measures

The Guideline Chair ensures that each recommendation explicitly states the certainty or strength of its supporting evidence, clearly differentiating between evidence-based recommendations and consensus-based recommendations (see GPP definition in Step 3: Develop Guideline Recommendations). Recommendations include hyperlinks directly linking to their corresponding Evidence to Decision (EtD) tables (see Appendix 1), facilitating transparency, traceability, and ease of access to decision-making. All content consistently adheres to Australian English language standards and the inclusive language principles

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outlined in Appendix 3: Inclusive Language and Terminology, which provides detailed guidance on respectful, people-first language and the avoidance of stigmatising or pathologising terms.

Unresolved Issues and Escalation

Any unresolved disagreements, contentious issues, or situations where consensus is not achieved during the drafting phase are documented by ASHM. Such matters are promptly escalated for detailed review by the Guideline Chair and the GOC Representative (GOC Rep), who collaborate with the ASHM Senior Project Officer or Program Manager to address these issues comprehensively.

If resolution remains unattainable at this level, the issue is formally escalated to the Guideline Oversight Committee (GOC). The GOC conducts a structured review, providing a clear and documented resolution. The GOC's final decision, along with its rationale, is transparently communicated back to the Guideline Committee, ensuring clarity and closure on the issue.

Steps 5 and 6: Public Consultation, Final Approval, and Publication

The purpose of the consultation and approval process is to ensure that guideline recommendations are practically implementable, clinically relevant, and methodologically robust. It also aims to guarantee that recommendations are inclusive of diverse stakeholder perspectives, addressing equity and accessibility, and accurately reflecting comprehensive input from relevant experts, healthcare professionals, and community representatives before final approval and publication.

Structured Consultation Process

Following the internal quality review by the Guideline Oversight Committee (GOC), the draft guideline undergoes a structured public consultation period, typically lasting four to six weeks.

Definition of Public Consultation:

"Public consultation," in this context, involves explicitly engaging with a clearly defined group of stakeholders and experts relevant to the specific disease area or health topic of the guideline. Stakeholders typically include:

- Clinical Experts: Specialists, general practitioners, nurses, pharmacists, epidemiologists, and other relevant healthcare professionals.

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- Community Representatives: Individuals from priority populations, patient advocacy groups, people with lived experience, Aboriginal and Torres Strait Islander communities, culturally and linguistically diverse (CALD) groups, and LGBTQIA+ communities.

- Professional Bodies and Organisations: Relevant medical and health associations, government health departments, academic institutions, non-governmental organisations (NGOs), and research organisations.

- Methodological Experts: Specialists experienced in guideline methodology, evidence synthesis, systematic reviews, and clinical guideline implementation.

The draft guideline is disseminated clearly through targeted communication channels, including email distributions, ASHM newsletters, relevant professional networks, and community group platforms. Stakeholders provide detailed feedback through structured means such as:

- Online feedback forms and surveys
- Webinars, workshops, and structured consultation meetings
- Direct email submissions or formal written responses from key organisations

Feedback Integration Process:

All feedback received during consultation is clearly documented, categorised, and systematically reviewed by the Guideline Committee. Integration of feedback is managed as follows:

- Minor edits (grammar, formatting, and minor wording changes): These edits are managed and implemented directly by the Guideline Chair, without further committee approval.

- Substantial content-related changes (recommendation adjustments, significant wording revisions, changes in key messages): These require documented re-review and explicit approval by the Guideline Committee. The review and approval process are coordinated collaboratively by the Guideline Chair, GOC Representative (GOC Rep), and ASHM Senior Project Officer or Program Manager. A minimum consensus of 75% from the Guideline Committee is necessary. If consensus cannot be achieved, unresolved issues are explicitly escalated to the Guideline Oversight Committee (GOC) and ASHM Program Manager or Senior Project Officer for final review and resolution. For further details on managing unresolved consensus, see the Consensus Decision-Making Process section.

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Final Quality Review and Approval by the Guideline Oversight Committee (GOC)

Following the integration of feedback, if changes were made to clinical recommendations, the GOC undertakes a final quality review. This final assessment explicitly includes:

- Methodological Rigour: Ensuring guidelines adhere strictly to established methodological standards. For substantial changes, the AGREE II appraisal tool is explicitly reapplied.

- Transparency and Clarity: Confirming clarity of the guideline content, transparency in decision-making, and explicit documentation of all changes made in response to consultation feedback.

- Inclusivity and Practicality: Ensuring recommendations reflect diverse stakeholder input, are inclusive, equitable, and practically implementable for end-users.

4. Guideline Review Schedule (Formal and Rapid Reviews)

To ensure guidelines remain current, evidence-based, and responsive to evolving clinical needs, each guideline undergoes a scheduled formal review at least every two years from the date of publication. The Guideline Oversight Committee (GOC), supported by the ASHM Senior Project Officer or Program Manager, explicitly maintains this review schedule and oversees the review process.

ASHM continues to maintain a dedicated "Feedback Log". Feedback will be collated into this log from a variety of sources, including an online feedback form linked directly from each guideline webpage, to provide stakeholders with an accessible, ongoing method to submit feedback about the guidelines.

Process:

- Feedback Submission: Stakeholders submit structured feedback specifying guideline sections, practical experiences, emerging evidence, or identified gaps.
- Feedback log entry: Submissions populate the Feedback Log, securely stored on ASHM's internal systems.

Inclusion in Analysis:

- Review cycle: Feedback is reviewed continuously, and formally every six months by the ASHM Program Manager or Senior Project Officer with the Guideline Chair, to determine if rapid guidance is required.
- Acknowledgement: ASHM provides timely confirmation to stakeholders that feedback has been received and is under consideration.

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Interim and Rapid Guidance Reviews: In addition to regularly scheduled reviews, interim or rapid guidance reviews may be initiated earlier under specific circumstances, including:

- Emergence of Critical New Evidence: When significant new evidence is published, such as influential clinical trials, authoritative studies, or robust conference abstracts that substantially impact clinical practice or decision-making.

- Policy or Regulatory Changes: Rapid reviews are explicitly triggered by sudden, substantial changes in policy, regulations, or authoritative health guidance affecting clinical practice or service delivery.

- Public Health Emergencies or Urgent Clinical Needs: If a public health emergency, infectious disease outbreak, or another urgent clinical scenario occurs, immediate, rapid guidance review processes may be activated to provide timely clinical direction.

Decision-Making for Interim Reviews: Decisions regarding the need for interim or rapid guidance reviews are explicitly and collaboratively made by the Guideline Oversight Committee (GOC), the Guideline Chair, the GOC Representative (GOC Rep), and the ASHM Senior Project Officer or Program Manager. Each decision is documented, specifying reasons, timelines, methods, and expected outputs to ensure transparency, clarity, and responsiveness.

Recommendations summarise the available evidence to inform clinical practice. Where robust, high-quality evidence is not available, Good Practice Points (GPPs) based on expert consensus and clinical experience are provided, clearly marked to differentiate them from evidence-based recommendations.

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Appendix 1: Evidence to Decision Table Tool

Purpose: The Evidence to Decision (EtD) Table Tool supports the structured, transparent, and explicit development of guideline recommendations. It helps authors systematically document the rationale, evidence base, considerations, and explicit judgments behind each recommendation, ensuring methodological rigour, transparency, and practical applicability.

Components:
The tool comprises two main components:

1. Evidence to Decision (EtD) Table – Author Draft Template
   Instructions for Completion: The EtD table should be completed by the author(s) or the guideline writing group during recommendation drafting. Each table must document:

   - Recommendation Statement: Provide a clear, specific, actionable recommendation.
   - Rationale: Justification for the recommendation, referencing explicitly supporting evidence, clinical rationale, or consensus-driven considerations.
   - Summary of Evidence: Condense the relevant evidence, specifying the type, quality, certainty, and applicability of studies or authoritative sources supporting the recommendation.
   - Benefits and Harms: Outline anticipated clinical or public health benefits, alongside any potential risks, harms, or unintended consequences associated with the recommendation.
   - Feasibility and Resource Implications: Document considerations around implementation feasibility, including necessary resources, workforce implications, training requirements, and potential barriers.
   - Acceptability: Outline anticipated acceptability among healthcare providers, stakeholders, and affected communities.
   - Equity Considerations: Identify and address considerations relating to equity, inclusivity, accessibility, and impact on priority or marginalised populations.
   - Final Judgements and Decisions: Document the final judgement and decision of the Guideline Committee, coordinated and supported explicitly by the GOC Representative (GOC Rep) and the ASHM Senior Project Officer or Program

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Manager. Include detailed documentation of specific actions required, any further considerations, or unresolved issues arising explicitly from the structured consensus decision-making process established by ASHM.

2. Internal Reviewer Quality Checklist

Purpose: Completed after author submission, this structured internal quality checklist is typically completed by the Guideline Oversight Committee (GOC) reviewers, in collaboration with the Guideline Committee Chair, GOC Representative (GOC Rep), and the ASHM Senior Project Officer or Program Manager. This comprehensive internal review evaluates the completeness, transparency, and methodological rigour of each recommendation. The checklist explicitly assesses whether each component of the EtD table is adequately addressed, ensuring robust methodological quality, explicit transparency, and thorough documentation of decisions.

Usage and Documentation

All completed EtD tables and internal reviewer checklists must be documented, securely stored, and made available upon request for audit, accountability, and transparency. ASHM explicitly maintains these records to ensure ongoing methodological rigour and guideline quality assurance.

Evidence to Decision Table - Author Draft Template

Section	Response
Recommendation	
Rationale	
Stakeholder Input	
Implementation Considerations	
Equity Considerations	
Potential Risks or Harms	
Resource Use	
Author(s) and Date	

Example: Completed Evidence to Decision Table

This example demonstrates how guideline authors can use the EtD table to develop structured recommendations. It shows how to document each key element — including rationale, stakeholder input, implementation feasibility, equity considerations, potential risks or harms, and resource implications — in a clear and consistent format.

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Section	Instructions / Example
Recommendation	Offers opt-out HIV testing in general practice.
Rationale	Opt-out testing reduces stigma and increases early detection.
Stakeholder Input	Input explicitly gathered from general practitioners, primary healthcare providers, community health organisations, and patient advocacy groups.
Implementation Considerations	Effortlessly and rapidly implementable in primary care settings with minimal additional training or resource requirements.
Equity Considerations	Explicitly improves healthcare access among marginalised, underserved, and high-risk populations, reducing existing inequities in HIV diagnosis and treatment access.
Potential Risks or Harms	Minimal risks identified. Potential patient misunderstanding can be mitigated through structured communication, educational resources, and clear patient-provider discussions.
Resource Use	Demonstrated cost-effectiveness due to significantly reduced costs associated with late-stage HIV diagnosis, ongoing healthcare management, and improved public health outcomes.
Author(s) and Date	Dr. J. Smith, Joel Paparello – April 2025

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Appendix 2: Agree II Appraisal (Internal Reviewer Quality Checklist)

Purpose: This internal reviewer quality checklist, based explicitly on the internationally recognised AGREE II appraisal tool, is completed by the Guideline Oversight Committee (GOC) in collaboration with the Guideline Committee Chair, GOC Representative (GOC Rep), and the ASHM Senior Project Officer or Program Manager after guideline authors submit their final draft recommendations.

The checklist ensures each recommendation meets ASHM's internal quality standards for:

- Clarity
- Transparency
- Stakeholder inclusion
- Feasibility
- Equity
- Practical implementation

Instructions for use:

- Review each criterion outlined in the checklist.
- Mark the appropriate column (Yes/No).
- Document clear comments or recommendations for improvement, providing a detailed rationale for all assessments.

Consensus Recommendation – Reviewer Checklist Template

This blank template is to be completed for each recommendation submitted. Reviewers should:

- Tick the appropriate column for each criterion.
- Provide comments where necessary to clarify decisions or suggest improvements.

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Evaluation Question	☑ Yes	✕ No	Comments (explicitly document rationale or recommendations)
1. Is the recommendation clearly and explicitly stated, including its intended audience and specific actions?	☐	☐	
2. Is the rationale explicitly provided, clearly justified by high-quality evidence or expert consensus?	☐	☐	
3. Have all relevant stakeholders explicitly been involved or represented in developing this recommendation?	☐	☐	
4. Are the feasibility and practical implementation considerations explicitly addressed?	☐	☐	
5. Have explicit equity and inclusivity considerations been clearly documented and addressed?	☐	☐	
6. Are potential risks, harms, or unintended consequences explicitly stated and mitigated?	☐	☐	
7. Is resource use explicitly and transparently documented, including necessary resources, costs, and practical implications?	☐	☐	
8. Are the authors listed, and is the development date explicitly documented?	☐	☐	
9. Is the recommendation explicitly aligned with ASHM methodological and transparency standards?	☐	☐	

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Appendix 3: Inclusive Language and Terminology

Purpose: This guidance promotes respectful, people-first, and inclusive language across all ASHM guidelines, guides, and commentaries. It reflects ASHM's commitment to creating stigma-free healthcare environments and centring the lived experiences and dignity of individuals in all published materials.

Language Guidance for Authors and Reviewers

When drafting or reviewing ASHM guidelines and related documents, contributors must explicitly adhere to the following inclusive language standards:

- Use People-First Language: Prioritise the person before the condition or status (e.g., "people living with HIV" instead of "HIV-infected").

- Avoid Stigmatising and Pathologising Terms: Replace terms that may stigmatise or negatively label individuals (e.g., replace "non-compliant" with "experiencing adherence challenges," "addict" with "person who uses drugs," and "high-risk" with "priority population").

- Respect Individual Identities and Preferences: Use preferred pronouns, self-identifiers, and descriptors, ensuring dignity and inclusivity.

- Avoid Assumptions: Do not make assumptions based on appearance, gender identity, cultural background, age, or ethnicity.

- Use Inclusive Terms Around Gender, Sexuality, Disability, and Drug Use: Employ language inclusive of all genders and sexual orientations, respectful of people with disabilities, and non-judgmental regarding drug use or behavioural choices.

- Reference Anatomy, Not Gender Identity, When Clinically Relevant: When clinical precision is needed, explicitly use anatomical terms rather than gender-based terms (e.g., "people with a cervix" rather than gendered terms).

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Required Resources and References

All contributors and reviewers are explicitly expected to review and follow the guidance provided by:

- The ASHM Language Guide (2025 edition): This comprehensive guide provides detailed recommendations on preferred inclusive terminology across all ASHM materials.

  Follow this link to access the ASHM Language Guide (2025 edition): ASHM Language Guide

- The People First Charter for Language Guidance in HIV, Drug Use, and Sexual Health Content: A structured resource specifically designed to ensure people-first, inclusive, and stigma-free language is consistently used across all relevant contexts.

  Follow this link to read the People First Charter: People First Charter

Practical Note for Contributors

Contributors — including Guideline Committee members, Community Organisation Representatives, individuals with lived experience, the Guideline Committee Chair, GOC, and GOC Representative — are integral to the guideline development process.

- Consult with community representatives and individuals with lived experience to clarify preferred terminology or wording.
- If community feedback identifies preferred language or terminology, prioritise this over standardised clinical terminology to ensure guidelines remain respectful, inclusive, accurate, and relevant to the communities they serve.

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