

Infertility: Guidelines, Gaps and Tools



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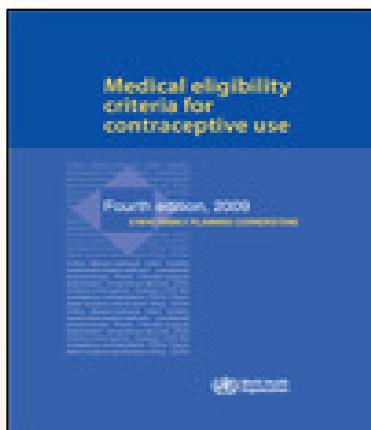
Strategic vision: a fully integrated approach to "family planning"

Substantial reduction in the unmet need for contraception and improved access to infertility prevention and care services have been achieved, allowing people to realize their fertility goals

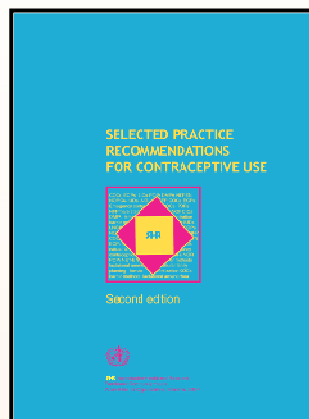
Guidelines and Tools - Family Planning

http://www.who.int/reproductivehealth/topics/family_planning/en/index.html

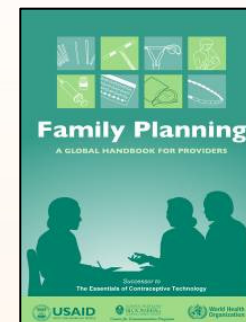
Family planning (contraception) guidelines and tools



4th edition,
published 2010

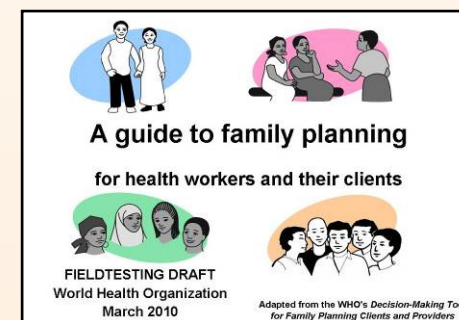
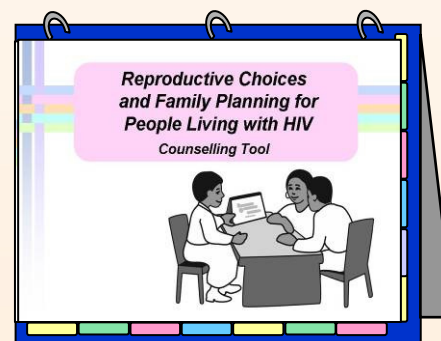
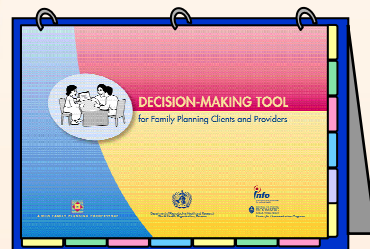
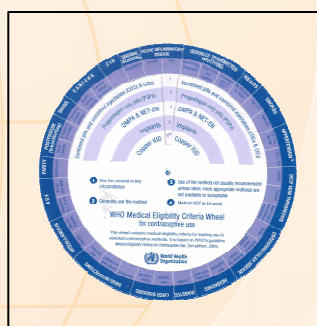


Selected Practice
Recommendations



Global **Handbook**

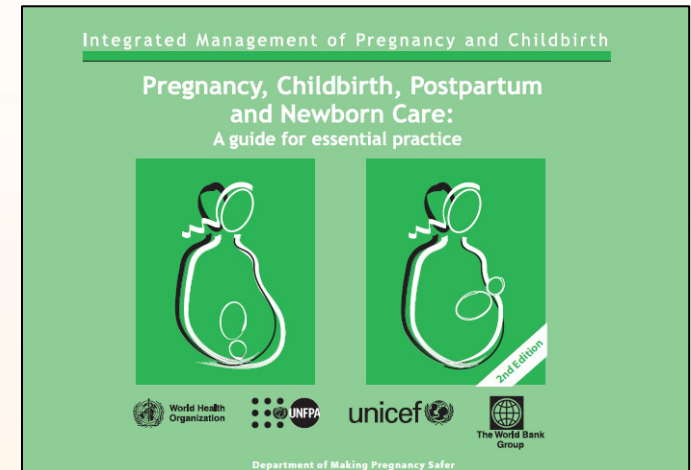
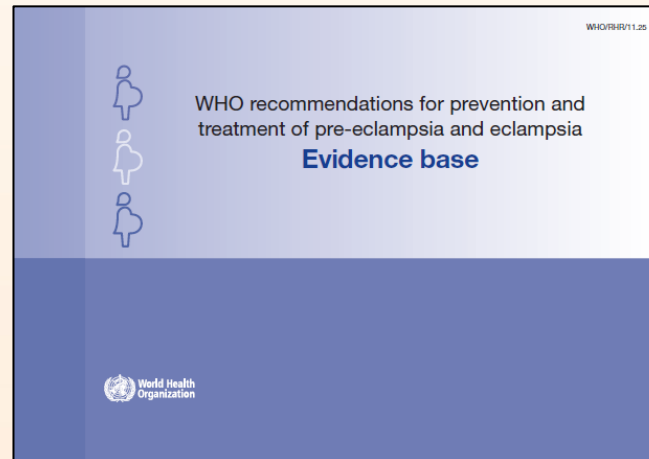
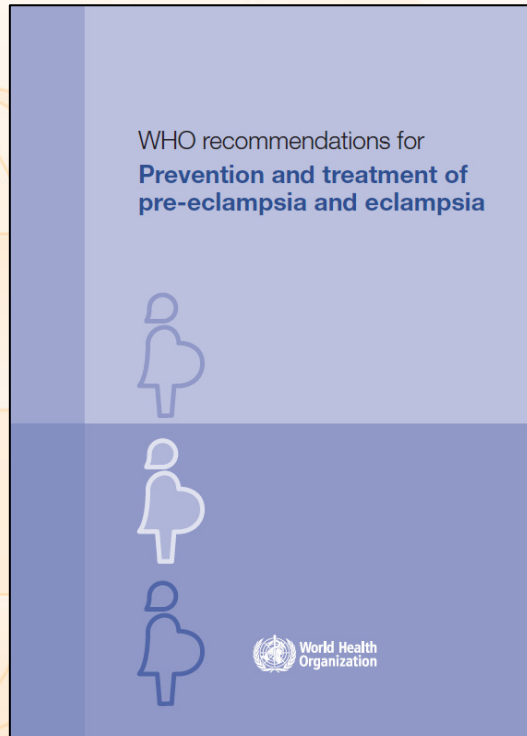
↓ **From Guidelines to Handbooks and Tools** ↓



Decision-Making **Tools**

MPH: From GRADED evidence to being placed within a subsequent revision of a practical guide/ manual

WHO Guideline with Recommendations and Evidence base



WHO **Manual** - Guide to essential practice

Guidelines - Infertility

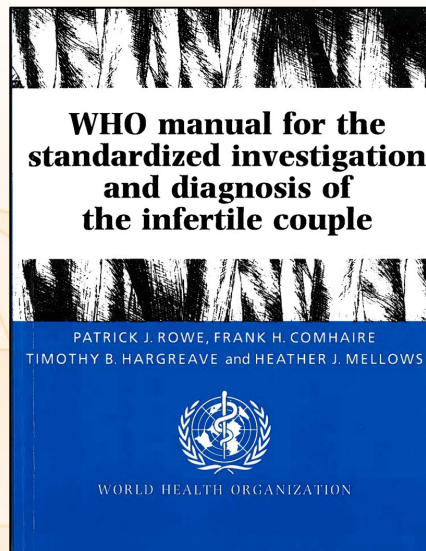
http://whqlibdoc.who.int/trs/WHO_TRS_820.pdf

From 1980 to 1986, the Task Force on the Diagnosis and Treatment of Infertility, part of WHO HRP Programme, conducted a study involving 8500 couples in 33 centres in 25 countries using a standardized protocol for the investigation and diagnosis of the infertile couple. The principal regional differences were between the 4 sub-Saharan African centres and the 16 in developed countries (11 European), while results obtained in the other centres in developing countries in Asia, Latin America and the Eastern Mediterranean were in general intermediate between the two extremes.

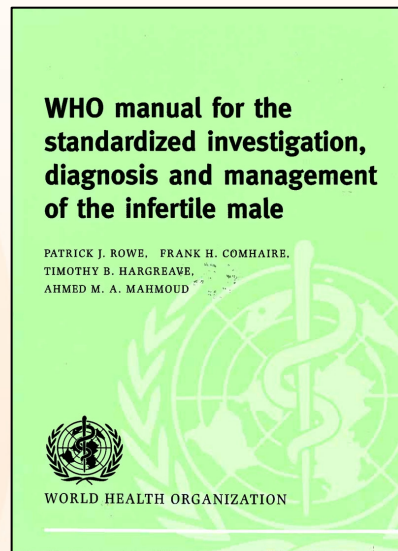
(Focus on RMNCH-integrated care:

Maternal and child outcome indicators were identified and collected.)

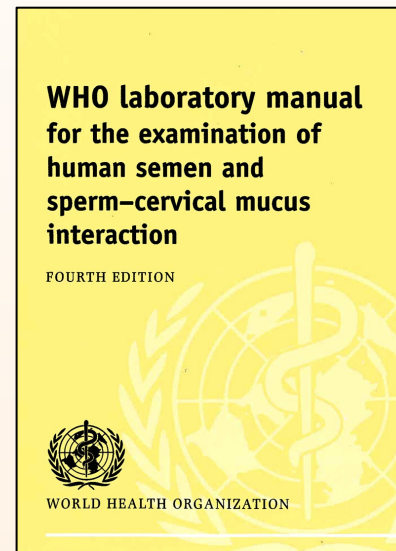
Tools/ Manuals: currently expert opinion based, field-tested research diagnostic protocol or evidence-informed (not GRC-approved or global-consensus using GRADE)



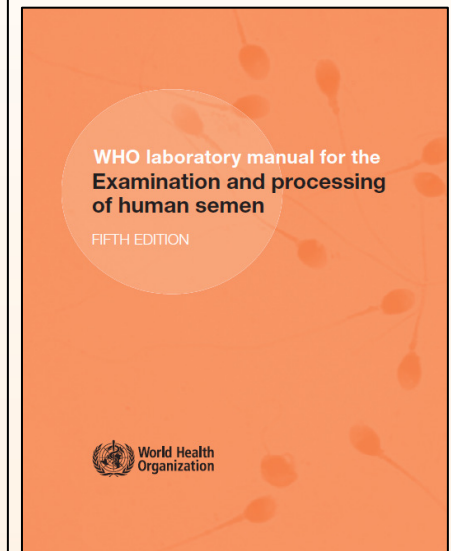
1993



2000



1999



2010

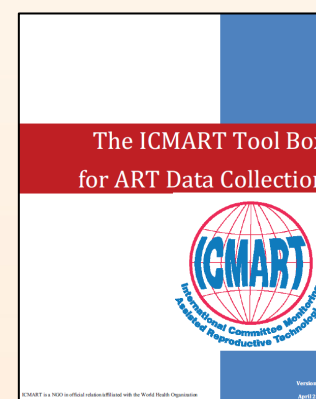
Clinical ↔ Laboratory
Companions

New Revised Guidelines and Tools - Infertility

Infertility Tools:

which are in process of development or require endorsement, however need evidence-based WHO Official Guidelines to reach final support and fulfill WHO recommended actions

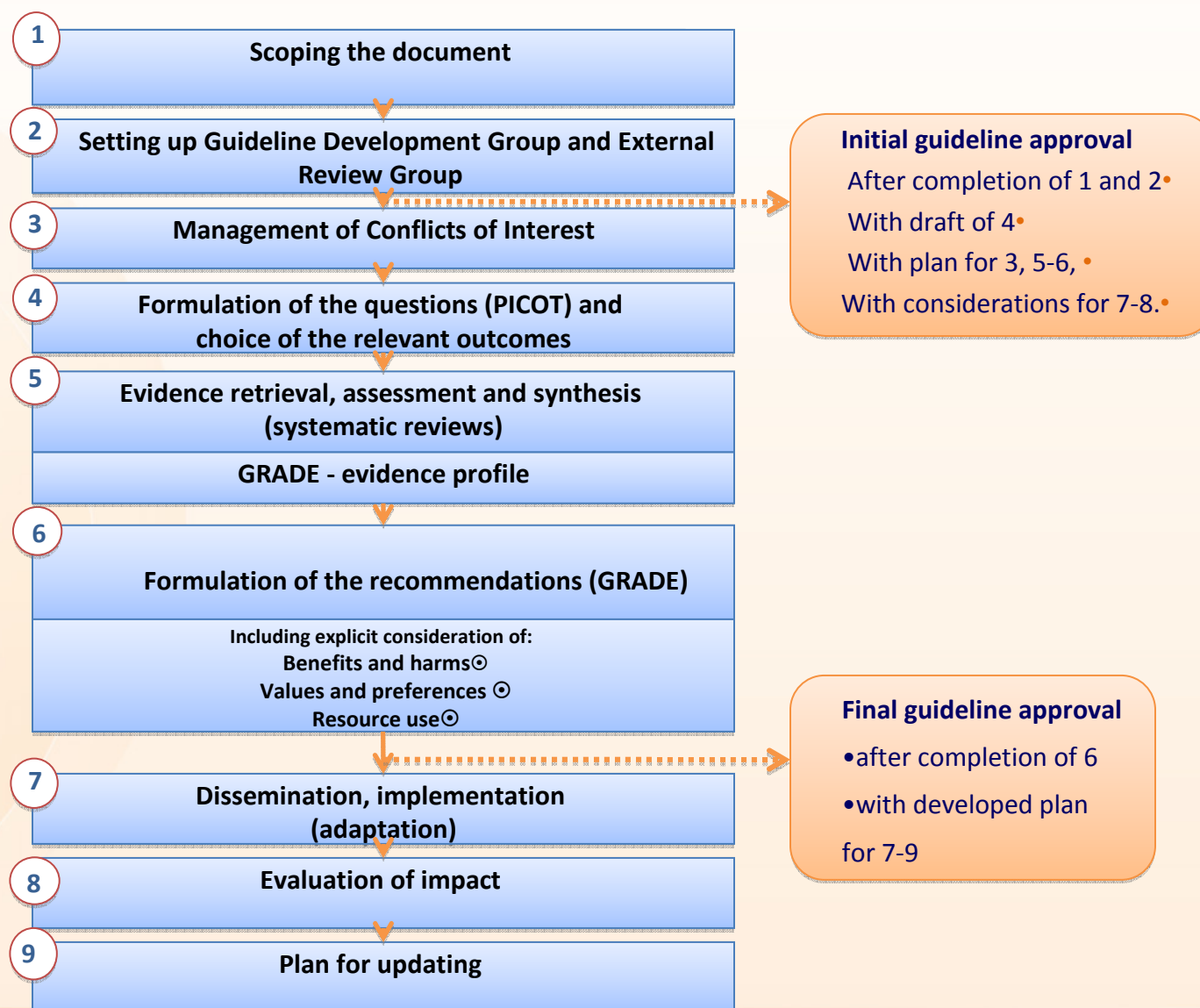
- ❑ Health workers and clients - Infertility patient education tool (WHO Draft)
- ❑ Fertility awareness and assessment; provider/client research tool for field-testing and adaptation at community level (Cardiff-WHO Draft)
- ❑ WHO recommended interventions for improving infertility services: Integrated management from community through tertiary level care (WHO Draft)
- ❑ Algorithms for integrated management of the male and female partner - addressing fertility problems (GFMER)
- ❑ ELSI Tool Box (IFFS-WHO Draft)
- ❑ ICMART Tool Box for ART data collection



Infertility Guideline Development

- ❑ **Underpin the process to assist UN member states:**
 - with the formation or assessment, if required, of national guidelines, regulations and policies
 - to help provide and maintain an evidence-base on best practice
 - to provide, based upon global consultation, assurance of best evidence-based practice guidelines which are likely to be adaptable in various settings
 - to assist with formation of manuals describing best practice
 - to ensure that tools developed for health care providers and their clients/patients are evidence-based
 - to identify research gaps - to address quality or strength of evidence for best practice

WHO Guidelines Process - We are at Level 4



Role of the Infertility Guidelines Steering Committee

1. Identification and scoping of priority topics with collaborators
2. Expert Working Group (EWG)
 1. Identify and invite Chairs for prioritized areas of practice
 2. Work with EWG Chairs and collaborators to form working groups
 3. Provide official letters of invitation and recognition for work to be undertaken
3. Mechanisms to ensure contributions from additional infertility experts representing global deliberations
4. Submitting and ensuring Guidelines formation follow approved WHO processes
5. Working with EWG Chairs and monitoring progress

A stylized graphic of a globe, showing latitude and longitude lines, positioned on the left side of the slide.

1. Scoping the field of infertility **(discussion during consultation -** **included discussions of conflicts of interest)**

DRAFT:

Scoping of Infertility management, care and interventions (those underlined are Working Groups initiated)

Male	female	general
<u>Diagnosis and management</u>	<u>Diagnosis and management</u>	<ul style="list-style-type: none">- prevention (uterine TB, chlamydia, gonorrhoea, HPV, HSV, FGM, etc.)- managing HIV+/HIV discordant couples with a child wish or infertile- psycho-social components- cross border reproductive care- donor gametes- surrogacy
	<u>PCOS, ovulation induction</u>	
	<u>Controlled ovarian stimulation for IVF</u>	
<u>IVF, ISCI</u>		
<u>IUI</u>	<u>IUI with/without controlled ovarian stimulation</u>	
<ul style="list-style-type: none">- Therapy- Peri-conception- Fertility surgery- Oncofertility/ fertility preservation	<ul style="list-style-type: none">- Periconception- An-ovulatory infertility, non-PCOS- Endometriosis- Fertility surgery- OHSS- Ovarian insufficiency- Recurrent miscarriage- Uterine factors- Oncofertility- Tubal peritoneal factors	

2. Expert Working Groups (individual presentations - see link - included discussions of conflict of interest)

- ❑ Initial suggestions and formation of working groups
- ❑ Formulation of questions that would address vital issues and identify key Cochrane/systematic reviews and meta-analyses that could be adapted (to be formulated into PICO questions for establishing an evidence-based for a GRADE table)
- ❑ Considerations for adapting recommendations for low resource settings or within specific populations
- ❑ Current national, regional or societal guidelines which currently inform scoped area of practice

EWG Chairs and Members-

Following discussions during consultation

EWG: Female: Infertility work-up and general management

- ❑ Chair: Hans Evers
- ❑ Neil Johnson (New Zealand)
- ❑ Guo Sun-Wei (China)
- ❑ Ben Willem Mol (Netherlands)
- ❑ Ed Hughes (Canada)

EWG: PCOS

- ❑ Chair: Adam Balen (UK)
- ❑ Steve Franks (UK)
- ❑ Rick Legro (USA)
- ❑ Rob Norman (Australia)
- ❑ Chandrika Wijeyeratne (Sri Lanka)

EWG: Male: Infertility work-up and general management

- ❑ Chair: Chris Barrett (UK)
- ❑ Herman Tournaye (Belgium)
- ❑ Rob McLachlan (Australia)
- ❑ Christopher De Jonge (USA)
- ❑ Lars Björndahl (Sweden)
- ❑ Bob Oates (USA)

EWG: IUI with or without ovarian stimulation

- ❑ Chair: Willem Ombet (Belgium)
- ❑ Ben Cohlen (the Netherlands)
- ❑ Geeta Nargund (UK)
- ❑ Carin Huyser (South Africa)
- ❑ Aucky Hinting (Indonesia)

EWG Chairs and Members-

Following discussions during consultation

EWG: IVF, ICSI

- ❑ Chair: André van Steirteghem (Belgium)
- ❑ John Collins (Canada)
- ❑ Arne Sunde (Norway)
- ❑ Laura Rienzi (Italy)
- ❑ Catherine Racowsky (USA)
- ❑ Andy LaBarbera (USA)

EWG: Ovarian Stimulation for ART

- ❑ Chair: Anders Nyboe-Andersen (Denmark)
- ❑ Georg Griesinger (Germany)
- ❑ Basil Tarlatzis (Greece)
- ❑ Alan Penzias (USA)
- ❑ Frank Broekmans (Netherlands)

3. Mechanisms to ensure contributions from additional infertility experts representing global reflections

- ❑ **GFMER - WHO Global Guidelines Virtual Consultation 2012-2013**
 - Co-Coordiators:
Aldo Campana, Bruce Dunphy, Sheryl VanderPoel
 - In collaboration with ASRM using evidence-based modules on EWG topics.
 - Participants from countries around the world, from both more rural and urban centres will:
 - provide feedback (values, preferences; benefits, disadvantages; resource use; feasibility) based upon the balance sheet for the suggested EWG infertility recommendations;
 - and, help to identify key research gaps unique to their country situation.

4. Submitting and ensuring Guidelines formation follow approved WHO processes

STEP 1: Initiation of Guideline Development

- ❑ Formation of key questions
- ❑ Generate PICO questions (or key questions when PICO not possible)
 - Provide to Steering Committee in order for WHO Secretariat to:
 - Share questions with all current GRC Chairs to address cross-over issues
 - Informative prioritization exercise via WHO mechanisms will be completed on PICO questions
 - Complete WHO-GRC clearance forms

4. Submitting and ensuring Guidelines formation follow approved WHO processes

STEP 2:

❑ **Compiling evidence base**

- (RCTs and/or observational studies; Current Guidelines with GRADING process; or, In the case of diagnosis, observational studies or prior art/best practice;)

❑ **Liaise with Steering Committee**

- if require official mechanisms to access background materials on existing Guidelines being used for adaptation to WHO guidelines.

❑ **Begin formulation of GRADE tables and draft Recommendations**

- Provide to Steering Committee when completed (either individually or as a set, as decided by EWG Chair)

4. Submitting and ensuring Guidelines formation follow approved WHO processes

STEP 3:

- ❑ **Virtual (on-line) GFMER-WHO consultation**
 - reviewing draft Recommendations and evidence using the balance sheet
 - potential non-English language literature considerations

STEP 4:

- ❑ **Global consensus meeting at WHO-HQ**
 - all EWG members,
 - key stakeholders, and
 - key contributors from the GFMER virtual consultation

PICO question formation from Key questions

- to a DRAFT Recommendation

- ❑ Generating PICO(T) questions for the GRADE tables, is essentially unpacking the key question to further define the scope of the evidence which would be considered for the GRADE analysis. For example:
- ❑ **KEY QUESTION:** Is a compression device for removal of foreskin a recommended mechanism for performing adult male circumcision?
- ❑ **PICO QUESTION**
 - Population: Adult men aged 15-49 years of age
 - Intervention: Male circumcision device that compresses the foreskin and remains on the body for at least one hour
 - Comparator: Conventional surgical male circumcision
 - Outcome: Complete and safe removal of the foreskin.

PICOT question - AN Example

- ❑ To address T or a time frame which may be part of some key questions if looking at health baby outcome or proof of pregnancy:
- ❑ **PICOT QUESTION**
 - Population: Adult men aged 15-49 years of age
 - Intervention: Male circumcision device that compresses the foreskin and remains on the body for at least one hour
 - Comparator: Conventional surgical male circumcision performed by skilled surgeons
 - Outcome: Lower, equivalent or higher side effect, complication and adverse event rates
 - Time: Up to complete wound healing.

PICO question formation from Key questions

- to a DRAFT Recommendation

- ❑ **PICO(T) QUESTIONS:**
 - shared and agreed amongst EWG Chairs and Steering Committee
- ❑ **On line prioritization (10-14 days)**
 - managed by WHO Secretariat
- ❑ **Evidence**
 - prior art, observational studies or RCTs which addressed PICO question
- ❑ **Analysis with development of GRADE tables**
- ❑ **DRAFT RECOMMENDATION (for example):**
 - WHO recommends a compression device for the removal of foreskin to perform an adult male circumcision.

Draft Recommendation - WHO consensus process

- ❑ **STEP 3: Contribution from virtual consultation (GFMER-WHO)**
- ❑ **STEP 4: Global consultation at WHO-HQ will determine if Guideline Recommendation(s) would be strong or weak.**

Clarification on Final STEP 4

- ❑ **The Guideline Document for each EWG:**
 - The WHO Secretariat together with the Steering Committee and EWGs will prepare the Guideline document BEFORE the consensus meeting at WHO-HQ.
- ❑ **Outcome of the consensus meeting will be:**
 - ENDORSEMENT OR ANY REVISIONS to the Guideline document
 - now FINAL Recommendation given a strong or weak grade.