

Collaboration and synergy among different actors making or influencing decisions on drug utilization may avoid duplication of efforts, resource waste and inconsistency

Improving Access to Essential Medicines Through a Synergic Approach. WHO Essential Medicines List Application of Treatments for Multiple Sclerosis.

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BACKGROUND

- Healthcare decision making often suffers from poor coordination among involved actors (systematic reviews authors, guideline developers, essential medicines decision makers, etc.). This may lead to duplication of efforts and decision misalignment [1]
- Updated every 2 years by an Expert Committee appointed by WHO, the **WHO Essential Medicines List (EML)** contains the medicines considered to be the most effective and safe to meet the priority health needs of a health system and is intended as a reference handbook for national and regional health authorities around the world.
- When developing an application for the inclusion of drugs in the WHO EML, equitable access to medicines at a global level is at stake, particularly in settings with limited resources
- Multiple Sclerosis (MS) is an immune-mediated disease of the central nervous system affecting about 2.8 million people worldwide, with a substantial health burden, being one of the most common causes of neurological disability in young people (onset age 20 – 50, female/male ratio 3:1).
- Variation in prevalence across global regions, largely linked to healthcare expenditure per capita, suggests MS may be largely underdiagnosed in lower income countries.
- No DMTs are currently included in the WHO EML
- We present a coordination effort among different entities aimed at submitting an application for the inclusion of disease-modifying treatments (DMTs) for MS in the WHO EML.

METHODS

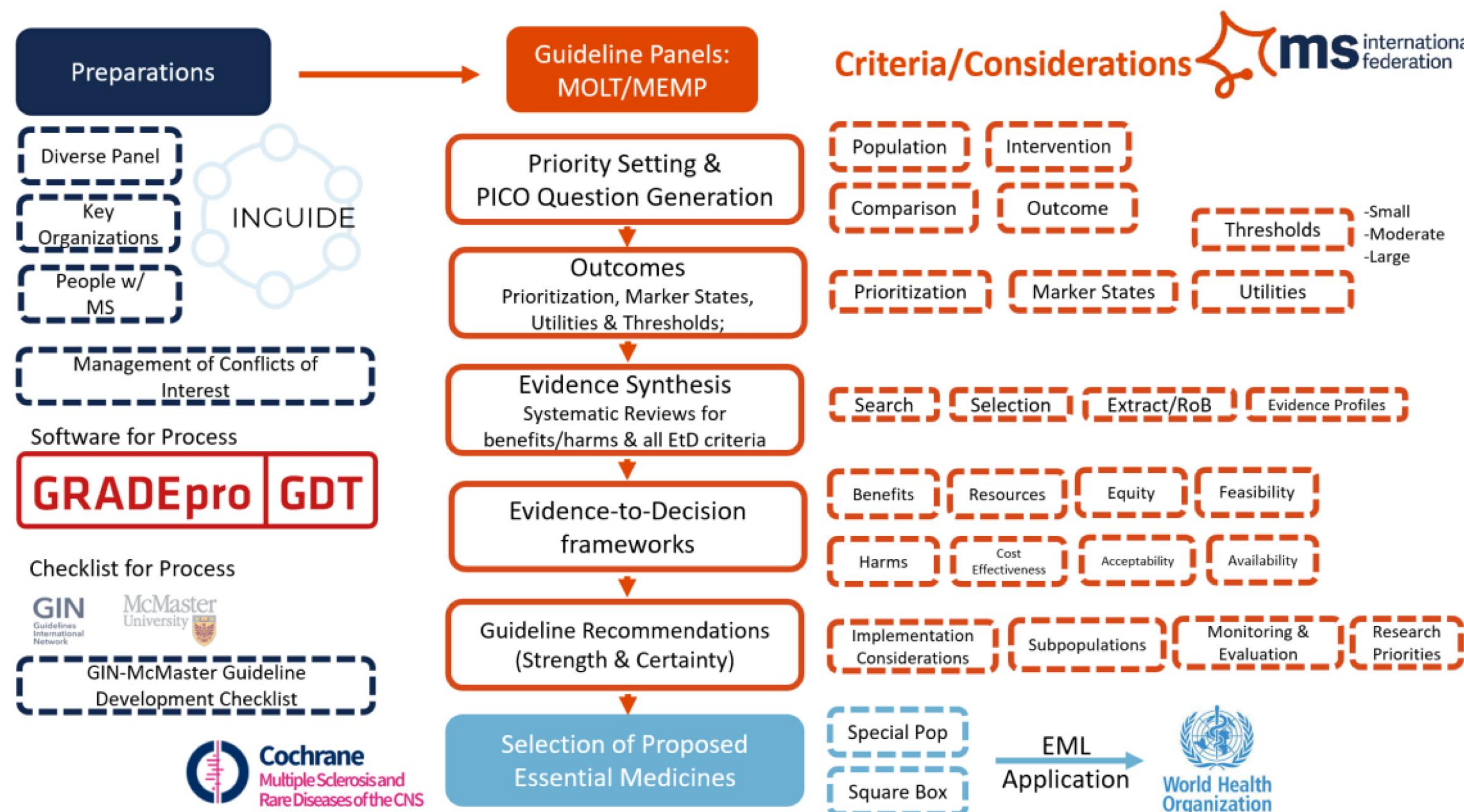
- MSIF appointed the MS Cochrane Review Group to develop evidence syntheses on efficacy and safety of DMTs
- MSIF appointed two multi-stakeholder guideline development groups (MOLT, MSIF Off-Label Task Force, and MEMP, MSIF Essential Medicines Panel) to formulate evidence-based recommendations on the use of DMTs by means of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) methodology
- Methodological support was provided by the McMaster University's GRADE Center, Department of Health Research Methods, Evidence & Impact (HEI)
- The criteria of the GRADE Evidence to Decision Framework were assessed from a limited resource setting perspective
- MSIF and the Bologna WHO Collaborating Centre co-developed an application, informed by the recommendations of the guideline development groups, for the inclusion in the WHO EML of DMTs.

RESULTS

- Systematic reviews and meta-analyses on all available DMTs for MS [2-5]
- Development by the two multi-stakeholder guideline development groups (MOLT and MEMP) of evidence-based recommendations on off-label and labelled DMTs for MS
- Submission to the WHO EML Secretariat of an application for the inclusion of the first-ever DMTs for MS (rituximab, cladribine, glatiramer acetate) in the WHO Essential Medicines List [6]

CONCLUSIONS

- A synergic effort among organisations with different roles in the decision-making process led to evidence syntheses and evidence-based recommendations informing decisions by the WHO Expert Committee on the inclusion of medicines for MS in the EML
- Early planning alignment of guideline development groups mandated by a representative advocacy group facilitated shared participation of all key stakeholders and broad endorsement [7]
- Development of recommendations by means of the GRADE EtD Framework allowed shared assessment of criteria specific to the perspective of limited resource settings adopted by the WHO EML application developers [7]



Methods for the linkage between MOLT/MEMP recommendations and the application for the inclusion of DMTs in the WHO EML [6]

EtD Framework criteria visualization [6]



REFERENCES

- Schunemann HJ et al. The ecosystem of health decision making: from fragmentation to synergy. *Lancet Public Health*. 2022 Apr;7(4):e378-e390. doi: 10.1016/S2468-2667(22)00057-3.
- Filippini G et al. Rituximab for people with multiple sclerosis. *Cochrane Database Syst Rev*. 2021 Nov 8;11(11):CD013874. doi: 10.1002/14651858.CD013874.pub2.
- Gonzalez-Lorenzo M et al. Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis [submitted]
- Ridley B et al. Immunomodulators and immunosuppressants for progressive multiple sclerosis: a network meta-analysis [submitted]
- Ridley B et al. Azathioprine for people with multiple sclerosis [submitted]
- Multiple Sclerosis International Federation (MSIF), London (UK), WHO Collaborating Centre in Evidence-Based Research Synthesis and Guideline Development Direzione Generale Cura della Persona Salute e Welfare Regione Emilia-Romagna, Bologna (Italy). Proposal for inclusion of multiple sclerosis disease-modifying therapies (DMTs) on the complementary WHO Model Lists of Essential Medicines. https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/24th-eml-expert-committee/a10_ms-dmts
- Piggott T et al. GRADE concepts: linking guideline recommendations to trustworthy Essential Medicine Lists [in preparation]

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