The role of essential medicines in emergency and humanitarian settings: MSF perspectives

23rd WHO Expert Committee on the Selection and Use of Essential Medicines
Public Session, 21 June 2021

Dr Daniela Garone
International Medical Coordinator
Médecins Sans Frontières | International Office

EML: which lens?

- The EML is a **key tool for Primary Health Care**
- The EML must be **inclusive** for the treatment of most vulnerable populations in humanitarian crises and low resource settings
  - Medicines should be **available**, **affordable** and **quality assured**
- Populations in humanitarian emergencies and low resource settings have the **same morbidities** than the settings where they are coming from but we need adapted treatment options

MEDECINS SANS FRONTIERES

Humanitarian crises and essential medicines

Recommended characteristics for essential medicines to use in humanitarian crisis:

- **Adapted formulations**
  - FDC
  - Dispersible tablets, granules, or pellets rather than syrups for paediatric formulations
  - Single doses treatment and long-acting formulations (PrEP and treatment)
  - Thermostable single doses formulations rather than cold-chain
  - Longer shelf-life
  - Breakable formulation
  - Ready to use preparations/self-administration
- **Improved safety profiles** in settings where pharmacovigilance and monitoring is challenging
  - Allowing distribution by lay staff (CHW-peers - counselors)
- **Larger field of approved indications for ATB**: broader use per medicine (early stage of emergency response)
- **Affordability and availability**
- **Importation mechanisms that reduce lead time** e.g. for narcotics and controlled medicines

Adapted formulations

Fixed doses combinations

- **TPT:**
  - rifapentine 300 + isoniazid 300
- **HCV:**
  - sofosbuvir + daclatasvir
  - sofosbuvir + velpatasvir
  - glecaprevir + pibrentasvir

Dispersible tablets, granules, or pellets for paediatric formulations (not syrups)

- **TB:**
  - bedaquiline 20 mg scored tablet (ready to be dissolved in water, then mixed with other beverage or soft food)
  - delamanid 25 mg dispersible tablet
- **HIV:**
  - dolutegravir 10 mg scored dispersible tablet
  - "4in1" FDC abacavir 30 mg + lamivudine 15 mg + lopinavir/ritonavir 40mg/10mg granules in capsules.

Adapted formulations

Long-acting formulations

- **Antipsychotic:**
  - paliperidone LAI: one injection / month

Formulations with higher strengths: reducing pill burden and storage volume

- **new strengths of oral antibiotics**
  - amoxicillin 1g
  - cefalexin 500mg
  - phenoxymethylpenicillin 500mg
  - ciprofloxacin 500mg
- **new dosage:**
  - amoxicillin + clavulanic acid (7:1 ratio). MSF suggests to consider also 8:1 ratio and child-friendly formulations.

Adapted formulations

Ready to use preparations

- **Antipsychotic:**
  - Paliperidone prefilled syringe
- **Antibiotics:**
  - Injectable ATB not needing reconstitution

Extended shelf-life

- **Antiseptics, biocides:**
  - **Hypochlorous acid:**
    - stable
    - concentrated
    - shelf-life ≥ 3 years
    - ready-to-dilute product

Larger field of approved indications

- **Hypochlorous acid**
  - Broad spectrum of bactericidal, virucidal, and fungicidal activity
  - Wound-cleansing agent with antiseptic and healing properties
  - Well-studied, non-toxic, non-corrosive, easy to use compound, and more effective and safer alternative to other chlorine generating disinfectant agents
- **New indications for already listed ATB:**
  - Necrotizing fascitis (ceftriaxone, clindamycin, metronidazole, piperacillin-tazobactam and vancomycin)
  - Neonatal meningitis (gentamicin) Intra-abdominal infections (gentamicin and ampicillin)

Specific case

Insulin analogues

- **Lack of data for humanitarian, food-insecure, and other low resource settings for which the EML is most relevant**
  - Where is the safety and efficacy data in the context of food insecurity?
  - What should we do for migrants with diabetes? Children with diabetes living in food insecure contexts?
- **Quality, price and supply**
  - The cost of production for insulins is known; data should be updated
  - Further price reductions can be achieved if a number of biosimilar manufacturers enter the market
  - Ensure regulatory processes support quality assured biosimilar insulins to enter the market. Expedite / prioritize WHO PQ for biosimilar insulins, especially now post-WHA Resolution.
  - Need increased number of manufacturers to ensure growing global needs will be met with sufficient supplies.

MSF perspective on submissions of significant impact for humanitarian settings

- **MMS**, long-awaited antenatal supplement
- **Combined hormonal vaginal ring**, useful alternative to oral contraception but too expensive
- Re-instatement of **eRIG** and inclusion of ARV **mAbs for rabies** PEP
- **Others:** paliperidone LAI, child-friendly antiTB drugs,child-friendly ARVs, direct-acting antivirals (DAAs) for HCV

MEDECINS SANS FRONTIERES

Affordability and availability of QA'd sources of EML medicines

- WHO study estimating **10% of medicines are substandard or falsified**: greatest proportion are substandard, more in LICs
- **Registration to aid availability and procurement gaps:**
  - lack of source, price and registration data on FDCs for HTN (2019 EML)
  - most carbapenems not registered or available in many LMICs
  - only half of new antibiotics entering the market between 1999 and 2014 were registered in more than ten countries
  - companies often do not file for or withdraw registration due to the costs
- **There is little planning for market introductions based upon burden of disease (case of antibiotics)**
  - only four out of 28 antibiotics under late-stage development in 2017 were accompanied by company plans to ensure access and only two of these focused on stewardship
  - RCTs (incl. post approval) must focus also on gaps in clinical needs such as serious infections seen in low resource settings (e.g. sepsis, meningitis, osteomyelitis); MDR/XDR bacterial strains; and paediatrics / neonates

A few additional and final points

- Submissions for EML should provide all existing studies (RCTs, PK, cost-effectiveness…) and data (effectiveness, tolerability, availability, affordability)
- **Alignment between EML and PQ** scope is crucial to guide LMICs
- When a medicine is no longer recommended as single, but in combination: if co-packaged/co-formulations available, single medicine should be deleted from the EML
- **Square Box:** critical to allow selection of the best treatment based on availability, affordability, ease of import, logistical and practical constraints
- **All medicines must be**
  - quality-assured (internationally agreed quality standards),
  - manufactured according international GMP regulations,
  - affordable for LMICs,
  - distributed according to international GDP regulations.

MEDECINS SANS FRONTIERES

MEDECINS SANS FRONTIERES

Thank You