

### **I.7 - Proposal for the addition of complicated intra-abdominal infections in neonates and children as a new indication for ampicillin and gentamicin in the WHO Model List of Essential Medicines for Children.**

MSF supports the addition of the new indication of complicated intra-abdominal infections in neonates and children to the existing indications listed for ampicillin and gentamicin in the core list in section 6.2.1 Access group antibiotics, in the WHO Model List of Essential Medicines for Children (EMLc).

Ampicillin is included since 1977 in the WHO Model List of Essential Medicines (EML) and since 2017, ampicillin is included in the core list in section 6.2.1 Access group antibiotics of both the EMLs, as first choice for community-acquired pneumonia (severe, children), complicated acute malnutrition (children), sepsis in neonates and children, and as second choice for acute bacterial meningitis. In the electronic EML, the paediatric indications listed for ampicillin as first choice are acute malnutrition on infants, children or adolescents (complicated, co-prescribed with gentamicin), sepsis without septic shock (co-prescribed with gentamicin), and community-acquired pneumonia (severe, co-prescribed with gentamicin) and as second choice, bacterial meningitis.

Gentamicin is included since 1977 in the WHO Model List of Essential Medicines (EML) and since 2017, gentamicin is included in the core list in section 6.2.1 Access group antibiotics of both the EMLs, as first choice for community-acquired pneumonia (severe, children), complicated acute malnutrition (children), sepsis in neonates and children and as second choice for surgical prophylaxis. In the electronic EML, the paediatric indications listed for gentamicin as first choice are sepsis without septic shock (co-prescribed with amoxicillin or ampicillin or benzylpenicillin), community-acquired pneumonia (severe, co-prescribed with amoxicillin or ampicillin or benzylpenicillin), acute malnutrition in infants, children and adolescents (complicated, co-prescribed with ampicillin or benzylpenicillin) and as second choice, other specified prophylactic measures.

The 2017 Surgical Infection Society revised “Guidelines on the management of intra-abdominal infections” recommend using ampicillin, gentamicin, and either metronidazole or clindamycin; ampicillin, cefotaxime, and either metronidazole or clindamycin; or meropenem in pediatric patients less than one month of age for the treatment of intra-abdominal infections.

The 2017 updated WHO “Recommendations on newborn health” state that neonates with suspected necrotizing enterocolitis should be treated with IV or IM ampicillin (or penicillin) and gentamicin as first-line antibiotic treatment for 10 days.

The 2013 WHO “Pocket book of hospital care for children, guidelines for the management of common childhood illnesses” state that ampicillin + gentamicin + metronidazole should be given as preoperative antibiotics before and for 3–5 days after the operation. In case of appendicitis, peritonitis, incarcerated hernia, abscess, the following regimen is recommended: ampicillin (25–50 mg/kg IM or IV four times a day), gentamicin (7.5 mg/kg IM or IV once a day) and metronidazole (10 mg/kg three times a day).

The 2010 Surgical Infection Society and the Infectious Diseases Society of America Guidelines “Diagnosis and management of complicated intra-abdominal infection in adults and children” state that broad-spectrum antimicrobial regimens for neonates include ampicillin, gentamicin, and metronidazole; ampicillin, cefotaxime, and metronidazole; or meropenem. Vancomycin may be used instead of ampicillin for suspected methicillin-resistant *Staphylococcus aureus* (MRSA) or ampicillin-resistant enterococcal infection. Fluconazole or amphotericin B should be used if the Gram stain or cultures of specimens obtained at operation are consistent with a fungal infection. Broad spectrum antimicrobial regimens for pediatric patients include ceftriaxone, cefotaxime, cefepime, or ceftazidime, each in combination with metronidazole; gentamicin in combination with metronidazole or clindamycin, and with or without ampicillin.

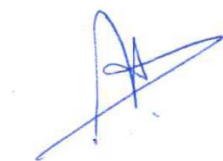
Previously all products listed in the WHO Model List of Essential Medicines for Children were also on the WHO Model List of Essential Medicines: if this logic is maintained, the indication of complicated intra-abdominal infections in neonates and children should also be added to the existing indications listed for ampicillin and gentamicin in the core list in section 6.2.1 Access group antibiotics of the WHO Model List of Essential Medicines.

MSF recommends using gentamicin + ampicillin + metronidazole for the treatment of necrotizing enterocolitis in neonates in its programs.

MSF has been using ampicillin and gentamicin in its programs since 1988. Gentamicin and ampicillin are usually widely available antibiotics, particularly in low- and middle-income countries.

MSF urges the 23<sup>rd</sup> Expert Committee on the Selection and Use of Essential Medicines to add the indication of complicated intra-abdominal infections in neonates and children to the existing indications listed for ampicillin and gentamicin in the core list in section 6.2.1 Access group antibiotics of both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children.

For Médecins Sans Frontières



Myriam Henkens, MD, MPH  
International Medical Coordinator