

WHO/UNICEF JOINT STATEMENT



Managing possible serious bacterial infection in young infants 0–59 days old when referral is not feasible



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Key points in this Joint Statement

- Infections are currently responsible for about one fifth of the world's neonatal deaths
- Prompt identification and treatment of sick young infants having signs of possible serious bacterial infection (PSBI) is essential to reduce mortality and morbidity
- A new guideline is available to guide treatment of sick young infants with effective simplified antibiotic regimens in resource-limited settings when families do not accept or cannot access referral care
- Careful introduction and implementation of the guideline will increase access and adherence to treatment, and thus save lives
- Effective implementation of the guideline requires countries to strengthen their health systems to ensure high quality, accessible and family-friendly first-level facility care
- Ministries of health, international, regional and country-level medical professionals, including paediatric associations, have important roles in supporting the careful introduction and adaptation of this new guideline into policy and practice

Bacterial infection in young infants¹ is one of the leading causes of preventable death and morbidity

Infections are responsible for more than 560 000, about one fifth, of the world's annual 2.7 million neonatal deaths; up to 400 000 of these deaths were attributed to sepsis and meningitis and 160 000 to pneumonia in 2015 (1). In South Asia and sub-Saharan Africa about one quarter of all neonatal deaths are due to infections.² Most young infant mortality is in low- and middle-income countries.

The World Health Organization (WHO) reference standard for sick young infants with PSBI³ remains referral to a hospital (2) for inpatient treatment with a 7- to 10-day course of ampicillin or benzylpenicillin plus gentamicin (3).

However, many sick babies are not recognized to have infection because of non-specific signs, such as being unable to feed or movement only when stimulated. Home visits in the first

week after birth are recommended for care of the mother and newborn in order to counsel families, and to facilitate identification of danger signs and promote care seeking (4). They can be made by clinicians, midwives and other skilled providers including trained community health workers (CHWs).

Even when danger signs are detected, hospitalization and life-saving treatment may not be accessible, acceptable or affordable to families in settings with high newborn mortality. Key studies in South Asia (5,6,7) and in Africa (8,9) indicate that up to two thirds or more of families do not accept referral for hospitalization of a young infant with PSBI.

Context for new guideline

The new WHO guideline (*Managing possible serious bacterial infection in young infants when referral is not feasible*) (10) addresses care in settings where families with sick young infants do not accept or cannot access referral care, but can be managed in outpatient settings by an appropriately trained health worker.⁴

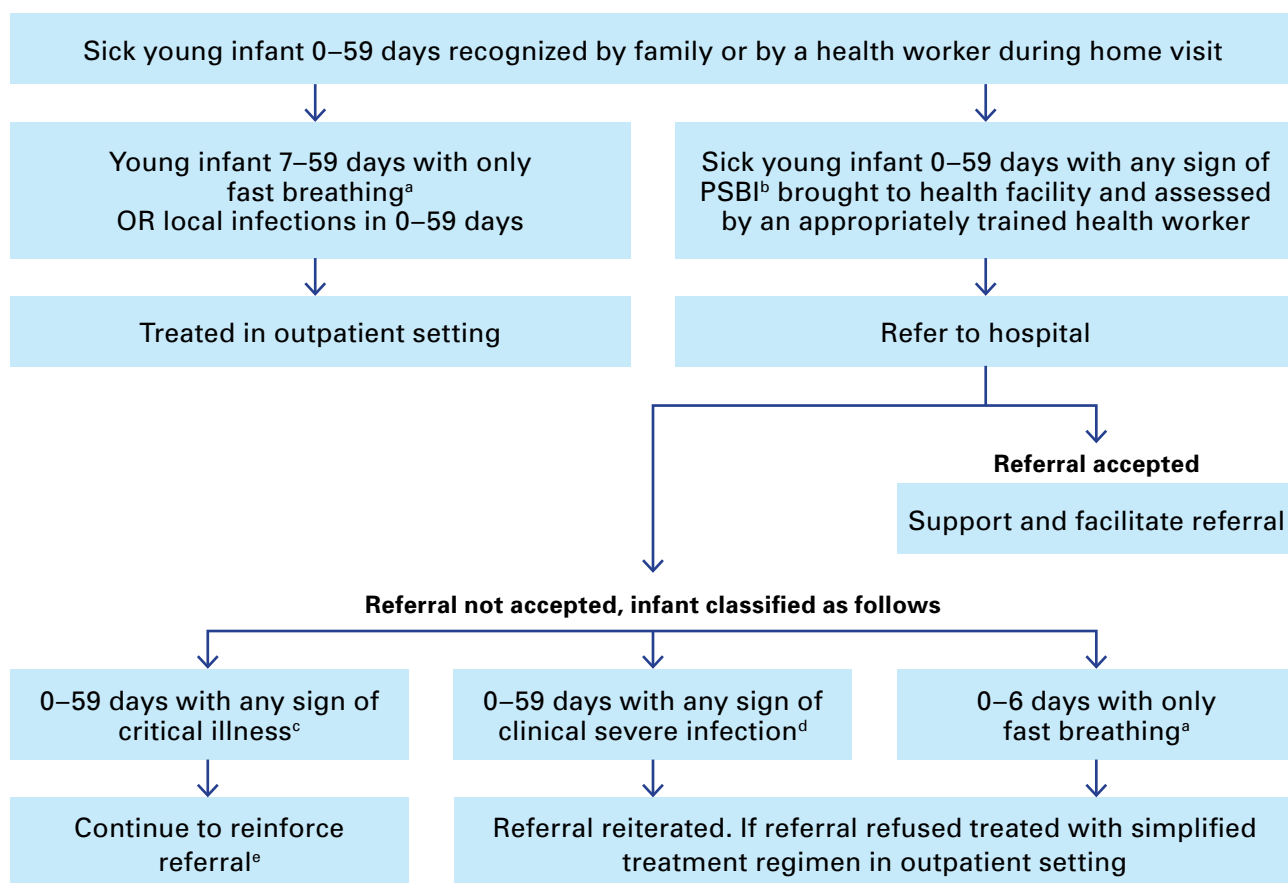
¹ Unless otherwise specified, "young infant" refers to the period 0–59 days after birth, including the neonatal period.

² Alliance for Maternal and Newborn Health Improvement [AMANH], personal communication with WHO Department of Maternal, Newborn, Child and Adolescent Health, 2016.

³ See figure for definition.

⁴ "Appropriately trained" refers to health workers based at primary health care facilities who are allowed by their governments to give injectable therapy.

Management of the sick young infant with PSBI



^a Fast breathing: respiratory rate equal to or greater than 60 breaths per minute.

^b Signs of PSBI: not able to feed since birth or stopped feeding well or not feeding at all, convulsions, severe chest in-drawing, fever (temperature ≥ 38 °C), low body temperature (< 35.5 °C), movement only when stimulated or no movement at all, fast breathing (60 breaths per minute or more) in infants less than 7 days old.

^c Critical Illness: convulsions, unable to feed at all, no movement on stimulation, unable to cry, bulging fontanelle and cyanosis.

^d Clinical severe infection: not feeding well, fever (temperature ≥ 38 °C), low body temperature (< 35.5 °C), severe chest in-drawing, movement only when stimulated.

^e When referral is not feasible these young infants should be treated in the health facility with once daily injectable gentamicin plus at least twice daily injectable ampicillin for 7 days (10).

The guideline offers primary care clinical guidance for resource-limited settings on the use of simplified antibiotic regimens that are both safe and effective for outpatient treatment of 'clinical severe infection' and 'pneumonia' (defined as fast breathing only)⁵ among infants weighing at least 1.5 kg. It also provides programmatic guidance on the role of CHWs and home visits in recognizing clinical signs of PSBI.

The PSBI guideline puts forward a systematic process for managing sick young infants:

Identification: Signs of illness in the young infant are recognized in the home by the family or by a CHW, or in a health facility by a health worker. The family then seeks care from a health provider who can manage PSBI.

Assessment and classification: The young infant is assessed according to clinical signs, and the illness is classified.

Treatment: The sick young infant with signs of infection is treated according to one of the recommended regimens:⁶

- Young infants 7–59 days old with fast breathing as the only sign of illness should

⁵ See figure for definitions.

⁶ These recommendations do not apply to infants with birth weight less than 1.5 kg; these infants must be treated in hospital.

be treated in an outpatient setting with oral amoxicillin⁷ twice daily for 7 days by an appropriately trained health worker. They do not need hospitalization.⁸

- Newborns 0–6 days old with fast breathing as the only sign of illness should be referred to hospital after receiving pre-referral treatment. Families should be counselled on the importance of referral. If the family does not accept or cannot access referral care, the infant should be treated with oral amoxicillin⁷ twice daily for 7 days by an appropriately trained health worker.
- Young infants 0–59 days old with clinical severe infection⁹ should be referred to hospital after pre-referral treatment. Families should be counselled on the importance of referral. If the family does not accept or cannot access referral care, the infant should be managed in outpatient settings by an appropriately trained health worker according to one of two recommended regimens.¹⁰

— Option 1: Oral amoxicillin⁷ twice daily for 7 days plus injectable gentamicin¹¹ once daily for 7 days.

— Option 2: Oral amoxicillin⁷ twice daily for 7 days plus injectable gentamicin¹¹ once daily for 2 days.

Option 1 has more available evidence, but little difference in key outcomes was observed between the two options when data were reviewed. The choice of option 1 versus option 2 will be dependent upon a particular health system's ability to provide 7 versus 2 days of injectable antibiotics.

- Young infants 0–59 days old who have any sign of critical illness should be given pre-referral treatment and referred to hospital.

⁷ 50 mg/kg per dose of oral amoxicillin.

⁸ Follow-up for young infants receiving daily gentamicin injections for 7 days should be daily; young infants receiving two injections of gentamicin should be followed up on day 2 and day 4. Young infants with only fast breathing should be followed up after completing 3 days of treatment, i.e. on day 4.

⁹ See figure for definition.

¹⁰ Individual countries are expected to adapt the recommendations to suit the local social, cultural and economic contexts.

¹¹ 5–7.5 mg/kg (first week of life for low-birth-weight infants 3 mg/kg) of injectable gentamicin.

Putting the new guideline into action

This new guideline must be implemented within the context of national health strategies. It requires integration into a continuum of care across levels of the health system, and within the available intervention packages of services, consistent with the Every Newborn Action Plan.¹² Additional research will potentially contribute to improving the care for this vulnerable group.

National policy development will require:

- ✓ advocacy for and dissemination of the PSBI guideline to ensure that policy-makers are aware of and are committed to implementation about the new recommendations;
- ✓ key stakeholder discussions leading to adoption and the adaptation or revision of existing national guidelines or protocols, to suit the local context;
- ✓ distribution of the national guidelines to all relevant parties;
- ✓ creating and supporting a sustained enabling environment for applying the recommendations, including supporting health care practitioners in new practices.

Implementation will require:

- ✓ integrating the new recommendations into national standards of care and service packages;
- ✓ adapting guidelines and training materials (including those for the Integrated Management of Childhood Illness [IMCI] and basic teaching) for health facility workers and CHWs;
- ✓ training and refresher training;
- ✓ providing and distributing commodities (e.g. essential antibiotics, appropriate syringes, thermometers and weighing scales);
- ✓ investing in creating demand and empowering families and communities to identify illness and seek timely care from an appropriate provider;

¹² For information on the Plan, see <https://www.everynewborn.org/>.

- ✓ strengthening referral mechanisms and pathways between communities, first-level health facilities and referral-level health facilities;
- ✓ investing in strengthening quality and accessibility of care at first-level and at referral facilities;
- ✓ mapping of the situation as regards home visits for newborns, and strengthening the community platform as a first step in areas with difficult access;
- ✓ investing in supportive supervision, monitoring and evaluation;
- ✓ conducting implementation research to determine how best to implement and to scale-up managing PSBI in young infants when families cannot access referral care.

Governments, professional bodies, civil society and development partners must work together to:

- ✓ facilitate policy dialogue and orientation meetings at national and sub-national levels;
- ✓ establish early implementation sites to create a learning platform for implementing the new guideline in preparation for scaling-up;
- ✓ share experiences and materials of early adopter countries;
- ✓ facilitate documentation and exchange between countries with experience and countries with needs;
- ✓ develop a pool of qualified consultants/experts to support countries;
- ✓ ensure the availability of infant-friendly formulations of injectable gentamicin and oral amoxicillin;
- ✓ strengthen referral systems from the community to first- and referral-level health facilities;
- ✓ develop and support an implementation guide, emphasizing integration with existing programmes, and update relevant pre-service curricula and training materials;
- ✓ use PSBI implementation as an opportunity to re-double existing quality assurance and safety activities;
- ✓ mobilize resources.

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Process of development of this statement

A technical consultation on issues related to the implementation of the WHO guideline, *Managing possible serious bacterial infection in young infants when referral is not feasible*, was jointly organized by WHO, Save the Children (SC) and the United States Agency for International Development (USAID) in London in December 2015. During this consultation a draft of this Joint Statement prepared by WHO and UNICEF was reviewed by staff from SC, USAID, the International Pediatric Association (IPA), representatives of national paediatric associations and other experts. The experts declared no conflicts of interest. A revised version was widely distributed for further input from WHO and UNICEF country and regional office staff, SC, USAID, IPA, PATH and representatives from ministries of health; their comments were incorporated into the final version. This Joint Statement will be reviewed and updated three years after publication.



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