Operationalizing management of sick young infants with possible serious bacterial infection (PSBI) when referral is not feasible in the context of existing maternal, newborn, and child health programmes

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Annexes

Acknowledgement

Following the 2015 release of the WHO GUIDELINE *Managing Possible Serious Bacterial Infection (PSBI) in Young Infants When Referral Is Not Feasible*, an interagency group convened to discuss implementation. This group recognized the need for practical guidance on how to operationalize the guidelines in the context of a country's ongoing maternal, newborn and child health programmes.

This guidance was developed under the technical direction of this group and coordinated by Dr Samira Aboubaker. Core members are:

Dr Samira Aboubaker and Dr Shamim Qazi of the Department of Maternal, Newborn, Child and Adolescent Health and Development of the World Health Organization (WHO) Geneva; Dr Neal Brandes and Dr Troy Jacobs of the United States Agency for International Development (USAID) Washington DC, USA); Dr Steve Wall, Sitrin Deborah and Greta Wetzel of Save the Children, Washington DC, USA.

Acknowledgement is also given to the participants at a technical consultation on issues related to the implementation of the WHO guideline, jointly organized by WHO, Save the Children and USAID in London in December 2015. During this consultation a draft of this guidance was reviewed by staff from SC, USAID, the International Pediatric Association (IPA), representatives of national paediatric associations and other experts.

A later draft was reviewed by participants at the Meeting of Principal Investigators for PSBI Implementation Research in Lagos, Nigeria, November 2017. Many thanks go to these participants for their comments and input based on their experiences with early implementation of the WHO guidelines.

Thanks also go to other members of these agencies who contributed ideas and comments on this guidance and to Patricia W Shirey, consultant to Save the Children and WHO, who developed and edited the drafts.

Acronyms

CHW	Community Health Worker
DHS	Demographic and Health Survey
DHIS2	District Health Information System 2
ENAP	Every newborn action plan
ENC	Essential Newborn Care
FP	Family planning
HBB	Helping babies breathe
HMIS	Health management information system
ICF	Individuals, families and communities
KMC	Kangaroo Mother Care
LGA	Local Government Area
LMIS	Logistics Management Information System
MIS	Management Information System
MNCH	Maternal, Newborn and Child Health
MOH	Ministry of Health
MPS	Making Pregnancy Safer
PHC	Primary Health Care
PSBI	Possible Severe Bacterial Infection
TBA	Traditional Birth Attendant

Definitions of key terms

For classification of sick young infants (0–59 days old) at primary health care facility:

POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI): A clinical syndrome used in the Integrated Management of Childhood Illness package. A young infant is classified as having PSBI or Very Severe Disease when any one or more of the following signs is present:

- not able to feed since birth or stopped feeding well (confirmed by observation)
- convulsions
- fast breathing (60 breaths per minute or more)
- severe chest in-drawing
- fever (38 °C or greater)
- low body temperature (less than 35.5 °C)

PNEUMONIA: In a young infant 7–59 days old, fast breathing as the only sign of possible infection.

LOCAL BACTERIAL INFECTION: In a young infant (0–59 days old), an umbilical or skin infection

Other possible SEVERE classifications that require referral to hospital include:

- SEVERE JAUNDICE
- SEVERE DEHYDRATION

Other classifications that may be treated at the PHC facility include:

- JAUNDICE
- SOME DEHYDRATION
- CONFIRMED HIV INFECTION
- HIV EXPOSED: POSSIBLE HIV INFECTION
- FEEDING PROBLEM OR LOW WEIGHT FOR AGE

When families do not accept or cannot access referral for Possible Serious Bacterial Infection or very severe disease, further assessment and classification:

SEVERE PNEUMONIA: In a young infant less than 7 days old, fast breathing (60 breaths per minute or more) as the only sign of illness

CLINICAL SEVERE INFECTION: at least one sign of severe infection, i.e. not feeding well on observation, temperature 38 °C or more, temperature less than 35.5°C, severe chest indrawing, movement only when stimulated.

CRITICAL ILLNESS: In a young infant, presence of any of the following signs: convulsions, unable to feed at all, no movement on stimulation, unable to cry, bulging fontanelle, cyanosis.

Other terms used in this document:

iCCM: Integrated Community Case Management is a strategy to extend case management of childhood illness beyond health facilities so that more children have access to lifesaving treatments. The iCCM package can differ, but most commonly includes diarrhea, pneumonia, malaria, malnutrition and newborn health. In the module *Caring for the Sick Child in the Community*, community health workers are trained in diagnosis and treatment of key childhood illnesses, and also in identifying children in need of immediate referral.

The module *Caring for the Newborn at Home* teaches community health workers to make antenatal and postnatal home visits to counsel on pregnancy care, facility delivery, care of the newborn, and signs of illness; and to assess the newborn and facilitate care-seeking if danger signs are found.

IMCI: Integrated Management of Childhood Illness is an integrated approach to child health that focuses on the well-being of the whole child. IMCI has the aims of prevention, or early detection and treatment of the leading childhood killers as well as improved growth and development among children less than five years of age. IMCI seeks to reduce childhood mortality and morbidity by improving family and community practices for the home management of illness, and improving case management of skills of health workers in the wider health system.

Children brought for medical treatment in the developing world are often suffering from more than one condition, making a single diagnosis impossible. In health facilities, the IMCI strategy uses a syndromic approach to enable primary health care workers to identify common combinations of signs of illness in sick children in outpatient settings and provide appropriate combined treatment of the major illnesses. The package can differ but commonly includes management of pneumonia, diarrhoea, malaria, measles, ear infection, malnutrition, anaemia, and HIV infection. It also strengthens the counselling of caretakers, and speeds up the referral of severely ill children. In the home setting, it promotes appropriate care-seeking behaviours, prevention of disease through immunization, exclusive breastfeeding and improved nutrition, and supports the correct implementation of prescribed care.

IMNCI: Integrated Management of Neonatal and Childhood Illnesses is the name given in some countries to the IMCI approach to which care of newborns and young infants (under age 2 months) has been added. The neonatal component emphasizes early initiation of breastfeeding immediately after birth and counseling for exclusive breastfeeding; keeping the young infant warm; hygienic cord care, skin and eye care; recognition of illness in the newborn and prompt care-seeking for management or referral; immunization; and home visits by a trained health worker during the postnatal period. In primary health facilities, sick young infants are promptly assessed, given treatment, or, if illness is severe, the infant is quickly referred to hospital. Where referral is not feasible, sick young infants with PSBI may be given simplified antibiotic treatment according to the 2015 WHO guideline and monitored closely.

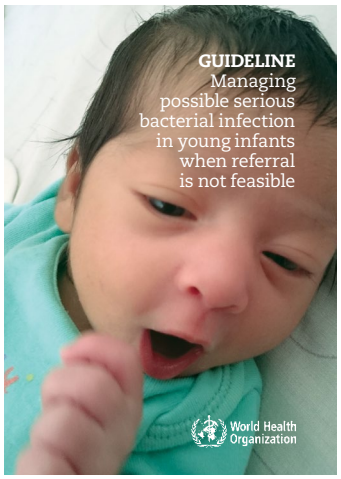
Evidence from randomized controlled trials showed that simplified antibiotic treatment of PSBI can save newborn lives in situations when families do not accept or cannot access referral. This new strategy to reduce newborn mortality and increase access to treatment for young infants with PSBI is recommended by WHO, USAID, and Save the Children.

A. Introduction

It is estimated that as many as 600 000 newborns die each year from serious infection, and that most of these deaths could be averted by preventive measures, timely care-seeking, treatment with appropriate antibiotics and follow up. Approximately 10% of newborn infants develop signs of possible serious bacterial infection (PSBI)[1] and require antibiotics.

Currently it is WHO policy that countries treat sick young infants (from birth up to 2 months of age) with PSBI or very severe disease by referring these infants to hospitals where additional expertise, necessary medicines, procedures and supportive care should be available. However, many sick young infants do not receive the urgent treatments that would save their lives.

Young infants fall ill and their families may not recognize the illness. When young infants are recognized as being sick, many are not taken to any health facility or are taken to traditional practitioners. When brought to a primary health care facility, IMCI-trained health workers refer sick young infants who have severe disease for hospital care. When referred, some families lack access to a hospital or do not accept referral. In those cases, primary health care facility staff have little to offer and these infants may return home without treatment. Some sick young infants arrive at the hospital moribund having received no treatment yet. Families who go to the hospital may find that the hospital lacks sufficient equipment and medicines for care of young infants. Thus, mortality in newborns and young infants remains distressingly high.



In September, 2015, the WHO GUIDELINE *Managing Possible Serious Bacterial Infection (PSBI) in Young Infants When Referral Is Not Feasible* was released. The guideline is intended for application in resource-limited settings in situations when hospitalization is not accessible, acceptable or affordable to families. The guideline provides evidence from randomized clinical trials and **recommendations for simplified antibiotic regimens for treatment of sick young infants 0–59 days old when referral is not feasible**. It provides clinical guidance on simplified antibiotic regimens that are both safe and effective for outpatient treatment of clinical severe infection or severe pneumonia. In addition, the guideline provides programmatic guidance on the role of Community Health Workers (CHWs) and home visits in identifying sick young infants with signs of PSBI.

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[1] A young infant is classified as having PSBI or Very Severe Disease when any one or more of the following signs is present:
- not able to feed since birth or stopped feeding well (confirmed by observation)
- convulsions
- fast breathing (60 breaths per minute or more) among infants less than 7 days old
- severe chest in-drawing
- fever (38 °C or greater)
- low body temperature (less than 35.5 °C)

The new recommendations for outpatient treatment using simplified antibiotic regimens can increase access to treatment of pneumonia and PSBI in sick young infants when referral is not accepted or not feasible and reduce inequity in access to care. They will enable many young infants with PSBI who will not reach hospital care to receive life-saving care at primary health care facilities.

In countries that will implement these new recommendations, there is need for practical guidance on how to operationalize (meaning, put into effect) the guidelines in the context of a country's ongoing maternal, newborn and child health programmes. The concept of outpatient treatment of PSBI where referral is not feasible is a recent development in the field; WHO and key partners such as UNICEF, USAID, and Save the Children have developed this guide to help countries prepare to integrate these recommendations into routine care of sick young infants at primary health care facilities and undertake activities in the community to empower and engage mothers and families to improve maternal and newborn health. Integration of management of sick young infants with PSBI where referral is not feasible should also include activities to support and strengthen implementation of interventions across the continuum of care at community, primary health care facilities and referral facilities.

As countries work toward universal healthcare and ending preventable newborn deaths, the recommendations should be implemented within the context of national health strategies, the Every Newborn Action Plan, and the available intervention packages – in many countries, within IMCI or IMNCI. Implementation should include steps for introduction and scaling up application of these recommendations as a part of routine (IMCI) care at primary health care facilities and empowering families to identify newborn illness and seek care at a primary health care facility as part of iCCM implementation and other community activities. Implementation should also measure progress in treating sick young infants where referral is not feasible in order to identify problems affecting coverage and make adjustments. The WHO-UNICEF Joint Statement [1] suggests action steps for putting the new guideline into action.

[1] WHO-UNICEF Joint Statement: Managing possible serious bacterial infection in young infants 0–59 days old when referral is not feasible. WHO/MCA/17.01
http://apps.who.int/iris/bitstream/10665/254502/1/WHO-MCA-17.01-eng.pdf

B. Strategies to achieve the objective of reducing newborn and young infant mortality due to PSBI or very severe disease

The WHO recommended strategies for preventing and treating PSBI or very severe disease in young infants have underpinned the WHO-UNICEF training courses for primary health care facility workers, *IMCI Management of the Sick Child* (2014),[1] and for community health workers, *Caring for the Newborn at Home* (2015).[2] Those strategies are as follows:

In the community:

- Prevention of infections in young infants by early initiation of breastfeeding and continued exclusive breastfeeding, consistent appropriate hand cleansing in the health facility and the home, and appropriate hygienic care of the umbilical cord.
- Early recognition of illness in a young infant by family members or by CHWs during home visits to the newborn. (This relies on a thorough understanding of danger signs by family members. Consistent education about danger signs should begin early in antenatal care, be repeated frequently, and be reinforced during postnatal counselling before discharge after a facility delivery or during postnatal home visits.)
- Prompt care-seeking by family members upon recognition of a danger sign (bringing the young infant to the primary health care facility).

In primary health care facilities:

- Prompt assessment and classification of the sick young infant at primary health care facility according to IMNCI guidelines. [3]
  - Check for signs of very severe disease, pneumonia and local bacterial infection. Then classify the young infant based on the signs found.
  - Check for the presence of jaundice.
  - Ask about diarrhoea. If the infant has diarrhoea, assess the related signs. Classify the young infant for dehydration.
  - Check for HIV infection. Classify HIV infection by test result.
  - Check for feeding problem or low weight for age. Then classify feeding.
  - Check the young infant's immunization status.
  - Assess any other problems.
- Prompt treatment at the primary health care health facility of sick young infants with non-severe signs of illness:
  - Pneumonia (in infant 7 to 59 days old with fast breathing as the only sign of illness)
  - Local Bacterial Infection

[1] http://apps.who.int/iris/bitstream/10665/104772/16/9789241506823_Chartbook_eng.pdf?ua=1
[2] http://www.who.int/maternal_child_adolescent/documents/caring_for_newborn/en/
[3] Or similar national guidelines for integrated and systematic assessment, classification and evidence-based treatment of sick children and young infants.

  - Jaundice
  - Some Dehydration
  - Confirmed HIV Infection
  - HIV Exposed: Possible HIV Infection
  - Feeding Problem or Low Weight for Age
- Referral to hospital of sick young infants with any sign of PSBI or Very Severe Disease (see Definition of Terms for explanation of this classification), Severe Jaundice or Severe Dehydration
- Pre-referral treatments are given before transport if the young infant is being referred.

In the hospital:

- Treatment at hospital of young infants who have PSBI or Very Severe Disease and/or have other severe problems utilizing parenteral antibiotics, oxygen, other supportive care and round-the-clock monitoring.

New additional strategies to manage young infants with PSBI or Very Severe Disease as recommended in the *GUIDELINE: Managing Possible Serious Bacterial Infection (PSBI) in Young Infants When Referral Is Not Feasible* include (see Figure 1):

- **Simplified antibiotic treatment** at the primary health care facility of sick young infants who are classified as PNEUMONIA (fast breathing as the only sign of illness in age 7 to 59 days)
- When the family does not accept or cannot access referral, further assessment and classification[1] of the sick young infant with PSBI or very severe disease followed by **simplified antibiotic treatment** at the primary health care facility of
  - young infants age 0 to 7 days who are classified as SEVERE PNEUMONIA and
  - young infants age 0 to 59 days who are classified as CLINICAL SEVERE INFECTION.

  The most serious further classification for young infants age 0 to 59 days is CRITICAL ILLNESS. Young infants with this classification are at high risk of dying and require urgent referral to hospital including pre-referral treatment with antibiotics.

  Note that all young infants who receive antibiotic treatment as outpatients must be closely monitored to quickly identify any who deteriorate or do not improve during the first days of antibiotic treatment. They are referred urgently to hospital for additional assessment, diagnosis, and treatment.

These new recommendations ***do not*** replace the WHO-recommended inpatient management at hospital as the standard of care for young infants who have signs of PSBI or Very Severe Disease.

As before, high quality antenatal care and facility delivery are key strategies of any programmes to reduce maternal and newborn mortality, in addition to essential newborn care (ENC) and management of newborn illness.

[1] Because features of the health system or primary health care workers do not allow diagnosis of sepsis or pneumonia by laboratory results, and because danger signs in a sick young infant are non-specific and are not diagnostic, these classifications of a sick young infant are based on a syndromic approach. Evidence supports empiric use of antibiotics for outpatient treatment of sick young infants based on the specified classifications.

FIG. 1

Simplified Antibiotic Regimens For Treating Infants Age 0 to 59 Days with PBSI or Very Severe Disease[a] Proven Effective In Randomized Clinical Trials

CLASSIFICATION OF SICK YOUNG INFANT	RECOMMENDED MANAGEMENT	SIMPLIFIED ANTIBIOTIC REGIMEN
Age 7–59 days with PNEUMONIA (fast breathing as the only sign of illness[b])	• Outpatient treatment • Follow up on day 4 of treatment	Oral amoxicillin 50 mg/kg per dose given twice daily at home for 7 days
Age less than 7 days with fast breathing as the only sign of illness, or Age 0–59 days with PSBI OR VERY SEVERE DISEASE (signs other than fast breathing alone)	• Referral to hospital	Pre-referral antibiotic treatment with: • First dose of intramuscular gentamicin 5–7.5 mg/kg, and • Oral amoxicillin 50 mg/kg per dose

When Families Do Not Accept or Cannot Access Referral, Further Assessment And Classification Followed By:

CLASSIFICATION OF SICK YOUNG INFANT	RECOMMENDED MANAGEMENT	SIMPLIFIED ANTIBIOTIC REGIMEN
Age less than 7 days with SEVERE PNEUMONIA (fast breathing as the only sign of illness)	• Outpatient treatment • Follow up on day 4 of treatment	Oral amoxicillin 50 mg/kg per dose given twice daily for 7 days
Age 0–59 days with CLINICAL SEVERE INFECTION	• Outpatient treatment • Reassessment at each visit for injection, and • Follow up on day 4 and on day 8	—Gentamicin injections 5–7.5 mg/kg once daily (for 2 or 7 days[c]) and —Twice-daily oral amoxicillin 50 mg/kg per dose for 7 days
Age 0 to 59 days with CRITICAL ILLNESS	• Referral to hospital	Pre-referral treatment with 2 injectable antibiotics: Give first dose of both ampicillin (50 mg/kg per dose) or benzyl penicillin (50 000 units/kg per dose) and gentamicin (5–7.5 mg/kg per dose) intramuscularly[d]

[a] These recommendations do not apply for infants less than 1.5 kg.

[b] Signs of illness – of PSBI or very severe disease – in a sick young infant include: not able to feed since birth or stopped feeding well (confirmed by observation), convulsions, fast breathing (60 breaths per minute or more), severe chest in-drawing, fever (38 °C or greater), low body temperature (less than 35.5 °C)

[c] Countries may decide to treat CLINICAL SEVERE INFECTION with IM gentamicin for 7 days or 2 days. Seven days is the preferred option, but where the health system does not allow this to be implemented, 2 days may be considered.

[d] If a young infant is classified as CRITICAL ILLNESS but the family will not take the sick young infant to hospital, there is no simplified antibiotic regimen that can be used; treatment with two injectable antibiotics at the primary health care facility may be given as a last resort, as has been recommended in IMCI for some years. However, few primary health care facilities have the injectable antibiotics (ampicillin and gentamicin), and necessary supplies and trained staff to provide multiple injections for 5 days.

C. Planning for Implementation

1. Situation analysis to inform operationalizing management of sick young infants with PSBI where referral is not feasible

Most health systems implement numerous programmes and strategies to reduce maternal and newborn mortality to some extent, including mortality due to PSBI. All of these strategies remain important for achievement of the objective – reduction of newborn mortality. Thus, planning for implementation of the new recommendations should include a situation analysis of all relevant services to prevent and treat newborn illness and prevent deaths, and their ***current*** coverage and implementation strengths.

This analysis can point to geographic areas and underserved communities most in need of increased access to care for sick young infants. It can also indicate whether the strength of implementation of some programmes or strategies requires improvement. The new strategies for care of sick young infants with PSBI when families do not accept or cannot access referral offer a way to improve the current scenario for delivery of care for mothers and newborns.

For example, when planners examine where referral facilities are available or unavailable and the extent that they are used, they can identify the geographic areas where implementation of the simplified antibiotic treatment of PSBI in primary care facilities may make an important contribution to saving young infant lives. If they find high rates of care-seeking at primary care facilities, plans will focus on providing medicines and trained staff to manage sick newborns. Where care-seeking is low, major efforts will also be needed to inform and build trust of families that the primary health care facility can care for sick newborns.

As another example, in some countries there are trained community workers who make home visits for antenatal counselling and postnatal care. During home visits these community health workers should:

- effectively counsel families on facility delivery, early initiation of breastfeeding, exclusive breastfeeding, care of the newborn, recognition of danger signs, and prompt and appropriate care-seeking
- assess young infants for danger signs of illness during the visit and facilitate taking any sick young infant that they identify to the primary care facility right away

Assessment may show that home visits by community health workers should be expanded to reach more pregnant women and newborns and/or that community worker training and supervision will need to be improved.

When planners and managers can agree on the priority issues for improvement, the list becomes a blueprint for planning activities of implementation and identifying important indicators to monitor.

A situation analysis that reviews the information listed below will give a picture of the most important health problems and factors contributing to them, and the strengths and weaknesses of delivery of current services for maternal, newborn and child health. Make a rough and quick situation analysis using available data compiled from several sources or descriptions of the current situation. If your country recently completed a programme review, situation analysis or bottleneck analysis, some of the relevant information will be collected and analyzed.

Then you will be able to understand what will be needed to:

- operationalize the new recommendations for managing young infants with PSBI where referral is not feasible[1] into current health services for sick newborns, and
- improve implementation of current strategies for prevention and treatment of illness in young infants.

When data are not readily available, further investigation may be undertaken as part of planning. Hard data are often not available, but that does not mean information is unavailable. Consulting with experts, partners and stakeholders can provide estimates of coverage or implementation strength and information on system bottlenecks and their causes. A special study might be done to understand certain aspects of current coverage and practices, if a country can accomplish the study quickly enough to use the results for planning or as baseline.

Specific information items to review are listed below in 3 groups:

- Current newborn mortality and morbidity
- Current coverage of maternal and newborn health interventions
- Strength of implementation of ongoing maternal and newborn health programs and services including access, availability, quality, knowledge of families and demand.

[1] "Not feasible" means that the family either does not accept or cannot access referral. If a health worker recommends referral, but the family will not take the young infant for referral, regardless of the reason, the health worker should provide care according to the updated guidelines for simplified antibiotic treatment of young infants with PSBI.

I. Review current newborn mortality and morbidity

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
a. Neonatal mortality rate and main causes	To understand the size of the problem of neonatal deaths To understand the importance of improving care of sick young infants To understand the importance of preventing newborn illness	• UN Interagency Group for Child Mortality Estimation (IGME)[a] • Most recent national household survey eg, Demographic and Health Survey (DHS)
b. Geographic areas or social groups with high newborn mortality	To identify areas or groups that have high rates of preventable newborn deaths To identify areas or groups that are not receiving adequate health care, and that may not have access to adequate referral care	• Most recent national household survey • DHIS2
c. Newborn morbidity, incidence of pneumonia in young infants, incidence of PSBI	To understand the extent of newborn morbidity, and the extent of pneumonia and PSBI in young infants To understand the importance of preventing and treating these illnesses	• MOH's health management information system • Local surveillance studies (if available) • 2012 regional estimates published by AC Seale et al in *The Lancet*[b]

[a] http://www.childmortality.org

[b] Seale AC, Blencowe H, Manu AA, et al. Estimates of possible severe bacterial infection in neonates in sub-Saharan Africa, south Asia

II. Review current coverage of maternal and newborn health interventions

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
a. Treatment coverage rates for sick young infants	To understand current use of facilities by young infants; whether families recognize when young infants are sick and when they are very sick; whether families bring sick young infants to a primary care facility	• MOH records or local surveillance studies (if available)
b. Antenatal care (ANC) attendance rate	To understand extent that women use ANC services and the extent that those women may receive information on newborn care, danger signs, and care-seeking If ANC use is low, a priority may be to increase it. It may also be a priority to plan additional ways to reach women and families with important messages on essential newborn care, danger signs and prompt care-seeking, such as through counselling of community groups.	• Most recent national survey (DHS recently added questions on essential newborn care including cord care and chlorhexidine application[a])
c. Facility delivery rate	To understand the proportion of women who deliver in a facility, and may receive information on essential newborn care, and danger signs and prompt care-seeking To understand the effectiveness of ANC and community activities to increase facility delivery rates	
d. Postnatal care attendance rate	To understand the extent that women come to a facility for postnatal care To understand the extent that postnatal women could be reached with information on essential newborn care during postnatal visits to a facility	(same as above)

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
e. Early initiation of breastfeeding	To understand if mothers are initiating breastfeeding early (within one hour of birth)	• Most recent national household survey • Unicef's State of the World's Children report[b]
f. Exclusive breastfeeding rate	To understand whether breastfeeding rates are high or low (low rates may be an important cause of infection in young infants) To understand whether messages on early initiation of breastfeeding and exclusive breastfeeding are reaching families and whether mothers are improving breastfeeding practices	
g. Immunization rates	To understand whether young infants and children are being reached by the primary health care facilities; extent that mothers bring infants for preventive care; extent that mothers use the health services.	

[a] DHS Phase 7 women's questionnaire (http://dhsprogram.com/pubs/pdf/DHSQ7/DHS7-Womans-QRE-EN-17May2016-DHSQ7.pdf) and optional newborn module (http://dhsprogram.com/publications/publication-DHSQM-DHS-Questionnaires-and-Manuals.cfm)

[b] UNICEF. 2014. State of the World's Children 2015. Geneva: UNICEF http://www.data.unicef.org/resources/the-state-of-the-world-s-children-report-2015-statistical-tables

III. Review strength of implementation of ongoing maternal and newborn health programs and services including access, availability, quality, knowledge of families, and demand

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
a. Access to primary health care facility services for young infants; number of facilities and locations; population with access and population without access (numbers and proportions)	To map areas with geographic access to primary health care facilities and areas without To quantify population groups with access and populations without	• MOH records • Special study
b. Existing programmes/ platforms for care of sick young infants and children in primary care facilities	To identify programmes/platforms into which activities related to sick young infants including PSBI management may be introduced and integrated (e.g. MPS, IMNCI, iCCM, ENC, HBB, KMC, maternity waiting homes, women's action cycles)	• National child health / IMCI strategies • Community health programme plans – iCCM stategy and plan • Maternal and newborn programme strategies and plans
c. Underserved populations (who do not use facilities)	To map communities and identify social groups who do not use facilities; to try to understand why they do not	• Special study
d. Access to 24-hour attended childbirth and child health services, whether services have basic supplies including resuscitation supplies (i.e. bag and mask), whether infant care is offered there	To understand whether delivery care is adequate To understand whether mothers are likely to return there when infant is sick To understand how to best to provide follow up and treatment	• MOH records • Facility survey

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
e. Access to referral facility (hospital) care for young infants and children; numbers and locations	To map communities where geographic access to referral care is available and where it is not; to quantify populations without access to hospital	• MOH records • Special study
f. Existing programmes/ platforms in communities that engage families for teaching and counselling on health	To identify programmes/platforms into which messages and activities to inform mothers and families about newborn illness and to empower them to seek care for a sick newborn can be integrated	• District and MOH workplans and records
g. Communities with access to a CHW making home visits to newborns and their mothers within the first week of life (and/or proportion of families with a newborn visited by a CHW in the first week of life)	To map communities where CHWs or other workers make home visits to newborns; to identify communities in which mothers do not get postnatal home visits To understand whether all newborns in a community are visited To assess whether more CHWs are needed in a community; whether more communities need a trained CHW	• MOH records • Special study
h. Care-seeking preferences and practices for sick newborns/young infants/children	To understand care-seeking behavior – where families first take sick young infants (private sector, traditional healers, primary facilities, hospitals) and where they do not take them To understand what influences their decisions about care-seeking To understand whether delays in young infants receiving care are due to going to other providers first; to determine reasons families do not take young infants to primary care facilities	• Special study
i. Extent that private sector providers give child/infant care services; what types of providers give child/ infant care; services they provide j. Proportion of families/ infants who obtain care from private providers	To understand the extent that families use private providers in comparison to primary care facilities To understand why families go to private providers instead of primary care facilities (quality, accessibility, cost, cultural reasons?) To understand the importance of involving and coordinating with private providers to identify sick young infants and to inform and encourage them to refer sick young infants to primary care facilities	• Special study • Household surveys
k. Availability of human resources at primary health care facilities for provision of care and for supervision of that care (adequate or inadequate?); opening hours; whether the same health care providers also have a private practice	To understand reasons that health services may be limited or not adequate to serve populations currently; feasibility to expand/improve services; feasibility to introduce any new tasks for primary health care workers or their supervisors To understand likelihood that changes in practices may extend to private providers or will be resisted by private providers	• MOH record • Recent facility survey • Special study

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
l. Quality of primary health care services for children and young infants; proportion of health facilities with staff trained in IMNCI; whether injection safety measures are implemented	To understand the platform for delivery of services for children and young infants at the primary care level To determine the extent of implementation of IMNCI training To determine quality of injection safety measures in primary care facilities	• MOH records • Recent facility survey • Special study
m. Proportion of communities with CHW trained in iCCM	To understand the platform for delivery of services for children and young infants at community level To determine the extent of implementation of iCCM training	• MOH records
n. Basic facilities readiness for management of sick young infants and children at primary care facilities • Suitable primary health care building is available and open weekdays • Staff available at all open hours for managing young infants and children • Staff trained in IMNCI • Job aid available • Clean water supply is present • Electricity is available (x% of time) • Functioning system is in place for regular supply of medicines and supplies	To determine if facilities meet the most basic requirements for care of young infants and children before introducing new guidelines	• Health facility survey • Supervisory visit reports
o. Availability of necessary medicines and supplies for management of sick young infants and children at primary care facilities, e.g. ORS, zinc tablets, malaria tests, paracetamol, anti-malarial treatment, amoxicillin dispersible tablets, mebendazole, etc. p. Availability of medicines or presentations of medicines, or supplies needed for implementation of improved management of young infants with PSBI, (including oral amoxicillin in syrup and dispersible tablets, injectable gentamicin in pediatric formulation and ampicillin, pediatric syringes, 1–2 ml and 25G needles, distilled water, gentian violet, weighing scales, thermometers, sharps disposal containers) q. Whether antibiotics (oral amoxicillin, injectable gentamicin and ampicillin) are used for populations other than young infants and quantities used	To understand whether the supply chain is currently working to provide IMNCI medicines and supplies to primary care facilities and to identify its strengths and weaknesses; to identify the logistics system to which additional medicines would be added for treatment of PSBI when families do not accept or cannot access referral To identify any additional medicines or presentations of medicines, or supplies that need to be added to items provided to primary health care facilities or increased in quantity. To identify potential supply problems when pediatric supplies are used for other populations; to determine quantities needed	• MOH's logistic management information system • Recent facility survey • Supervisory visit reports

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
r. Availability of registers, case recording forms, referral slips, job aids at primary care facilities	To determine whether health workers have required forms or whether there are shortages; reasons for any shortages	• Health facility survey • Supervisory visit reports
s. Availability of necessary medicines, equipment and supplies for care of sick young infants at referral facilities	To understand whether referral facilities are limited in the quality of care by inadequate supplies of medicines, etc. and whether shortages are caused by problems in procurement, distribution, wastage, or other problems	• MOH's logistic management information system • Recent facility survey
t. Proportion of sick young infants who are referred to hospital who accept the referral; reasons that families do and do not accept referral	To understand the extent to which families accept and complete referral; areas or social groups where families complete referral and reasons why; areas or social groups that do not complete referral to hospital and reasons why	• Special study • Facility records
u. Number of sick young infants seen at primary health care facilities v. Number of sick young infants seen at referral facilities	To understand current care-seeking patterns for young infants To understand referral linkages	• MOH's health management information system (HMIS) • Hospital records • Special studies
w. Primary health care facility workers supervised in the previous 2 months	To determine whether primary care facility workers currently receive support and feedback in IMCI; whether supervisors of health workers could likely provide close supervision and clinical mentoring for introduction of new recommendations for PSBI treatment where referral is not feasible.	• MOH's supervision records • Recent facility survey with health worker interviews • Review of supervision forms
x. Checklists and forms currently used by supervisors of first level facility health workers; reports completed after supervisory visits y. Problems currently preventing or impairing supervision being carried out as planned	To assess whether supervisors provide supportive supervision currently and whether it is impacting/sustaining performance To understand problems with current supervision, whether they are under staff control or system influence, and possible solutions to problems preventing good supervision	
z. Community health workers who make home visits supervised in the previous 3 months aa. Community health workers who identify 90% of pregnant women in their community and perform antenatal and postnatal home visits	To understand whether CHWs receive supervisory support; if not, how extensive/serious is this problem; whether CHWs can be expected to perform/improve their work related to visiting newborns and teaching family members about danger signs and prompt care-seeking	• MOH's supervision records • Special study with CHW interviews • Review of supervision forms • CHWs register
bb. Policies that enable and support CHWs making home visits to newborns in the first week of life	To determine whether CHWs are limited in making home visits to newborns by an existing policy or whether current policies support these visits	• Review of policies

INFORMATION TO REVIEW	HOW THIS INFORMATION IS USEFUL FOR PLANNING	SUGGESTED DATA SOURCES
cc. Policies that enable (or limit) trained health workers giving antibiotic injections at primary health care facilities	Whether trained primary health care workers are limited or enabled to give antibiotic injections; types of health workers that are able to give antibiotic injections in primary health care facilities.	• Review of policies • Review of training materials and guidelines
dd. HMIS information collected on number of sick young infants seen at primary and referral levels, treatment and referral	To understand what information is available to support decision-making and management To identify what needs to be added to the HMIS	• Review of HMIS data collection and reporting tools and reports

When planners and managers can agree on the priority issues for improvement, the list becomes a blueprint for planning activities of implementation and identifying important indicators to monitor.

2. Framework for planning how to operationalize management of PSBI in sick young infants where referral is not feasible in the context of a country's ongoing maternal, newborn and child health programmes

From here on, this guide will suggest a framework and highlight some important issues to consider when planning how to integrate the new strategies to reduce newborn and young infant mortality due to PSBI or very severe disease into the existing programmes and service delivery platforms for care of sick young infants and children; in most countries the primary platform is IMNCI. Planning must also include integrating into ongoing programmes that engage with families and communities some important messages and activities to inform mothers and families about newborn illness and empower them to seek care for a sick newborn.

Planning will identify important actions to be taken based on the situation analysis, and then those actions should be integrated with activities for all ongoing child and infant care services, just as the care of sick young infants will be integrated with delivery of other services in primary care facilities. For example, one activity will be to design training to update current providers at primary health care facilities or to train new providers on assessment, classification and treatment of sick young infants including, when referral is not feasible, the new simplified antibiotic regimens; conducting that training should then be integrated with ongoing training activities for health workers. The trained health care provider will manage sick young infants with PSBI as she has been trained to do, along with managing sick children according to her IMCI training and other duties.

This guide will use 8 components as a framework for organizing the analysis, planning and implementation of the new strategies. This or a similar breakdown will be familiar to those who plan, implement or evaluate health programmes. The 8 components are:

1) Coordination and policy setting

2) Human resources

3) Supply chain management

4) Service delivery and referral

5) Communication and social mobilization

6) Supervision and performance quality assurance

7) Monitoring and evaluation, and health information systems

8) Costing and financing

Planning activities to operationalize management of young infants with PSBI

Activities are planned and implemented in the 8 component areas with the intention to operationalize management of PSBI in sick young infants at primary health care facilities. Improvements should also be made in implementation of other strategies for prevention of illness and death in young infants, including in the community (early identification of illness in young infants and prompt care-seeking), and at referral facilities.

A framework for planning the introduction and implementation of management of the sick young infant with PSBI is shown in 8 steps in Figure 2 on page 19. Though shown in a sequence from top to bottom, the planning steps are not strictly sequential but may overlap and be going on at the same time.

However, some decisions earlier in the sequence (e.g. mapping of geographic areas where referral to hospital is not feasible; identifying the number of health workers in primary health care facilities that will manage sick young infants with PSBI when referral is not feasible) must be made before later steps can be completed (e.g. planning to conduct updated IMNCI training, and planning for additional items or increased quantities of medicines and supplies for those primary health care facilities). As planning continues, adjustments may be needed in earlier plans; this should be seen as a cycle of planning.

Be mindful that this guide is generic; knowledge and understanding of the context in your country is crucial for your planning of how to operationalize management of sick young infants with PSBI there. Your country's plans must reflect your team's best estimation of what will be effective given the unique context.

Annex A lists some national benchmarks, grouped by component. These benchmarks help countries assess their readiness to operationalize management of sick young infants with PSBI and may be useful for tracking progress in implementation and scale up. It is also a useful tool to engage planners and researchers in discussion with Ministry of Health managers and supervisors who will implement the interventions. Together they can review the benchmarks and select priorities to work on.

The case for starting in a few demonstration sites

The effectiveness of the WHO-recommended interventions to manage sick young infants with PSBI where referral is not feasible and save newborn lives is proven. What is not known, however, is how to best operationalize these recommendations in the context of ongoing maternal, newborn and child health programmes and in different countries.

Initiating implementation of the interventions within ongoing programmes in one district or a few demonstration sites provides an opportunity to try out your planned approach to operationalizing the recommendations in your country's context and without committing vast resources, only to possibly discover that planned activities were not feasible, or not effective, or created other problems. When bottlenecks are encountered in a demonstration district, it is relatively easy to test solutions and modify activities as needed.

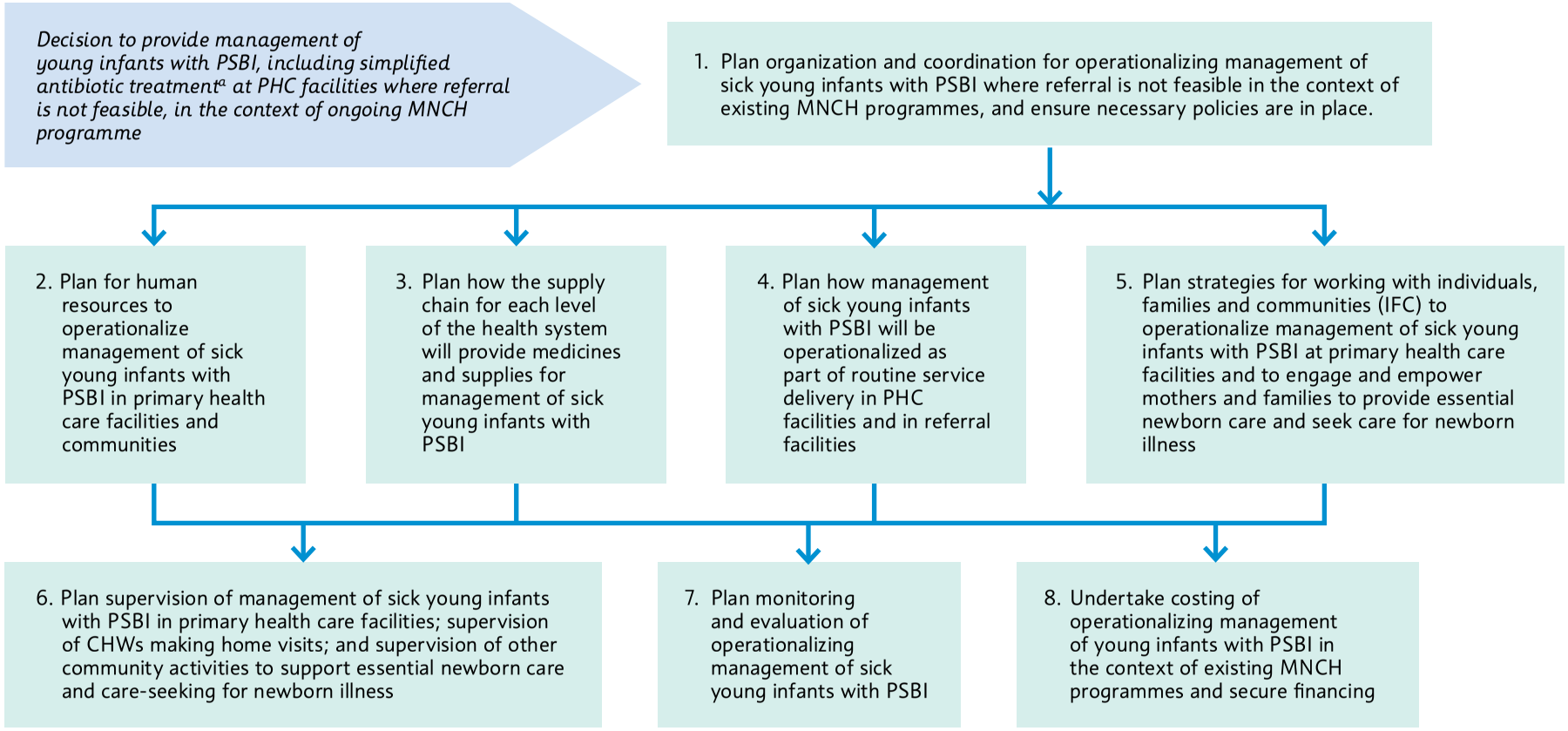
In a demonstration district, you can:

- Identify and try different ways to integrate with current programmes and activities, such as IMNCI, or iCCM, to train health workers in primary care facilities and in communities about management of young infants with PSBI, supply the additional medicines and supplies required, supervise health workers, and collect additional monitoring data.
- Identify challenges in implementation and modify procedures as needed to integrate management of sick young infants with PSBI in ongoing maternal, newborn and child health services in a way that can be effectively delivered at scale.
- Identify challenges in engaging and empowering families and communities to recognize danger signs in young infants and seek care from an appropriate provider and adjust activities accordingly.
- Identify implications for a successful implementation of PSBI as part of the existing newborn and child health agenda.
- Gather local evidence of benefits of providing management of sick young infants with PSBI where referral is not feasible, which can be used to advocate for scale-up.
- When an approach to operationalizing is shown to be reasonably successful, assess feasibility of scaling it up.

It is essential that the regional/district MOH plan undertake the demonstration work if it is to be useful and sustainable; a demonstration should not be undertaken as a research project with dedicated staff and extraordinary resources. In the demonstration site, regular MOH health facility staff must manage the sick young infants according to the new recommendations and counsel their mothers, along with their regular work. Existing types of community health workers must conduct the home visits to newborns or for follow up of sick newborns. Any special funding and staff brought in to the demonstration site should perform only functions specific to operational research aspects such as special data collection. If this is not the case, little is learned about how to operationalize the guidelines in a real setting, and the care of sick young infants will not be sustained when the special staff and resources are withdrawn.

FIG. 2

Steps to operationalize management of sick young infants with PSBI at primary health care facilities where referral is not feasible



[a] Simplified antibiotic treatment of sick young infants with PSBI is recommended in districts or areas where referral is not feasible for any reason: referral facilities are not available or families do not accept referral. Reasons for non-acceptance might include lack of transport, costs, culture, or perception and quality of care at referral level. Existing services may include IMNCI, community-based newborn care, quality improvement programmes, etc.

D. Guidance on planning to operationalize management of sick young infants with PSBI where referral is not feasible into routine care at primary health care facilities

Each step for planning implementation shown in Figure 2 above can be further broken down into substeps. In this section, substeps are specified below each main step, some with explanations and guidance.

1. Plan organization and coordination for operationalizing management of sick young infants with PSBI where referral is not feasible in the context of existing MNCH programmes, and ensure necessary policies are in place

1.1 Undertake orientation meetings with stakeholders (professional bodies, national and regional/district MOH, development partners) to communicate the neonatal mortality problem, policies and intentions for improving newborn survival including management of sick young infant with PSBI at primary care facilities when referral is not feasible.

1.2 Agree on national coordinating mechanisms for operationalizing management of young infants with PSBI when referral is not feasible.

This may include appointing a national focal person for newborn survival and revitalising a national working group linked to the IMNCI task force for child survival to strengthen efforts to improve young infant health. It can be effective to appoint a focal person for newborn survival in each district that will include a demonstration site and in subsequent districts when scaling up implementation.

1.3 Agree on the level of health facility that will operationalize the WHO recommendations for management of sick young infants with PSBI when referral is not feasible. In some countries this will be obvious; it will be the primary health care facilities that provide IMNCI care for infants and children. However, in some countries there are multiple levels of facilities with some differences in capabilities that may be considered.

If choosing between two levels, consider that the higher level may have better availability of skilled staff and medicines, but families will likely come less readily, for initial care or for follow up, because higher level facilities are farther away. A lower level facility may have fewer staff and fewer open hours and days, but may be more accessible to families with sick young infants. If one level currently has the trust of the community (as indicated by their frequent attendance for care of young infants and children), it would be a good choice. If neither currently has this trust, building it over time will be important in order to increase care-seeking.

1.4 Plan communications to sensitize government, professional and civil society leaders at sub-national levels about the need for referral care for very sick young infants, and when families do not accept or cannot access referral, the effectiveness and feasibility of simplified antibiotic treatment of young infants with PSBI in primary care facilities.

Application of the new recommendation will have the benefit that fewer sick young infants will be referred from primary health care facilities: young infants 7–59 days old with PNEUMONIA (fast breathing as the only sign of illness) are no longer routinely referred and can be safely and effectively treated at home with oral amoxicillin given twice daily for 7 days. Research results include that 30–35% of all sick young infants are in this group. Thus implementation of this recommendation could ease the burden on referral facilities and decrease the overall number of injections that need to be administered to sick young infants by 30%.

Note that in many countries acceptance of the new strategies by professional societies (medicine, pediatrics) is key for their acceptance by government. Involve their leaders early in planning for demonstration sites, invite leaders and members to visit demonstration sites, and keep them informed of impact.

Championship of the leading pediatricians will help to create an acceptance among pediatricians and other doctors in the country.

Also, if those who determine or influence the care standards and budget of referral facilities understand the new strategies and need for quality referral care for very sick young infants, they may influence improvements in medicines, equipment and procedures at referral facilities.

1.5 Select the treatment option for Clinical Severe Infection in young infants with PSBI to be used in primary health care facilities. Use the WHO guideline to decide on best options for your setting taking into account local social, cultural and economic contexts. Two options are proposed for consideration by countries and these include simplified treatment with either 7 days **or** 2 days IM gentamicin **plus** 7 days oral amoxicillin.

Below is guidance for making this decision from the *GUIDELINE: Managing Possible Serious Bacterial Infection (PSBI) in Young Infants When Referral Is Not Feasible*.

Young infants 0–59 days old with clinical severe infection whose families do not accept or cannot access referral care should be managed in outpatient settings by an appropriately trained health worker with one of the following regimens:

*Option 1: Intramuscular gentamicin 5–7.5 mg/kg (for low-birth-weight infants gentamicin 3–4 mg/kg) once daily for **seven days** and twice daily oral amoxicillin, 50 mg/kg per dose for seven days. Close follow-up is essential.*

*Option 2: Intramuscular gentamicin 5–7.5 mg/kg (for low-birth-weight infants gentamicin 3–4 mg/kg) once daily for **two days** and twice daily oral amoxicillin, 50 mg/kg per dose for seven days. Close follow-up is essential. A careful assessment on day 4 is mandatory.*

Countries are encouraged to hold key stakeholder discussions to inform the decision-making on use and introduction of the recommendations into national programmes.

1.6 Ensure a policy is in place for home visits to pregnant women and newborns to counsel families on danger signs of a sick young infant and prompt care-seeking, and to identify sick young infants. The success of the strategy will depend on how early sick young infants are identified and brought to the primary health facility for care.

1.7 Ensure a policy is in place to ensure primary health care facilities are supplied with intramuscular gentamicin, oral amoxicillin and other medicines for simplified treatment of young infants with PSBI when referral is not feasible, and primary health care facility workers are authorized to administer intramuscular antibiotics.

1.8 Adopt updated clinical guidelines for management of the sick young infant with PSBI that include simplified antibiotic treatment when families do not accept or cannot access

Young infants 7–59 days old with pneumonia (fast breathing as the only sign of illness) are no longer routinely referred and can be safely and effectively treated at home with oral amoxicillin given twice daily for 7 days. Research results include that 30–35% of all sick young infants are in this group. Thus implementation of this recommendation could ease the burden on referral facilities and decrease the overall number of injections that need to be administered to sick young infants by 30%.

referral; update current guidelines for primary health care, IMNCI, and iCCM to align with new guidelines to avoid inconsistent management protocols.

The WHO-UNICEF IMCI training course has been updated to include management of young infants with PSBI in primary health facilities when referral is not feasible. The module titled *Management of the Sick Young Infant Age up to 2 Months*[1] will be helpful to provide the standard guidelines and ready-to-use training materials and job aids for health workers at primary health care facilities.

The iCCM module titled *Care of the Newborn at Home* teaches community health workers to make a series of home visits to counsel a woman and her family during pregnancy and after a baby's birth, and supports the visits with specific job aids. At the postnatal visits, the CHW looks for danger signs in a newborn and if any are present, refers the newborn to a facility. She also counsels families about essential newborn care practices, recognition of danger signs, and prompt care-seeking. These materials provide the standard guidelines, ready-to-use training materials and job aids for CHWs.

2. Plan for human resources to operationalize management of sick young infants with PSBI in primary health care facilities and communities

2.1 Identify the cadre who manages sick children and young infants at primary health care facilities and their tasks; determine whether they are trained on IMNCI guidelines or on other packages that included assessment and treatment of sick young infants and children.

2.2 Specify the primary health care facilities that will need to integrate management of sick young infants with PSBI when referral is not feasible into routine care.

2.2.1 On a map, identify the primary health care facilities that do not have access to a referral facility.

2.2.2 Determine the number of these health facilities and specify the number of providers that should be available in these facilities.

2.3 Check whether there is a cadre, e.g. (CHWs) that makes home visits to pregnant women and newborns and has been trained using the iCCM package *Caring for the Newborn at Home*. Determine whether the cadre will be sufficient to do the tasks needed and any modifications or additional support they will need.

2.3.1 If the country has not yet implemented the iCCM training package *Caring for the Newborn at Home*, consider implementing it prior to introducing the new recommendations for management of PSBI. The success of the PSBI strategy will depend on how early sick young infants are identified and brought to the primary health facility for care.

[1] *Management of the Sick Young Infant Age up to 2 Months* was updated in 2016. Materials include the *Participant Manual*, *Chart Booklet*, and *Facilitator Guidelines*.

Caring for the Newborn at Home teaches community health workers to make antenatal and postnatal visits to counsel on pregnancy care, facility delivery, care of the newborn, and signs of illness; and to assess the newborn and facilitate care-seeking if danger signs are found.

2.3.2 If the country has implemented the training package *Caring for the Newborn at Home*, determine whether currently these CHWs correctly counsel families during home visits on care of the newborn at home, recognition of a sick young infant and prompt care-seeking; and whether they identify sick young infants.

2.3.3 Identify the communities where these CHWs work and communities that are not reached by home visits. Assess whether the numbers of CHWs are sufficient to make visits to all pregnant women/newborns in their communities.

2.3.4 Assess whether CHWs who make these home visits are given ongoing support and supervision after training.

2.3.5 Specify modifications or improvements in the cadre of CHWs (e.g. more CHWs, increased supervision) desired to facilitate their effectiveness in identifying and referring newborns with danger signs and empowering family members to recognize danger signs and seek care at a facility.

2.4 Identify the technical supervisors or clinical mentors of health care providers for young infants and children at primary health facilities.

These supervisors may work at the same facility with the care providers, or may visit the facility to supervise clinical work. The training of the care providers will be scheduled to follow the training of their supervisors. See Chapter 6: Plan supervision of management of sick young infants with PSBI in primary health care facilities.

2.5 Develop a training plan for delivering initial IMNCI training and updated training on care of the sick young infant in primary health care facilities.

There are two likely groups of health workers to be trained:

- Health workers already trained in IMNCI and caring for sick children and infants according to those guidelines
- Health workers who are new and/or not trained in IMNCI

The first group needs to be updated on management of sick young infants with PBSI when referral is not feasible. Their previous IMNCI training on care of a sick young infant taught them to refer all of sick young infants and did not provide an alternative. They will need to understand they will no longer follow those guidelines and will use the new guideline instead. Demonstration sites in several countries have found that health workers were sometimes confused about the differences in the new protocol and the existing IMCI protocol for sick young infants.

The second group needs to be trained in IMNCI management of sick children and sick young infants, using a complete IMNCI course which includes the updated module on care of sick young infants.

Because management of a sick young infant with PSBI when referral is not feasible may include giving gentamicin injections, health workers' training (and supervision) must include accurate weighing and dosing and emphasize all aspects of injection safety.

Experience has shown that health workers at primary care facilities often lack the confidence to give gentamicin injections to young infants with PSBI according to the guidelines. They may fear giving an injectable antibiotic to such a tiny baby and do not want to make any possible mistake. It is therefore essential that initial training and ongoing

supervision and mentoring provide support and encouragement to give the injection when it is needed. Through observation of other health workers, repetition, sharing of concerns and experiences with other health workers, and realizing that the treatment can save a newborn's life, health workers can develop the skills and confidence over time. Since in most cases health workers have no doctor present to turn to, they need to know that the government and pediatricians support them giving gentamicin injections to a young infant with PSBI when referral is not feasible, in order to save a baby's life.

See Annex B which describes how to develop a training plan to teach improved management of the sick young infant in primary health care facilities.

Also plan how to train supervisors how to guide primary health care workers implementing new guidelines for management of sick young infants with PSBI and how to provide clinical mentoring (see step 6.2).

2.6 Revise job descriptions, if necessary, of health care providers at primary care facilities to include management of sick young infants.

Job descriptions should show how management of sick young infants with PSBI is integrated into routine care. This includes providing outpatient treatment with antibiotics for sick young infants 7 to 59 days old with fast breathing as the only sign of illness. It also includes providing simplified antibiotic treatment when families do not accept or cannot access referral for a sick young infant with PSBI.

2.7 Plan to update IMNCI guidelines for care of young infants in preservice curricula and training materials and institutions.

2.8 Provide information to professional associations and private sector providers on the problem of neonatal deaths and how they can be prevented; encourage the private sector to be involved in improvements in management of young infants with PSBI.

2.9 Specify training needed to increase capacity at primary health care facilities and at district level to collect and use data on management of sick young infants for monitoring and evaluation.

3. Plan how the supply chain for each level of the health system will provide medicines and supplies for management of sick young infants with PSBI

3.1 Specify the medicines to be added to the essential medicines list for treatment of young infants with PBSI at primary care facilities, with formulations appropriate for young infants (age 0–2 months), and packaging for efficient distribution to and use at primary care facilities.

MEDICINES

- Intramuscular gentamicin (strength 20 mg/ml or 40 mg/ml or 80mg/2ml)
- (Note: Strength 10 mg/ml is not recommended as the volume is too large for administration to a young infant.)
- Intramuscular ampicillin (strength 250 mg/1.5 ml)
- Sugar
- Amoxicillin dispersible tablets 250 mg or 125 mg in blister packs
- Amoxicillin syrup (strength 125 mg in 5 ml)

- Ringer's Lactate Solution
- ORS packets
- Full strength gentian violet (0.5%)
- Half-strength gentian violet (0.25%)
- ART medicines for infants and their mothers
- Vaccines: BCG, HepB, OPV, DPT+HIB+ HepB; rotavirus; PCV
- Chlorhexidine gluconate (4%)

3.2 Specify additional supplies (e.g. syringes, needles and water for injection) and equipment required for management of sick young infants with PBSI at primary care facilities.

SUPPLIES

- Minute timer
- Thermometer
- Infant weighing scale
- Syringes: 5ml syringe with 0.2 ml markings, 3 ml with 0.1ml markings, 1 ml syringe with 0.1 ml markings
- Needles: 23–25 Gauge of up to 2.5 cm in length
- Water for injection
- Antiseptic swabs
- Clean water
- Nasogastric tubes
- IV giving sets
- Litre containers for mixing ORS solution, cups and spoons for giving ORS, containers for sending ORS with referred infant
- Sharps containers (for safe disposal and incineration of used needles and syringes)

3.3 Do forecasting for medicines and other supplies needed for PSBI management at primary health care facilities. Most of the medicines and supplies are stocked currently but increased quantities or different formulations may be needed for use in young infants. Base forecasts on carefully calculated estimates of pneumonia and PSBI cases expected.

3.4 Ensure that the medicines and supplies for simplified treatment of young infants with PBSI at primary health care facilities will be added to the country's supply chain for essential medicines, including procurement, storage and distribution, to provide the medicines and supplies at the point of service delivery, primary health care facilities. Gentamicin and supplies for safe injection may be new for some primary health care facilities.

It may be advisable to consider providing starter packs of PSBI commodities for primary health facilities to accompany trainings, to ensure health workers have the medicines and supplies for PSBI (e.g. thermometers, ARI timers, case forms, referral slips) immediately available after training, instead of waiting for them to filter down the supply chain. However, after that, the products should be provided through the usual process for ordering and distribution.

3.5 Plan how to incorporate data on medicines and supplies for management of young infants with PSBI in primary health care facilities into the logistics information system (LMIS) or the equivalent; ensure that the data are used for decision-making on distribution.

4. Plan how management of sick young infants with PSBI will be operationalized as part of routine service delivery in primary health care facilities and in referral facilities

4.1 Gather stakeholders and partners for operationalizing management of young infants with PSBI and plan how the recommendations will be integrated into routine service delivery at primary health care facilities near patient's homes; communicate with groups working in communities, primary health care providers (e.g. NGOs) and providers at different levels who may be involved.

Countries are encouraged to hold key stakeholder discussions to inform the decision-making on use and introduction of the recommendations into national programmes.

4.2 Develop or update guidelines and tools (e.g. registers, job aids) as needed to reflect the new guidelines for management of young infants with PSBI, and ensure that they are in place in primary health care facilities, referral facilities, and communities.

Available job aids include *Caring for the Newborn at Home: Counselling Cards* for community health workers; the *Chart Booklet for Management of the Sick Young Infant* for primary health care facilities; WHO P*ocket Book for Hospital Care of Children: Guidelines for the Management of Common Illnesses with Limited Resources* (2013) for referral facilities.

Other important tools for primary health care facilities include registers (updated to include young infants and PSBI), young infant case forms, and referral slips. Community health workers need registers (to record visits, sick young infants identified, and perhaps follow up of sick young infants).

4.3 Identify barriers for a CHW referring a sick young infant to a primary health care facility (e.g. transportation, family beliefs about young infants leaving the home) and plan how improvements may be developed in the community. Review or undertake studies of current care-seeking practices, barriers, facilitating factors, and the links of the CHW with the community. In many locations, studies have shown that sick newborns are not brought for care.

Facilitate and support communities developing and implementing ways to overcome barriers. For example, if lack of transportation to a health facility is a common barrier, the community may choose to help the family with transport when a young infant is critically ill.

Find additional ways to engage family members who are significant influencers of care-seeking behavior (e.g. fathers, mothers-in-law) and teach them about danger signs and the need to seek care urgently if they appear.

4.4 Plan how young infants who receive antibiotic treatment as outpatients will be closely monitored including a mandatory visit with a health worker on day 4.

Planning should include how to determine whether families complete treatment and whether the infant receives a careful assessment on Day 4 or not. If not, assessing the reasons why will help to identify appropriate measures that health workers (at the primary care facility or in the community) could take to increase compliance.

A simple follow-up register may be helpful for health workers to track patients, when they should return for treatment (e.g. for daily antibiotic injections) and monitoring, and whether and when they return. A job aid could outline the procedures that a health worker should take to ensure follow up on Day 4 and completion of treatment , such as

counselling the mother on when to bring back the infant for treatment and monitoring, telephoning the family to remind them when to come back, telephoning as soon as an expected visit is missed, and making a home visit if the mother does not bring the infant back. CHWs could make home visits to encourage completion of injections and oral antibiotics and returning to the heath facility for follow up.

Whether families and health workers use mobile telephones, distances from homes to health facilities, availability of transportation for families and health workers, availability of health facility staff and CHWs, will all affect the procedures for ensuring completion of treatment and follow up chosen in the context of your country's ongoing programmes.

Demonstration sites can measure whether infants who start treatment for PSBI where referral is not feasible are brought back on day 2 for a second gentamicin injection and again on day 4 for follow up; this can test effectiveness of counselling and follow-up procedures and point toward ways to improve them.

4.5 Identify barriers to completion of referral from primary health care facility to hospital; review current referral procedures at primary health care facilities and assess their quality; and plan how to make improvements.

Studies of care-seeking and referral completion can identify reasons families do not complete referral, describe the referral procedures at primary health care facilities and assess their quality and effectiveness. For example, how do health workers counsel families on the need and urgency for hospital treatment? Do they provide a referral note? Do they ask the family if there are problems completing referral and discuss them? Do they help families solve problems? Do they need training on how to counsel on referral?

Training should improve the skills of health workers to counsel families and give assistance to complete referral when a young infant needs referral care. However, training should also inform and support health workers to provide simplified antibiotic treatment when a family is not going to take their sick young infant for recommended referral care, regardless of the reasons (whether lack of physical access, difficulty with transport, cultural or social beliefs or practices, or personal feelings). Health workers should not assess the validity of a reason for non-acceptance; if the family will not take the young infant to a referral facility for needed care, the health worker should provide care according to the guidelines.

4.6 Identify barriers to good quality of care of young infants at referral facilities and implement quality improvement measures. Activities of implementation may include improvements in hospital skills, equipment and medicines to enable better care of sick young infants who can complete referral. Copies of the WHO *Pocket Book for Hospital Care of Children: Guidelines for the Management of Common Illnesses with Limited Resources* (2013) may be distributed to all referral facilities.

Health workers should not assess the validity of a reason for not accepting referral; if the family will not take the sick young infant with PSBI to a referral facility for needed care, the health worker should provide simplified antibiotic treatment according to the guidelines.

Development or improvement of procedures for referral, including sending a referral slip with a sick young infant referred to hospital, and the hospital providing feedback to the primary care facility on the outcome of the referred case, can facilitate successful referral, urgent treatment, and continued care of a sick young infant. It can also strengthen the relationship between the health facility staff and the hospital, so that health workers may be more confident and effective when counselling families about referral.

5. Plan strategies for working with individuals, families and communities (IFC) to operationalize management of sick young infants with PSBI at primary health care facilities and to engage and empower mothers and families to provide essential newborn care and seek care for newborn illness

5.1 Examine current care for sick young infants, care-seeking practices and barriers to providing the recommended care.

Planning strategies for working with individuals, families and communities (IFC) should begin with steps to better understand current care and care-seeking practices and barriers to providing the recommended care. In many locations, studies have shown that sick newborns are not brought for care. The particular reasons that families use or do not use health facilities and reasons they do not bring sick young infants to a health care facility must be understood and addressed when developing appropriate strategies for engaging and empowering mothers, families and communities.

Section C of this guide recommends a situation analysis to inform operationalizing management of sick young infants with PSBI where referral is not feasible. Many of the information items relate to the extent that families use primary health facilities for sick newborns and reasons that they do or do not bring sick newborns for care. Individuals who are planning IFC strategies should carefully review the relevant findings in the situation analysis. If any essential information is missing, additional interviews with community representatives and local authorities may be planned to understand the reasons.

5.2 Plan strategies for working with individuals, families and communities to operationalize management of sick young infants with PSBI at primary health care facilities

The different findings of the situation analysis and any additional interviews should be discussed with the health facility management committee, community health committee or with local authorities and different community leaders. Then these groups should discuss how to address the different factors that affect appropriate care and care-seeking and develop appropriate strategies and activities to work with individuals, families and communities.

These include:

- Developing capacities to stay healthy, make healthy decisions and respond to neonatal emergencies
- Increasing awareness of the rights, needs and potential problems related to maternal and newborn health
- Strengthening linkages for social support between women, men, families and communities and with the health care delivery system
- Improving quality of care at health services and quality of their interactions with women, men, families and communities.

You need to implement all of the above strategies in order to meet objectives.

As regards management of PSBI, developing capacities and increasing awareness could include:

- empowering women and families with knowledge and skills to give essential care for the newborn

- building support in the family and community for self-care of the mother and newborn, (e.g. early initiation of breastfeeding and exclusive breastfeeding for the first 6 months of life)
- empowering women and family members to recognize danger signs in sick young infants and understand the need for prompt, appropriate care-seeking.

Strengthening linkages for social support could include activities to increase involvement of men as fathers and partners and improve household communication. With men's improved understanding of the seriousness of neonatal illness, the need for prompt care, and the services provided by the health facility, they can better support women to go to a health facility to seek care for a sick newborn. During the process of ANC, in making a plan for birth and complication readiness, the head of household often consents for the woman to go to the facility without further discussion or permission in the case of a maternal or newborn emergency.

Another important linkage is the relationship of community providers such as CHWs with community members. This relationship has been shown to be very important for compliance of families referred by the CHW to the health facility.

Development of strategies should involve state stakeholders from inception and throughout. At the district and lower levels, planning should engage traditional leaders and community leaders as well. Organize meetings with local leaders and partners to ensure buy-in and plan next steps. Ensure that mechanisms are in place to obtain women's input and enable women's voices to be heard.

5.3 Plan for community sensitization and mobilization to increase demand for and support care of young infants with PSBI in primary health care facilities and referral to hospital when needed.

The intervention, facilitated participatory learning and action cycles with women's groups to improve maternal and newborn health, has been shown in studies to have an impact on improving essential care of the newborn, including breastfeeding, and reducing newborn mortality in rural areas.[1] This method includes discussion of a sequence of topics in women's group meetings, identification of priority problems by the women, and implementation of priority actions. Trained facilitators are key for establishing and maintaining the groups and helping them to be effective. The intervention should continue at least three years to have an impact. Also it is important to simultaneously implement interventions to address quality of care at the health facility.

Community health committees can be critical actors to plan activities to reach families with relevant information about PSBI and support their use of health services when a young infant is ill. They know their community, the context and how community members are likely to respond. They can plan and carry out activities to build awareness of maternal and newborn deaths in the community and can sensitize community members about the problems identifying sick infants early and difficulties faced when seeking care.

Community leaders and community meetings can enhance the knowledge and attitudes of men and other individuals influential in household decision making. Household decision makers need to support healthy self-care for women and newborns, appropriate care-seeking, and compliance with care recommendations (e.g. to bring the young infant with PSBI back for the second injection and for a follow up visit on Day 4 of treatment).

[1] WHO recommendation on community mobilization through facilitated participatory learning and action cycles with women's groups for maternal and newborn health. World Health Organization. 2014. http://www.who.int/maternal_child_adolescent/documents/community-mobilization-maternal-newborn/en/

It is important to build the community's confidence in the health workers and service at primary care facilities. A mother who had a sick newborn can tell other mothers or community members about her experience seeking care at the health facility, the care the baby was given and how the baby improved to help build confidence in the health services.

5.4 Plan ways to improve the health services including the community's perception of them

People do not learn or change their actions by simply receiving information or by being told what to do. Health care providers at facilities and CHWs need the skills to dialogue and help people think out what the information means to them and how they are going to put it into action. Health care providers should be given training focusing on interpersonal skills and attitudes and intercultural competence, in order to improve the quality of health services and the quality of interactions with women and communities.

The health service must encourage and welcome community involvement in improving the quality of care.

Over time, as families seek and receive quality care at the primary health facility for sick newborns with PSBI or other illness, acceptance and use of the facility as a place to take a young infant for care should increase.

5.5 Monitor messages given to families and communities through different outlets on essential newborn care, newborn danger signs, care-seeking for sick young infants and adherence with treatment prescribed at the primary health care facility, and make improvements as needed.

Coordinate and harmonize the messages for counselling during antenatal care visits, after childbirth at maternity facilities, at postnatal visits to a health facility, and during CHW household visits before and after birth. Also provide clear information points, posters, flyers, videos, etc. that can be used in women's groups, community meetings and with other channels such as local drama, social media, television and radio.

5.6 Plan how to engage the private sector in promoting healthy newborn care practices including appropriate care-seeking.

Identify private sector providers used by the community for care of sick newborns or very young children. These might include medical staff in private practice, private clinics, or traditional healers or TBAs. They can be sensitized and engaged to recognize newborn danger signs and encourage referral of a sick young infant to a primary health care facility.

Deliberately provide coordinated messages for private providers and traditional healers so that community members will hear messages consistent with those that they learn through the health services.

5.7 Involve pediatric and other professionals in the roll-out of new messages or activities to build support among individuals, families and communities for outpatient management of young infants with PSBI where referral is not possible, and promotion of care-seeking and use of health services for care of young infants with PSBI.

Any intervention to increase access to health services should be implemented in tandem with strategies to improve health services. Where the quality of health services is poor, women may understandably choose not to use them despite mobilization efforts.[a]

[a] WHO recommendation on community mobilization through facilitated participatory learning and action cycles with women's groups for maternal and newborn health. World Health Organization, 2014

6. Plan supervision of management of sick young infants with PSBI in primary health care facilities; supervision of CHWs making home visits; and supervision of other community activities to support essential newborn care and care-seeking for newborn illness

6.1 Identify an approach for strengthening supportive supervision, coaching, peer review, and mentoring of health workers at primary care facilities that will include supervision of management of young infants with PSBI.

Information gathered during the situation analysis about the current methods for supervision and effectiveness of technical supervisors will inform plans for strengthening it.

To supervise management of sick young infants, a clinically trained supervisor is required. Effective, cost-effective, and affordable approaches to assessing and sustaining clinical skills are an area of ongoing research. The supervisor may visit health workers in their facility, or health workers may visit the supervisor in his or her facility, usually one with a greater case load. Current approaches to this type of supervision, sometimes called clinical mentoring, include:

- Assessment of a health worker's performance by a clinically trained supervisor including:
  - Reviewing the treatment register (to assess for consistency among recorded assessment, classification and treatment steps)
  - Orally administering structured case scenarios (to test knowledge)
  - Directly observing case management (to assess knowledge and practice)
  - Conducting exit interviews (to assess client's understanding and adherence)
  - Directly observing with re-examination by assessor to validate the health worker's decisions against a 'gold standard.'
- Feedback and coaching to remedy skill or knowledge gaps and build competency and confidence by:
  - Demonstrating correct performance of a clinical task or particular skills
  - Giving feedback on the health worker's performance with advice on improvements
  - Working side by side with the health worker to give in-the-moment guidance
  - Arranging for additional practice of clinical tasks in the facility, with clinical supervisor or competent peer to give feedback and encouragement
- Periodic (e.g. quarterly) repeat of the mentoring visit for assessment of performance and improvement of skills as described in the bullets above in order to:
  - Sustain skills and knowledge, or refresh seldom-used skills (e.g. recognition of certain danger signs), or skills that have deteriorated
  - Build a relationship between the health worker and the supervisor to foster understanding of the others' work and to aid working together (e.g. for care of referrals, problem solving)

Supervision should be more intense (e.g. monthly for 3 months) after initial training, and may be less intense thereafter (e.g. shorter visits) especially for well-performing health workers. Health workers who have difficulty performing tasks will need more frequent supervision with extended coaching.

Supervision may include regular review meetings to share findings and refresher training on some practices. For example, if register review shows most families do not return for a second gentamicin injection, discuss with the health workers why and plan solutions, perhaps including improved counselling. If day-4 follow up is not occurring, discuss its importance and strategies for encouraging families to return or how staff could make home visits to them.

6.2 Plan to train supervisors of health care providers at primary health care facilities in management of sick young infants with PSBI where referral is not possible and in skills to supervise implementation of the new guidelines.

6.2.1 Plan how to train supervisors in clinical skills for management of sick young infants with PSBI where referral is not possible.

Supervisors' clinical skills will vary according to their previous training and experience. All supervisors will need to be trained in the tasks and skills taught to health workers for updated management of sick young infants, so that they know exactly what performance is expected (and what performance should be discontinued).

Probably the best way to train supervisors to perform the health workers' tasks is to conduct the IMNCI training course for them, including the exercises and clinical practice (or just the updated module *Management of the Sick Young Infant Age up to 2 Months*, 2016, if they have completed the IMCI course before). It may be that because of their prior skills, they can complete the training more quickly; however, it is a mistake to expect any trainee to read the materials on their own and acquire the necessary skills and knowledge. Practice is a necessary part of any effective training.

Emphasize the tasks that are more difficult (e.g. assessment of danger signs) or that require more confidence (e.g. giving injections to sick and small infants) and that can have serious consequences if performed incorrectly (e.g. using safe injection procedures).

Supervisors must be clinically competent in order to do clinical supervision, give refresher training, and ensure adherence to protocols for management of sick young infants, including injection safety.

6.2.2 Plan how to train supervisors in supervisory skills.

Specify the supervisory skills that will be required of supervisors, in addition to clinical skills. See Figure 3 below for an example list.

Then plan how the supervisors will be trained. Supervisors must be trained to master the supervisory skills and not just be handed a checklist. They must be trained how to use it as well as the skills of planning, analyzing, communicating and motivating. Supervision training should include both theory and practice of supervisory tasks, with feedback. See Annex C for an outline of how to plan training for supervisors.

Trainers should also assess the attitudes of supervisors toward supervision and improve them. Some individuals will be technically competent but will not demonstrate patience and other attitudes required for supportive supervision. The helpful attitude considers the supervisor as part of a team that is committed to good performance and values improvement; the supervisor helps by providing coaching and facilitating improvements.

FIG. 3

Example List of Supervisory Skills

- Planning periodic supervision schedule that reaches each health worker
- Implementing monthly supervision schedule
- Using supervision checklists and tools correctly
- Encouraging a health worker to identify any problems and frustrations
- Problem-solving, together with the health worker
- Reviewing registers to identify any problems in filling the register or with the health worker's work
- Cross-checking inventory of medicines with register and resupplying medicines, supplies, job aids as needed
- Observing service delivery (observe case management, counselling) to assess the health worker's performance
- Administering case scenarios to identify any knowledge gaps
- Providing performance feedback in a constructive, friendly way and providing extra coaching for those who need it
- Providing or planning for support to strengthen any identified weaknesses
- Completing supervisory checklist
- Planning for next supervision
- Aggregating several health workers' activities and health facility data on the relevant forms

Some less helpful but commonly observed attitudes include impatience and arrogance. Some see the role of the supervisor as policing, fault-finding and shaming into compliance. Supervision by fear is the antithesis of the desired 'culture of quality' which values not hiding problems but wanting to identify and solve them.

These unhelpful supervisory practices and attitudes should be dispelled, such as by teaching the positive outcomes of supportive supervision and clarifying that abuse and shaming are not acceptable supervisory approaches. Some supervisors report boredom. This may arise from not knowing what to do and can be prevented by good training and job aids.

6.3 Update appropriate tools for supervision (e.g. PHC, IMCI, ENC checklists) to include management of sick young infants with PSBI where referral is not feasible.

Supervision checklists or forms should integrate PSBI management and other services to encourage comprehensive supervision to strengthen provider skills. Supervision forms should facilitate checking necessary medicines and supplies for PSBI, recording data on stock-outs, and planning resupply. They can also be used to verify data reported by facilities. A supervisory checklist, however, should encourage supportive technical supervision, not just administrative checks of supplies and reports.

Another necessary supervisory tool is a set of case scenarios that supervisors use to test the knowledge of health workers who manage sick young infants. (Scenario-based testing does not replace observation of how the health worker manages cases, but is helpful when observation is limited by scarcity of sick young infants during a supervisory visit.)

Some countries have developed a smartphone monitoring system with simple data entry by supervisors. Data is then sent up to a dashboard that can be viewed monthly to focus on areas that need strengthening.

6.4 Ensure that supervisors have the necessary resources (transportation, time, tools) to conduct regular supervision and coaching of care providers at primary health care facilities.

Supervisory activities are doomed if the resources are lacking: vehicles and petrol, public transport, per diem, time dedicated to that purpose, checklists. Budget cuts and scarce resources work against supervisors; however, we know that without supportive supervision, health worker performance quality and motivation are likely to deteriorate.

Some supervisors report frustration with their job, which can result from knowing what to do but not having the support to do it. Lack of support (e.g. transport, per diem, time, acknowledgement from superiors) should be prevented by a good and well-funded supervision plan. When problems occur, they should be addressed through on-going problem solving by supervisors and their superiors to make the essential resources available.

6.5 As a part of country quality improvement, planning and assurance, determine how the supervisors will be guided to do problem solving and take corrective measures as needed as primary care facilities integrate management of sick young infants with PSBI into routine care.

Supervisors should use monthly meetings to give health staff feedback on register reviews and observations and to reinforce guidelines.

Supervisors should also work in close collaboration with the district health staff and partners to share findings, do joint supervision, conduct review meetings, and solve problems. For example, district health officials often reposted workers who were recently trained in management of sick young infants with PSBI, leaving no trained staff at those facilities. When they were informed about this problem, the district officials said they would try to avoid transferring recently trained health staff and would support more frequent training sessions to train more health workers.

6.6 Identify an approach for strengthening supervision of CHWs or other health workers who make home visits to pregnant women and newborns.

Supervision of CHWs should include assessing and strengthening their skills to identify sick young infants and counsel families. The job aid *Caring for the Newborn at Home: Counselling Cards* lists, for each home visit during pregnancy and after the birth, the tasks and counselling messages that community health workers should address. It can also serve as a guide or checklist for the supervisor who is observing a visit, and is a good tool to reinforce correct practice when any weaknesses are observed in the CHW's performance. Assessments have shown some CHWs incorrectly count breathing rates, even after training and supervision; observation of performance is essential to identify such problems.

Supervision of a CHW should also include doing problem solving and taking corrective measures as needed to improve coverage of households and effectiveness of counselling. Assessments have shown that some CHWs are involved in so many activities, that it is difficult for them to keep up. Supervisors must monitor that CHWs can maintain motivation; their motivation may lag over time, when new initiatives are introduced, or when they become very weary volunteers. The *Planning Handbook*[1] includes detailed plans for training and supervising CHWs who make home visits.

6.7 Ensure that supervision processes and data are linked to the logistics management information system, human resources information system, and other health information systems.

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[1] Caring for newborns and children in the community: Planning Handbook for Programme Managers and Planners, World Health Organization 2015
http://apps.who.int/iris/bitstream/10665/204457/1/9789241508599_eng.pdf

7. Plan monitoring and evaluation of operationalizing management of sick young infants with PSBI

7.1 Select indicators to measure progress of operationalizing management of sick young infants with PSBI where referral is not possible.

Selection of indicators is the first step for planning data collection, analysis, and use. Management of young infants with PSBI is complex in that it requires several actions by families and health workers including identification of illness, seeking care at appropriate points of treatment, correct classification based on symptoms, initiation of treatment, and completion of the antibiotic course. Community members should support care-seeking for sick young infants from appropriate providers.

Many health system pieces must be in place to make PSBI management possible (skilled and supervised providers, antibiotics, community outreach, etc.) and there are different treatment outcomes that indicate programme quality and safety. The Monitoring and Evaluation (M&E) Framework on the next 2 pages proposes a conceptual framework for selecting indicators to monitor programme implementation strength, coverage across an action sequence for managing PSBI, and outcome indicators.

The M&E Framework for demonstration sites (page 33) includes a recommended minimal set of indicators to understand how well a programme functions. These indicators will help identify problems, which likely require further quantitative and/or qualitative investigation into bottlenecks preventing successful implementation. Some recommended indicators may not be appropriate to all settings; collaboration between programme designers and data experts is essential when selecting indicators.

After the demonstration phase is complete, scale-up can accelerate with a smaller number of indicators that are feasible to track through regular data gathering methods used for newborn and child health (page 33). If these indicators show the programme is not functioning as expected, additional investigation and data collection may be necessary. It may also be necessary to do another intensive demonstration when implementation starts in areas of the country that are contextually very different, for example moving from rural into urban settings.

Among indicators recommended for monitoring nationally, some are already included in national survey tools, such as the Demographic and Health Survey (DHS). Other indicators need to be incorporated into the national routine Health Management Information System (HMIS). Since outpatient treatment of sick young infants is a new WHO recommendation, the validity, feasibility, and utility of routine indicators are being tested.

7.2 Specify data sources and tools for monitoring.

Recommended indicators will need to be collected from a variety of data sources. See the indicator definitions table in Annex D for recommended indicators with definitions and suggested data sources. In some cases, the same indicator can be gathered from multiple sources. The source should be selected based on what is feasible. At demonstration sites, it is ideal to collect indicators from multiple sources for comparison, since each source can have bias.

The most important data source will be routinely collected service delivery data from communities or facilities. Routine data is collected on an ongoing basis and therefore can be used for regularly tracking performance, which is critical to supervision, problem identification, and programme management. Other indicators will be collected periodically; the frequency will depend on how practical it is to collect the data and programmatic need. For example, large national population-based surveys (such as Demographic and

M&E Framework for demonstration sites

Implementation Readiness	Coverage along the action-sequence for managing Possible Severe Bacterial Infection (PSBI) in young infants (0-2 months)				
	Reach families to enable care-seeking for illness (Contact)	Recognition of PSBI (Capture)	Antibiotic treatment initiated (Care)	Antibiotic treatment and follow up completed (Completion)	
• % PHCFs with HWs who demonstrate knowledge/skills in managing PSBI in young infants • % PHCFs that received a supervision visit that included managing sick young infants with PSBI during the last 3 months • % PHCFs with gentamicin, amoxicillin, thermometer, weighing scale, and timer available for PSBI[1] *(alternative: No stock-out in past 3 months)* • % CHWs who demonstrate knowledge/skills in counseling, identification of PSBI, and referral • % targeted community groups oriented on promoting care-seeking for sick young infants from appropriate providers	• % pregnant women visited at home by a CHW during pregnancy • % of births reported to a CHW within 24 hours after birth • % recently delivered women and newborns visited at home by a CHW within 2 days after birth • % recently delivered women counseled on newborn danger signs within 2 days after birth • % recently delivered women counseled on newborn danger signs before discharge after facility birth • % recently delivered women knowledgeable about danger signs and where to seek care	• % of newborns visited at home by a CHW who were referred for presence of sign(s) of infection • % newborns with sign(s) of infection for whom care was sought from an appropriate facility (PHCF or higher) within 24 hours of appearance of signs • % expected PSBI cases in young infants that are identified at PHCFs	• % identified sick young infants with PSBI receiving at least one dose of antibiotic injection appropriate for PSBI in a PHCF • % identified sick young infants with PSBI accepting referral to higher level • % identified sick young infants with PSBI who refused referral receiving 2 doses of appropriate injectable antibiotic in a PHCF **Outcomes** • % cases treated at PHCFs who had a serious adverse event(s) • % cases treated at PHCFs who have treatment failure	• % sick young infants with PSBI treated at PHCFs who receive appropriate antibiotics per protocol for at least 5 days • % sick young infants with PSBI treated at PHCFs who receive follow-up assessment on day 4	**IMPACT:** REDUCE YOUNG INFANT DEATHS DUE TO INFECTION

Recommended indicators for National implementation

Implementation Readiness	Coverage along the action-sequence for managing Possible Severe Bacterial Infection (PSBI) in young infants (0-2 months)				
	Reach families to enable care-seeking for illness (Contact)	Recognition of pSBI (Capture)	Antibiotic treatment initiated (Care)	Antibiotic treatment and follow up completed (Completion)	
• % PHCFs with gentamicin, amoxicillin, thermometer, weighing scale, and timer available for PSBI *(alternative: No stock-out in past 3 months)* **Source:** LMIS or national facility survey	• % recently delivered women counseled on newborn danger signs within 2 days after birth **Source:** National household survey (DHS, MICS)		• % (expected) sick young infants with PSBI accepting referral to higher level **Source:** HMIS • % (expected) sick young infants with PSBI receiving at least one dose of antibiotic injection appropriate for PSBI in a PHCF **Source:** HMIS		**IMPACT:** REDUCE YOUNG INFANT DEATHS DUE TO INFECTION

Health Surveys) are usually conducted every five years. National facility assessments are often less frequent.

Routine data

Sources for routine data include service registers (facility and community) and surveillance registers, supervision checklists, and logistics trackers. Data on management of sick young infants should be integrated into existing tools that feed into the routine MOH reporting system. Some indicators may already be collected and reported. For example, some HMIS may include CHWs recording and reporting the number of pregnant or postnatal mothers visited. It is important to review existing tools to find the best way to include the data needed and to avoid any duplication.

In demonstration sites, new tools may be developed to collect more extensive data. Adapt national tools for use in demonstration sites, to learn how basic data on sick infants and PSBI can be added/recorded. Then selected items from these tested tools can be used when scaling up.

Well-designed registers can also serve as job aids for health workers who provide care, by prompting them to check for certain symptoms, assisting with illness classification, and reminding of treatment regimens. For example, the age 0–2 months and the classification PSBI may be added to an integrated register for all sick children under 5 seen at a primary care facility.

Supervision checklists or forms should integrate management of sick young infants with PSBI and other services. (See step 6.3.)

Periodic survey data

Some of the recommended indicators have already been incorporated into standardized survey tools, such as the DHS questionnaires and the Service Provision Assessment (SPA) inventory tool. However, these changes are recent; therefore, data may not be available in all countries at the start of implementation. Also, national surveys are infrequent and often do not have a large enough sample sizes to produce sub-national estimates. Therefore, programme surveys (e.g. facility survey) will probably be necessary in demonstration sites. Data from programme surveys can be compared with data collected through routine systems as a data quality check.

Complementary data

Special studies will be necessary to collect indicators recommended in the M&E Framework that cannot be gathered from routine sources or population-based surveys, such as the experiences of families of young infants receiving treatment. Methods to collect these indicators – interviews with community health workers, facility exit interviews after delivery, reviews of programme records, and follow-up interviews with families of young infants receiving treatment – are not feasible to do regularly at large scale. They may be collected just once or at a few points during the demonstration phase, but not during scale-up.

However, at any stage of implementation, indicators from routine or periodic sources may show that some aspect of the programme is not functioning well. Additional studies may be necessary to understand bottlenecks hindering implementation. These follow-up studies need to be designed under the leadership of implementers who are well informed about how the programme is functioning, with a clear plan to share findings with other parties involved in implementation.

7.3 Plan methods to collect data and calculate indicators.

Data collection

Reporting forms for routine data should collect the minimal amount of data required to calculate indicators. This strategy minimizes the burden of aggregating data and data entry, which will help ensure data quality. Reporting forms should include clear instructions on how data should be aggregated.

Existing data collection methods should be used. However, current reporting forms and databases should not be modified until data collection tools have been tested and outpatient PSBI management is ready for scale up. Opportunities to modify the HMIS are often limited and the timeframe may not align with requirements to monitor PSBI management. A temporary parallel system may be required, even as scale up begins. Yet with many countries now using flexible online databases for data entry, reporting, and storage, it may be possible to customize the national database for demonstration districts without changing it nationally. These changes can then be made in other districts, as the programme rolls out.

Frequency of data collection for each indicator should depend on what is feasible given the source of data and the needs of decision-makers who must act on the data. The indicator definitions table in Annex D suggests the frequency for each indicator.

Definitions or terminology for classification and treatment will differ between primary facilities using a simplified outpatient regimen and hospitals with admitting capabilities, making it difficult to compare service utilization across levels of the system. Data from primary facilities and higher levels should be aggregated separately to permit analysis for each level.

Estimating denominators

For the proposed coverage indicators, the ideal denominator may not be readily available or easy to calculate. In many cases, we do not know the precise number of births or cases of PSBI in young infants. Expected live births should be gathered from MOH (often based on latest census). The proportion of births that can be expected to develop signs of PSBI should be based on local incidence data, if available. If local data are not available, 2012 regional and global estimates of PSBI incidence risk published in *The Lancet* can be used: http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(14)70804-7/abstract

While these estimates can be helpful, they can also be misleading if they are far from the true number. It is important for coverage indicators to be interpreted cautiously. In the early stages of implementation, it is often most important to focus on the numerators (i.e. number of births identified or number of cases initiating treatment) and identify trends over time. For example, knowing if service utilization is going up or down, stagnating, increasing linearly or exponentially is very useful. Meanwhile, it is important to advocate for strengthening civil registration systems and disease surveillance so that more reliable denominators are available in the future.

Data quality

It is important to specify methods for assuring data quality, particularly for data collected through routine systems. Methods can include training on data collection (including the health workers who record information), assisting data quality during supervision visits, and formal data quality assessments. A range of general tools for data quality assurance are available through Measure Evaluation: http://www.cpc.unc.edu/measure/resources/tools/monitoring-evaluation-systems/data-quality-assurance-tools

7.4 Specify methods for analysis and use of data to identify problems and make decisions.

Data must be analyzed to assess programme performance. Graphs, tables, maps, or other means of display may be used for key indicators. Where auto-generated data displays (dashboards) exist, PSBI data should be included with other newborn-related indicators. Where manual calculation and displays are used, PSBI data should be integrated with guidance on how to do calculations and present data for meaningful interpretation.

Analysis must be easily accessible at all levels. Dashboards or other data display tools should be tailored to the audience, with appropriate disaggregation to facilitate interpretation and decision-making at each level. For example, national level audiences may need to see data disaggregated by district, while district level officials may need to see data disaggregated by facility or sub-district. These audiences should be involved in selecting the indicators that go into the data displays, based on the data they need for programme management and decision-making.

Data reviews must be included on the agenda of meetings where programme decisions are made. Decision-makers may need guidance and mentoring on how to use and interpret PSBI indicators. Guidance on how each of the recommended indicators can be used for decision-making is included in Annex D.

There is need for flexibility to quickly investigate implementation bottlenecks that are identified through monitoring data, particularly during a demonstration phase.

7.5 Specify methods for using data for quality improvement and assurance.

WHO SEARO has identified a systematic process with seven key components for implementing improvements[1]. Key principles include understanding work in terms of processes and systems; developing solutions by teams of health workers (and patients); focusing on the patient's needs; testing and measuring effects of changes; and shared learning.

7.6 Plan evaluation including main questions, methods and general timelines.

A systematic examination of programme effectiveness should be planned prior to start of implementation. Evaluation questions and methods should be identified with a plan to synthesize findings to answer key questions at the end of the demonstration phase and prior to expansion. An evaluation may also be done after a period of scale-up, though such large-scale evaluations are rare due to cost and difficulty.

A range of stakeholders should be involved in refining and prioritizing evaluation questions, to ensure learning is responsive to the needs and concerns of different parties involved in implementation. Evaluation plans should specify how and when findings will be reviewed and shared.

Evaluations should employ qualitative and quantitative methods to explain progress and effectiveness in operationalizing PSBI management or lack thereof. Evaluations should use monitoring data as well as compare monitoring data to other sources to check consistency. Ongoing assessments of the context are also critical to include in the evaluation design as it will help with interpreting data.

Evaluating impact on mortality is often not possible during programme evaluations. Therefore, outcome targets should be specified based on expected levels needed for health impacts. Sometimes costing data may be collected, which can be useful for justifying cost per infant treated and for planning scale-up.

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[1] Improving the Quality of Care for Reproductive, Maternal, Neonatal, Child, and Adolescent Health in South-East Asia Region, 2014 http://apps.searo.who.int/PDS_DOCS/B5143.pdf
There is also an updated version which is not yet available online.

8. Undertake costing of operationalizing management of sick young infants with PSBI and secure financing

8.1 Develop a budget for operationalizing management of sick young infants with PSBI including integrating simplified treatment where referral is not feasible with routine care at primary health care facilities (including medicines and supplies, training and supervision, social mobilization and communications, monitoring and evaluation) with detailed, activity-based, bottom-up budgeting.

8.2 Develop a costed plan for operationalizing management of sick young infants with PSBI where referral is not feasible into routine care, and incorporate it in the national child health plan.

8.3 Seek out funding (from MOH, partners and donors) for the budget planned, and transitional funds for medicines and supplies until the government system can begin to provide them.

8.4 Advocate to government that quality of referral services must be satisfactory; as needed, advocate for resources for improving quality of care of sick young infants at hospitals such as improving availability of essential medicines, equipment and supplies for hospital care of young infants; advocate that partners and professional associations invest in improvement of care of young infants at hospitals.

ANNEXES

ANNEX A National Planning Benchmarks for operationalizing WHO guidelines for management of sick young infants with PSBI where referral is not feasible

Assess achievement of each benchmark and rate as ***Yes***, ***Partial*** or ***No***.

- Benchmarks rated ***Yes*** indicate that the MOH is ready to implement simplified PSBI management.
- ***Partial*** indicates that significant preparations are underway and may indicate what still needs to be completed.
- ***No*** indicates that there has been little or no progress on this aspect of preparations.

NO.	BENCHMARK	DEFINITION	CRITERIA FOR RATING
COORDINATION AND POLICY SETTING			
1	National coordination to include a representation of all stakeholders, implementers, and civil society	A functional national coordination committee with representation from maternal, newborn, and child health programmes has mandate to oversee operationalization of simplified antibiotic outpatient regimen for treating PSBI in young infants when referral is not feasible	**Yes** – Group functional and overseeing implementation **Partial** – Group for MNCH exists and has discussed overseeing implementation, but not yet decided or group has the mandate but not meeting **No** – No group has mandate
2	Home visit policy in place	Feasible policy in place for home visits (antenatal and postnatal) and includes counseling families on danger signs and care-seeking and identifying sick babies	**Yes** – Feasible home visit policy in place that includes antentatal and postnatal visits with counseling on danger signs and care-seeking for young infants **Partial** – Home visit policy in place but not feasible (too many visits or cadre unable to make visits) and/or does not include both antenatal and postnatal visits and/or does not include counseling on danger signs and care-seeking for young infants **No** – No home visit policy
3	Outpatient PSBI management policy in place	Policy adopted with a treatment option for outpatient management when referral is not feasible in alignment with WHO guidelines (with follow up on 4th day of treatment) and referral procedures.	**Yes** – Policy adopted **Partial** – Policy drafted and under consideration **No** – No policy
4	Primary providers authorized to administer antibiotics to young infants	Policy adapted to allow primary health care providers to administer injections to young infants (0–2 months).	**Yes** – PHC providers authorized to provide injections for newborns **Partial** – Policy to authorize PHC providers to provide injections for newborns is in process **No** – PHC providers not authorized

NO.	BENCHMARK	DEFINITION	CRITERIA FOR RATING
5	Gentamicin and ampicillin distribution authorized	Policy and programmes adapted to allow gentamicin and ampicillin distribution to primary health care facilities.	**Yes** – Policy permits gentamicin and ampicillin distribution to PHC facilities **Partial** – Policy to allow gentamicin and ampicillin distribution to PHC facilities in process **No** – Policy does not allow gentamicin and ampicillin distribution to PHC facilities
6	Guidelines aligned and integrated with existing programme	Guidelines for primary health care (PHC), PSBI management, iCCM, IMNCI and ENC aligned and integrated to avoid inconsistent management protocols.	**Yes** – Guidelines aligned for consistent management protocols and integrated with existing programme **Partial** – Guideline alignment and integration in process **No** – Guidelines not aligned
HUMAN RESOURCES			
7	Training plan and training materials developed	Training plan developed for in-service training in newborn care including PSBI management, including training manuals and job aids, and appropriate pre-service curricula revised	**Yes** – In-service training plan with manuals and job aids developed and pre-service curricula revised **Partial** -In-service and pre-service curricula revised but not both or in process **No** – No plan or revision to in-service or pre-service training
8	Job descriptions updated	Job descriptions of health care providers at each appropriate level revised to add PSBI management to newborn care with consideration of existing workload and task-shifting to make workload feasible.	**Yes** – JDs revised for providers at PHC and referral facilities to reflect new PSBI management guidelines **Partial** – JD revisions in process **No** – JDs have not been revised
SUPPLY CHAIN MANAGEMENT			
9	Essential drug list updated	Necessary medicines added to the essential drug list with consideration of formulations appropriate for young infants (0–2 months).	**Yes** – Injectable gentamicin and ampicillin, and oral amoxicillin added to the essential drug list with formulations that can be used for young infants **Partial** – Only injectable gentamicin and ampicillin, or oral amoxicillin on essential drug list, or on list but in formulations not recommended for young infants **No** – Injectable gentamicin and oral amoxicillin not on essential drug list
10	Supply system assessed	Supply system assessed and necessary improvements identified	**Yes** – Supply system assessed and necessary improvements identified **Partial** – Supply system assessed but no improvements planned yet **No** – Supply system not assessed
11	National logistics management information system (LMIS) updated	LMIS incorporates PSBI medicines and other supplies.	**Yes** – LMIS includes reporting on stocks of injectable gentamicin and oral amoxicillin in formulations that can be used for young infants **Partial** – LMIS includes only injectable gentamicin or oral amoxicillin, or includes both but not in formulations that can be used for young infants **No** – LMIS does not include injectable gentamicin or oral amoxicillin

NO.	BENCHMARK	DEFINITION	CRITERIA FOR RATING
SERVICE DELIVERY AND REFERRAL			
12	Guidelines developed	Guidelines developed for PSBI outpatient management when referral is not feasible (including clinical assessment, classification, management, referral, and follow up).	**Yes** – Guidelines developed for PSBI outpatient management when referral is not feasible and includes clinical assessment, classification, management, referral, and follow up **Partial** – Guidelines in process or missing a key element **No** – No guidelines
13	Existing functional referral system strengthened	Existing referral system assessed, found to be functional, improvements identified and implemented	**Yes** – Existing functional referral system strengthened **Partial** – Referral system is functional and plans made to strengthen it **No** – Referral system is not functional or has not been assessed
14	Information, education, communication (IEC) materials developed for families providing outpatient antibiotic treatment	Effective (tested) materials developed to help families adhere with treatment protocol including returning for follow up and completion of antibiotic course	**Yes** – Materials developed to help families adhere with treatment protocol including returning for follow up **Partial** – Materials drafted or in process **No** – No materials
COMMUNICATION AND SOCIAL MOBILIZATION			
15	Messages and modes of delivery determined	Communication and social mobilization strategies, with appropriate messages, developed to increase family recognition of sick young infants and prompt, appropriate care-seeking	**Yes** – Strategies and messages developed to increase family recognition of sick young infants and prompt, appropriate care-seeking **Partial** – Strategies or messages in process **No** – No strategies or messages for families
16	Plan for engagement of civil society developed and discussions underway	Plans developed for engagement of civil society in promoting healthy newborn care practices including appropriate care-seeking and discussions with civil society groups underway	**Yes** – Civil society organizations are involved in planning how to promote healthy newborn care practices including appropriate care-seeking for sick young infants **Partial** – Civil society organizations are involved in RMNCH, but not care-seeking for sick young infants **No** – Civil society organizations not involved
SUPERVISION AND QUALITY ASSURANCE			
17	Supervision tools updated and pretested before finalization and finalized	PSBI management integrated into IMCI, IMNCI, iCCM, and/or ENC supervision guidelines and tools.	**Yes** – Outpatient management of young infants with PSBI integrated into existing supervision guidelines and tools, pretested and finalized **Partial** – Supervision guidelines or tools for PSBI are separate, or integrated tools in process of being updated and pretested **No** – No supervision guidelines or tools for outpatient management of PSBI in young infants
18	Plan to train supervisors	Plan in place for training, monitoring, and support of technical supervisors for PSBI management which includes adaptation and validation of training materials and supervisory tools.	**Yes** – Plan in place to train, monitor, and support technical supervisors for PSBI management **Partial** – Plan in process **No** – No plan

NO.	BENCHMARK	DEFINITION	CRITERIA FOR RATING
MONITORING			
19	Monitoring tools developed	Registers and reporting forms revised or developed to include management of sick young infants (0–2 months).	**Yes** – Registers and reporting forms with management of PSBI in young infants tested and ready for use nationally **Partial** – Registers and reporting forms are being tested **No** – No registers or reporting forms developed
20	Key PSBI indicators included in HMIS	Indicators defined and incorporated into HMIS (see indicators in M&E Framework)	**Yes** – All key PSBI indicators included in national HMIS **Partial** – Some PSBI indicators included in national HMIS (at least one) **No** – No PSBI indicators included in national HMIS
21	National targets established	Agreement reached on calculations for projecting expected PSBI cases and coverage targets.	**Yes** – National targets set **Partial** – National targets in progress but not finalized **No** – National targets not set
COSTING AND FINANCING			
22	Budget in operations plans	National operations plans updated to include budget for operationalization of PSBI guidelines (including supplies, HR, equipment, social behavior change communication, etc.) based on an informed cost projection.	**Yes** – National operations plans include budget for implementation of PBSI guidelines including supplies, HR, equipment, social behavior change communication **Partial** – National operations plans being revised or missing key element(s) for implementation of PSBI guidelines **No** – National operations plans do not include implementation of PSBI guidelines
23	Costed plan exists	Costed plan to sustain PSBI implementation exists.	**Yes** – Costed implementation plan for scale up of outpatient PSBI management available at national level **Partial** – Costed implementation plan in progress **No** – No costed implementation plan

ANNEX B How to develop a training plan to teach management of the sick young infant to staff of primary health care facilities

1. Consider whether the country should introduce the training package *Caring for the Newborn at Home* prior to introducing the new recommendations for management of PSBI at primary care facilities.

The success of the PSBI strategy for management of sick young infants at primary health care facilities will depend on how early sick young infants are identified and brought to the primary health facility for care. If sick young infants are not brought to a facility or are brought too late, when they are moribund, no management strategy can save them.

Caring for the Newborn at Home teaches community health workers to make antenatal and postnatal visits to counsel on pregnancy care, facility delivery, care of the newborn, and signs of illness; and to assess the newborn and facilitate care-seeking if danger signs are found.

If the country has not yet implemented the training package *Caring for the Newborn at Home*, consider implementing it prior to introducing the new recommendations for management of PSBI.

If CHWs have been trained and are making home visits, it will be important to assess whether visits are made timely and include the necessary topics and tasks; if not, supervision should be strengthened. Also assess the numbers and locations of the communities where trained CHWs work and communities that do not receive home visits. To improve the effectiveness of the implementation of the new PSBI recommendations, action may be needed to increase the number of communities served by a CHW who makes home visits as described in *Caring for the Newborn at Home*.

2. Identify the target health workers to be trained to manage young infants with PSBI and the new skills that they need

There are two likely groups of health workers to be trained:

- Health workers already trained in IMNCI and caring for sick children and infants according to those guidelines
- Health workers who are new and/or not trained in IMNCI

The first group needs to be updated to give improved care of sick young infants including simplified treatment of young infants with PBSI when families do not accept or cannot access referral. Previous IMNCI training on care of a sick young infant taught them to refer all sick young infants and did not provide an alternative. They will need to understand they will no longer follow those guidelines and will use the new guidelines for management of young infants with PSBI instead.

The second group needs to be trained in IMNCI management of sick children and sick young infants, using the most recent IMNCI course which includes the updated module on care of sick young infants that includes simplified antibiotic treatment of young infants with PSBI.

3. Review and adapt WHO-UNICEF training courses and job aids

Most countries are using an IMCI course that has been adapted for their country's health workers to teach management of sick children and sick young infants. Planners should now review the new 2016 version of the module, *Management of the Sick Young Infant Age up to 2 Months*, which reflects the new WHO guidelines for management of PSBI. They may decide to use the updated module as is, or adapt it, to teach the skills and knowledge to manage sick young infants, including simplified treatment of young infants with PBSI when families do not accept or cannot access referral. If the former version of the young infant module is currently used in IMNCI training, it should be discontinued and the new version used instead. The chart booklet must also be updated to reflect the new guidelines for managing the sick young infant.

4. Develop a training plan (methods, materials, sequencing)

The training materials listed under each package below are used to conduct the training course. The items in bold type are also used by the health workers as they work at the health facility. The WHO-UNICEF IMCI training materials include:

MANAGEMENT OF THE SICK YOUNG INFANT AGE UP TO 2 MONTHS

- Participant Manual
- **IMCI Chart Booklet**
- **Young Infant Recording Form**
- DVD
- Photo booklet
- Facilitator Guide

MANAGEMENT OF THE SICK CHILD AGE 2 MONTHS UP TO 5 YEARS

- Participant modules: Introduction, Assess the sick child, Identify treatment, Treat the child, Counsel the mother, Follow up
- **IMCI Chart Booklet**
- **IMCI Recording Form**
- DVD
- Photo booklet
- Facilitator Guide

These WHO-UNICEF training courses apply adult learning principles to achieve the required competencies. The training methods include reading, classroom learning, group discussions, games, role plays, use of job aids, and most importantly, hands-on supervised hospital/clinic practice. The methods and materials have been tested and proven effective, when the guidelines provided for training facilitators and conducting the course are followed.

It is never recommended to shorten the training drastically to fit it into a given block of time or at the end of another training course. The training should include time for teaching the essential skills and knowledge, having health workers practice using the relevant job aids, reinforcing the skills through clinical practice sessions (including practice counseling), and assessing whether the health workers have acquired the skills and knowledge they need to perform the tasks.

5. Plan the training process from initial training through refresher training

- *Initial training* – Completing the updated training course (either IMCI training in both management of the sick child and also the sick young infant, or only the updated sick young infant module) to learn the knowledge and skills needed.
- *Certification* – upon demonstration of required knowledge and skills either at the end of training or shortly after beginning work. Direct observation of complex skills is essential to assess competence. A written post-test is helpful for testing knowledge. Do not equate a 'certificate of attendance' with certification of skills.

  It must be possible for a participant to fail, but this should be rare. High failure rates suggest inappropriate candidate selection criteria, ineffective training methods, or insufficient time. It is important to specify a procedure to help candidates who need additional support; such support may be given through targeted outreach for training, ideally linked to other supervisory or mentoring activities.
- *Follow up after training* – This should be accomplished by the trainer or supervisor who completes a systematic schedule of visiting each of the health workers in their facility to reinforce new skills learned in the training, identify problems quickly, and coach health workers with difficulties.
- *Periodic refresher training* – yearly or more often through supervision. It should refresh skills, teach any new tasks, and may include re-certification. It can also boost motivation when health workers can share experiences and receive feedback from supervisors and each other.

6. Plan how to deliver the training to health workers

Preparing multiple levels of trainers and delivering training is sometimes called a 'training cascade.' This includes activities at multiple levels, usually national, district, health facility and community. MOH staff and NGO partners could be involved. The more levels, however, the greater the chance of a loss of training quality.

The common steps in the cascade are:

Step 1: National master training of trainers, who in turn conduct

Step 2: Regional and/or district training of trainers, who in turn conduct

Step 3: – Training for health facility staff who need IMCI training in management of the sick child and management of the sick young infant, and

– Training for health facility staff who need training in updated management of the sick young infant

The numbers of participants and the number of training courses that must be conducted increase with each step. Planners must specify:

a. Selection criteria for each level of trainee

For step 2, select district personnel (in every district implementing the new PSBI guidelines) who will become master trainers in their districts.

For step 3, select health facility staff who care for sick children and young infants. If NGO facilities will implement the guidelines, their staff should be included in training.

b. Number of trainees to be trained in each step

Conduct a quick situation analysis to determine how many of the stated trainees at each step are already trained and how many need to be trained.

Step 1: National level master trainers

Step 2: District personnel who will be master trainers for their district

Step 3: Health facility staff

You will need to plan how you will determine the number of new health workers in each primary care facility to be given initial training in IMCI (management of both sick children and sick young infants) and how many will need only an updated training on management of sick young infants.

You should repeat this analysis each year to assess how many trainees still need to be trained at each step, and plan how many will be trained in the coming year.

c. Type of venue for each training course (e.g. busy clinical facility)

Management of the Sick Young Infant must include clinical practice with sick infants and must therefore be conducted in a health facility and hospital where young infants will be available, including infants with signs of severe illness. Conducting training at large health facilities (with guaranteed case-loads) is costly, but training at the nearby smaller facilities risks insufficient cases and consequent lack of practice recognizing danger signs.

d. Ratio of trainer to trainee with number of each per round of training courses

e. Duration of each training course

f. Number of times each training course will be conducted (during the year)

g. Training materials, equipment and supplies (and quantities of each of these) that will be needed at each level.

h. Then summarize the training plans. For example:

We will train ..... national-level trainers/focal persons by ..... (date) ..... .

National-level trainers will train ..... regional and/or district trainers by ..... (date) ..... in ..... courses.

..... regional and/or district trainers will train ..... new health workers in IMNCI by ..... (date) ..... . There will be ..... training courses of ..... days duration conducted during the year.

..... regional and/or district trainers will train ..... health workers in the updated management of sick young infants by ..... (date) ..... . There will be ..... of these training courses (of ..... days duration) conducted during the year.

Health worker training will have a trainer/trainee ratio of ..... to ..... .

i. Prepare a training schedule with detail on dates and venues for each training course, the trainers, and the health workers to attend (by name or by facility).

Note that health workers who are trained must also be equipped and supplied to begin their new tasks on return to their facilities. Training workers who lack the necessary tools and medicines to perform is disheartening and wasteful; the workers often require retraining after supplies are made available. Therefore, coordinate training schedules for the designated health facilities in a district with plans to supply the health facilities in that district with the necessary medicines and supplies to implement the new guidelines.

Similar planning will be needed for periodic refresher training also (for example, yearly updates and review).

Note: Also plan how to train supervisors how to guide primary health facility workers implementing new guidelines for care of sick young infants (see step 6.2). Supervisors should be trained **before** the health workers in the facility are trained, so that they can answer questions and give guidance when health facility workers begin to apply their training.

ANNEX C How to develop a training plan for supervisors of health workers who manage sick young infants in primary health care facilities

1. Identify the target supervisors to be trained and the new skills that they need

Identify all public health facilities where health workers will implement management of sick young infants with PSBI according to the new guidelines and the supervisors at each (and who visit each). These supervisors should be trained **before** the health workers in the facility are trained, so that they can answer questions and give guidance when health facility workers begin to apply their training.

Supervisors will need two sets of skills to supervise primary health facility workers who manage sick young infants with PSBI:

A. Clinical skills to assess and treat sick young infants with PSBI according to the new guidelines including simplified antibiotic treatment where referral is not feasible (as well as management of sick children under age 5 years according to the country's guidelines for IMCI).

B. Supervisory skills

2. Review and adapt WHO-UNICEF training courses and job aids

To learn the *clinical skills*, supervisors of health workers should complete the same clinical training, using the same materials, as the health workers themselves. This is essential so that the supervisor understands and will be competent to assess and provide treatment to sick young infants, and can therefore assess and provide technical guidance to improve the performance of the health workers.

Most countries are using an IMNCI course that has been adapted for their country's health workers to teach management of sick children and sick young infants. Planners will review the new 2016 version of the module, *Management of the Sick Young Infant Age up to 2 Months*, which reflects the new WHO guidelines for management of PSBI, and use it as is or adapt it to teach health workers the updated skills and knowledge to manage sick young infants.

Plan to use either the complete IMNCI training or just the updated training on management of the sick young infant to provide supervisors with the clinical skills that they are lacking.

To learn *supervisory skills*, supervisors will need to be trained on the specific skills that analysis has identified to be important for them. (See step 6. 1 and the example list of supervisory skills in Figure 3.)

If they have already been trained to provide supportive supervision and clinical mentoring to health workers who manage sick children, only the details for assessing and giving feedback on management of sick young infants will be necessary, for example, using the

updated checklist, and administering case scenarios about sick young infants. If they have not received training in supervisory skills, they will require more comprehensive training and practice.

3. Develop a training plan (methods, materials, sequencing)

Materials should include the IMNCI clinical materials used to train health workers implementing improved management of sick young infants with PSBI, as well as additional materials on supervisory skills.

4. Plan the training process from initial training through refresher training

- *Initial training* – Completing the training to learn the knowledge and skills needed: clinical training plus supervisory training
- *Certification* – upon demonstration of required knowledge and skills either at the end of training or shortly after beginning work. Direct observation of complex skills is essential to assess competence, for example, a supervisor's competence doing clinical mentoring including assessing a health worker's management of a sick young infant, identifying any problems, and giving guidance to improve the health worker's skills. A written post-test is helpful for testing knowledge
- *Follow up after training* – This should be accomplished by the trainer completing a systematic schedule of visiting each of the supervisors, to observe how they interact with health workers in their facility or another facility to reinforce new skills learned in the training, identify problems quickly, and coach health workers with difficulties.
- *Periodic refresher training* – yearly or more often through meetings for supervision. It should refresh skills, give feedback, and provide technical or logistical updates. It can also boost motivation when supervisors can share experiences and receive feedback from each other.

5. Plan how to deliver the training to supervisors

Preparing multiple levels of trainers and delivering training is sometimes called a 'training cascade.' This includes activities at multiple levels, usually national, district and health facility. MOH staff and NGO partners could be involved. The more levels, however, the greater the chance of a loss of training quality.

The common steps in the cascade are:

Step 1: National master training of trainers, who in turn conduct

Step 2: Regional and/or district training of trainers, who in turn conduct

Step 3: Training for supervisors of health facility staff

The numbers of participants and the number of training courses that must be conducted increase with each step. Planners must specify:

a. Selection criteria for each level of trainee

For step 2, select district personnel (in every district implementing the new PSBI guidelines) who will become trainers in their districts.

For step 3, select all supervisors of health facility staff who care for sick children and young infants.

b. Number of trainees to be trained in each step

Conduct a quick situation analysis to determine how many of the stated trainees at each step are already trained and how many need to be trained.

Step 1: National level master trainers

Step 2: District personnel who will be trainers for their district

Step 3: Health facility supervisors

You will need to plan how you will determine the number of new supervisors in each district to be given initial training in IMCI (management of both sick children and sick young infants) and how many will need only an updated training on management of sick young infants.

All supervisors will benefit from supervisory training, either to provide new skills or as a refresher. Supervisory training should include practice using new tools, e.g. a supervisory checklist that includes improved management of sick young infants with PSBI.

You should repeat this analysis each year to assess how many supervisors still need to be trained, and plan how many will be trained in the coming year.

c. Type of venue for each training course (e.g. busy clinical facility)

Management of the Sick Young Infant must include clinical practice with sick infants and must therefore be conducted in a health facility and hospital where young infants will be available, including infants with signs of severe illness.

Training in supervisory skills must include practice observing and giving feedback to health workers. It may be possible to visit different facilities during training to give each trainee-supervisor practice with several health workers. Practice should include observation of the supervisory contact by the trainer followed by feedback on how the supervision could be improved.

d. Ratio of trainer to trainee with number of each per round of training courses

e. Duration of each training course

f. Number of times each training course will be conducted (during the year)

g. Training materials, equipment and supplies (and quantities of each of these) that will be needed at each level.

h. Then summarize the training plans. For example:

FOR CLINICAL TRAINING:

Regional and/or district trainers will train ..... new supervisors in IMNCI by ..... (date) ..... .

Regional and/or district trainers will train ..... supervisors in the updated management of sick young infants by ..... (date) ..... .

FOR SUPERVISORY TRAINING:

We will train ..... national-level trainers/focal persons in supervisory training by ..... (date) ..... .

National-level trainers will train ..... regional and/or district trainers to provide supervisory training by ..... (date) ..... .

Regional and/or district trainers will train ..... supervisors in supervisory skills.

Supervisory training will have a trainer/trainee ratio of ..... to ..... .

i. Prepare a training schedule with detail on dates and venues for each training course, the trainers, and the supervisors to attend (by name or by facility).

A supervisor's training should precede that of the health workers that he or she will supervise. It will be most efficient if supervisors who are trained will soon be able to perform supervision of improved management of young infants with PSBI, while their new skills and knowledge are fresh. Supervisors will need to be prepared to answer questions and give guidance when health facility workers begin to apply their training.

Therefore, coordinate training schedules for supervisors in the designated health facilities in a district with plans to train health workers and supply the health facilities in that district with the necessary medicines and supplies to implement the new guideline

ANNEX D Indicator definitions, methods for data collection, and how to use indicators

	INDICATOR	METRICS	DATA COLLECTION METHOD(S)[a]	INDICATOR USE AND RECOMMENDED FREQUENCY
IMPLEMENTATION STRENGTH	% PHCFs with HWs who demonstrate knowledge/skills in managing PSBI in young infants	*Numerator:* Number of primary health care facilities where all interviewed/ observed health workers demonstrate knowledge/ skills[b] in managing PSBI in young infants (0–2 months) *Denominator:* Number of primary health care facilities assessed	Facility assessment with knowledge and skills test	Collect to assess if facilities have staff capacity to manage PSBI in young infants. Recommended when cadre(s) responsible for managing cases has not previously treated sick young infants. Since infection is a rare event and observation difficult, scenarios or observation of assessment skills in healthy babies (taking temperature, measuring breathing rate, etc) may be used. Collect soon after training to assess skills acquisition and after a longer period of implementation (eg, 1 year) to assess skill retention. During learning phase, collect periodically.
	% PHCFs that received a supervision visit that included managing sick young infants with PSBI during the last 3 months	*Numerator:* Number of primary health care facilities that received a supervision that included managing sick young infants with PSBI during the last 3 months[c] *Denominator:* Number of primary health care facilities assessed *or* Total number of primary health care facilities	Facility assessment *or* Supervision form	Collect to assess if facilities receive supervision. During learning phase, collect periodically when using facility assessment; monthly or quarterly when using a routine supervision form. This indicator focuses on supervision from outside the facility rather than mentoring/supervision done within a facility, which may also be assessed through additional special studies.
	% PHCFs with gentamicin, amoxicillin, thermometer, weighing scale, and timer available for PSBI (alternative: no stock-outs in past 3 months)	*Numerator:* Number of primary health care facilities with gentamicin, amoxicillin, thermometer, weighing scale, and timer observed *or* reported *Denominator:* Number of primary health care facilities assessed *or* supervised/ reporting *Disaggregate by:* drug/ supply	Facility assessment *or* Routine form (supervision form or logistics reporting form)	Collect to assess if facilities have the minimum capacity to treat infections in young infants. During learning phase, collect periodically when using facility assessment; monthly or quarterly when using routine supervision/logistics form. Already included in standard facility assessment tools, such as the MEASURE DHS Service Provision Assessment (SPA) and WHO Service Availability and Readiness Assessment (SARA), for periodic national tracking.

	INDICATOR	METRICS	DATA COLLECTION METHOD(S)	INDICATOR USE AND RECOMMENDED FREQUENCY
IMPLEMENTATION STRENGTH	% CHWs who demonstrate knowledge/skills in counseling, identification of danger signs, and referral	*Numerator:* Number of interviewed/observed CHWs who demonstrate knowledge/skills on counseling, identification of danger signs, and referral[d] *Denominator:* Number of interviewed CHWs	Knowledge or skills assessment of CHWs	Collect to assess if CHWs have the capacity to counsel families on danger sign recognition and care-seeking, identify danger signs, and refer. Collect soon after training to assess knowledge or skills acquisition and after a longer period of implementation (eg, 1 year) to assess knowledge or skill retention. During learning phase, collect periodically.
	% targeted community groups oriented on promoting care-seeking for sick young infants from appropriate providers	*Numerator:* Number of community groups oriented on promoting care-seeking for sick young infants from appropriate providers *Denominator:* Number of targeted community groups4	Programme records	Collect to track engagement of community groups to change social norms around care-seeking. During learning phase, collect periodically based on programme targets for community engagement.
CONTACT	% pregnant women visited at home by a CHW during pregnancy	*Numerator:* Number of women reporting a visit from a CHW during pregnancy *or* Reported number of women visited by a CHW during pregnancy *Denominator:* Number of interviewed women *or* Number of expected pregnancies *Disaggregate by:* Place of birth	Household survey *or* CHW register (Expected pregnancies may come from most recent census)	Collect to track coverage of home visits during pregnancy, an important contact with the health system. Information on the content of visits may also be collected. During learning phase, collect periodically when using household survey; monthly or quarterly when using routine reporting of CHW register.
	% births reported to a CHW within 24 hours after birth	*Numerator:* Number of women reporting a CHW was notified within 24 hours after birth *or* Reported number of birth notifications received by CHWs within 24 hours *Denominator:* Number of interviewed women *or* Number of expected births *Disaggregate by:* Place of birth	Household survey *or* CHW register (Expected births may come from most recent census)	Collect to assess if CHW are notified when births occur, which affects how many newborns they will visit for counseling, assessment, and identification of illness.

	INDICATOR	METRICS	DATA COLLECTION METHOD(S)	INDICATOR USE AND RECOMMENDED FREQUENCY
CONTACT	% recently delivered women and newborns visited at home by a CHW within 2 days[e] after birth	*Numerator:* Number of women reporting a visit from a CHW within 2 days after birth *or* Reported number of women visited by a CHW within 2 days after birth *Denominator:* Number of interviewed women[f] *or* Number of expected births *Disaggregate by:* Place of birth	Household survey *or* CHW register (Expected births may come from most recent census)	Collect to assess coverage of postnatal home visits, which are important contacts, especially for home births. Information on content of visits may also be collected. During learning phase, collect periodically when using household survey; monthly or quarterly when using routine reporting of CHW register. DHS and Multiple Indicator Cluster Survey (MICS) now ask about the first post-discharge check for newborns, which can be used to estimate home visit coverage nationally.
	% recently delivered women counseled on newborn danger signs within 2 days after birth	*Numerator:* Number of women counseled on newborn danger signs within 2 days after birth *Denominator:* Number of interviewed women[g]	Household survey	Collect to assess if mothers receive information on danger signs soon after birth. During learning phase, collect periodically. Recently added to DHS (Q457 in DHS Phase 7 women's questionnaire) for periodic national tracking.
	% recently delivered women counseled on newborn danger signs before discharge after facility birth	*Numerator:* Number of women counseled on newborn danger signs before discharge after facility birth *Denominator:* Number of interviewed women who delivered at a facility	Facility exit interviews with recently delivered women *or* Household survey	Recommended for programmes emphasizing pre-discharge counseling. During learning phase, may collect periodically through exit interviews or household survey.
	% recently delivered women knowledgeable about danger signs and where to seek care	*Numerator:* Number of women who mention at least three signs of PSBI and know care is available at primary health care facilities *Denominator:* Number of interviewed women *Disaggregate by:* Source of information	Household survey	Collect to assess information reaching mothers, with disaggregation by source of information to determine source that appears most important for changing knowledge. During learning phase, collect periodically.
CAPTURE	% newborns visited at home by a CHW who were referred for presence of danger signs	*Numerator:* Number of newborns visited at home by a CHW who were referred for presence of danger signs *Denominator:* Number of (last born) children born in the past 2 years[h] who were visited by a CHW *or* Number of newborns reported as receiving a visit	Household survey *or* CHW register (Expected births may come from most recent census)	Collect to assess detection of danger signs by CHWs. During learning phase, collect periodically when using household survey; monthly or quarterly when using routine reporting of CHW register.

	INDICATOR	METRICS	DATA COLLECTION METHOD(S)	INDICATOR USE AND RECOMMENDED FREQUENCY
CAPTURE	% newborns with danger sign(s) for whom care was sought from an appropriate facility (PHCF or higher) within 24 hours of appearance of signs	*Numerator:* Number of children who had danger sign(s) of infection during the first *two* months of life and care was sought from an appropriate facility (PHCF or higher) within 24 hours of appearance of signs *Denominator:* Number of (last born) children born in the past 2 years[i] who had sign(s) of infection during the first month of life	Household survey	Collect to assess timely and appropriate care seeking, which is especially important in areas where care seeking from facilities is low. Denominator based on prompted questions on danger signs; 'baby was unwell' may be used instead of asking about signs the baby experienced. Note – denominator should not be used to estimate incidence of infection as mother/family report of symptoms not proven to be reliable. During learning phase, collect periodically.
	% expected PSBI cases in young infants that are identified at PHCFs	*Numerator:* Number of young infants (0–2 months) classified with PSBI at primary health care facilities *Denominator:* Number of expected PSBI cases in young infants *Disaggregate by:* Classification (isolated fast breathing, clinical severe infection, critical illness) Self vs CHW referral (if recorded)	*Numerator:* Facility register/form *Denominator:* Estimated based on expected live births[j]	Collect to assess the proportion of cases captured by the health system and case mix. Disaggregation by self-referral versus CHW referral can be used to assess the importance of active case detection. During learning phase, collect periodically when using record review of facility register; monthly or quarterly when using routine reporting of facility register/ form.
CARE	% identified sick young infants with PSBI receiving at least one dose of antibiotic injection appropriate for PSBI in a PHCF	*Numerator:* Number of young infants (0–2 months) who receive at least one dose of gentamicin (or other appropriate antibiotic) injection at a primary health center *Denominator:* Number of identified sick young infants with clinical severe infection or critical illness at primary health facilities *Disaggregate by:* Classification	*Numerator:* Facility register/form *Denominator:* TBD	Collect to track initiation of sick young infants on antibiotic treatment, including a pre-referral dose. During learning phase, collect periodically when conducting record review of facility register; monthly or quarterly when using routine reporting of facility register/form.
	% identified sick young infants with PSBI accepting referral to higher level	*Numerator:* Number of young infants (0–2 months) accepting referral to higher level facility *Denominator:* Number of identified sick young infants with PSBI at primary health facilities *Disaggregate by:* Classification	Facility register/form	Collect to understand the demands on the referral system and to inform optimal resource allocation to primary and higher facilities. During learning phase, collect periodically when using record review of facility register; monthly or quarterly when using routine reporting of facility register/ form.

	INDICATOR	METRICS	DATA COLLECTION METHOD(S)	INDICATOR USE AND RECOMMENDED FREQUENCY
CARE	% identified sick young infants with PSBI who did not accept referral receiving 2 doses of appropriate injectable antibiotic in a PHCF	*Numerator:* Number of young infants (0–2 months) who did not accept referral receiving 2 doses of appropriate injectable antibiotic in a primary health center *Denominator:* Number of identified sick young infants with clinical severe infection treated at primary health facilities (referral not accepted)	Facility register/form	Collect to assess the proportion of cases that receive the appropriate injectable antibiotic regimen after not accepting referral. During learning phase, collect periodically when using record review of facility register; monthly or quarterly when using routine reporting of facility register/ form.
COMPLETION	% sick young infants with PSBI treated at PHCFs who receive appropriate antibiotics per protocol for at least 5 days	*Numerator:* Number of treated young infants (0–2 months) who receive appropriate antibiotics per protocol for at least 5 days *Denominator:* Number of identified sick young infants with PSBI treated at primary health facilities (referral not accepted) *Disaggregate by:* Classification	[Facility register/form PLUS CHW register][k] *or* Household interview[l]	Collect to determine treatment completion. Because antibiotics are administered at the facility and at home, this indicator is a composite of data collected at the facility and reported by the family (to CHW or household interviewers). During learning phase, collect periodically when using record review of registers *or* household interviews; monthly or quarterly through routine reporting of registers/forms.
	% sick young infants with PSBI treated at PHCFs who receive follow-up assessment on day 4	*Numerator:* Number of treated young infants (0–2 months) who receive a follow-up assessment on day 4 *Denominator:* Number of identified sick young infants with PSBI treated at primary health facilities (referral not accepted) *Disaggregate by:* Classification	[Facility or CHW register/ form] *or* Household interviews	Collect to determine adherence with the recommended 4th day follow up assessment. May be routinely collected at facility or home, depending where the 4th day follow up assessment occurs per the local protocol. During learning phase, collect periodically when using record review of register/form *or* household interview; monthly or quarterly when using routine reporting of register/ form.
OUTCOMES	% cases treated at PHCFs who had a serious adverse event(s)	*Numerator:* Number of treated young infants (0–2 months) who had a serious adverse event(s)[m] *Denominator:* Number of identified sick young infants with PSBI treated at primary health facilities (referral not accepted) *Disaggregate by:* Classification	Household interview	Outcome indicator to assess the safety of outpatient infection management in young infants. During learning phase, collect periodically. Note – routine registers could also be used if local protocol includes a follow up visit after treatment completion.

	INDICATOR	METRICS	DATA COLLECTION METHOD(S)	INDICATOR USE AND RECOMMENDED FREQUENCY
OUTCOMES	% cases treated at PHCFs who have treatment failure	*Numerator:* Number of treated young infants (0–2 months) who have treatment failure (symptoms do not go away after treatment or new symptoms appear) *Denominator:* Number of identified sick young infants with PSBI treated at primary health facilities (referral not accepted) *Disaggregate by:* Classification	Household interview	Outcome indicator to assess programme quality and understand demands on the referral system.

[a] Some indicators have more than one possible data source. One should be selected, depending on what is feasible in the demonstration site. Or multiple sources can be used to triangulate data.

[b] A minimum score for knowledge or skills tests must be determined at country/site level (eg, 'demonstrated skills' may mean completing 50%, 80%, or 100% of tasks from an observation checklist). Knowledge or skills testing must be based on the locally used training materials. In most settings, knowledge or skills testing will be done for small number of providers per facility because primary facilities usually have only 1–2 providers trained to treat infections. However, if a large number of providers are observed per facility, the indicator definition may be changed to: *% of facilities where at least xx% of observed providers demonstrate knowledge/skills*.

[c] Reference period may be longer if supervision visits are intended to be less frequent.

[d] A minimum score for knowledge or skills tests must be determined at country/site level. Knowledge or skills testing must be based on the locally used training materials.

[e] Reference period should match the locally recommended home visit schedule.

[f] DHS and MICS interview women with a live birth in the past 2 or 5 years. A shorter recall period may be used.

[g] DHS and MICS interview women with a live birth in the past 2 or 5 years. A shorter recall period may be used.

[h] A shorter recall period may be used.

[i] A shorter recall period may be used.

[j] Expected live births should be gathered from MOH (often based on latest census). The proportion of births that can be expected to develop signs of PSBI should be based on local incidence data, if available. If local data are not available, 2012 regional and global estimates of PSBI incidence risk published in *The Lancet* can be used: http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(14)70804-7/abstract

[k] If CHWs conduct follow up home visits as part of the local protocol.

[l] Since PSBI is a rare event, household interviews to collect completion and outcome indicators must be done for treated cases (not population-based surveys), ideally soon after treatment to minimize recall bias.

[m] A list of qualifying serious adverse events should be determined before the start of the demonstration.

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