

**POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI)
HISTORY OF EVIDENCE TO POLICY TO IMPLEMENTATION
LEARNING**

SNL Legacy e-talks 8 October 2020

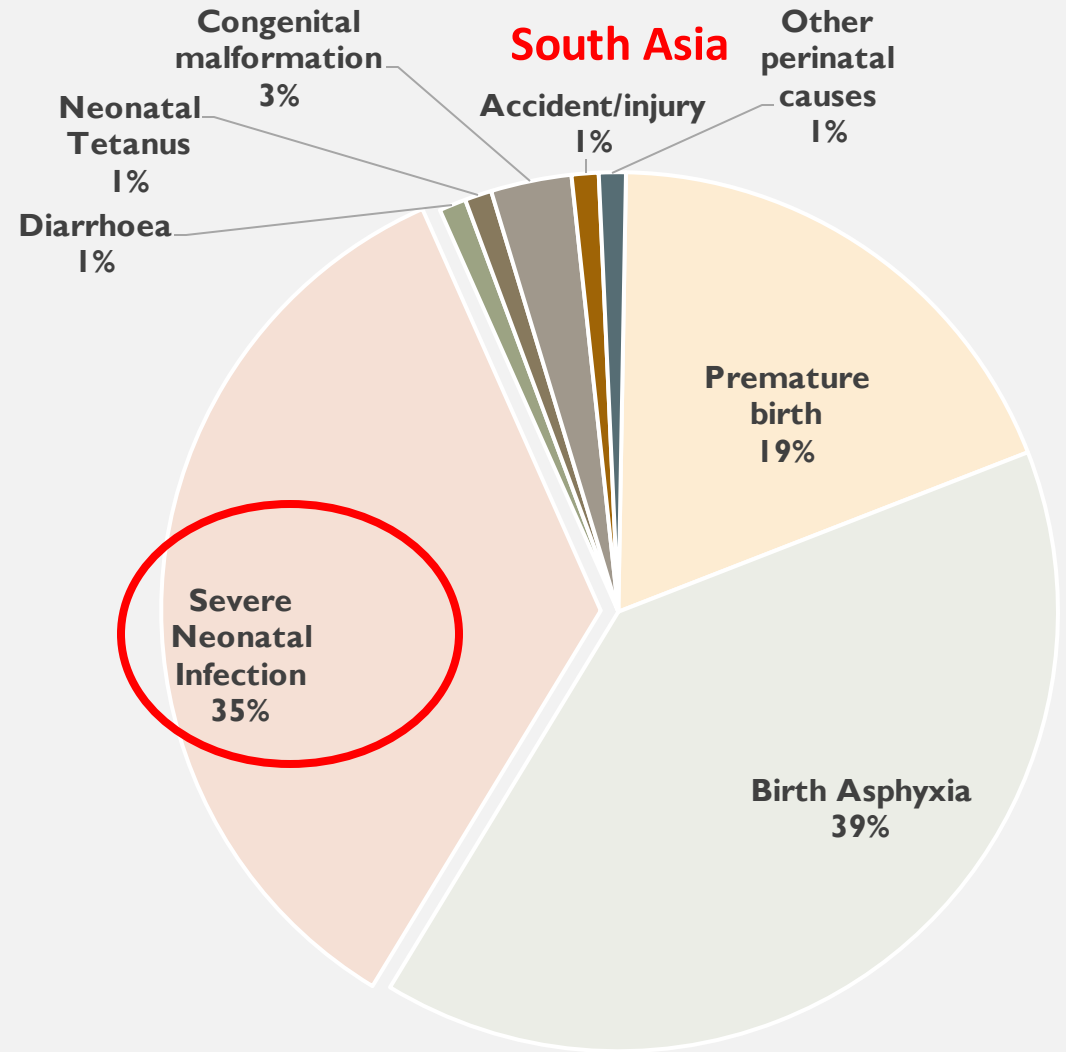
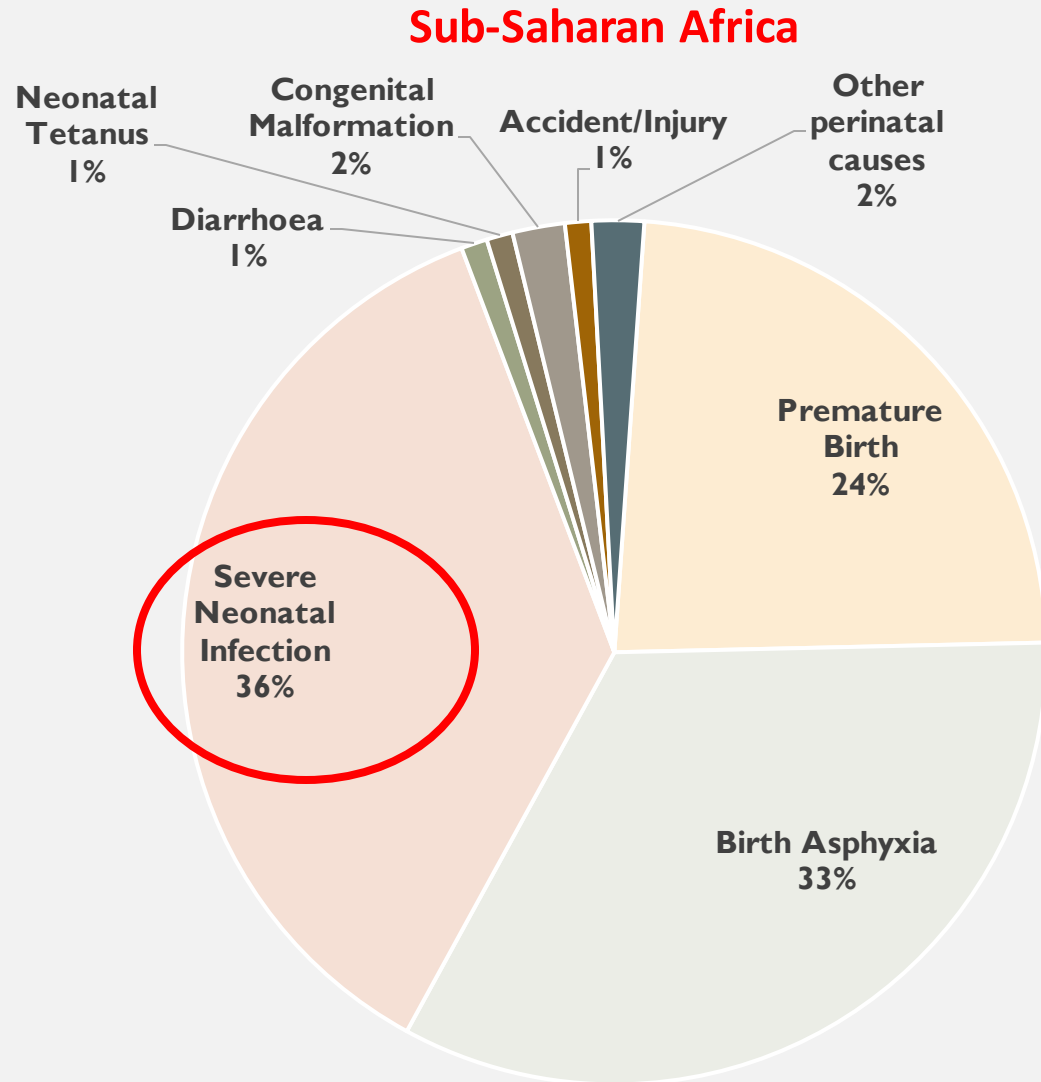
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OUTLINE OF PRESENTATION

- Burden of neonatal infections
- Strategies to improve coverage of treatment and evidence generation
- WHO guideline and tools when referral is not feasible
- Implementation research - putting guideline to practice – key findings
- Impact of WHO PSBI guideline on neonatal and young infant survival

NEONATAL MORTALITY AND INFECTIONS

2.5 million neonatal deaths occurred globally in 2018



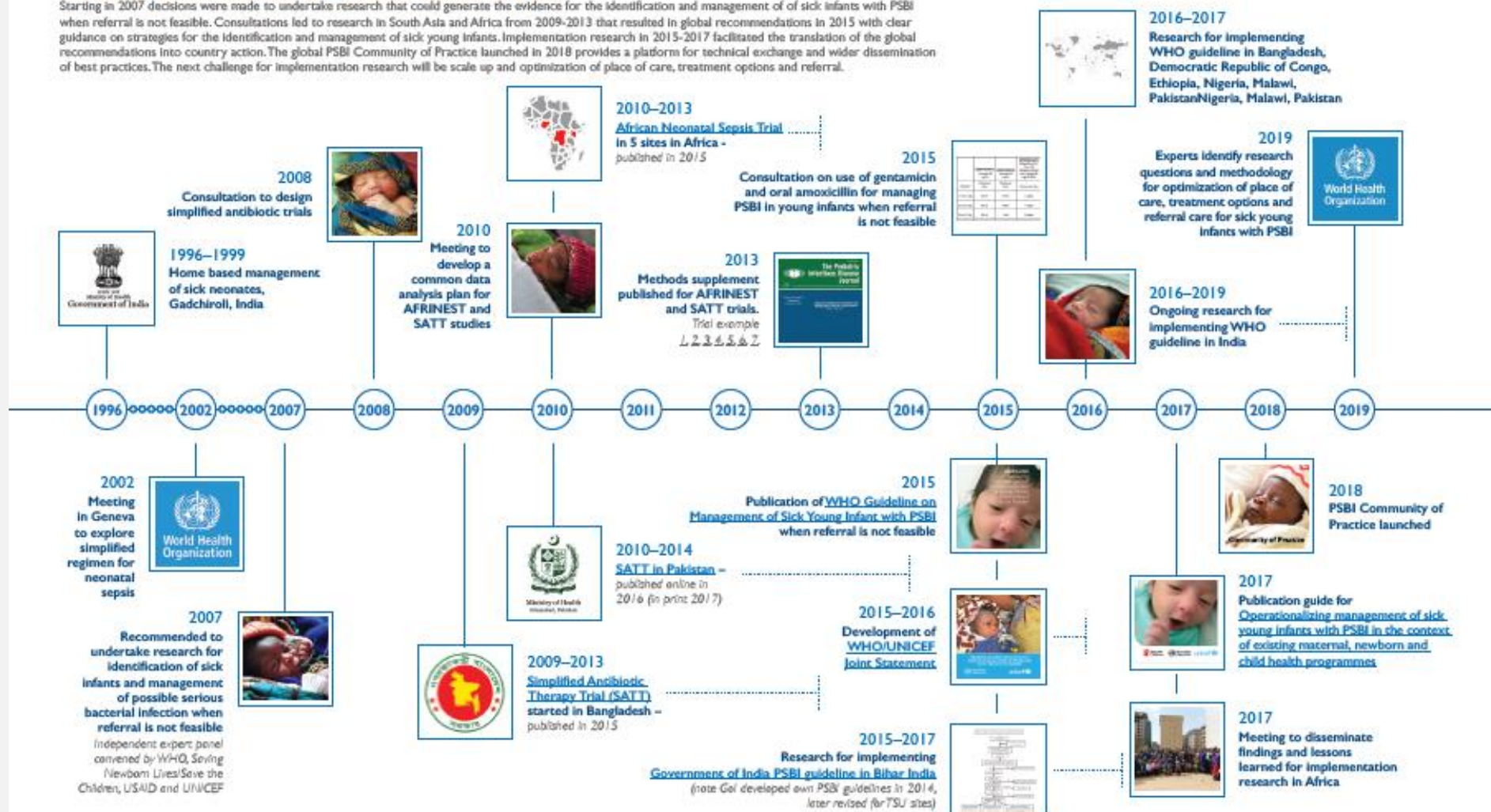
BURDEN OF POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI)

- 6.9 million cases of PSBI were estimated in 2012
 - 3.5 million in South Asia
 - 2.6 million in Sub-Saharan Africa
- 0.68 million PSBI died
- Case fatality risk (CFR) associated with PSBI (with treatment) – 7.0% (95% CI 5.1-9.4)
- CFR associated with PSBI (with or without treatment) – 9.8% (95% CI 7.4-12.2)

TIMELINE- EVIDENCE, POLICY AND PRACTICE MANAGEMENT OF PSBI WHEN REFERRAL IS NOT FEASIBLE

PSBI Timeline: Identification of needs to generation of evidence for action

Starting in 2007 decisions were made to undertake research that could generate the evidence for the identification and management of sick infants with PSBI when referral is not feasible. Consultations led to research in South Asia and Africa from 2009-2013 that resulted in global recommendations in 2015 with clear guidance on strategies for the identification and management of sick young infants. Implementation research in 2015-2017 facilitated the translation of the global recommendations into country action. The global PSBI Community of Practice launched in 2018 provides a platform for technical exchange and wider dissemination of best practices. The next challenge for implementation research will be scale up and optimization of place of care, treatment options and referral.



CONCEPTUAL FRAMEWORK: MANAGEMENT OF SEPSIS/PSBI

ALL young infants with any sign of serious bacterial infection should be **IDENTIFIED**



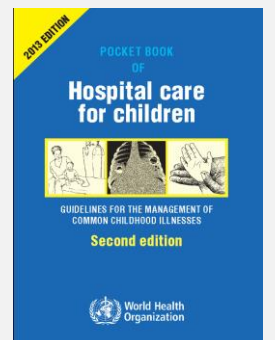
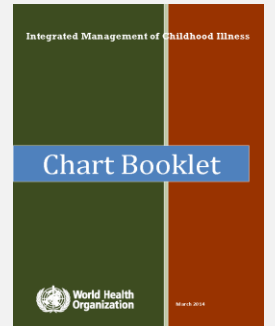
ALL identified cases of neonatal infections/PSBI should be **CONFIRMED** by a trained health worker

A major issue - low compliance to hospital referral - only 25-30% neonatal infections/PSBI cases accepted referral

ALL confirmed cases of neonatal infection should be **REFERRED** to a hospital



ALL confirmed cases of neonatal infection should be Effectively **TREATED** at a hospital



POTENTIAL SOLUTIONS FOR MANAGEMENT OF PSBI WHEN REFERRAL IS NOT FEASIBLE

- 1995-1998 - Gadchiroli – India *Bang et al Lancet 1999*
- 2003-2005 - Karachi Pakistan – *Zaidi et al PIDJ 2012*
- 2003-2006 - Sylhet, Bangladesh 2003-2005 – *Baqui et al Lancet 2008*
- 2005-2007 - Morang, Nepal - *Khanal et al JHPN 2011*

- 2008-2012 - Oromia & Southern SNNP regions - *Mathewos et al HPP 2017*
- 2012-2014 – Karachi Pakistan – *Tikmani et al CID 2016*

COLLABORATIVE EFFORTS BY WHO, SNL, USAID,
BMGF, UNICEF AND OTHER PARTNERS

ACTIVITIES TO ADDRESS MANAGEMENT OF PSBI

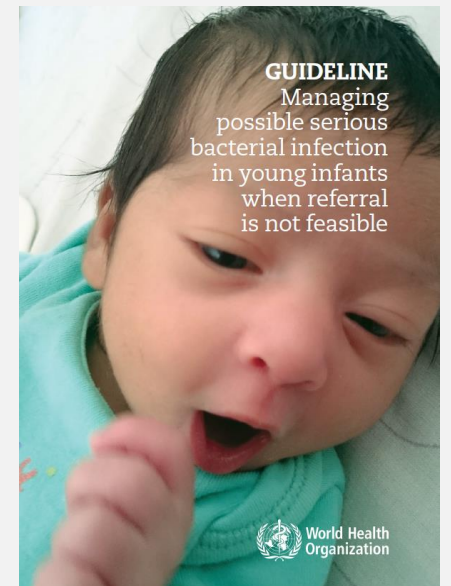
- 2002 – Geneva - WHO meeting to explore simplified antibiotic regimens for management of PSBI
- 2004 – Karachi – RCT protocol developed to compare simplified antibiotic regimens vs. standard therapy for management of PSBI in a hospital setting
- 2007 – London – Consultative meeting to explore simplified antibiotic regimens for management of PSBI when referral is not possible
 - Compare simplified antibiotic regimens for management of PSBI in an outpatient setting when families refuse referral to a hospital
 - Reducing number of injections; switch therapy (injection to oral antibiotics); only oral antibiotic
- 2009 – Neonatal infections supplement PIDJ

SYSTEMATIC EVIDENCE GENERATION MANAGEMENT OF PSBI WHEN REFERRAL IS NOT FEASIBLE

- 2010-2013 – 4 arm Clinical Severe Infection -AFRINEST in DR Congo, Kenya, Nigeria - 1.5 million population
AFRINEST Lancet 2015
- 2010-2013 – 2 arm fast breathing-AFRINEST in DR Congo, Kenya, Nigeria - 1.5 million population
AFRINEST Lancet 2015
- 2009-2013 – 3 arm clinical severe infection SATT Bangladesh - 5 hospitals *Baqi et al Lancet GH 2015*
- 2010-2014 – 3 arm clinical severe infection SATT Pakistan - 350,000 population *Mir et al Lancet GH 2017*

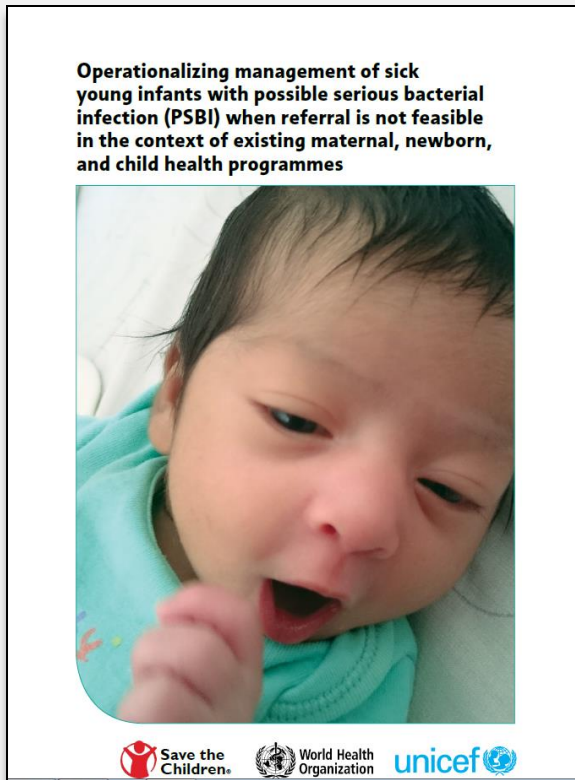
WHO GUIDELINE FOR THE MANAGEMENT OF PSBI WHEN REFERRAL IS NOT FEASIBLE - 2015

- Improved identification of infants with PSBI by families and CHWs
- Outpatient treatment of fast breathing in 7-59d old with oral antibiotics without referral
- Improved referral to hospital for other cases of PSBI (critical illness and clinical severe infection)
- If referral is not feasible, provided outpatient treatment for clinical severe infection (twice daily oral amoxicillin for 7 days and once daily injection gentamicin for 2/7 days)



GUIDELINE TO PRACTICE

- Operational Guide (2017)



- Revised Young Infant IMCI Chart Booklet (2019)



COMMUNITY OF PRACTICE

- 2018 - Telephone calls of 7-10 people grew into over 600 members from 73 countries – USAID supported
<https://www.harpnet.org/communities-of-practice/>
- Members include policymakers, implementers, researchers, ministry of health, international organizations, NGOs, academic institutions
- Webinar topics included evidence, guidelines, tools for policy dialogue and implementation at country level, implementation research, learnings for translating global guidance into country specific actions

IMPLEMENTATION RESEARCH IN 7 COUNTRIES

- Bangladesh, Democratic Republic of Congo, Ethiopia, India, Malawi, Nigeria and Pakistan
- Improved identification of infants with PSBI by families and CHWs
- Treatment of fast breathing in 7-59d olds with oral antibiotics at first level health facilities
- Improved referral to hospital for other cases of PSBI
- If referral is not possible, provided outpatient treatment at first level health facilities for young infants with clinical severe infection

STEPS IN IMPLEMENTATION RESEARCH

- Orientation and Policy dialogue – multi stakeholder engagement and collaboration
- Informed decisions on treatment choices for early implementation in selected sites
- Establishment of early implementation sites and Technical Support Units (TSUs)
- Aligning PSBI management with IMCI
- Assisting health care managers in planning and programming of activities
- Capacity building of health care providers and creating a learning platform (TSU)
- Provision of commodities and minimizing stockouts
- Engaging community to improve care seeking practices
- Implementation, supervision, and monitoring

IMPLEMENTATION RESEARCH IN 7 COUNTRIES IMPLEMENTATION EXPERIENCE

	Bangladesh	DRC	Ethiopia	India	Malawi	Nigeria	Pakistan
TSU role in implementation	Low	High	Low	Low	Low	High	Low
Feasible/Acceptable	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Treatment completion	56%	96%	95%	69%	94%	95%	81%
Day 4 follow-up	21%	98%	95%	87%	90%	98%	90%
No treated /year	29/UHC	53/HC	10/HP, 32/HC	23/HC	50/HC	51/HC	110/HC
Treatment failure	4%	9%	0.3%	6%	4%	7%	7%
Treatment coverage (Hospital + Outpatient)	31%	88%	61%	65%	58%	95%	97%

IMPLEMENTATION RESEARCH IN 6 COUNTRIES
MORTALITY AMONG ALL IDENTIFIED CASES

	% of PSBI cases	Deaths (CFR)
Fast breathing (7-59 days)	38%	3/2220 (0.1%)
Clinical Severe Infection	56%	87/3178 (2.7%)
Critical Illness	6%	48/332 (14.6%)

Overall CFR 2.4% compared to 7.8% reported by Seale et al

HIGH LEVEL LESSONS FROM IMPLEMENTATION RESEARCH

- Implementation of the new PSBI treatment strategy is feasible in programme settings, and can result in high treatment coverage
- When outpatient treatment was only available at very low (e.g. Bihar, India) or very high (e.g. Bangladesh) level facilities, treatment coverage was low
- With outpatient treatment at appropriate facilities, postnatal home visits and a functional health system were critical for high treatment coverage
- Technical support units played an important role in achieving high-quality implementation
- Low treatment failure and mortality rates were achieved, which should motivate countries to scale-up the new PSBI treatment strategy

SPECIFIC LEARNINGS FROM IMPLEMENTATION RESEARCH

- Community engagement - Empower mothers to identify sick young infants and seek appropriate care and involve them and families to increase utilization of services
- Capacity building – sustaining knowledge, skills, communication with the caretakers and adherence to guidelines (classification, referral, pre-referral antibiotics)
- Supply chain – appropriate resource allocation and planning required
- Follow-up – mandatory follow-up of patients and tracking outcomes, particularly for those who accept referral to hospitals
- Documentation – Improve data collection at all levels, minimize missing data and integrate PSBI management in routine health management system (HMIS)
- Programme learnings – Documentation of challenges and barriers and finding solutions

POTENTIAL IMPACT ON YOUNG INFANT SURVIVAL

Coverage: proportion of expected cases who received treatment (at hospital or outpatient facility)	75%
Case fatality: Proportion of deaths among the ~6000 total cases identified as PSBI (with new treatment strategy)	2%
Potential lives saved per year <i>Assumption 1:</i> SS Africa and South Asia have 6 million PSBI cases <i>Assumption 2:</i> Scale up can achieve 75% coverage <i>Assumption 3:</i> Previous strategy had 7% case fatality (Seale et al 2012)	225,000

SUMMARY

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