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The Role of Pragmatic Clinical Trials in Bridging the Equity Gap in the Diagnostics and Management of Neonatal Sepsis

44TH ANNUAL MEETING OF THE
EUROPEAN SOCIETY FOR
PAEDIATRIC INFECTIOUS DISEASES

Organised jointly by ESPID and the ESPID Foundation

#ESPID2026

espidmeeting.org

Conflict of Interest

	No, Nothing to disclose
X	Yes, please specify

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Gates Foundation			X					
National Health and Medical Research Council			X					
Medical Research Future Fund			X					

We have made minimal progress in diminishing neonatal sepsis – and AMR threatens to *increase* this morbidity & mortality burden

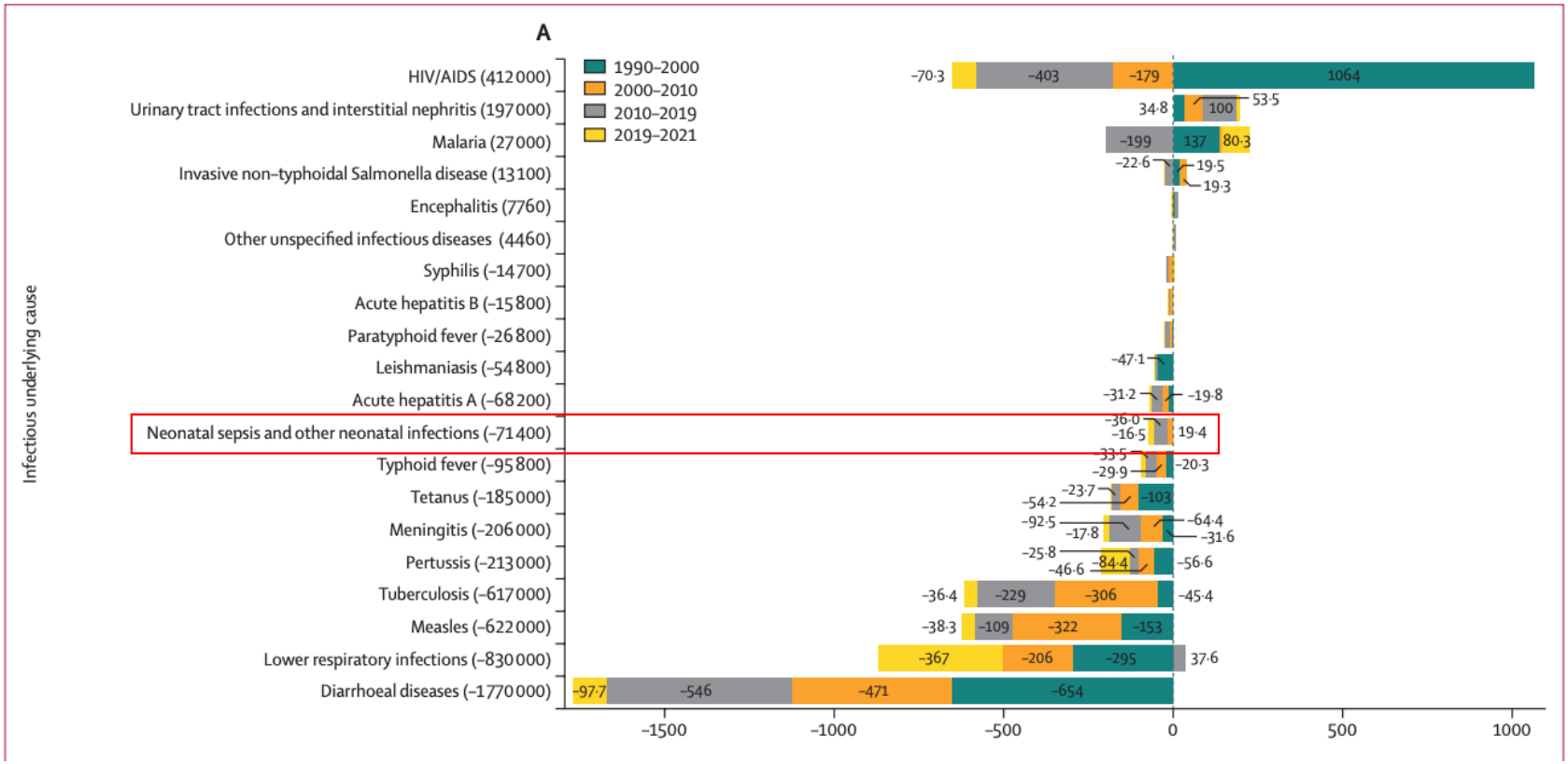
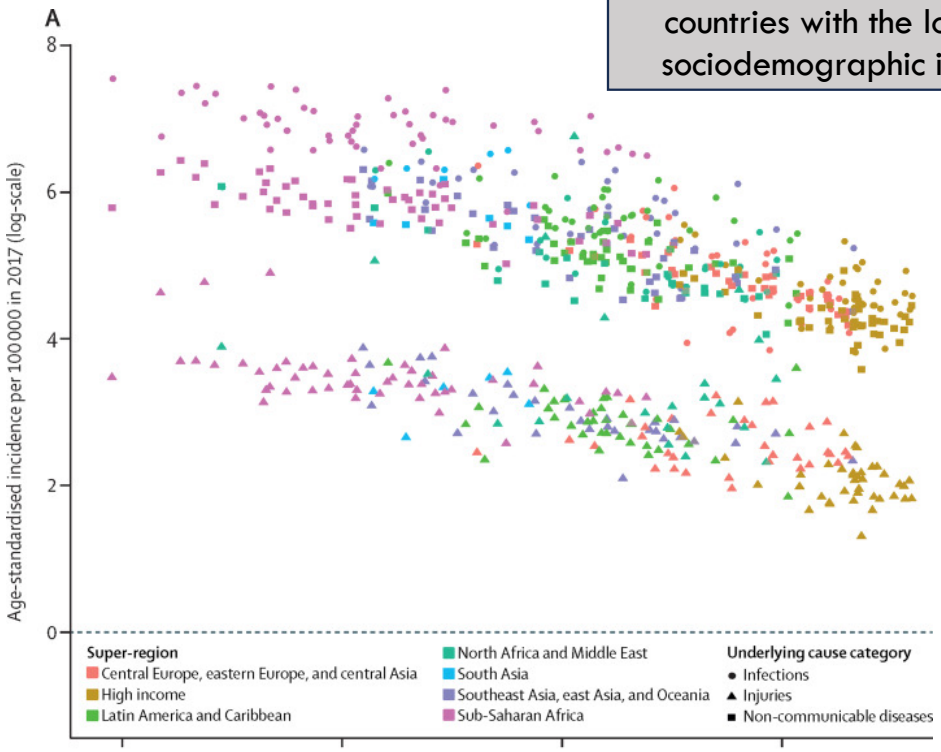


Figure 4: **Change in global sepsis-related deaths co-occurring with the leading 20 infectious (A) and non-infectious (B) underlying causes, by time period, from 1990–2021**
Each row represents the change in the number of sepsis-related deaths across a time period (1990–2000, 2000–2010, 2010–2019, and 2019–2021) for a given leading underlying cause (top 20 underlying causes for sepsis-related deaths in 1990), listed by change in mean deaths. The change in mean deaths is shown in parentheses. A bar to the right of 0 represents an increase in the number of cause-specific sepsis deaths and a bar to the left of 0 represents a decrease in the number of cause-specific sepsis deaths. For readability, values less than 15 000 in panel A and values less than 1000 in panel B are not displayed.

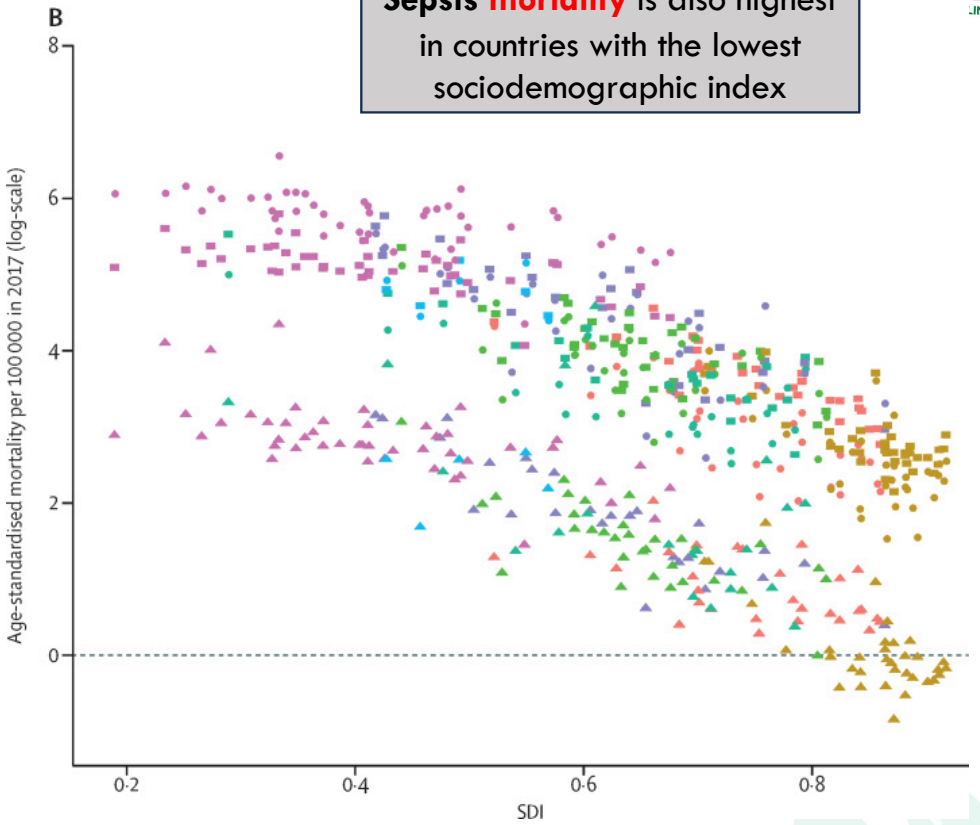
GBD 2021 Collaborators. Lancet Global Health, 2025.

Sepsis is a disease of inequity

Sepsis incidence is highest in countries with the lowest sociodemographic index

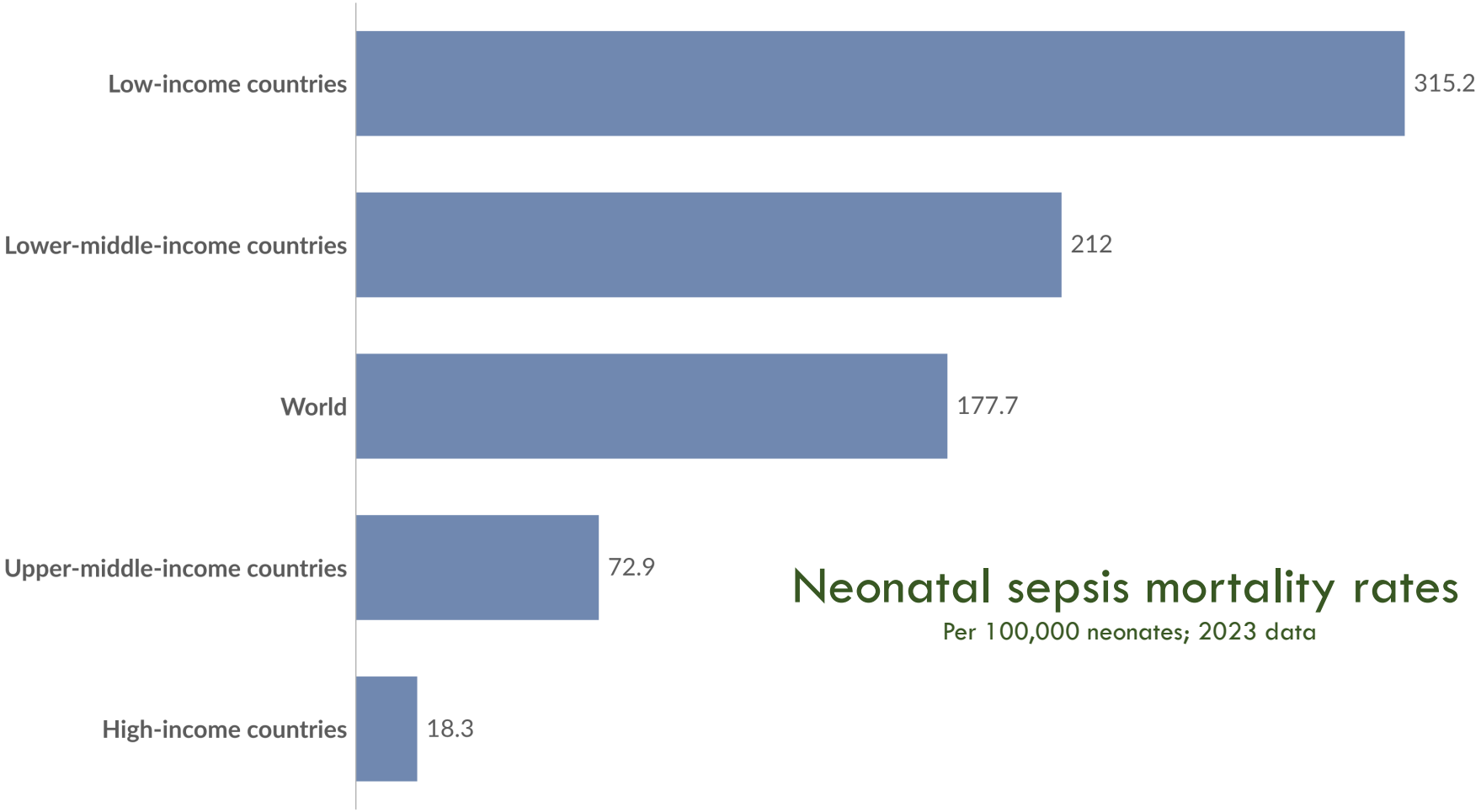


Sepsis mortality is also highest in countries with the lowest sociodemographic index



Age-standardised sepsis incidence (A) and mortality (B) per 100 000 population and SDI, by location and underlying cause category for both sexes, in 2017
Every point represents one country or territory. 195 countries and territories worldwide are categorised according to SDI.
SDI=Socio-demographic Index: a composite index of income, education and fertility rate
Rudd KE *et al.* The Lancet 2021

Neonatal Sepsis is a disease of inequity



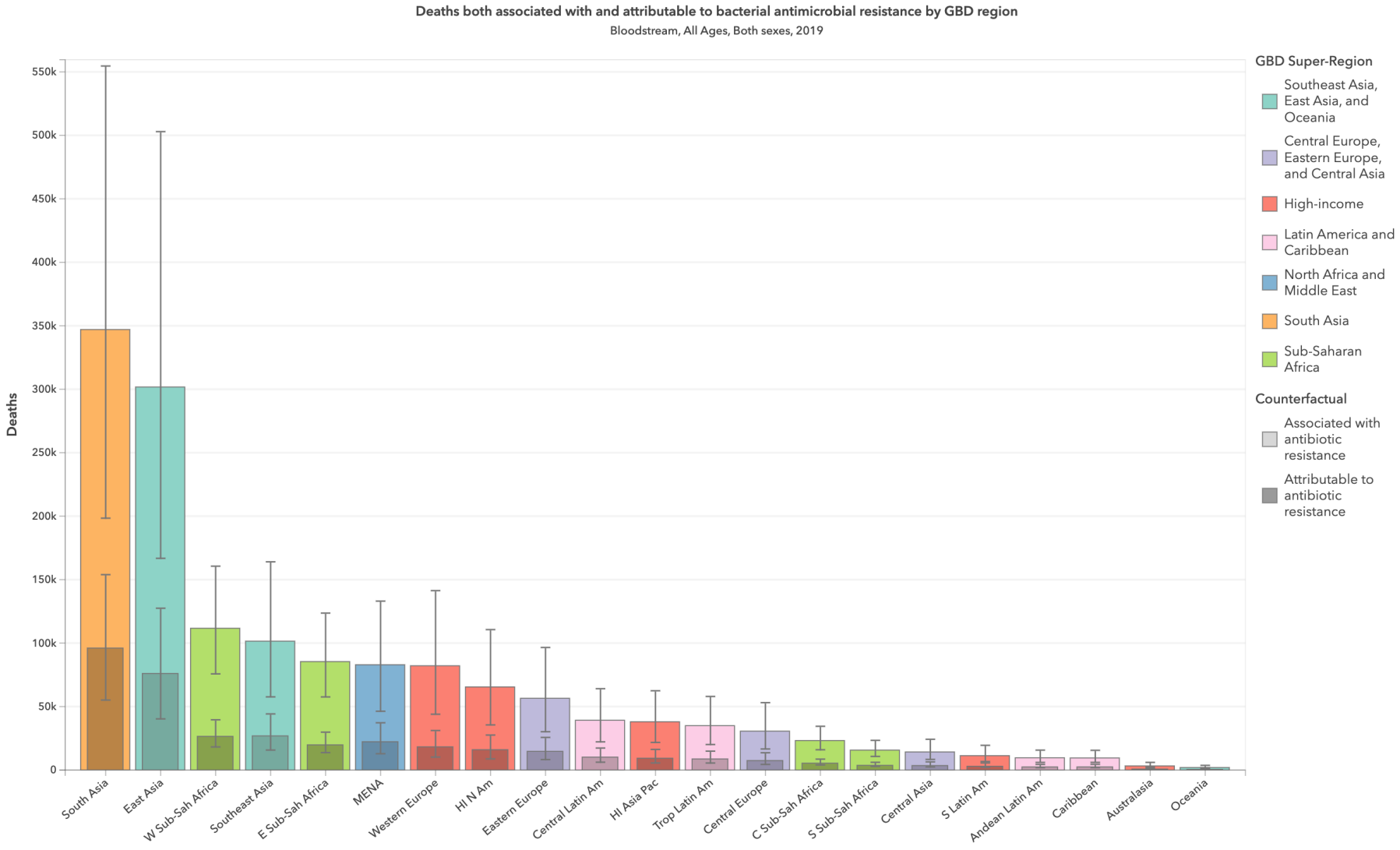
Neonatal sepsis mortality rates

Per 100,000 neonates; 2023 data

#ESPID2026

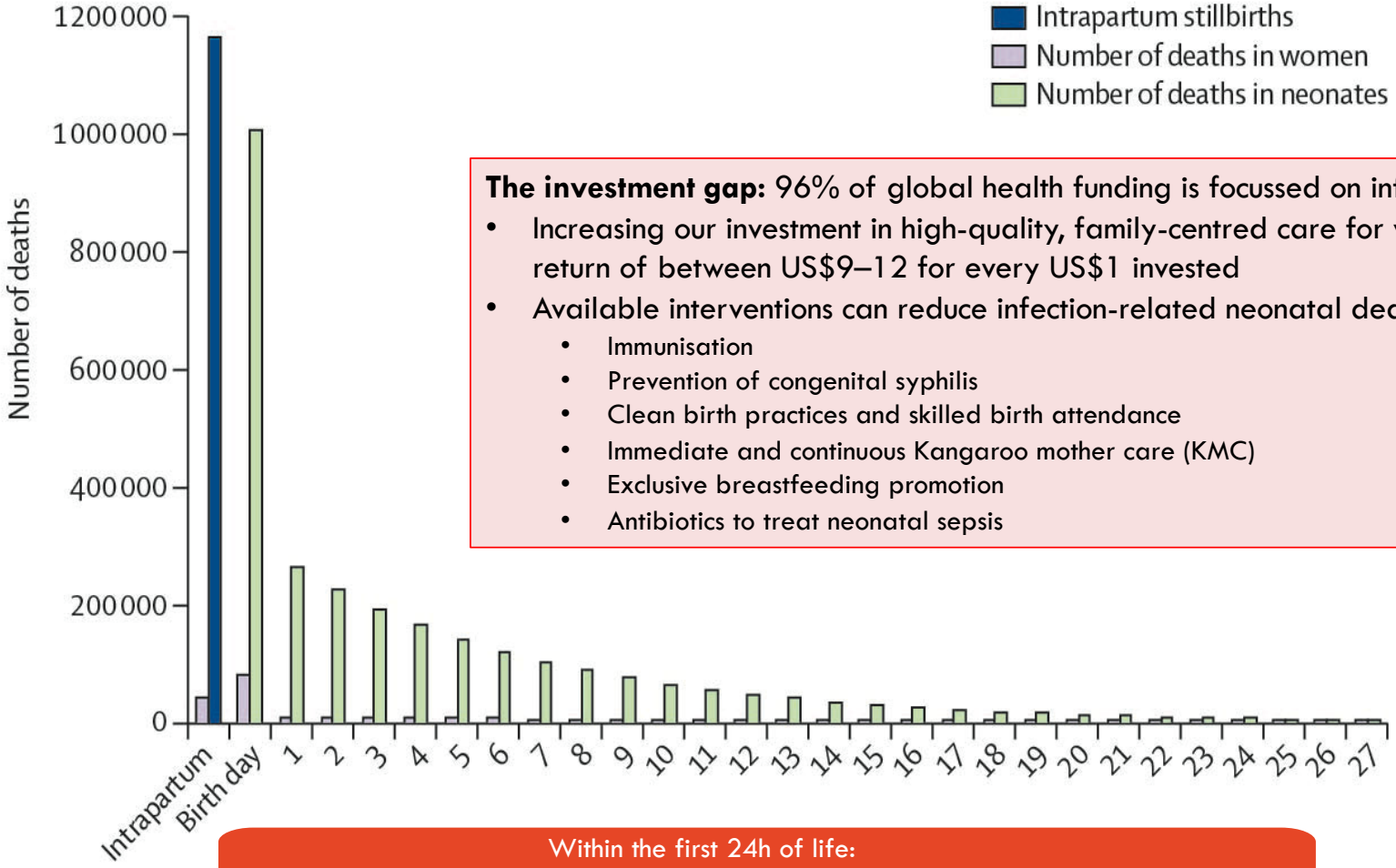
Data source: IHME, Global Burden of Disease (2025)

The growing burden of AMR is also inequitably geographically distributed



Murray CJL et al. Lancet 2022;399:629e55

Investing in neonates provides a ~10-fold return on investment



The investment gap: 96% of global health funding is focussed on infants and children

- Increasing our investment in high-quality, family-centred care for vulnerable newborns provides a return of between US$9–12 for every US$1 invested
- Available interventions can reduce infection-related neonatal deaths by 84%
  - Immunisation
  - Prevention of congenital syphilis
  - Clean birth practices and skilled birth attendance
  - Immediate and continuous Kangaroo mother care (KMC)
  - Exclusive breastfeeding promotion
  - Antibiotics to treat neonatal sepsis

Within the first 24h of life:
1.2 million intrapartum stillbirths; >1m neonatal deaths

www.lancet.com/series/everynewborn
Bhutta *et al.* Lancet 2024.
Rudd KE *et al.* The Lancet 20201. doi: 10.1016/S0140-6736(19)32989-7
Murless-Collins S *et al.* Reproductive Health 2025

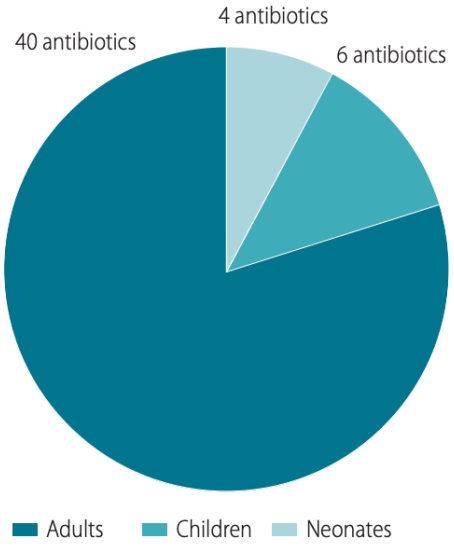
The Research Gap

Only 4 new anti-infectives have been approved for use in neonates this century (v's 44 for adults)

Antibiotics needed to treat multidrug-resistant infections in neonates

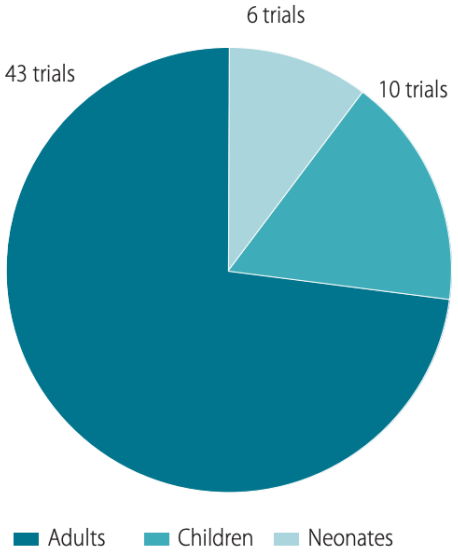
Phoebe CM Williams,[a] Shamim A Qazi,[b] Ramesh Agarwal,[c] Sithembiso Velaphi,[d] Julia A Bielicki,[e] Sumathi Nambiar,[f] Carlo Giaquinto,[g] John Bradley,[h] Gary J Noel,[i] Sally Ellis,[j] Seamus O'Brien,[j] Manica Balasegaram[j] & Michael Sharland[e]

Fig. 1. **Number of antibiotics approved for use since 2000, by age cohort, 2022**



Note: We systematically collated data from the ClinicalTrials.gov database, Food and Drug Administration, European Medicines Agency, PEW Charitable Trusts,[8] World Health Organization[9] and Butler et al.[10,11]

Fig. 2. **Number of antibiotic clinical trials recruiting patients, by age cohort, 2022**



Note: We systematically collated data from the ClinicalTrials.gov database, Food and Drug Administration, European Medicines Agency, PEW Charitable Trusts,[8] World Health Organization[9] and Butler et al.[10,11]

Why conventional evidence-generation fails neonatal sepsis research

Neonatal sepsis is poorly defined

SYSTEMATIC REVIEW OPEN

Neonatal sepsis definitions from randomised clinical trials

Rían Hayes[1], Jack Hartnett[1], Gergana Semova[1], Cian Murray[1], Katherine Murphy[1], Leah Carroll[1], Helena Plapp[1], Louise Hession[1], Jonathan O'Toole[1], Danielle McCollum[1], Edna Roche[1], Elinor Jenkins[1], David Mockler[2], Tim Hurley[1,3], Matthew McGovern[1,3], John Allen[1,3,4], Judith Meehan[1,4], Frans B. Plötz[5,6], Tobias Strunk[7,8], Willem P. de Boode[9], Richard Polin[10], James L. Wynn[11,12], Marina Degtyareva[13], Helmut Küster[14], Jan Janota[15,16], Eric Giannoni[17], Luregn J. Schlapbach[18,19,20], Fleur M. Keij[21], Irwin K. M. Reiss[21], Joseph Bliss[22], Joyce M. Koenig[23], Mark A. Turner[24], Christopher Gale[25], Eleanor J. Molloy[1,3,4,26,27]✉ and On behalf of the Infection, Inflammation, Immunology and Immunisation (I4) section of the European Society for Paediatric Research (ESPR)

Table 3. Signs and symptoms present and frequency in the RCT definitions reviewed.

Constitutional		Respiratory		Cardiovascular		Neurological		Gastrointestinal		Miscellaneous	
Symptom	***N***	**Symptom**	***N***	**Symptom**	***N***	**Symptom**	***N***	**Symptom**	***N***	**Symptom**	***N***
Lethargy	27	Apnoea	22	Haemodynamic instability	8	Altered consciousness	7	Abdominal distension	11	Disseminated haemorrhage	2
Temperature instability	27	Respiratory distress	12	Hypotension	7	Seizure	6	Vomiting	5	Unexplained bleeding	2
Feeding intolerance	17	Tachypnoea	10	Poor perfusion	7	Hypotonia	4	Hepatomegaly	5	Petechiae	1
Glucose intolerance	9	Ventilatory support	6	Tachycardia	6	Reduced reflexes	2	Splenomegaly	4	Purpura	1
Irritability	5	Supplemental O_2	6	Bradycardia	6	Bulging fontanelle	1	Jaundice/icterus	4	Pyoderma	1
Hypothermia	4	Desaturations	4	Inotropic/fluid support	5			Increased gastric aspirate	1	Sclerema	1
Hyperthermia	3			CRT > 3 s	5					Conjunctivitis	1
Fever	3	Grunting	4	Pallor	3					Organ dysfunction [unspecified]	3
Poor feeding	3	Cyanosis	3	Rate > 2 SD above normal	2					Staff concern	1
Excessive crying	1	Gagging	1	Shock	2						
Poor cry	1	Apnoea	22	Cardiovascular collapse	2						
Colour	1	Respiratory distress	12	BP < 2 SD below normal	2						
		Tachypnoea	10	Rate instability	1						
				Cold extremities	1						

Table 1. Definitions of neonatal sepsis by primary criteria.

Combination of primary criteria	*N*
Culture alone	35
Culture + signs	29
Signs + laboratory	25
Culture + signs + laboratory	12
Signs alone	7
Culture + labs	6
Signs + radiology	6
Laboratory alone	4
Signs + risk factors	2
Culture + laboratory + radiology	1
Radiology alone	1

Microbiological culture was a component of 83 out of 128 definitions of neonatal sepsis (Table 1). These 83 definitions were from 68 different papers.

Culture source: Of the 83 culture-related definitions, 74 specified a site the culture sample was taken from, while 9 mentioned 'culture' without specifying a sample site. Of the 74 that specified culture sites, the frequency of each site mentioned is outlined in Table 2. Three definitions required two positive cultures to diagnose sepsis.

Pathogen: 12 definitions specified a pathogen sought by microbiological culture. Five specified bacteria, 4 specified fungi, and the remainder mentioned 'known virulent pathogens', or 'not *Staphylococcus epidermidis*'.

Incubation time: Only one study mentioned incubation time, which outlined that a microorganism was regarded as infectious if it grew within 48 h incubation.

- The most common signs and symptoms are completely non-specific
- Some studies require clinical + laboratory diagnostics, others don't
- Even for culture-positive infections, there's a lack of consistency in interpretation of pathogenic vs contaminant bacteria

Hayes *et al*. Neonatal sepsis definitions from randomised clinical trials. Nature, 2021.

Limitations in attempts to define neonatal sepsis

The nSOFA score

Adult sepsis definitions have moved away from a microbiological focus, and instead multiorgan dysfunction predominates as the key inclusion for sepsis trials

Published in final edited form as:
Pediatr Res. 2020 July ; 88(1): 85–90. doi:10.1038/s41390-019-0517-2.

A Neonatal Sequential Organ Failure Assessment Score Predicts Mortality to Late-Onset Sepsis in Preterm Very Low Birth Weight Infants

James L. Wynn[1,2], Richard A. Polin[3]

Table 1.

Neonatal sequential organ failure (nSOFA) components and scoring (0–15 point range).

Respiratory score	**0**	**2**	**4**	**6**	**8**
Criteria	Not intubated ***OR*** Intubated, SpO_2/FiO_2 ≥ 300	Intubated, SpO_2/FiO_2 <300	Intubated, SpO_2/FiO_2 <200	Intubated, SpO_2/FiO_2 <150	Intubated, SpO_2/FiO_2 <100
Cardiovascular score	**0**	**1**	**2**	**3**	**4**
Criteria	No inotropes ***AND*** No systemic steroids	No inotropes ***AND*** Systemic steroid treatment	One inotrope ***AND*** No systemic steroids	Two or more inotropes ***OR*** One inotrope AND systemic steroid treatment	Two or more inotropes ***AND*** Systemic steroid treatment
Hematologic score	**0**	**1**	**2**	**3**	
Criteria	Platelet count ≥ 150 × 10^3	Platelet count 100–149 × 10^3	Platelet count <100 × 10^3	Platelet count <50 × 10^3	

Unrealistic in LMIC settings,
where the bulk of neonatal infections occur

The Pathophysiology of Neonatal Sepsis is Unique

01 Rapidly changing PK/PD

Postnatal age, gestational age & weight drive variable ADME — leading to considerable variation in dosing guidelines across formularies.

High-quality PK/PD data are lacking for many drugs used in neonates.

02 No identifiable infection source

Unlike adults, neonates frequently have bloodstream infection without a focal source

This is one of the **key reasons neonates are excluded from trials for new antibiotics** – which are frequently licensed for specific indications (cIAI, HAP/VAP etc)

03 Permeable blood-brain barrier

Neonates are more likely to develop CNS infections, requiring drugs with CNS penetration – **a property that many newer antibiotics in the pipeline lack.**

04 Heterogeneous clinical presentation

Sepsis signs mimic many other serious conditions.

Results in **non-standardised trial populations** and makes it hard to extrapolate adult syndrome-based trial findings.

05 High rates of culture-negative sepsis

Due to
-Frequent pre-exposure to antibiotics (intrapartum & postnatal)
-Difficulties in obtaining adequate neonatal blood culture volumes
-Limited microbiological capacity in many health-care settings

The Neonatal Sepsis Management Gap

Empiric Guidelines were curated using data from high-income healthcare settings

1970s
EOS/LOS dichotomy established in US NICUs

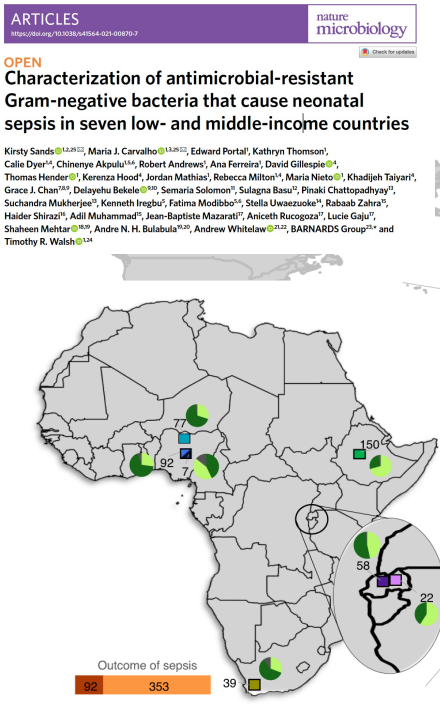
1990s
GBS + *E. coli* entrenched as primary EOS pathogens (HIC data)

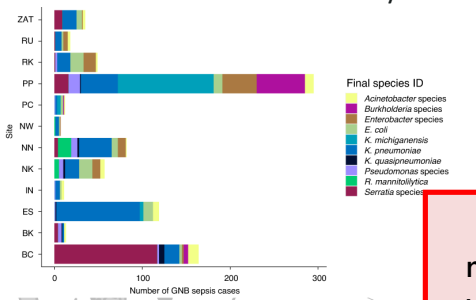
2005
2013
WHO Pocketbook: Amp + Gent as first-line globally

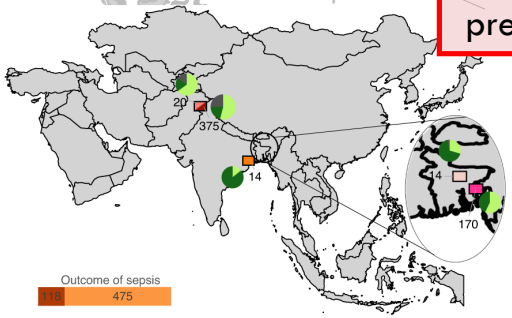
2015-2025
Data from multiple studies focused on high-burden neonatal sepsis countries (DeNIS, ANISA, BARNARDS, NeoObs & NeoSEAP) reveal **high rates of MDR gram-negative infections** as early as day one of life

Today
Clinicians increasingly need to use broad-spectrum empiric (carbapenem-based) therapy → propagates AMR

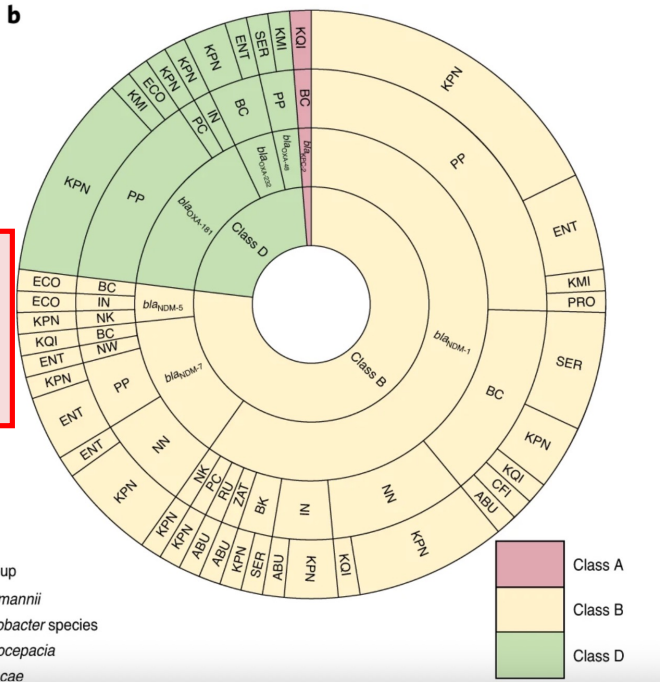
Today
Increasing burden of infections due to multidrug-resistant infections: MBLs predominate







Class B metallo-β-lactamases predominate



The Antibiotic Pipeline includes very few agents with activity against MBLs

Table 1. Microbiological targets.

	ESBL	KPC	MBL	AmpC	OXA-48	*P. aeruginosa* (MDR/XDR)	*Acinetobacter* (MDR/XDR)	*S. maltophilia*
Aztreonam/avibactam								
Cefepime/enmetazobactam								
Cefepime/taniborbactam								
Cefepime/zidebactam								
Cefiderocol								
Ceftaroline/avibactam								
Ceftolozane/tazobactam								
Ceftazidime/avibactam								
Imipenem/relebactam								
Meropenem/nacubactam								
Meropenem/vaborbactam								

Green = antimicrobial activity, red = no antimicrobial activity, yellow = partial antimicrobial activity, grey = not available. ESBL = extended-spectrum β-lactamase, Ambler Class A β-lactamases; KPC = *Klebsiella pneumoniae* carbapenemase, Ambler Class A β-lactamases; MBL = metallo-β-lactamases, Ambler Class B β-lactamases; AmpC = cephalosporinase, Ambler Class C β-lactamases; OXA-48 = oxicillinase-48, Ambler Class D β-lactamases; MDR = multidrug resistant; XDR = extended drug resistant.

Pincipe *et al.* Pharmaceuticals 2022

The Neonatal Sepsis Management Gap

In high-income countries
Off-label use of the few active agents is increasing

Successful Use of Cefiderocol to Treat a Multidrug-resistant *Stenotrophomonas maltophilia* Ventilator-associated Pneumonia in an Extremely Preterm Neonate

Archana Koirala, MBChB, MIPH,†‡§ Bharath Krishnappa, MBBS, MD,¶ Caroline Banh, BSc Adv, MBBS, MIPH,*‖ Ulrike Brandenburg, MD,¶ Michael Findlay, BMedSc, MBBS,*‖ and Phoebe C. M. Williams, MBBS(Hons), MSc(Global Health), DPhil†‡§***

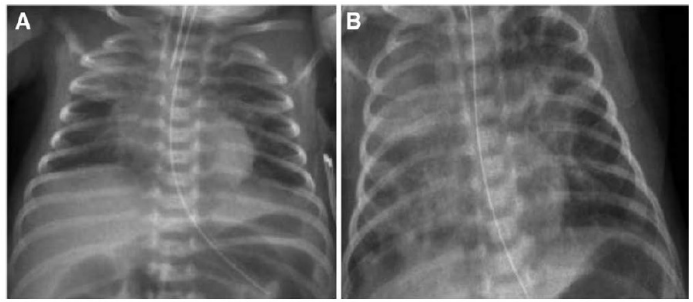


FIGURE 1. Chest radiograph of the 24+6 gestational age neonate with evolving ventilator-associated pneumonia at (A) day 18: right upper lobe collapse (B) day 20: consolidation over the entire right lung.

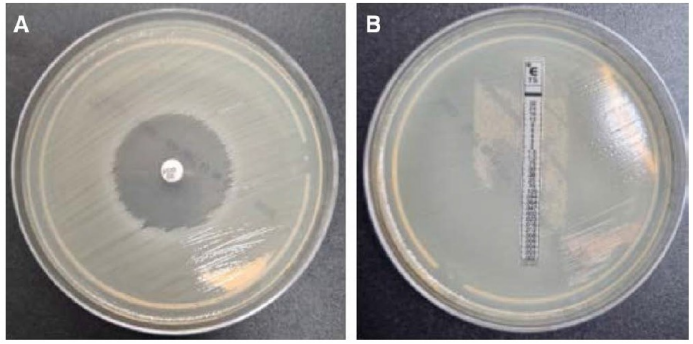
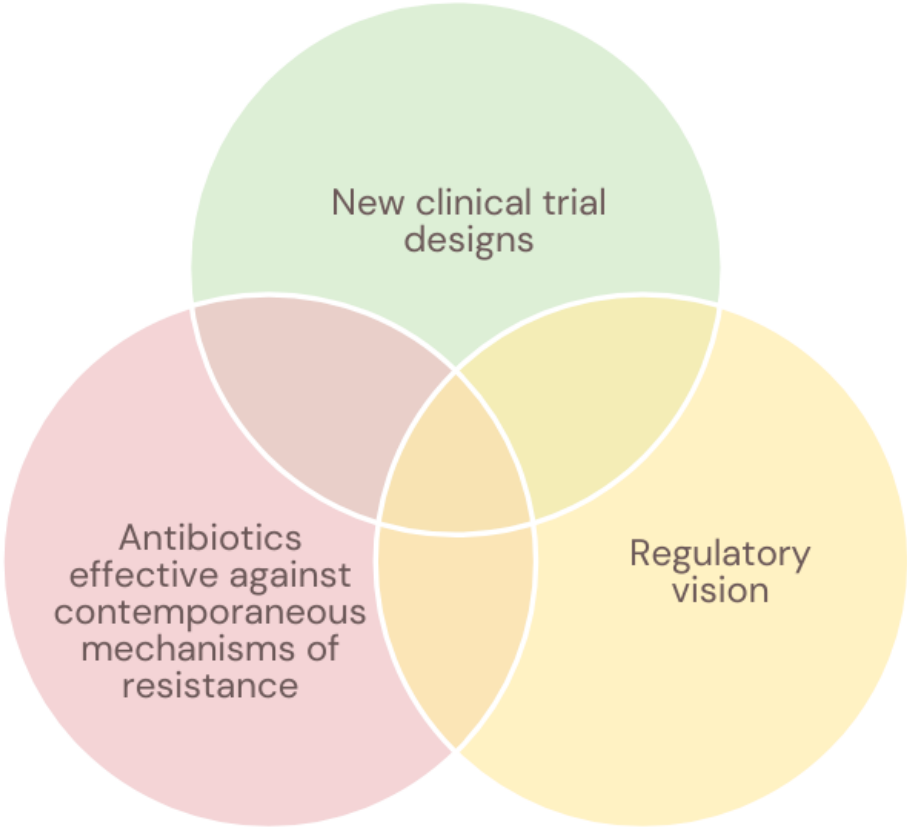


FIGURE 2. Susceptibility testing results for *Stenotrophomonas maltophilia*: (A) disc diffusion with cefiderocol showing susceptibility with a 28 mm zone diameter (B) gradient diffusion (ETEST) with trimethoprim/sulfamethoxazole showing resistance.

In low/middle-income countries
Neonatal mortality is increasing

Neonatal sepsis requires a different evidence-generation paradigm

WHAT IS NEEDED FOR OPTIMISED PAEDIATRIC ANTIBACTERIAL DEVELOPMENT?



Focussed research efforts on the licensing of antibiotics that will treat the pathogens causative of neonatal sepsis globally

ie, with coverage against MBLs

Tackling the threat of antimicrobial resistance in neonates and children: outcomes from the first WHO-convened Paediatric Drug Optimisation exercise for antibiotics

Alasdair Bamford, Tiziana Masini, Phoebe Williams, Mike Sharland, Valeria Gigante, Devika Dixit, Hatim Sati, Benedikt Huttner, Yasir Bin Nis
Bernadette Cappello, Wilson Were, Jennifer Cohn*, Martina Penazzato*, on behalf of the PADO-antibiotics participants†

***Panel 2*: Main results of the Paediatric Drug Optimisation (PADO) exercise adapted from the PADO report[32]**

PADO priority list

Short-term (3–5 years) time horizon for development of paediatric formulations or approval of paediatric indications

- Amoxicillin–clavulanic acid
- Nitrofurantoin
- Azithromycin
- Cefiderocol

PADO watch list

Medium-term and long-term (5–10 years) time horizon for development of paediatric indications and formulations

- Cefepime–taniborbactam
- Sulbactam–durlobactam

Noteworthy compounds

- Cefepime–zidebactam
- Aztreonam–avibactam

World Health Organization

Antibiotics needed to treat multidrug-resistant infections in neonates

Phoebe CM Williams,[a] Shamim A Qazi,[b] Ramesh Agarwal,[c] Sithembiso Velaphi,[d] Julia A Bielicki,[e] Sumathi Nambiar,[f] Carlo Giaquinto,[g] John Bradley,[h] Gary J Noel,[i] Sally Ellis,[j] Seamus O'Brien,[j] Manica Balasegaram[j] & Michael Sharland[e]

Table 3. **Potential neonatal priority antibiotics for accelerated development, 2022**

Priority antibiotic in development	Priority pathogens against which activity is anticipated	Development stage and clinical indication	Other benefits	Limitations
Cefiderocol – a siderophore cephalosporin that forms a complex with iron which is actively transported into the bacterial cell via iron receptors	• Activity against ESBL-producing *Escherichia coli* and *Klebsiella pneumoniae* • Activity against carbapenem-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii*, although warnings exist against its use for the latter infections in critically ill patients • Activity against gram-negative carbapenemases, including class B MBLs	• Phase III trial in adults (complicated urinary tract infection and hospital- and ventilator-acquired pneumonia in adults) – complete • Phase II trial in children > 3 months – recruiting	• Likely cerebrospinal fluid penetration • Predictable pharmacokinetic profile[34]	Requires infusions over 3 hours, three times a day
Cefepime + taniborbactam – anti-pseudomonal fourth-generation cephalosporin plus a new cyclic boronate β-lactamase inhibitor	• Activity against ESBL-producing *E. coli* and *K. pneumoniae* • Activity against gram-negative carbapenemases, including clinically relevant class B MBLs • Activity against carbapenem-resistant *P. aeruginosa*	• Phase III trial in adults – complete (complicated urinary tract infection)	• Likely cerebrospinal fluid penetration	Possible neurotoxicity effects associated with cefepime
Sulbactam + durlobactam – dual β-lactamase inhibitor combination therapy	• Activity against MDR *A. baumannii* complex • Activity against class A, C and D β-lactamase producing Enterobacteriaceae	• Phase III trial in adults – complete	• Likely cerebrospinal fluid penetration	Requires infusions over 3 hours, four times a day

ESBL: extended-spectrum β-lactamase; MBL: metallo-β-lactamase; MDR: multidrug resistant.

Focussed research efforts on improving our PK/PD data of antibiotics that will treat the pathogens causative of neonatal sepsis globally

Alongside efforts focused on developing neonatal dosing and licensing for new candidate drugs, enhanced PK and efficacy data for older antibiotics should also be prioritised

Original research

OPEN ACCESS

Randomised controlled trial of fosfomycin in neonatal sepsis: pharmacokinetics and safety in relation to sodium overload

Christina W Obiero ,[1,2] Phoebe Williams,[1,3] Sheila Murunga,[1] Johnstone Thitiri,[1] Raymond Omollo,[4] Ann Sarah Walker,[5] Thaddaeus Egondi,[4] Borna Nyaoke,[4] Erika Correia,[6] Zoe Kane,[7] Silke Gastine,[7] Karin Kipper,[8,9] Joseph F Standing,[7] Sally Ellis,[6] Mike Sharland,[10] James Alexander Berkley ,[1,3,11] for the NeoFosfo Study Group

AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy

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| Antimicrobial Chemotherapy | Full-Length Text

Pharmacokinetics and safety of fosfomycin and flomoxef administered as part of neonatal sepsis treatment (NeoSep1 Part 1)

Adrie Bekker,[1] Navarat Panjasawatwong,[2] Louise F. Hill,[3] Wolfgang Stohr,[4] A. Sarah Walker,[4] Sally Ellis,[5] Angela Dramowski,[1] Andrew Whitelaw,[6] Christina Obiero,[7] James A. Berkley,[7,8] Alexander Makazi,[7] Sithembiso Velaphi,[9] Reenu Thomas,[9] Petronella Magagula,[9] Ilhaam Abrahams,[1] Firdose L. Nakwa,[9] Mohammed M. Barday,[1] Alison Van Kwawegen,[9] Kamla Pillay,[3] Silke Gastine,[10] Joseph F. Standing,[10,11] Peter Skoutari,[4] Francesca Schiavone,[4] Mike Sharland,[3] Seamus O'Brien,[5] Julia A. Bielicki,[4,12] Tim R. Cressey,[13] On behalf of the NeoSep Study Team

- Broad susceptibility profile
- Penetrates the BBB
- Promising safety profile
- PK studies complete in neonates:
  - Only requires twice-daily dosing (without the need for a prolonged infusion)
  - Stability at room temperature

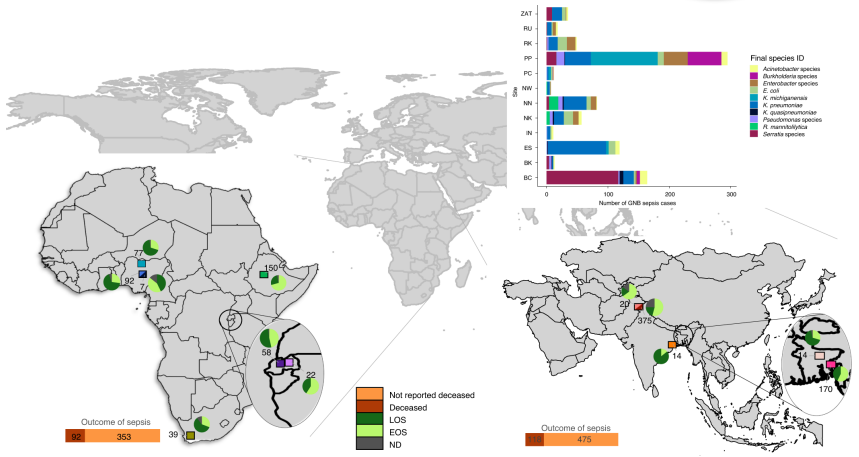
New clinical trial designs

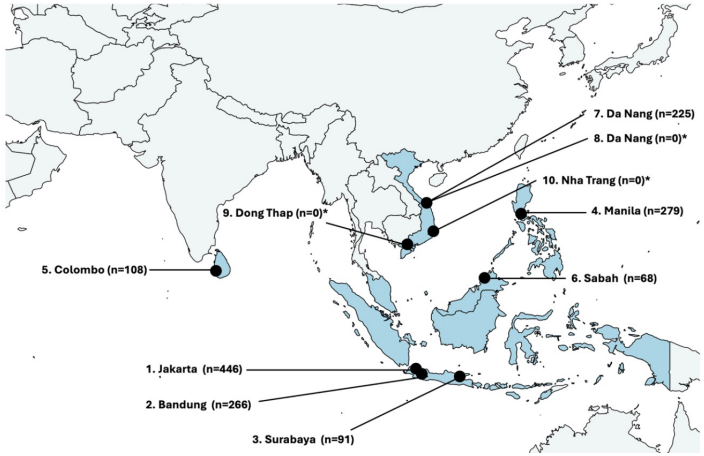
Improve Neonatal Trial Recruitment & Completion

New clinical trial designs

- **A shift is needed from single independent RCTs to <u>global network approaches</u> involving multiple stakeholders including academia, industry and non-governmental bodies.**
  - Standardised neonatal sepsis definition
  - Key inclusion/exclusion criteria
  - Standardise safety reporting

- **Ensure representation from resource-rich & resource-constrained settings**
  - Enrol neonates with both CAI and HAI
  - Build on the research networks already collaborating (ACORN, BARNARDS, NEOSEAP, NEOSEP1)

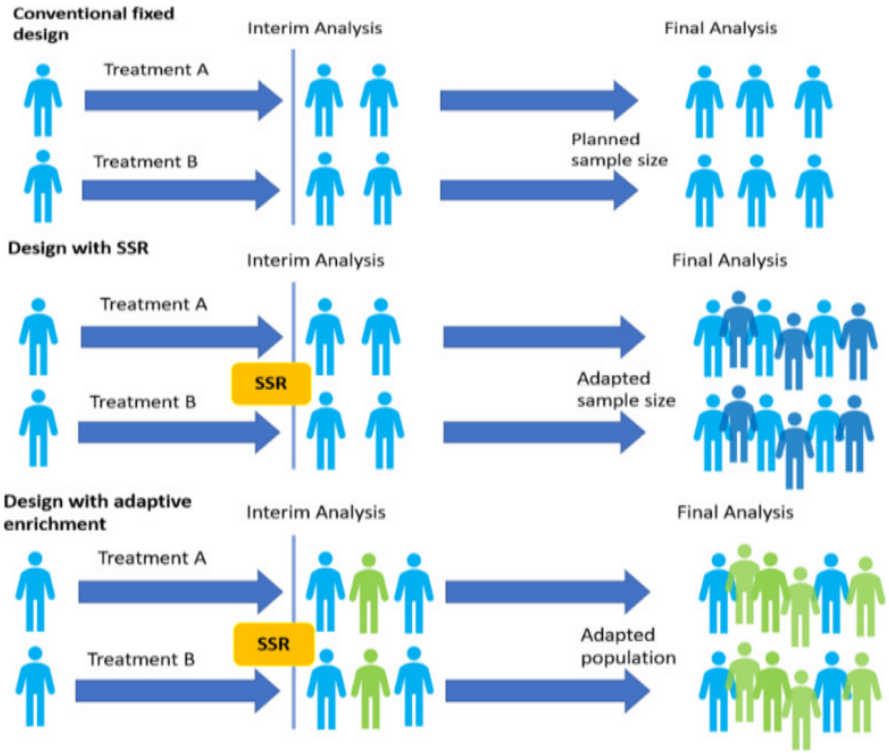




We have achieved this before (eg, development of optimal formulations to treat paediatric HIV or TB) and can do it again

Neonatal sepsis needs new trial designs

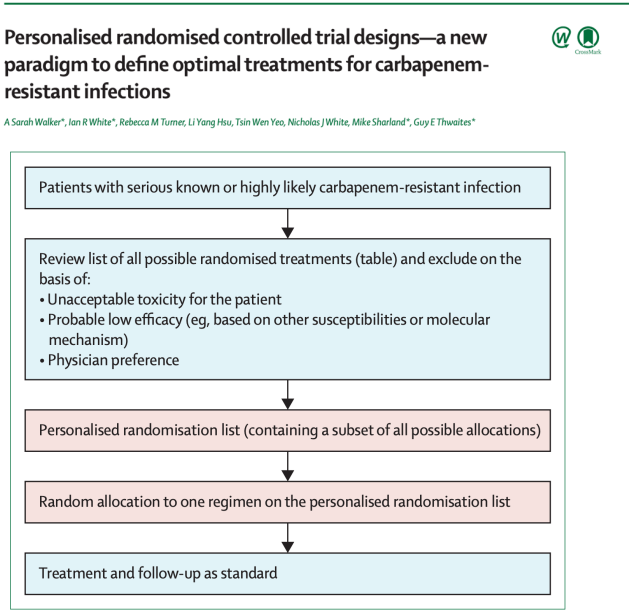
New clinical trial designs

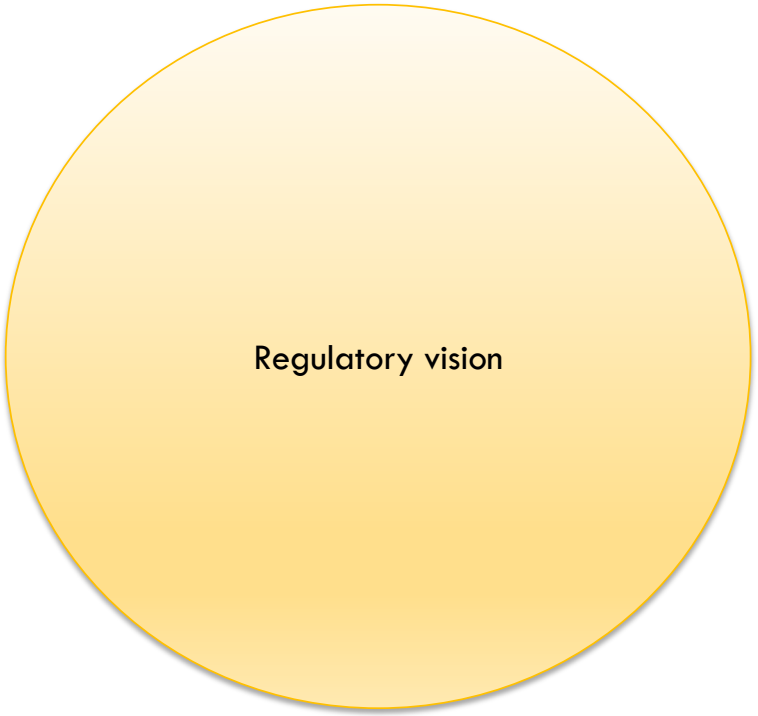


Schematic comparison of conventional fixed design and adaptive design with sample size re-assessment (SSR) and adaptive enrichment

Thorlund et al. (2018)

- Adoption of **adaptive trial protocols**
  - Allow the prospectively planned modification of a clinical trial design using accumulated data
- Personalised Randomised Controlled Trial (PRACTical) design
  - Pragmatic eligibility criteria to enhance recruitment
  - Currently utilised in the NeoSEP1 study

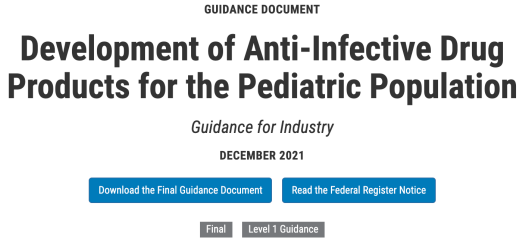



Regulatory vision

Streamline regulatory approval

Regulatory vision

- Promote adaptive trials
- Parallel enrolment (not sequential) should be utilised, to ensure neonates are not studied last
- Harmonise neonatal sepsis definitions and safety reporting
- Embed PK/safety cohorts into adaptive platform trials
- Enrol adolescents (≥12 years) in phase 3 adult trials
- Ensure representation (and prioritisation) of sites from high-burden, resource-constrained healthcare settings


GUIDANCE DOCUMENT

Development of Anti-Infective Drug Products for the Pediatric Population

Guidance for Industry

DECEMBER 2021

Download the Final Guidance Document | Read the Federal Register Notice

Final | Level 1 Guidance


Adaptive Designs for Clinical Trials of Drugs and Biologics

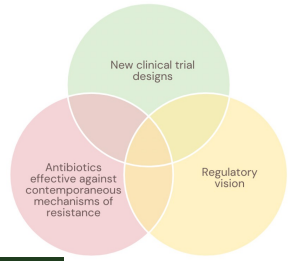
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2019
Biostatistics

In Summary

What do we need from clinical trials to bridge the diagnostic and management gap in neonatal sepsis?



What we Need	Why it matters
Affordable and accessible antibiotics effective against MDR gram-negative pathogens and their resistance mechanisms	-Current empirical therapy guidelines are built on data from high-income countries -The burden of neonatal sepsis is highest in LMICs. *Klebsiella* spp. dominate and are frequently multidrug-resistant.
Antibiotics with a good safety profile across all gestational and postnatal ages	Preterm neonates have immature renal/hepatic function: toxicity risk differs markedly from term infants and adults and needs evaluation for less common drug classes.
Predictable, well-characterised PK parameters in neonates with adequate CNS penetration	-Rapidly changing ADME: dosing cannot be extrapolated from adults or older children -Permeable blood-brain barrier means any agents licensed and recommended to treat neonatal sepsis need to have good BBB penetration
Antibiotics with Pragmatic Dosing Requirements	Neonates have difficult central access, and the burden is highest in resource-constrained healthcare settings. New guidelines should focus on agents with short infusion times, less frequent dosing requirements, and prolonged stability at ambient temperatures.
Accessible and affordable across all healthcare settings	Most neonatal sepsis deaths occur in LMICs. New antibiotics must reach district-level facilities in these settings, not just tertiary NICUs.

Questions?