Treatment of newborn sepsis is threatened

Effective antibiotics are essential for children's survival
Antibiotics vs antimicrobials

Antibiotics are a type of antimicrobial medicine alongside antivirals, antifungals and antiparasitic agents. Resistance development to all of these medicines is what is known as antimicrobial resistance, whereas resistance development in bacteria only is known as antibiotic resistance. Sometimes however, these terms are used interchangeably. This report focuses on antibiotic resistance, unless where specifically noted. However, many of the problems and potential solutions are shared between the two.

ReAct - Action on Antibiotic Resistance surveyed over 400 doctors that work with neonates globally between 29 July and 14 October 2020. The findings provide insight to the current perceptions and challenges doctors face when treating neonatal sepsis due to pathogens resistant to antibiotics, a growing threat to the world’s most vulnerable.

Founded in 2005, ReAct was one of the first international networks established to articulate the complex nature of antibiotic resistance and its drivers. ReAct works as a catalyst, advocating and stimulating global engagement on antibiotic resistance collaborating with a broad range of organizations, individuals and stakeholders. We are a multidisciplinary team, which includes microbiologists, physicians, pharmacists, communication experts and global health specialists. ReAct works across disciplines to identify and promote innovative and ecologically grounded solutions to contain antibiotic resistance that contribute to universal health coverage, poverty reduction and global development.

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Neonatal Sepsis Due to Resistant Pathogens

Sepsis, a condition caused by the body’s response to infections, is responsible for one in five deaths every year globally.1 Children under five years living in lower income countries, particularly neonates, or children just under one month old, are most affected. Every year, approximately four million newborns develop sepsis worldwide leading to 15% of all neonatal deaths, where the majority occur in low-income countries.1,2,3 Further complicating matters is the rise of severe infections caused by microbes that have developed resistance to life-saving antibiotics. This phenomenon is known as antimicrobial resistance and is leaving us with fewer effective antibiotics or treatment options for severe bacterial infections such as neonatal sepsis. In fact, up to 40% of neonatal sepsis cases are due to resistant pathogens.2

Sadly, an estimated 84% of neonatal sepsis cases are preventable.4 Newborns at risk for sepsis include those born with a very low birth weight, born prematurely, that need any type of medical intervention, or are born to mothers who may not have had proper or any antenatal care.5 Most of these factors, especially those that would prolong a neonate’s hospital stay, increase a newborns exposure to infections such as hospital acquired infections and pathogens resistant to antibiotics.5,6

This report presents the outcomes of a web-based survey conducted to understand the perception and experiences of physicians treating neonatal sepsis caused by antibiotic resistant bacteria - just one area of medicine threatened by resistance. The survey included questions pertaining to the awareness, availability of guidelines, general practice and potential challenges physicians face around neonatal sepsis and antimicrobial resistance. The report concludes with key recommendations based on these findings for countries, policy makers, hospital staff and patient advocates that could help improve health outcomes and survival rates for children all over the world.

Our survey received 411 responses from 74 countries of which 364 responses from 69 countries were from physicians that treat neonates and thus were eligible for analysis. Breakdown of respondents by region, country income level, hospital type and setting are as follows (for methodology, limitations and more details, see Annex):

• Region: 22% Africa, 19% Americas, 37% Eastern Mediterranean, 8% Europe, 8% South East Asia, 6% West Pacific;
• Country income: 16% High Income, 56% Upper Middle Income, 19% Lower Middle Income, 10% Low Income;
• Hospital type and setting: 80% Public Hospital, 20% Private Hospital; 63% Central, 25% District/Provincial, 12% Community.

Overall, 60% of respondents are very or even extremely worried about antimicrobial resistance as a threat to the effective treatment of neonatal sepsis. 79% of respondents have seen an increasing trend of multidrug resistant infections over the last five years, regardless of the region and income level of the health care facility where they work.

Actions to tackle antimicrobial resistance are necessary to, first and foremost, protect our most vulnerable. We must also act to ensure higher quality and more resilient health systems to realize our global commitments towards reaching the Sustainable Development Goals.
Foreword

I am pleased to welcome the findings of ReAct’s research that highlight the voices of physicians from all over the world who treat newborns and the challenges they face in trying to tackle infections due to resistant pathogens.

Newborns are some of the most defenseless victims of antimicrobial resistance. Since their immune systems are not fully developed, they are even more vulnerable to infections. More and more of these infections are due to bacteria resistant to the antibiotics we rely on to treat them.

In Ghana, infections such as neonatal sepsis are the leading cause of death of newborns. This is also the case for many sub-Saharan African countries and many infections are due to resistant pathogens. My colleagues and I have been warning of the rise of untreatable infections for a long time and we need to act now.

The need for antimicrobial stewardship programs, clean water, effective and affordable antibiotics cannot be stressed enough. But this report also highlights the importance of building lab capacity, having continuous education for hospital staff, raising awareness, the development and availability of new antibiotics and rapid diagnostics, the need for antimicrobial resistance stewardship programs, clean water, sanitation and strictly following infection prevention and control measures.

Coordinated efforts at the global, regional, national and community levels to mobilize experts, and organizations are necessary to build better systems and tackle antimicrobial resistance.

Dr. Martha Gyansa-Lutterodt
Director Technical Coordination,
Ministry of Health, Ghana

Multidrug-resistant bacteria are a looming global health issue that threatens the existence of modern medicine. This is particularly devastating to child health, an area that has seen improvements over the last 20 years. Alarming signs are evident with the increasing mortality of newborns, which are largely due to infectious diseases.

ReAct’s study voices the concerns from doctors globally who notice an increase in multi-drug resistant bacteria and believe that the biggest reason treatments fail newborns with sepsis is because of resistant pathogens.

Access to antibiotics and the development of new antibiotics are crucial to address antibiotic resistance, but findings from this study show that relying on the development of new antibiotics alone is not enough. Improving surveillance and lab capacity in hospitals and within countries and regions will also be necessary, as will raising awareness, education and behavior change. Diagnostics are key in determining which antibiotics to use and commencing the right treatment as quickly as possible increasing the chance of survival, but is also a key component to antimicrobial stewardship programs. Efforts in infection prevention and control must also be ramped up. In other words, we need to strengthen health systems and make them resilient.

A systems approach will require strong political commitment from national governments and a collaborative global effort to break down silos and focus on integrated approaches to build back stronger health systems that prioritize antimicrobial resistance and prevention efforts.

Stefan Swartling Peterson
Professor of Global Health
Senior Advisor UNICEF Sweden
1. Antimicrobial resistance is increasing

Findings from this survey show that in some low-income countries, physicians report that over 50% of the newborns they treat develop sepsis. Very troubling is also that in some parts of the world, respondents observe that over 75% of neonatal sepsis cases are due to resistant pathogens (see Annex Figure 1). With so many cases of severely sick newborns, it is not a surprise that 60% of the physicians responding to the survey are very or even extremely worried about resistance as a threat to the effective treatment of neonatal sepsis.

Resistant pathogens have been found all over the world in urban and rural areas in both high- and low-income countries and the number of antibiotics that no longer work for many of these pathogens is growing. This is reflected in the survey, where 79% of physicians report seeing an increasing trend of multidrug resistant infections over the last 5 years.

In this survey, the most common antibiotic resistant pathogens physicians encounter in treating neonatal sepsis are *Klebsiella pneumoniae*, *Escherichia coli* and *Staphylococcus aureus*, which corresponds with findings from recent research and reports. This is alarming as these bacteria are naturally found in healthy humans (and animals), but have now become a common source of hospital acquired infections. All three are on the World Health Organization’s (WHO) priority list of pathogens, a list of bacteria that poses the greatest threat to human health.

"Now, antimicrobial resistance is an increasing trend, so every doctor should know that it is a problem and how to solve this problem with limited facilities."

— Physician, Myanmar
Over half (54%) of surveyed physicians believe that infection due to a resistant pathogen is the top reason for treatment failure of neonatal sepsis. Additional reasons are lack of all hospital staff routinely following existing infection prevention and control protocols; lack of diagnostics to identify sepsis quickly; and lack of awareness of antimicrobial resistance among hospital staff.

Preventing the spread of infection by developing and following infection prevention and control measures is one of the best ways to prevent neonatal sepsis and tackle antimicrobial resistance. When hospital staff do not follow protocol to prevent infection it increases the chances of newborns contracting resistant pathogens that are more difficult to treat, which can lead to higher mortality. Access to clean water, hygiene and sanitation in communities and in hospitals will further prevent infections and the need for antibiotics. When hospital staff do not have regular access to clean water, hygiene and sanitation, they are not able to follow protocol adequately.

“To tackle antimicrobial resistance you need to ensure the availability of diagnostic laboratory support within the hospital and make it affordable and accessible to patients.”

- Physician, Kenya
regardless of how much knowledge, awareness and training they get. One of the best ways to improve the quality of care for newborns and all patients is to be aware of the signs and symptoms of these severe infections. Diagnosing and treating neonatal sepsis as early as possible is crucial in ensuring newborn survival. Therefore, the development and access of diagnostics, especially reliable, affordable and suitable rapid diagnostics, is critical.

National and hospital awareness campaigns, as well as continuous education and training for all health care providers is a first step to reducing the emergence of these severe bacterial infections due to resistant pathogens, and ensure staff have the abilities and attitudes to implement change.

72% of physicians in the survey believe they had enough information in their education to understand how resistance develops and spreads; yet only 28% state that they always consider antimicrobial resistance when treating patients.

This may indicate the need for national and hospital awareness campaigns, continuous education and training programs, and to evaluate the efficiency of existing campaigns and programs.

Recommendations

1. Enable, adapt, and implement infection, prevention and control protocols. Ensure guidelines are in place and followed by all staff.

2. Improve awareness of antimicrobial resistance and neonatal sepsis through national and hospital awareness campaigns.

3. Fast track the development and access of reliable, affordable rapid diagnostics.

“Continue educating health personnel, creating awareness of the importance of the issue, and develop protocols that work, know the epidemiology of each hospital, and there must also be a committed government.”

– Physician, Colombia
3. Antimicrobial stewardship programs are needed

Only 50% of physicians have neonatal sepsis treatment protocols that address antibiotic resistant bacteria.

Only half (50%) of respondents state having neonatal sepsis treatment protocols that address pathogens resistant to antibiotics. Even fewer (43%) state having an infection prevention and control component in these protocols.

Antimicrobial stewardship is the careful and responsible management of antimicrobials and should include infection prevention and control protocols. Antimicrobial stewardship aims to improve patient outcomes, save health care costs, and reduce antimicrobial resistance and health acquired infections\(^\text{10,11,12}\). Antimicrobial stewardship is a key component of an integrated approach to health systems strengthening.\(^\text{6,10}\)

“Every hospital center must have an antimicrobial stewardship program; a pharmacist should join the neonatal service together with a neonatal infectologist to make better use of antibiotics; to adjust rationally the doses of antibiotics.”

– Physician, Chile
A key component of antimicrobial stewardship for neonatal care, and for any antimicrobial stewardship program, is having an interdisciplinary team and promoting routine collaborative efforts among intensive care physicians, infectious disease specialists, nurses, pharmacists, hospital epidemiologists, bioinformatics specialists as well as senior management of the facility. Other key activities such as rational antibiotic use protocols concerning the duration and selection of antibiotics should be tailored to individual hospitals, and be based on hospital surveillance data.\textsuperscript{13,14} In this study, 67% of respondents state that regularly available resistance burden data/statistics in their facility would improve neonatal sepsis patient outcomes. However, not all of the respondents in our survey had lab facilities for cultures and sensitivity testing which determines if a pathogen is resistant to antibiotics. Only 41% of respondents conduct culture and sensitivity testing for every patient suspected to have neonatal sepsis. In our survey, not a single respondent from a high-income country stated not having lab facilities for culture or sensitivity testing, which was in stark contrast with responses from lower income countries.

When physicians do not have clear guidelines and hospital protocols, in our survey they report consulting with fellow physicians or searching the internet. This takes time and is much less reliable than clear protocols based on National Antimicrobial Stewardship guidelines that have been tailored to disease states and hospitals. Other sources of information include: Consult with clinical pharmacists, WHO guidelines, other guidebooks, peer reviewed journals, and information from pharmaceutical companies.

\textit{“We need more information on drug resistance patterns in Madagascar and the ability to do culture and sensitivity testing.”}

-Physician, Madagascar

**Recommendations**

1. Antimicrobial stewardship programs must be developed and implemented otherwise physicians treating newborns are left to find information on the internet, or hope to find a colleague to consult.

2. An interdisciplinary team is integral to antimicrobial stewardship programs and should be convened and meet regularly.

3. Lab services need to be made available to improve neonatal sepsis outcomes.
Upon suspecting a newborn has sepsis, quick initiation of antibiotic therapy is recommended. Reasons for antibiotic choice varied between respondents from countries of different income levels. Respondents from high-income countries did not mention cost as a reason for choosing an antibiotic and respondents from low-income countries, where the burden is highest, mentioned this as the top reason. However, respondents from all income levels are having to choose treatment options for newborns with sepsis on whether the antibiotic is available in their hospital. Over 20% of physicians in our survey believe that treatments fail in neonatal sepsis because of the lack of available effective first line antibiotics.

"We need the following: 1. Better provision of up-to-date treatment recommendation towards first line and second line antibiotics-of-choice to be used empirically where culture and sensitivity is not available; 2. Applying routine infection prevention and control (IPC) practices among hospital workers; and 3. Educating and enforcing the implementation of IPC practices among nursing mothers, attendants and mothers."

- Physician, Ethiopia
Overall, the top three reasons for antibiotic choice were the following: hospital treatment protocol (when available), availability of antibiotics at the hospital, and the cost.

The rise of antibiotic resistance means that more commonly used antibiotics will not work. Thus, more expensive antibiotics with potentially more side effects will need to be used to treat infectious diseases like neonatal sepsis, if they are even available. Further complicating the issue is that new antibiotics are not being developed fast enough. In addition, of new antibiotics being developed, just two are being studied in children.\(^3\)
5. Recommendations

Overuse of antibiotics is part of what drives antimicrobial resistance, yet we need antibiotics to treat neonatal sepsis and other infections. Using antibiotics is leading to resistant pathogens that are making neonatal sepsis even more life-threatening.

Furthermore, due to a lack of first line effective antibiotics, newborns with sepsis are not surviving and thriving. When the wrong antibiotics are given to treat sepsis, it makes the problem of resistance worse. It is a vicious circle, but one that can be managed with a multi-pronged approach.

Based on the responses by physicians from all over the world it is clear that antibiotic resistance is already posing a great challenge in their daily treatment of neonates with sepsis, and an increasingly difficult situation is identified.

The following actions can have an impact on antimicrobial resistance and neonatal sepsis:

1. Policy changes and strong commitments from governments
   Policy changes and strong commitments from governments will be crucial in tackling antimicrobial resistance, starting with resource mobilization and budgetary allocations to implement and monitor National Antimicrobial Resistance Action Plans.

2. Improving awareness of neonatal sepsis and antimicrobial resistance among hospital staff can save lives
   Improving awareness of neonatal sepsis and antimicrobial resistance among hospital staff can save lives. Awareness is the first step in changing behavior and alerts staff to the signs and symptoms of sepsis, of resistant pathogens and how to prevent and manage the issues. Continuous educational programs for physicians and all hospital staff is a step toward improving awareness.

3. Antimicrobial stewardship and Infection Prevention and Control
   The development, adaptation, availability and implementation of antimicrobial stewardship and IPC protocols are practical steps and actions that promote multidisciplinary teamwork to prevent and treat neonatal sepsis and help address antimicrobial resistance. It is not enough to have antimicrobial stewardship and treatment protocols in place. Staff at health facilities must have access to clean water, sanitation and soap and must follow the protocols.

4. Availability of effective existing and new antibiotics
   Availability of effective existing and new antibiotics, and other treatments will be key in tackling pathogens resistant to antibiotics.

5. Availability of diagnostics and improving lab capacity
   Improving lab capacity and diagnostics to identify sepsis quickly are necessary to ensure our most vulnerable survive and thrive.

“We need availability of national regulatory policy, periodic research and study to map the profile and extent of antimicrobial resistance in the nation, use the data for preparation of national guidelines and protocols, including IPC, training and orientation of health service providers within and outside the hospitals including in the private sector and awareness creation in the general public.”

- Physician, Sierra Leone.


Annex

Methodology

Informed by a literature review and with one round of input from clinical and global experts on neonatal sepsis and antimicrobial resistance, a survey questionnaire was developed with 30 questions and aimed to address the following: the awareness, availability of guidelines, general practice and potential challenges physicians face around neonatal sepsis and antimicrobial resistance. Convenience sampling methods were utilized among pediatricians, neonatologists, and pediatric intensivists (where prescriptions are part of their daily practice). Through emails, discussion boards and other social media handles of various associations (WSPID, WFPICCS, ESPID, WHO AMR community of practice board, IPAHL) and global experts, the links of the questionnaire were sent to prospective respondents. No incentives were agreed or given to the respondents/associations. Data was collected using the Survey Monkey web-based platform. The survey was available in English, Spanish and French and responses were collected between July 29th - October 15th, 2020. Data were tabulated and analyzed in Excel (Microsoft, Redmond, WA). The survey was voluntary and anonymous and clicking on the Survey Monkey link and initiating the survey process implied consent.

Limitations

Since this study utilized convenience sampling and was provided on-line, a response rate could not be calculated, therefore, response bias cannot be excluded. Furthermore, dissemination of the survey occurred during a global pandemic where health care professionals were stretched likely contributing to a small sample size limiting the generalizability of the results.
Demographics

*A comparison of survey result scenarios was conducted (sensitivity analysis) to determine if findings were affected due to the over-representation of responses from Iraq. Results were not significantly affected by comparing the omission or inclusion of Iraq data averaging a difference of five percentage points.

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Summary of Results

Q1 Do you think your education gave you enough information on how resistance develops and spreads?
- 71% of respondents believe they had enough AMR info in their education

Q2 Are you aware of any national AMR awareness campaigns in the country where you primarily work?
- 55% of respondents are aware of national AMR awareness campaigns

Q3 Is your hospital or institution involved in any AMR awareness campaign?
- 51% of respondents are aware of AMR awareness campaigns in their institution or hospital

Q4 Do you consider antimicrobial resistance (AMR) when treating a patient?
- 28% of respondents always consider AMR when treating a patient
- 28% of respondents always consider AMR when treating a patient

Q5 In terms of performing your job effectively, how big of a problem do you think neonatal sepsis is in your current practice?
- 1% of respondents state it is not a problem with 0% of neonates developing sepsis
- 8% of respondents state 1-9% of neonates develop sepsis
- 30% of respondents state 10-19% of neonates develop sepsis
- 21% of respondents state 20-34% of neonates develop sepsis
- 14% of respondents state 35-9% of neonates develop sepsis
- 15% of respondents state it is a big problem

Q6 In terms of performing your job effectively, when considering all of the neonatal sepsis cases you encounter, how big of a problem do you think resistant pathogens are in your practice?
- 5% of respondents state it is not a problem with 0% of neonatal sepsis cases due to resistant pathogens
- 84% of respondents state 1-24% of neonatal sepsis cases are due to resistant pathogens
- 27% of respondents state 25-49% of neonatal sepsis cases are due to resistant pathogens
- 10% of respondents state 50-74% of neonatal sepsis cases are due to resistant pathogens
- 4% of respondents state it is a big problem with over 75% of all neonatal sepsis cases due to resistant pathogens

Q7 How worried are you about antibiotic resistance as a threat to the effective treatment of neonatal sepsis?
- 60% of respondents are very to extremely worried

Q8 Have you seen an increasing trend of multidrug resistant infections over the last 5 years?
- 79% of respondents have seen an increasing trend

Q9 What do you think are the biggest reasons for treatment failures in neonatal sepsis in your setting (may choose all that apply)?
- 54% - Resistant pathogens
- 47% - Lack of all hospital staff routinely following Infection Prevention and Control (IPC) protocols
- 42% - Lack of diagnostics to identify sepsis quickly
- 41% - Lack of awareness of antimicrobial resistance among hospital staff
- 39% - Patient presented for care late
- 37% - Lack of treatment protocols or stewardship
- 35% - Lack of Infection Prevention and Control (IPC) protocols
- 26% - Lack of awareness of signs of neonatal sepsis among hospital staff
- 24% - Lack of well-trained health personnel
- 21% - Lack of effective antibiotics
- 19% - Lack of supportive treatment medications
- 11% - Lack of first choice antibiotics

Q10 Does the hospital where you work have treatment protocols or guidelines for pathogens resistant to antibiotics?
- 60% of respondents state having hospital treatment protocols addressing pathogens resistant to antibiotics

Q11 Does the hospital where you work have treatment protocols or guidelines for pathogens resistant to antibiotics in neonatal sepsis?
- 50% of respondents state having neonatal sepsis treatment protocols addressing pathogens resistant to antibiotics

Q12 If Yes, do the guidelines differ between late or early onset neonatal sepsis?
- 49% of respondents state guidelines differ between late and early onset neonatal sepsis

Q13 Does the hospital where you work have infection prevention and control (IPC) guidelines related to neonatal care?
- 43% of respondents state the hospital where they work have IPC guidelines related to neonatal care

Q14 If you answered Yes to any of the above questions 10-13 regarding hospital guidelines, do you have access to them?
- Of those who stated yes, 70% of respondents who answered yes to questions 10 - 13 have access to the guidelines

Q15 If Yes, how confident are you in the antibiotic guidelines available?
- 10% of respondents are extremely confident
- 37% of respondents are very confident

Q16 Where do you go to consult for treatment for difficult neonatal sepsis cases (may choose all that apply)?
- 69% - Consult with fellow doctors
- 42% - Internet search
- 39% - Peer Reviewed Journals
- 37% - Hospital protocols/guidelines
- 35% - WHO Neonatal Sepsis guidelines
- 30% - Other guidebooks
- 25% - Consult with clinical pharmacists
- 9% - Other: textbooks, microbiologists, infectious disease specialists (national or consultants)
- 6% - Information from pharmaceutical companies
- 0.6% - Nowhere

Q17 Do you know of any immediate plans to develop AMR stewardship guidelines at your practice? If so, when?
- 21% of respondents know of plans to develop AMR stewardship guidelines at their practice
- These respondents state plans are currently being developed or will be completed by the end of 2021

Q18 How common is it to have culture and sensitivity test done on patients with neonatal sepsis?
- 41% - For every patient
- 27% - Before antibiotic treatment
- 22% - Only for cases of prolonged or of repeated infection
- 11% - No lab facilities for culture and sensitivity testing exist at my facility

Q19 Would regularly available antimicrobial resistance data/statistics regarding the burden within your facility improve neonatal sepsis patient outcomes in your facility?
- 67% of respondents state regularly available AMR burden data/statistics in their facility would improve neonatal sepsis patient outcomes

Q20 Which type of drug-resistant bacterial pathogens do you see most commonly in your neonatal sepsis patients (choose no more than three)?
- 43% - K. pneumoniae
- 39% - E. coli
- 37% - S. aureus

Q21 How confident are you in making antibiotic prescribing decisions?
- 10% of respondents are extremely confident
- 46% of respondents are very confident

Q22 What affects your choice of antibiotic in suspected neonatal sepsis cases (may choose all that apply)?
- 62% - Hospital treatment protocol
- 53% - Availability of antibiotics at the hospital
- 29% - The cost
- 25% - The WHO Guidelines or Essential Medicines List
- 23% - Hospital medicines formulary
- 22% - The National Essential Medicines List
- 12% - Whether a generic medicine is available
- 4% - Request from the patient’s family

Q23 Which of the following options would have an impact on the situation of antimicrobial resistance in your practice? (may choose all that apply)

RANKING 1: Most important to 10: Least important.
1. Improved awareness of neonatal sepsis among hospital staff
2. Improved awareness of antimicrobial resistance among hospital staff
3. Availability of treatment protocols or stewardship
4. Availability of Infection Prevention and Control (IPC) protocols
5. Routinely following existing Infection Prevention and Control (IPC) protocols
6. Availability of diagnostics to identify sepsis quickly
7. Availability of antibiotics
8. Availability of supportive treatment medications
9. Ongoing physicians’ educational programs
10. Policy changes from the Ministry of Health
Percentage of Cases of Neonatal Sepsis and Neonatal Sepsis Resistant Pathogens - Survey Responses
A world free from untreatable infections