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NeoSep1 Clinical Trial Expands to India to Combat Drug-Resistant Neonatal Sepsis and Rising Antimicrobial Resistance

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Recent Developments:

- The **NeoSep1 Clinical Trial**, funded by the **Global Antibiotic Research and Development Partnership (GARDP)** Foundation, has expanded to India to evaluate improved antibiotic treatment strategies for **drug-resistant neonatal sepsis**.
- The trial aims to generate evidence for treating newborn sepsis caused by multidrug-resistant bacteria, particularly in **low- and middle-income countries**, where resistance patterns differ significantly from high-income nations.

NeoSep1 Clinical Trial:

About the Trial:

- **NeoSep1** is the world's first large international clinical trial specifically designed to identify effective antibiotic regimens for **hospitalised newborns with sepsis**.
- The trial focuses on treating infections caused by **multidrug-resistant pathogens**, which are increasingly reducing the effectiveness of standard antibiotic therapies.
- The study is coordinated under the **Global Antibiotic Research and Development Partnership (GARDP)** in collaboration with international research institutions and participating hospitals.

Significance for India:

- India carries one of the world's highest burdens of **neonatal sepsis**, making the trial highly relevant for improving neonatal survival.
- The bacterial profile responsible for newborn sepsis in India differs from that observed in many developed countries, requiring locally appropriate treatment strategies.
- The trial is expected to generate evidence-based treatment protocols that can strengthen neonatal healthcare and reduce mortality associated with antimicrobial resistance.

Neonatal Sepsis:

Meaning:

- **Neonatal Sepsis** is a life-threatening bloodstream infection occurring in infants below **90 days** of age.
- Premature babies and infants with **low birth weight** are at significantly higher risk because of their immature immune systems.

Types:

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Plot A P.127, AF block, 6 th street, 11th Main Rd, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu 600040

Phone: **044 4353 9988 / 98403 94477 / Whatsapp : 09710729833**

- **Early-Onset Neonatal Sepsis (EONS):** Develops within the first **72 hours** after birth and is commonly associated with maternal infections transmitted during delivery.
- **Late-Onset Neonatal Sepsis (LONS):** Occurs between **72 hours and 28–90 days** after birth and is generally linked to hospital-acquired or community-acquired infections.

Major Causative Organisms in India:

- Unlike many developed countries where **Group B Streptococcus** is a leading cause, neonatal sepsis in India is predominantly caused by **drug-resistant Gram-negative bacteria**.
- Important pathogens include:
 - **Klebsiella pneumoniae**.
 - **Escherichia coli**.
 - **Acinetobacter** species.
 - **Pseudomonas aeruginosa**.

Clinical Features:

- Common symptoms include **fever, rapid breathing, fast heart rate, poor feeding, lethargy, confusion, and body pain**.
- Untreated infection may progress to **septic shock, multiple organ dysfunction**, and death.

Disease Burden in India:

- Neonatal sepsis contributes to nearly **30–40%** of neonatal deaths in India.
- An estimated **2–2.5 lakh** neonatal deaths each year are considered preventable through timely diagnosis and effective treatment.

Prevention:

- Maintaining **hand hygiene, infection prevention measures, clean water, safe sanitation, safe childbirth practices, vaccination, exclusive breastfeeding**, and **adequate maternal nutrition** significantly reduce the risk of neonatal infections.

Antimicrobial Resistance (AMR):

Meaning:

- **Antimicrobial Resistance (AMR)** refers to the ability of microorganisms to survive exposure to antimicrobial medicines that previously killed or inhibited them.
- The phenomenon affects **bacteria, viruses, fungi**, and **parasites**, reducing the effectiveness of antibiotics, antivirals, antifungals, and antiparasitic medicines.

Mechanism:

- Microorganisms develop resistance through **genetic mutations** and **natural selection**, particularly when antimicrobial medicines are misused or overused.
- Resistant microbes multiply and spread, making infections increasingly difficult to treat.

Consequences:

- Increased treatment failure.
- Higher disease transmission.
- Longer hospitalisation.
- Greater healthcare expenditure.

- Increased disability and mortality.
- Rising risk of untreatable multidrug-resistant infections.

Global Concern:

- The **World Health Organization (WHO)** recognises **Antimicrobial Resistance** as one of the top global public health threats of the **21st century**.
- Without effective interventions, antimicrobial resistance could become a major obstacle to modern medicine, affecting surgery, cancer treatment, organ transplantation, and neonatal care.

Factors Responsible for Rising Antimicrobial Resistance in India:

Excessive and Irrational Antibiotic Use:

- Over-prescription, self-medication, and irrational use of antibiotics accelerate the emergence of resistant microorganisms.

Poor Infection Prevention and Hygiene:

- Inadequate sanitation and weak infection-control practices in healthcare facilities facilitate the spread of resistant pathogens.

Inadequate Diagnostic Capacity:

- Antibiotics are frequently prescribed without laboratory confirmation, increasing unnecessary antimicrobial exposure.

Pharmaceutical Waste:

- Improper disposal of antibiotic manufacturing waste contaminates the environment and promotes the evolution of resistant bacteria.

Unregulated Use in Livestock:

- Antibiotics are widely used in **animal husbandry**, **dairy farming**, and **poultry production**, contributing to resistance across human and animal populations.

High Population Density and Mass Gatherings:

- Large religious gatherings, political events, and crowded social functions create conditions favourable for rapid transmission of infectious diseases.

Weak Public Awareness:

- Limited awareness regarding appropriate antibiotic use and incomplete treatment courses further accelerates antimicrobial resistance.

Government Initiatives to Combat Antimicrobial Resistance:

National Programme on AMR Containment:

- Launched during the **12th Five-Year Plan (2012–2017)** to strengthen national surveillance and containment efforts.
- The programme focuses on:
- Establishing laboratory-based **AMR surveillance**.

- Monitoring antimicrobial consumption.
- Promoting antimicrobial stewardship.
- Strengthening infection prevention and control measures.

Red Line Campaign:

- Prescription-only antibiotics are marked with a **red line** to discourage indiscriminate use and self-medication.

National Action Plan on AMR (2017):

- India became one of the earliest countries to adopt a comprehensive **National Action Plan on Antimicrobial Resistance**.
- The plan follows the **One Health Approach** involving coordinated action across human health, veterinary health, agriculture, food safety, and environmental sectors.

AMR Surveillance and Research Network (AMRSN):

- Established by the **Indian Council of Medical Research (ICMR)** in **2013**.
- The network monitors resistance trends, generates scientific evidence, and supports national policy formulation.

Research and International Collaboration:

- **ICMR** collaborates with national and international institutions for developing new antibiotics, improving diagnostics, and strengthening antimicrobial research.

National Centre for Disease Control (NCDC):

- The **National Centre for Disease Control** coordinates national surveillance, laboratory capacity building, and infection prevention programmes related to antimicrobial resistance.

Challenges in Combating AMR:

Limited Laboratory Infrastructure:

- Uneven diagnostic capacity delays accurate identification of resistant pathogens.

Implementation Gaps:

- Resource constraints affect effective implementation of the **National Action Plan on AMR**, particularly at State and district levels.

Shortage of New Antibiotics:

- Development of novel antimicrobial drugs remains limited because of high research costs and relatively low commercial returns.

Environmental Transmission:

- Antibiotic residues released into soil and water contribute to the environmental spread of antimicrobial resistance.

Way Forward:

Regulating Antibiotic Use:

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- Antibiotic use should be strictly regulated across human healthcare, veterinary medicine, agriculture, and food production.

Strengthening Diagnostic Capacity:

- Rapid and affordable diagnostic facilities should be expanded to ensure evidence-based antibiotic prescribing.

Improving Infection Prevention:

- Better sanitation, vaccination, hand hygiene, hospital infection-control practices, and clean water supply should be prioritised.

Promoting Rational Antibiotic Use:

- Doctors should prescribe antibiotics only when clinically indicated, while citizens should avoid self-medication and complete prescribed treatment courses.

Strengthening National Action Plan:

- Adequate financial resources, inter-ministerial coordination, and continuous monitoring should improve implementation of the **National Action Plan on AMR**.

Adopting the One Health Approach:

- Integrated action involving **human health, animal health, agriculture**, and the **environment** is essential because antimicrobial resistance transcends sectoral boundaries.

Value Addition for UPSC:

One Health Approach:

- The **One Health Approach** recognises that the health of humans, animals, plants, and ecosystems is interconnected and requires coordinated policy interventions.

WHO AWaRe Classification of Antibiotics:

- The **World Health Organization (WHO)** classifies antibiotics into **Access, Watch**, and **Reserve** categories to promote rational prescribing and reduce antimicrobial resistance.

WHO Priority Pathogens List:

- The **World Health Organization** periodically identifies priority antibiotic-resistant bacteria requiring urgent research and development of new antimicrobial medicines.

Sustainable Development Goal Linkages:

- **SDG 3:** Good Health and Well-being.
- **SDG 6:** Clean Water and Sanitation.
- **SDG 2:** Zero Hunger through safer livestock and food production systems