The Lancet Child & Adolescent Health Commission on the future of neonatology

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Care for newborn infants is in crisis: poor and missing research is one cause of this crisis

- 127 million babies are born each year; at least 10% of them need neonatal care
- Mortality is high and lifelong morbidity is common
- Barriers to research are experienced by / from:
  - Clinicians
  - Research Ethics Committees
  - Regulators
  - Industry
- The Lancet Child & Adolescent Health Commission on the future of neonatology considered these challenges and made some recommendations.
- We value the chance to discuss some of these recommendations

Lifelong Impact

Condition	Impact
Gestational diabetes	congenital anomalies, stillbirth, neonatal respiratory failure, and prematurity
People born preterm	high risk of early death and morbidities in adulthood, such as cardiovascular, respiratory, metabolic, renal, neurological, and psychiatric disorders
Transient tachypnoea of the neonate—the mildest of neonatal respiratory disorders burden of care and is	associated with recurrent wheezing, asthma, exercise intolerance, and the early development of chronic obstructive pulmonary disease later in life.
Bronchopulmonary dysplasia	can affect growth, respiratory, and general health across the whole lifespan.
Congenital disorders, such as congenital diaphragmatic hernia, often have relevant mortality	major long-term neurological, gastrointestinal, and respiratory problems.

Barriers arising from institutional review boards, ethics committees, and regulatory agencies

+ Excessive bureaucracy
+ Discrepancies between authorities
+ Privacy issues preventing data collection and sharing
+ Use of generic pharmacological criteria for medical device technologies

+ Uninformed considerations of neonatal clinical reality and lack of neonatologist expertise
+ Rigidity in neonatal research and clinical processes, originally designed for adult medicine
+ Insufficient support for industry
+ Perception of research and development projects for newborn health as unimportant

REC Recommendation 2: improve communication between research ethics committees and regulatory agencies

+ More crosstalk between regulatory agencies and research ethics committees and more active listening to the perspectives of neonatologists and families is required.
+ For example, when a trial is approved by a given agency, that approval should be automatically considered valid by ethics committees and regulatory agencies if sufficient commonalities exist, or at least used to facilitate and shorten the approval process.

REC Recommendation 3: develop flexible consent approaches for neonatal research

+ Approaching parents or guardians when they are under psychological stress, in pain, or under the effects of strong medications might be ethically unacceptable.
+ The Declaration of Helsinki outlines the specific circumstances in which study enrolment can proceed even if no legally authorised representative is available and the research cannot be delayed.
    - x specific reasons for involving participants with a condition that renders them unable to give informed consent have been stated in the research protocol;
    - x the research has been approved by a research ethics committee;
    - x third, free and informed consent to remain in the research will be obtained as soon as possible from a legally authorised representative.

REC Recommendation 4: focus on optimising outcomes and patients' best interests

+ Ethics boards and regulatory agencies must weigh the risks associated with a new intervention against the risks of maintaining the status quo.
+ Experiences across neonatology show how over-caution can be detrimental to newborn health.
+ [Avoid the] unfair and unhelpful view that treating a disease using existing drug and device technology is more ethical than testing new solutions under rigorous, closely monitored research pathways.

Industry Recommendation 3: simplify internal compliance procedures and avoid barriers to neonatal research and development

- The Industry must quickly and radically revise and simplify internal legal and compliance policies, seeking advice from key opinion leaders in neonatology.
- Industry policies tend to be risk averse and extremely precautionary, with barriers added to those of ethical boards and regulatory agencies, which do not serve the interests of patients or industry.
- This recommendation aligns with our recommendation to ethical bodies and regulatory agencies—that compliance procedures should consider the interests of industry, patients, and society more broadly, rather than only focus on unknown or theoretical risks.

Industry Recommendation 2: establish novel funding models and collaborate with other funders

+ The burden of this should not be exclusively on industry; industrial–academic collaborations are pivotal and require early and regular communication.
+ When the allocated funds from industry and the academic institution are not sufficient to develop a new intervention, alternative funding sources can come from private–public partnerships, collaborations with philanthropic groups, crowdfunding platforms, and charities.

A global alliance for improved neonatal health

+ “Global leadership is required to coordinate the actions outlined in this Commission and to oversee progress. We therefore propose a mission-oriented Global Alliance for Innovation in Newborn Health (GAINH) to tackle barriers to advancing improved newborn health through high-impact research and innovation.”

The Global Alliance for Innovation in Newborn Health

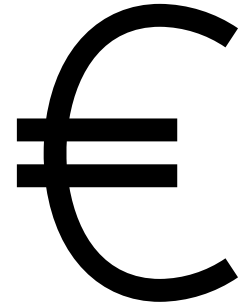
A recommendation of the Lancet Commission on the Future of Neonatology 2025

Global advocacy

To drive the adoption of national policies and the allocation of funding that prioritises infant health

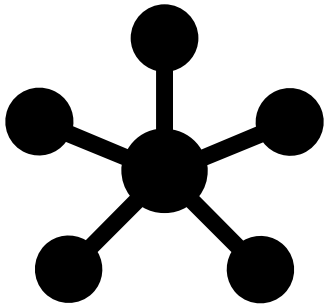
Global financing facility

To create a predictable market for industry



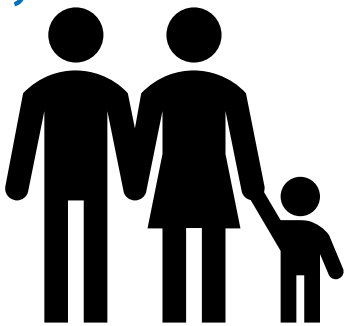
International Neonatal Research Consortium

A global network of neonatal translational research centres able to deliver efficient, cost-effective, state-of-the-art studies to common protocols with strong data infrastructure and inter-operability

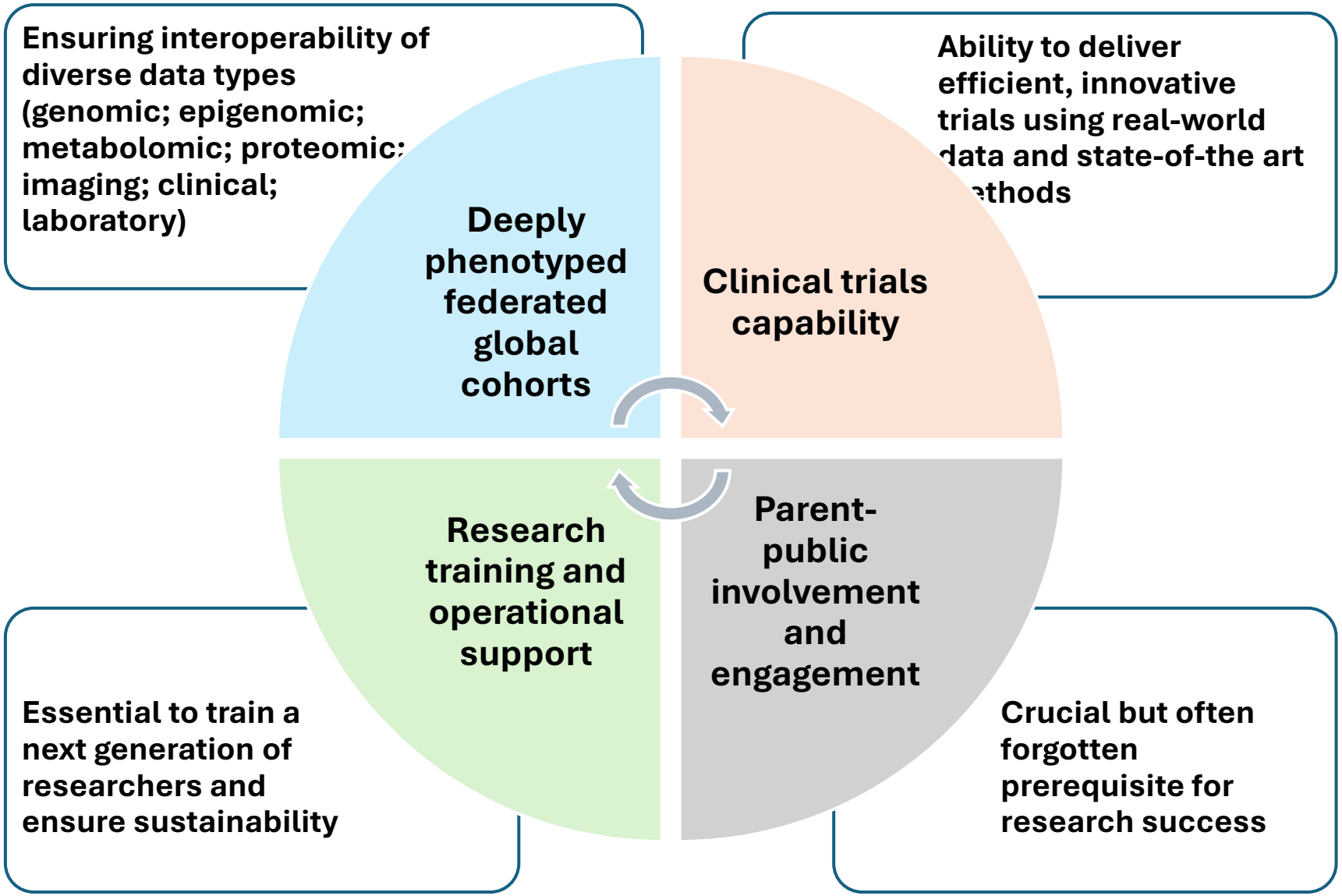


Global engagement, involvement, and empowerment of parents, patients, and families

To ensure research meets patient needs and is feasible and acceptable



The proposed International Neonatal Research Consortium



International Neonatal Research Consortium

- Funding is needed to create a “Central Coordinating Centre”
- Each individual initial site needs its own in-country funding (which is their responsibility and a pre-requisite for participation).
- Three initial tentative centres have been identified

Who can contribute and how?

- ACT-EU
- European funding
  - IHI
  - Other
- ERNs
- Learned Societies

Neonates and ERNs

ERN	Guard-HEART	ERN-LUNG	ERN-RND	ERNICA	ERN-EpiCARE
Condition	PDA	BPD/CLD	IVH/PVL/HIE	NEC	Neonatal seizures
Activity	No activity. Is PDA a rare disease?	No response	No activity	Outcome set for NEC	No response

Discussion

+ Neonatal research suffers from general and specific barriers
+ A global approach is under development
+ How can we promote the success of GAINH and INRC?