

Research Strategy Update (November 2023)

Our strategic focus

In 2022, The Lullaby Trust Board of Trustees agreed the charity's 5-year strategy update (2022-2026) and reaffirmed the central role of research in our mission. The overall strategy defines four objectives:

- A reduction in the proportion of families who experience the death of their baby or young child
- An increase in families and professionals accessing our life-saving advice and understanding their individual risks
- A rise in the number of bereaved families supported with specialist bereavement services
- Co-operation with partner organisations and services to address the risks that impact child mortality

The research strategy builds on our successful record over 50 years of funding and commissioning research, and translating research into policy and practice. Its purpose is to set out the future direction of research for the charity and outline how we will support research from January 2022 to 2026.

The research strategy was developed by the Scientific Committee (now the Grants Committee) of The Lullaby Trust and approved by the Board of Trustees. The research strategy informs our supporters on how we will invest their generous donations in research, and forms the framework for our future decision making when awarding research funding.

Our Terminology

SUDI/SUDC – (sudden unexpected death in infancy/childhood) All cases in which there is a death (or collapse leading to a death) of a child, which would not have been reasonably expected to occur 24 hours previously and in whom no pre-existing medical cause of death is apparent. This is a descriptive term used at the point of presentation and will include those deaths for which a cause is ultimately found (explained SUDI/SUDC) and those that remain unexplained following investigation (unexplained SUDI/SUDC). Unexplained cases include those where there is no clear cause of death and there are no features to suggest unnatural death or inflicted injury, but in which the

circumstances do not fit the criteria for SIDS (for example deaths in which the history, scene or circumstances suggest a high likelihood of asphyxia but in which positive evidence of accidental asphyxia is lacking).

SIDS – (sudden infant death syndrome) The sudden and unexpected death of an infant under

12 months of age, with onset of the lethal episode apparently occurring during normal sleep, which remains unexplained after a thorough investigation including performance of a complete post-mortem examination and review of the circumstances of death and the clinical history.

Unascertained - This is a legal term often used by coroners, pathologists and others involved with death investigation, where the medical cause of death has not been determined to the appropriate legal standard, which is usually the balance of probabilities.

The Lullaby Trust is entirely dependent on voluntary income to meet our charitable objectives. We do not receive any statutory income. As well as funding research, we run support services for bereaved families and provide universal public health education on reducing the risk of SIDS to parents and professionals in England and Wales.

Many parents who have lost a baby suddenly and unexpectedly are committed to raising funds for The Lullaby Trust, specifically for supporting research. Money raised for this purpose is restricted and separately accounted.

We are primarily a response-mode funder, encouraging the research community to identify the specific knowledge needed to advance our understanding of sudden infant deaths, and generate the research proposals needed to generate that knowledge. We may operate themed calls on particular topics if the Grants Committee identifies a key area in which we would like to generate proposals, or if we receive donations designated for specific issues.

We are keen to collaborate with other funders to support research areas of joint interest.

The Gaps project

Although great strides have been made in SUDI and SIDS research leading to ground breaking interventions, such as the Back to Sleep campaigns that saved the lives of many babies in the UK and throughout the world, the previous dramatic decline in numbers of deaths has slowed in recent years and the cause(s) of these deaths remains elusive.

In 2013, the Scientific Committee of The Lullaby Trust agreed a new research strategy was needed to help us to refocus the scientific research efforts in which we invest. To implement this process the Committee commissioned Dr Alexis Willett, an independent scientific policy consultant, to help us map the current research landscape, and identify important priorities. The International Society for the Prevention of Perinatal and Infant Death (ISPID) became interested in this work and it was decided to join forces with ISPID, SIDS and Kids (Australia) and the American SIDS Institute to undertake a full-scale research exercise. This became known as the GAPS project.

The Lullaby Trust invited experts, those with personal experience of bereavement, researchers and other professionals, to establish a consensus on where future research efforts should be focused. Using a normative group process developed by the James Lind Alliance, we collected on-line suggestions from colleagues based in over 20 countries on key areas for research. These suggestions were refined into 41 statements and verified by literature review. Respondents then rated these statements on a Likert scale. The 30 statements receiving the highest scores were taken forward to a series of workshops in the UK, US and Australia where mixed groups of professional and bereaved participants prioritised the suggestions to reach a mutually agreed list of 10 priorities. Participants in each country agreed their own priorities, and these were also aggregated across the three workshops to produce a combined priorities list.

While many shared priorities emerged between the three country workshops, a notable difference between the UK and US and Australia was that death scene investigation and systematic collection of data was viewed as a less strong priority in the UK. This reflects the fact that the investigation of SUDI and SIDS deaths and collection of data in UK is more standardised than in other parts of the world and subject to long standing multi-agency protocols developed by Baroness Kennedy in her report on child deaths, published by the Royal College of Pathologists and Royal College of Paediatrics and Child Health (2004).

As a result of GAPS, The Lullaby Trust identified a clear focus for our future research priorities. This priority setting exercise has confirmed that we should continue to fund and support a range of scientific approaches and disciplines. We were particularly

pleased that the GAPS priorities represent the first significant attempt to set a research agenda in the area of infant mortality that draws on the views of bereaved families as well as researchers and professionals.

Participants at our London workshop in December 2015 reached consensus on the ten most important research priorities for unexplained infant deaths in the UK.

Top 10 research priorities for the UK: (Priorities marked with * are pertinent for '2023 Expression of Interest' Applications)

1. Develop new ways to make safe sleep campaigns more effective.*

Traditionally, safe sleep information has been delivered to parents via leaflets handed out by health professionals. Unexplained infant deaths now predominantly occur in groups that are hard to reach with this method. We need to understand what approaches are effective in engaging this target group, and how to support them in implementing safe sleep information.

2. Study mechanisms that cause a baby to collapse and die and how they interact with environmental risk factors.

We know sleeping supine protects babies from SIDS but we don't know why, in the past, most babies who slept prone throughout infancy survived while others died on the first occasion they were placed to sleep on their front. Why are some babies unable to mount a normal defensive response to airway covering, or over-wrapping? How do the mechanisms that normally protect babies develop, and what makes them go awry?

3. Enable data from SUDI and non-SUDI deaths to be more systematically collected and shared, to allow better case control studies.

There is currently no central repository or database of infant/child deaths in the UK to facilitate epidemiological research, and therefore no systematic recording of crucial details collected about a particular death. Methods for standardizing and pooling such information are urgently needed.

Note: This priority has been taken forward by the National Child Mortality Database since 2017.

4. Identify specific biomarkers to assist pathologists in determining the cause of death.

One reason that sudden infant deaths can remain unexplained following post-mortem is because specific tools for identifying some causes of death (e.g. uncommon infections, metabolic errors) are not available or are not sufficiently sensitive for babies. In other cases, these tests might exist but are not routinely applied. Research is needed to identify which tests are most helpful and reliable.

5. Understand to what extent social and cultural factors affect parental choice in sleep practices and responses to risk reduction campaigns.*

Our population encompasses people bringing infant care behaviours and beliefs to the UK from around the world. Some of these families are unfamiliar with SIDS, and have come from environments where protecting babies from other causes of death (e.g. infections) is prioritized. How can we help them understand the risks to their babies in a UK setting, while respecting their cultural values and approaches to infant-care? And how can we better understand socio-economic factors affecting sleep safety in the UK?

6. Investigate how parental smoking (including vaping and NRTs) before and after birth affects risk for SUDI.

Pre- and post-natal exposure to cigarette smoke is the most common factor currently associated with SIDS (following the decline in prone sleeping) but the key component of smoking (e.g. exposure to nicotine, carbon monoxide, tar) and the mechanism associated with infant deaths (e.g. via brain stem development, respiration etc) remain unclear. Without this information we cannot ascertain whether nicotine replacement tools (e.g. patches, vaping) are a safer alternative to use in pregnancy.

7. Understand the role of genetic factors in SUDI risk.

Bereaved families need to know whether SIDS has a genetic component and whether their children or grandchildren may be at increased risk following an unexplained infant death in the family. Genetic studies require huge datasets of DNA on SIDS cases and their families, which are beyond our ability to fund, so we aim to support this research priority by promoting an encouraging the involvement of UK families in large international trials.

8. Identify what factors are associated with SUDI where all aspects of recommended risk reduction have been followed.

This is a priority for bereaved families who, in the absence of known risk factors, lack even a hint of an explanation for their baby's death. Continued examination

of factors associated with unexpected deaths in the absence of known risks may reveal new information, but as such deaths are nowadays very rare, new methods for addressing this question will also be needed.

9. Better understand the risk of sharing any sleep surface with an infant, notably how it interacts with other factors to make it more or less risky.*

Sharing a sleep surface with a baby (bed-sharing/co-sleeping) is a strategy that parents use for coping with night-time infant care. For some babies it can be extremely hazardous, while for others the increased risk is very small. Better understanding of the factors that makes sleep-sharing more or less hazardous will help us to tailor safe sleep information for parents while supporting their infant care choices.

10. Refine how we get messages through to health professionals so that they act appropriately to reduce risk of SUDI.*

Health professionals, and others who work directly with families, are on the front line of delivering new information about infant sleep safety, unexplained deaths, and risk factors – to do so they need to be informed of new guidance, research and explanations. We need to understand how to effectively train, support and empower front-line staff to converse with parents on these topics and offer them tailored information.

Additionally, a new priority has been added by The Lullaby Trust as a result of more recent research and the information gained from the National Child Mortality Database.

11. Understanding differences in sudden infant mortality rates among different ethnicities.*

There is ethnic disparity in the risk of sudden unexpected infant death in England and Wales, therefore further research needs to be done to understand why some ethnicities are at increased risk, whilst others have a lower incidence of SIDS.

Research Strategy 2022-2026

This research strategy will guide how funding is invested in future research.

The objectives of our research strategy are to:

- **Contribute to the discovery of how and why babies die suddenly and unexpectedly**
- **Understand how to effectively minimise the chances of sudden and unexpected infant death**
- **Develop and evaluate effective ways of conveying this information to parents from all socio-economic and cultural backgrounds with an emphasis on those whose babies are at the greatest risk**

In pursuit of these objectives we recognise the need to grow new research talent, to engage bereaved and non-bereaved parents in our research, and to encourage experienced researchers with appropriate expertise to turn their attention to our priority areas. We are therefore keen to support excellent research by new and experienced investigators with interests and expertise in a broad range of research areas (such as pathology, physiology, community health, health education, parenting and behaviour change) in growing research opportunities, in promoting research engagement, and in sharing our research findings.

Investing in people

We are keen to attract new talent and fresh ideas to help us reduce infant deaths in the UK. We also wish to help existing SIDS researchers to remain actively engaged in working on our key priorities.

We will:

- a) Support equality, diversity and inclusion in research, as defined by the Association of Medical Research Charities, by prioritising funding to academics in Departments and Institutions with an Athena Swan or Gender Equality Charter Mark or relevant confirmation of upholding equality, diversity and inclusion principles in non-academic organisations.

- b) Encourage inter-disciplinary collaboration between existing UK SIDS researchers and experts in other domains of health promotion and behaviour change research to foster the exchange of ideas and the development of novel interventions.

Promoting research engagement

We acknowledge the important role bereaved families play in our research and seek to ensure they are involved and engaged in all levels of research activity.

We will:

- a) Encourage bereaved parents who are part of our support network to volunteer to participate in projects where the insights from their particular experiences and view-points are crucial.
- b) Establish a network of parents (bereaved and non-bereaved), interested in supporting research into safe infant sleep and infant death reduction, to participate in project consultations, advisory boards and steering committees that researchers may call on when devising new interventions, seeking parents' opinions on new research proposals, or ensuring parents are represented on project management committees.
- c) Support researchers in efforts to engage parents in the highest-risk groups in their research by providing financial incentives, access to gate-keepers, and mentoring from experienced researchers and engagement staff.

Sharing our research findings

We value opportunities to share the results and implications of the research we have funded and supported with other researchers both nationally and internationally, with health professionals and others who work directly with parents, and with parents themselves.

We will:

- a) Encourage and support the researchers we fund to actively participate at relevant international conferences and engage with international academic research organisations, such as ISPID.

- b) Expect the researchers we fund to present their findings in person to The Lullaby Trust's Grants Committee.
- c) Work with researchers to widely disseminate their findings through our social networking and media channels, ensuring that all information is presented in an accessible way, using clear language and infographics.
- d) Incorporate significant research findings into our evidence-based information for health professionals, and guidance to parents, where appropriate.
- e) Communicate research findings, and those of other researchers to parents, professionals and other stakeholders via key pages on our website, training sessions and study days for health professionals and informational talks for parents.

This research strategy will be monitored and reviewed by the Grants Committee every two years.

November 2023