

Research Strategy 2017-2027

Our strategic focus

In 2014 the Lullaby Trust Board of Trustees agreed the charity's 5-year strategy (2015-2020) and reaffirmed the central role of research in our mission. The overall strategy defines four objectives:

- Reduce the numbers of babies who die from Sudden Infant Death Syndrome (SIDS) in the UK to below 150 by 2020
- Fund research into the causes and prevention of Sudden Unexpected Infant Death (SUDI) including SIDS
- Provide support to bereaved families affected by the unexpected death of a baby or toddler
- Work across the infant and child health community to reduce infant mortality in the UK

This research strategy builds on our successful record over 40 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 2017 to 2027.

The research strategy has been developed by the Scientific Committee of the Lullaby Trust and approved by the Board of Trustees. This 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.

Why we fund and promote research?

The death of any baby is a tragedy for a family. That tragedy is compounded when a baby dies suddenly and unexpectedly and no cause is found. The Lullaby Trust was originally founded as the Foundation for the Study of Infant Deaths (FSID) in 1971. This was in response to very high number of unexpected and unexplained infant deaths occurring in the UK at that time. In the 1980s, some 2000 babies between the age of one week and two years died unexpectedly, 90% of them before the age of eight months. In about 1500 of these cases, no cause of death was found following a post mortem. This equated to a death rate of approximately 2.35 per 1000 live births, often described as a "cot death epidemic" in the media. Thousands of families were profoundly affected by the unexplained death of a baby, not just in the UK but in many other countries.

During this time most parents were terrified by the prospect of "cot death" as little or no advice was available about how to prevent it. The charity recognised that raising funds for research to unlock the mystery of cot death (now more commonly referred to as Sudden Infant Death Syndrome) was vital. Since then, The Lullaby Trust has raised over £12 million with the help and support of bereaved families. We have funded a wide variety of projects which have informed our understanding of sudden infant death, and allowed us to give evidence based advice on safer sleep to parents. The most notable guidance was that of placing a baby supine rather than prone to sleep. This in turn led to a remarkable drop in the numbers of babies dying suddenly and unexpectedly and greatly reduced the rate of unexplained infant deaths over time to 0.3 per 1000 live births in 2014 in England and Wales (ONS 2016).

We are proud that the Lullaby Trust has played a major role in reducing SIDS in this country and believe our commitment to funding research has been instrumental in decreasing the number of deaths.

Although there has been a dramatic reduction, sadly, SIDS has not yet gone away. In 2014 212 infants died in England and Wales with no explanation. In Scotland, 14 babies died, with 4 deaths in Northern Ireland. In total, therefore, there were 230 unexplained infant deaths in the UK recorded in 2014. This equates to the death of 4 babies per week, making SIDS the UK's leading cause of post-neonatal death. Sadly, a further 14 deaths occurred in the UK of babies over the age of 12 months for which no cause was found (see box for definitions).

The vast majority of unexplained infant deaths now occur within economically and socially disadvantaged communities. It is vitally important that we pursue research to understand how and why sudden and unexplained infant deaths continue to occur in the most vulnerable families, and to devise and test evidence-based approaches to supporting families to reduce the risk of their baby dying.

We passionately believe that our original purpose to identify the causes of sudden infant death and to prevent these tragedies occurring is as relevant now as in 1971. Finding answers for grieving parents and preventing future infant deaths drives our mission. This can only be achieved by continuing to fund and facilitate high quality research, and ensuring this research is translated into practice, and conveyed to parents, in ways that will help them to use it.

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.

SUDI, unexplained Cases in which 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. In 2015/16, we raised £1.5m. Our fundraising team co-ordinates community fundraising, regular giving events, awards from charitable trusts and foundations, The Big Lottery and major gifts. We aim to raise at least £100,000 per year to allocate to new research projects, and have established a designated research fund of £100,000 to pump prime our new strategy.

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 Scientific 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.

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Our Strategic Review 2015

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 GAPS project

In 2015, the GAPS project was established to identify research priorities and to help us guide our future allocation of charitable research funding to those projects with the MOST potential to reduce infant deaths. The Lullaby Trust has limited funds and it is important to our donors, many of whom are bereaved parents, that we commit funding to projects that will have the most impact.

In order to achieve this we 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 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

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.

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.

Research Strategy 2017-2027

In the coming years we will strive to raise more money to fund research that will save babies' lives. This research strategy will guide how this 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.

Over the next 10 years we will:

- a) Invest in new PhD studentships to encourage talented new UK researchers to gain training and experience with established leading researchers in the UK.
- b) Support gender equality in research by prioritising funding to academics in Departments and Institutions with an Athena Swan or Gender Equality Charter Mark.
- c) 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.

Growing research opportunities

We recognise the importance of identifying new funding streams to support SIDS research and keep active SIDS researchers engaged with issues of UK infant mortality and safe sleep information.

Over the next 10 years we will:

- a) Offer a new 'Innovations' funding stream to support feasibility and pilot studies, to help researchers develop their projects to a stage where they are eligible for submission to RCUK or NIHR funding streams
- b) Identify and work with other organisations and charities with an interest in reducing infant mortality to establish partnership funding opportunities.

- c) Encourage researchers to approach us about co-funding research with other charities, research councils, academic institutions, government bodies and the NHS to maximise our research impact.
- d) Promote the involvement of UK researchers in large international projects by facilitating introductions, brokering agreements and supporting travel costs, where appropriate.

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.

Over the next 10 years 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.

Over the next 10 years 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 Trust's Annual Grant-holders meeting; participating fully in the grant-holder meeting throughout the day will be a condition of grant acceptance. This meeting is also open to our supporters and interested professionals.
- 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 our 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 Scientific Committee every two years.

January 2017

GUIDELINES

How to apply for a research grant from The Lullaby Trust

The Lullaby Trust is keen to encourage high quality applications from investigators who are passionate about helping us reduce infant and child mortality in the UK. The Lullaby Trust will accept applications for quantitative and qualitative research, from applicants who are appropriately qualified and, normally, employed in a UK institution. All prospective researchers should read these guidelines, along with our Research Strategy, before submitting a research proposal to us.

Our criteria for funding

The Scientific Committee will only commit funding to research proposals that meet the highest possible scientific standards and support the objectives of our research strategy. These 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 prioritising funding the Scientific Committee will also consider how proposals map on to the top 10 UK research priorities arrived at through the 2015 GAPS study (see Research Strategy)

We welcome applications from a wide range of clinical and academic disciplines to help us advance our objectives. Applications from young researchers embarking on their academic career will be particularly welcomed during the first three years covered by this strategy.

Availability of funding

The Lullaby Trust will normally aim to fund at least one and possibly two proposals every year depending on the level of income and reserves available to the charity to distribute over a 12 month period. The Lullaby Trust also provides information services and bereavement support as part of its charitable activities and trustees will have regard to appropriate balance of expenditure between these areas when setting the Annual Budget.

Standard Project grants

Project grants are for time-limited research up to three years in duration designed to answer a single question or a group of closely related questions. Project grants may provide funds for salaries and running costs. We do not provide funding for equipment or institutional overheads. Maximum award value: £200,000

Innovation funds

We provide pump-priming funding for pilot projects to allow researchers to test a hypotheses or the feasibility of an intervention. The maximum duration for innovation funding is 12 months. These projects may lead to further support from the project grants programme. Maximum award value £50,000

PhD studentships

We will aim to fund at least one PhD studentship for a UK domiciled student on a three yearly basis, depending on funds available to the charity. The awards will be made to individuals seeking a research career into SIDS, SUDI and or SUDC, and should be supported by the prospective supervisor of a UK institution with a highly regarded graduate training programme. Funding will cover fees and a stipend.

We will consider top up funds when a grant is awarded to supplement funds that have already been awarded by another funder.

The charity will only support direct costs in line with AMRC policy.

Our research governance

Funding applications for research support are considered by the Scientific Committee of the Lullaby Trust. The committee is composed of experts from the academic and clinical community with a strong research interest in infant deaths, and bereaved family members who have been directly affected by the death of a baby. Academic representatives are drawn from a range of relevant fields including paediatrics, pathology, physiology, psychology and epidemiology. Dr Helen Ball, Professor of Anthropology at Durham University was appointed to serve as Chair of the Scientific committee in September 2016. Professor Ball is a leading expert on infant sleep and is an independent Chair. The term of the Chair is limited to 3 years, but can be renewed for a further term. The Chair of the Scientific Committee is not member of the Board of Trustees but has observer status and speaking rights. .

The Scientific Committee meets twice a year, in October/November and in April/May to coincide with the charity's financial cycle. All recommendations to award funding for research will be presented the Board of Trustees of The Lullaby Trust by the Chair of the Scientific Committee. Before agreeing funding, the Board of Trustees will ensure that the charity has sufficient funds available to support the project proposal.

The Scientific Committee will issue a public call for research applications in January of each year from 2017. All applications will be subject to peer review. In addition, the charity has appointed a lay panel of bereaved parents who review all research proposals that are submitted to the charity. All applicants are asked to produce a lay summary of their proposal in addition to a completed application form. This documentation will be sent to members of the lay panel who will assess the application using a simple rating system and return the pro forma. These scores are used by the Scientific Committee to assess the value of the proposal from the bereaved parent's perspective. Applicants must also complete a detailed application form and demonstrate how the research proposal meets our criteria.

We abide by the guiding principles of peer review as set out by the AMRC to assess all applications. We will seek at least two qualified and independent experts to scrutinise each application and ask them to provide a written report on the proposal prior to any decision being taken by the Scientific Committee.

Our commitment to ethical practice

We support the AMRC position statement on animals in medical research, university indirect costs and peer review (www.amrc.org.uk). We require all research involving patients and control volunteers to have research ethics approval and that research that involves human tissues and sample is conducted in accordance with the Medical Research Council's guidelines Human Tissues and Biological Samples for use in Research.

This includes:

- Appropriate approval from a formally constituted ethics committee
- Appropriate consent from the patients/participants or next of kin
- Treatment of the material with appropriate respect and conformity to the Data Protection Act 1998

Intellectual property

As a charity we are under an obligation to ensure that useful results from the research that it funds are applied for the public good. In some circumstances, this obligation may be best achieved through the protection of intellectual property (IP) and commercial exploitation. Where IP arises from any grant provided, the grant holder will immediately notify the charity. We will expect the grant holder to take reasonable steps to ensure that such IP is protected and not published or otherwise disclosed publically prior to protection. We will also wish to ensure that the charity's permission will be sought to commercially exploit IP arising from research. We will set out these requirements fully in the terms and conditions of any grant that is awarded to an institution and grant holder.

For more information about our research strategy and an informal discussion about submitting a research proposal to The Lullaby Trust, please contact Francine Bates, Chief Executive, The Lullaby Trust at francineb@lullabytrust.org.uk or call 020 7802 3200.

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