

Position Paper

Involvement of parent representatives in neonatal research



Preamble

During the last few years the European Foundation for the Care of Newborn Infants (EFCNI) as well as parent organisations from EFCNI's network have been approached regularly by researchers to support different projects in the field of neonatal care and have since then gained a lot of experience in this field. A survey among EFCNI's partner parent organisations worldwide showed that similar challenges, gaps and needs can be found in different countries and settings.

This Position Paper has been developed as a result of the experiences of EFCNI and its partners in recent years, and follows discussions with representatives of national parent organisations and other stakeholders in this area, who all see the need for enhanced efforts to develop a wider partnership in neonatal research, to produce positive impact on the health of preterm or ill newborn babies, their families and society. It should be seen as a first step in a process towards partnership between researchers and parents and may in the future help to set principles for the interaction between parent representatives and researchers in order to facilitate a fruitful collaboration between stakeholders in neonatal research.

Aim of this Position Paper

This Position Paper should serve as a basis for future structured and meaningful involvement of parent representatives in research projects. It should be used as guidance and reference by all stakeholders involved in research projects, who wish to put into practice good collaboration and partnership with patients, and particularly when parent organisations are engaged as representatives of affected families. The paper highlights current challenges and gaps as experienced by EFCNI and its partner organisations, discusses and recommends possible next steps and suggests principles towards an infrastructure and framework that, in the long-term, will lead to a mutually beneficial partnership benefitting research and the overarching aim to meet the needs of the patients and families.

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Introduction

Historically and culturally, research has been performed **on** patients instead of **with** patients: Scientists used to determine and set-up their projects according to their ideas and areas of interest, with focus on scientific relevance rather than on the patient's perspective or the real needs of patients. The different stakeholders worked separately rather than collaboratively.

For various reasons, the focus of clinical research has started to shift towards a patient-centred approach, aiming for the provision of the best individualised healthcare for each patient. Working collaboratively, with the patient as the focus, is a necessary component to improve targeting in the development of new medicines and processes/pathways, with benefit for both the individual patient and the society. In neonatal research, the patient's perspective is represented by the parents. Researchers may lack insight into the needs of the family, or the real-life/day-to-day challenges parents are facing, particularly following the emotionally traumatic experience of a preterm birth. Expert knowledge differs from the experience of someone living with a health condition, receiving a treatment, or using a service.

The shift in research paradigms and research culture from scientific expert-driven projects that consider patients as "source of data" towards science-patient partnerships with patients as true collaborators is still an on-going process, which will move away from the label "research for society" to "research with society".

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„In the past, research used to be on patients and not with patients which makes a big difference for people who are personally affected. Questions that might be scientifically interesting may not always meet the patients' true and practical needs; it is therefore very important to involve them as equal partners as early as possible in research.“

Nicole Thiele, Vice Chair of the EFCNI Executive Board



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Definitions

Parents

The term “parents” in the context of this paper refers to

- **Individual parents:** Parents (guardians) whose child was born preterm, with an illness or suffers from a birth complication and requires hospitalisation in the neonatal period.
- **Parent representatives/Representatives of parent organisations:** Persons who are mandated to represent and express views of parents in the field of preterm or ill born neonates.

In the following, we are referring particularly to parents/persons as **members of parent organisations**, who are involved in research projects as (selected) representatives to reflect the point of view of a large group of affected families.

Parent representatives in research projects

Parents are parents; their first approach to research - also as representatives in research projects - will always be based on emotions rather than on data. Finding parent representatives capable and suitable to join research projects remains a big challenge for researchers. Parent representatives participating in (international) research delivery and governance are required to commit widely to the following:

- Investing time and resources
- Longitudinal motivation
- Sound knowledge of English
- Willingness to learn the academic and medical jargon and aspects of research
- Technical knowledge in research and development (R&D), study design or regulatory processes
- Knowledge on how to contribute to grant proposals, writing reports or lay summaries
- Openness to work collaboratively with the medical/professional world
- Having self-confidence to raise their voice in a big audience of scientific experts

Since parents are personally affected, it is recommended that parents are invited into research projects who are not in an acute phase or who are not too emotionally challenged. For some research it is helpful if they have a link or experience with a certain topic and are at the same time able to cope with negative long-term effects of a specific condition. Depending on the research project, individual parents might contribute valuable insights into their experiences of a specific condition, service or treatment. Other occasions may require a more general perspective from a parent representative, having the background and feeling confident in representing a large parental group with many different experiences, cultures, or socio-economic backgrounds.

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In both cases, parent organisations are the ideal first points of contact: These organisations often have a large network of affected parents and can help in identifying either individual parents or persons who are able to answer more general questions with a feedback of a bigger voice. With appropriate resources, parent organisations can join the research project with representatives of their own organisation, allowing them at the same time to gain experience and professionalism for future projects. When individual parents are involved in a project, a relevant parent organisation should also be included, to guide the parent and to provide (peer-to-peer) support and advice.

Consequently, a continuous, long-lasting, and proactive relationship between the research teams and the respective parent organisation is recommended.

Throughout the different stages of a research project, some form of mentoring, or supervision by experts of the research team, or if available, by “senior” (research experienced) parent representatives should be considered, particularly in case of parent representatives who are new to the research topic. This allows parent representatives to receive a better insight into the research components, to gain experience and confidence, but also for affected parents to address their anxieties or questions.

- *A “person specification” may help to define who you wish to involve.*
- *Contact parent organisations to identify appropriate parent representatives who are motivated and related to the research topic.*
- *Collaborate with parent organisations in a way that parents in very different conditions can be represented.*
- *Parent organisations can support the social relevance of a project during submitting applications.*
- *Allow time, as involving organisations or individuals almost always takes longer than expected. Define topics well before potential meetings to allow parent organisations time to do surveys or receive feedback from their community in order to find out broader opinions if necessary.*

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1. Why it is so important to involve parents in research

Only once parental insights into the day-to-day reality and the needs of the child and family are clearly understood, all stakeholders can work towards developing practical, implementable, effective solutions which meet the needs of the “end users”, in this case the parents and patients. This will have diverse benefits for the research project itself and for stakeholders:

- **Relevance:** Existing gaps or critical issues for parents can be uncovered and picked up by the project at the earliest possible stage; this may result in a wider set of research themes and will ensure relevance for the patients. The focus of research that is in the public interest can be ensured, and any concerns that money and resources are used inefficiently can be averted.
- **Trust and confidence:** Parental trust and openness to research can be created by selecting and discussing relevant topics with them at an early stage.
- **“Knowledge of the many”:** family experiences are critical to any planned project, as aspects of daily life and a variety of lived experiences may be incorporated into the study processes. Variations in experiences can shape attitudes and consequently influence individual opinions and contributions to research.
- **Sustainability:** Parents can act as multipliers, or peer educators, in their area of activity for the next generation during and after being involved in a project (prerequisite: dissemination/science communication/translation of research findings for parents).



„Families need to be at the centre of research done in neonatal units. There are many gaps in our knowledge and we lack many effective treatments. Researchers from the public sector and industry should build their research on the experience of families so that research meets real needs and is acceptable to parents. This Position Paper is an excellent summary of what every neonatal researcher needs to know.“

Dr Mark Turner, Neonatologist at the University of Liverpool and Chair of the European Network of Paediatric Research at the European Medicines Agency

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„Parents are increasingly anxious about the inclusion of their newborn baby in research. Working closely together with parents in the design, governance and execution of research studies will improve the acceptability of research inclusion requests, and ensure that clinical research maintains its focus on the things that matter to parents, and ultimately their child.“

Prof Dr Neil Marlow, Member of the EFCNI Executive Board and University College London



2. Principles guiding and defining the interaction

In this section, we discuss the necessary next steps towards an infrastructure and framework that may help to include parents and the patient’s voice at the centre of research projects for neonatal (and child) health. The neonatal patients cannot speak for themselves. They need a deputy voice, which is, by nature, represented by the child’s parents.

Increasing the involvement of parents demands a set of principles that all stakeholders of a research project should take into account. For a meaningful and ethical interaction, the involvement should be guided by values and principles, such as **Equity, Fairness, Transparency and Independency, or Capacity Building** (see also: *EUPATI Guidance on Patient Involvement*). Successful and mutually beneficial interaction needs to be based on **Open Dialogue, Active Listening, Respect and Mutual Trust**.

2.1. Equal, fair partnership



Parent representatives should participate on an equal footing from the moment a project is taking shape, through to analytics and implementation of study results into clinical practice. During all these steps, they should have the same rights as the other stakeholders in a project.

This kind of involvement is only possible when specific structures are created in which parents have access to compensation, knowledge, experience, and training that enable their engagement and commitment.

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- *Start by defining clear expectations and goals for the collaboration from both sides.*
- *Be transparent and honest about the potential impact their input can have and in case feedback may be required.*
- *Involve parent representatives from the beginning, and already in the thinking process.*
- *Let parent representatives form an equal partner in all topics.*
- *Allow prior discussion of critical ethical situations for the project and acknowledge the importance of their involvement.*
- *Be aware that parents might miss information shared on conferences or “corridor meetings” by professionals and try to find a way to compensate this lack of information.*
- *When parents feel supported they are more motivated to actively participate and contribute over a longer period.*

2.2. Transparency and legitimacy



The information given to parent representatives should be complete and balanced about positive and negative aspects of the research project. Given that many parents engage in their organisation as volunteers (in addition to their work and family), it is important to clearly state expectations at the outset. To ensure that expectations can be met, a project should be formally presented to potential partners, with a lay overview and comprehensive, relevant information (e.g. objectives, stakeholders, milestones, planned activities, including time and travel commitment). The information needs to be given with sufficient notice (about six weeks) to allow the parent representatives to come to an unpressured decision whether or not to collaborate in a specific project.

A template may provide helpful structure to the initial project information, so that parent representatives can gain a rapid and comprehensive insight into the main project components without having to read the often extensive and very technical project documents. A role description and information about training, payment, mentoring, or other resources will help the parent organisation to judge the feasibility of their involvement.

A non-disclosure-agreement between the parties involved maintains project details' confidentiality from the outset. During a project, partners should publically disclose their collaboration through e.g. their websites or in annual reports.

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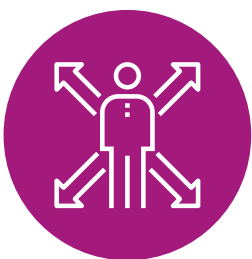
„When being involved in a research project, it is very important to know exactly what is expected from us. We have to plan our resources and therefore need to know all the milestones, the amount of travelling that will come up and the time we need to spend on a project. Since we are primarily parents and no researchers, the information we get needs to be in lay language so that we can optimally assess it. Only with full transparency in advance we can make sure that we can support the project in the best possible way.“

Silke Mader, Chairwoman of the EFCNI Executive Board



Involving parent representatives in a project also sets an example for parents directly involved in the study: they are more likely to have trust in the set-up and conduct of the study, because they might feel that the project has been checked and found worthy and of good quality by parent representatives.

2.3. Independency



The independency of parent representatives in the project should be respected and they must be free to refuse participation without fear of negative consequences. In case of a negative answer to a participation request, or in case the parental view conflicts with the researcher's view at some point of the project, parents should not be pressured to change their mind (e.g. by increased contacts or frequent phone calls, emotional arguments, or by utilising the parents' lack of expertise).

All interactions with parents should take place in a professional manner. Where available, codes of conduct should be the basis of a partnership.

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2.4. Capacity building - Training of parents and professionals



In order to be able to contribute to a project throughout the entire process, to better collaborate as partner, and to communicate their ideas more clearly, parents acting as representatives in research projects need to gain a firm understanding of research, as well as its potentials and limitations. They should acquire a certain scientific knowledge, learn the academic and medical jargon, know how to read and interpret studies, or how to write grant applications, reports or lay summaries.

At the same time, the parents need to develop their communication skills to represent themselves and the children's best interests successfully. They will need to gain confidence with regard to voicing opinions in group meetings with experts or researchers, and feel comfortable with public speaking to interact with professionals, policy makers, media, etc.

Researchers (research community) need to proactively support this learning process, e.g. by fostering the capacity building of umbrella organisations, supporting the cascading of information, and training in form of peer-to-peer support.

In parallel, (co-)researchers should receive training to change their way of thinking when it comes to patient perspective and the value of including parents in research in general, and more specifically during the different phases of a project, and how and where in the process parents can be involved. Research collaboration with parents requires a different way of communication throughout the project, a clear and simple language, a much more sensitive and empathetic wording, and eventually a structure to support parents to cope with possible "flash backs", or any negative outcomes for their own child.

Besides continuous networking between organisations and individuals, workshops in collaboration with parent representatives at the beginning of an interaction, workshops or sessions on scientific congresses or conferences, building respective content into training curricula, developed with the help of parent representatives, might help to drive this learning process faster.

At this stage of paradigm shift, the majority of parents involved in research still need the strong leadership by the consortium leader/principal investigator who should foster their inclusion in the project and guide parent representatives on how to give input.

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- *Train parents to better understand the aspects of research: study design, data collection, statistics, publications, meta-analyses, ...*
- *Parent representatives in research projects do not need to be research experts, but they need to know the basics of academic language and how research works, the potentials or limitations, etc.*
- *Professionals have to learn how to communicate with parents and to see, acknowledge and respect the value in their contributions.*
- *Including parent representatives in research projects requires a more sensitive way of communication.*

2.5. Longitudinal involvement and collaboration vs. consultation



Collaboration

A fair partnership also includes a longitudinal role of parent representatives during the research process. Collaboration should not be restricted to reviewing study documents or being involved in advisory committees (which would be better described by the term consultation). Meaningful collaboration in its core sense should be fostered in every step of the research lifecycle. Collaboration involves an on-going partnership between the research team and parent representatives, in which decisions about the research are shared. A longitudinal involvement will furthermore facilitate the collaboration for new research projects.

Consultation

Of course there might also be tasks which can be adequately managed by consultation (e.g. votes among the final informed consent documents initially worked out in collaboration). The consultation process can also be defined as follows: researchers ask a pool of parents for their views and researchers in turn use these views to inform their decision making. It is recommended that parents are given enough time to respond. They should be provided with feedback on the actions taken as a result of the consultation, otherwise parents might be left frustrated and unwilling to participate next time. But even this kind of consultation should ideally be coordinated and led by a parent organisation, which has a good understanding of parents' feelings and their way of thinking, and thus can help translate research tasks and give advice on user-friendliness and clarity. A structured approach of coordination of consultations and feedback through parent organisations can help to avoid the so-called danger of "consultation fatigue".

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What was the way of agreeing your organisation's participation in the research project/study? (multiple answers possible)

- *Involve parent representatives in the different steps of research: from identifying research topics, setting and prioritising research agendas in general to involvement in the thinking process for a project, submitting applications to the later project implementation.*
- *When developing the practical implementation, parent representatives can help to decide when to give which information and to whom. They can help to make informed consents, information brochures, and other material understandable and parent friendly. They can represent the reality of parents to predict the impact of the research on the families. Parent representatives can mentor researchers on how to best communicate with parents, how to understand the parents' needs.*
- *Parent organisations can help promote the research project among their networks and motivate families to participate by spreading information, by explaining the importance of research to the parental community, etc.*

2.6. Communication and dialogue



When the professional and parental worlds meet in a project, they will have to find a way to communicate with each other: Whereas parent representatives have to learn the technical, academic jargon, professionals have to adapt their language and behaviour to meet parents at equal footing.

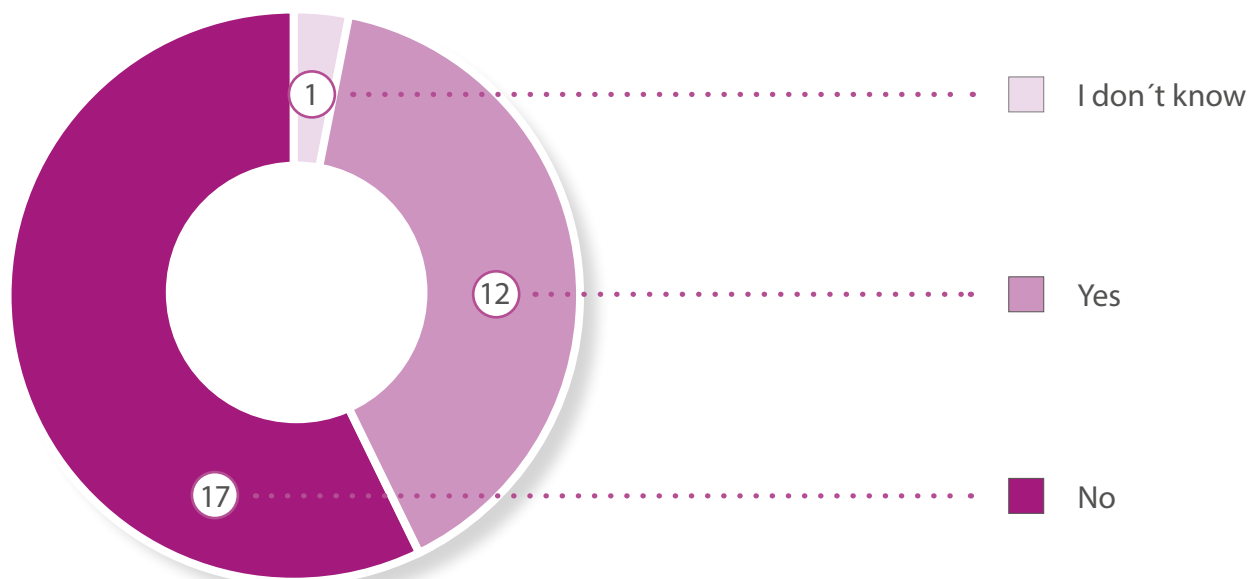
The communication flow is important to help parent representatives contribute to the project. It should be clearly defined at the beginning of a project how (e.g. through regular written or oral updates, newsletters or e-mails)

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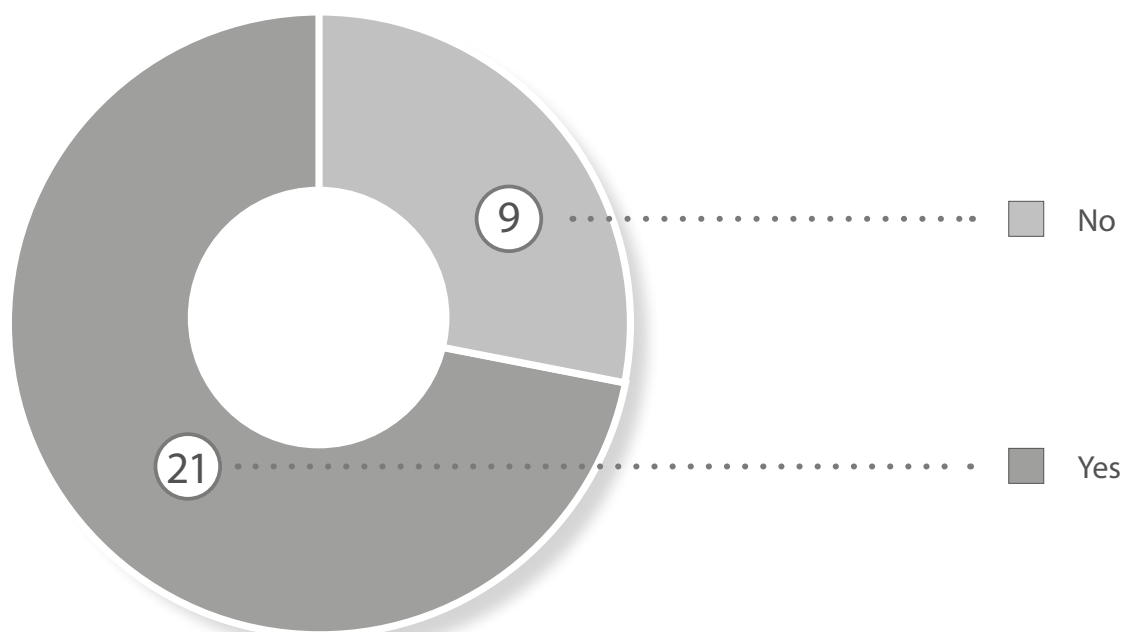


and who (e.g. coordinator, secretariat, project partner, ...) should keep the parent representatives informed on all project developments. Acknowledgement and recognition of the parents' impact is equally important: Information about changes brought about by the parents should be fed back to them. Their work should be recognised through e.g. news or articles on their achievements published on the project website or be acknowledged in the publication.

Did your feedback influence the research project/study?



Were you regularly informed about the progress of the study (e.g. by newsletters, phone calls)?



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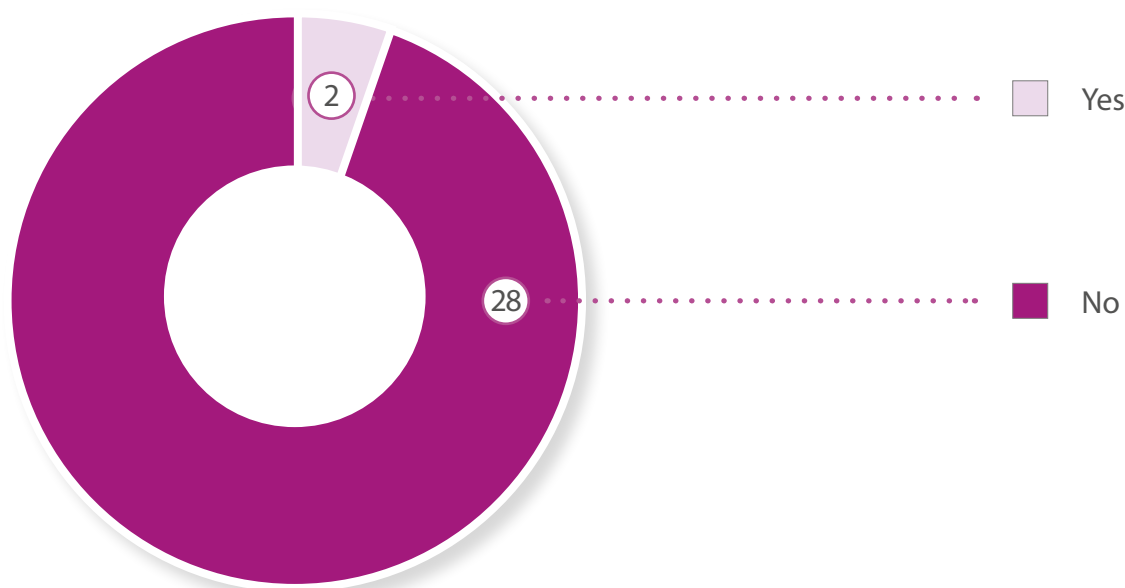
2.7. Compensation and payment



Parent organisations are the ideal bodies to nominate and coordinate parent representatives for research projects. However, they, as well as the later parent representatives in the projects, have only limited resources and time. They cannot cover research participation with their normal fundraising or through donations but have to receive compensation in order to be able to participate in research. It is important that parent representatives are financially supported to cover travel costs and to compensate for the time they invest in the preparation, attending and debriefing of meetings, their contributions as well as for any other expenses or administrative costs associated with the project.

Researchers need to be realistic about the resources required for patient involvement throughout their project: Compensation offered in addition to the administrative costs should be appropriate for the type of engagement and include logistical or organisational tasks. Adequate sums (same as other project partners) calculated in person-months for the work of parent organisations, as well as reimbursements and honoraria for individual parents have to be factored in the budget planning from the very beginning.

Did you receive financial support for your contribution to the research project?



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2.8. Written Agreement

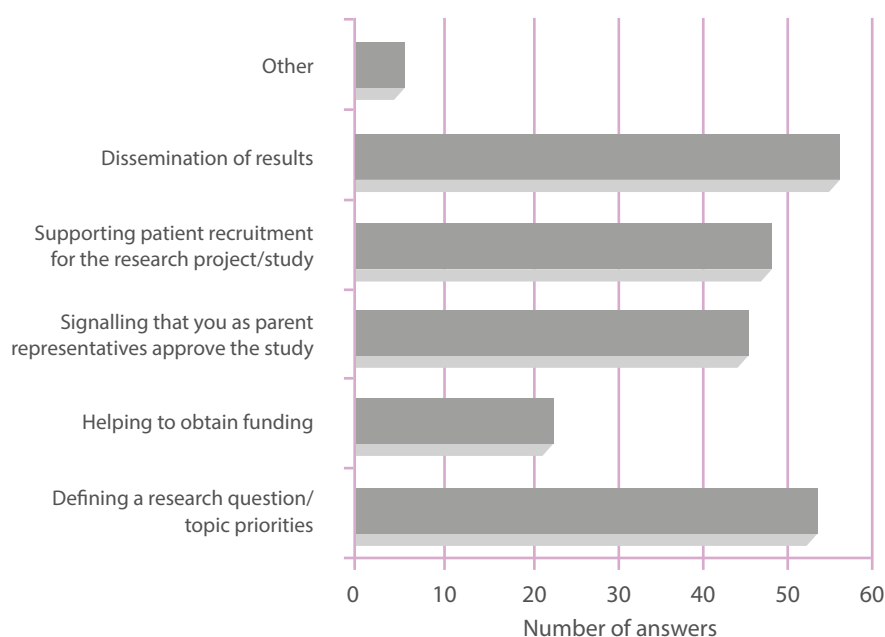


In order to provide clarity on the roles, the degree of involvement as well as on expectations or the financial compensation for resources to be invested, a reliable and binding document is needed. If not in form of a consortium agreement, at least a letter of agreement as used in case of business projects should define and describe the elements of the collaboration (e.g. project objectives, parties involved, tasks, duties, project milestones and duration, confidentiality, transparency, data privacy, compensation, intellectual property, etc.).

A comprehensive code of practice for a better guidance in the cooperation with various stakeholders in research or clinical trials (e.g. academics, industry) should be developed and endorsed by umbrella and national parent organisations.

3. Summary and recommendations

Research involving newborn infants should be meaningful for the individual child and families. Sharing of information and exchange of experience between researchers and families is essential and research should not happen in isolation from the families affected. Parent organisations as representatives of affected families are important bodies for fostering knowledge sharing and improved common understanding. They should be given a proactive role in research and be involved e.g. in identifying research questions, setting neonatal research agendas and research priorities or participating in the different phases of research projects.



If you were asked to participate in a research project in the future, when would you like to be involved?
(multiple answers possible)

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Being the proxy voice for the newborn, parents do not only have the moral right to be actively involved in research projects, they also bring invaluable expertise and first-hand insights that other stakeholders in a project might not see. Parent organisations as representatives of a larger group of families should be involved as partners throughout the entire research cycle, from planning, design or management to implementation.

For optimal support by parent representatives, capacity building (e.g. training, mentoring) and financial support are as essential as the adherence to a set of principles such as equality, independency, or transparency. Special projects related to research communication, dialogues and reports in a non-specialised language would ease a better understanding not only by the parent representatives involved, but also by a broader range of stakeholders (e.g. policy, media, society) and should be promoted.



„Research should not be a one way 'harvesting' of data from parents and children. Parents give their experience, their opinions, even their own child for research. The question 'What can we give them back?' should be asked. Research should also be meaningful for parents, so that parents feel cared for and engaged. The challenge is to find ways so that research is nourishing both researchers and parents.“

Yannic Verhaest, Chairwoman of Vlaamse Vereniging voor Ouders van Couveusekinderen (VVOC)

There are already some best practice examples of patient involvement in other health topics, e.g. in HIV/AIDS (the European Community Advisory Board) or oncology; there are platforms such as the Patient-Partner project (supported by the EU, expired in 2011), the public-private partnership European Patients' Academy on Therapeutic Innovation (www.eupati.eu), all stakeholders in the neonatal fields should learn from. These networks and platforms provide many valuable insights and tools for patient involvement in drug development and clinical trials.

Some scientific stakeholders demonstrate the shift towards valuing and incorporating the patient perspective in their work: Regulatory bodies such as the Food and Drug Administration or European Medicines Agency are inviting patients to provide their perspective during decision-making. The exchange and active communication with patients is becoming one central part of their work. Some medical journals (e.g. the British Medical Journal) already include patients in peer review processes, they invite experts to coproduce articles together with patients or are open to patients publishing articles.

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International and national research grants more and more demand an active involvement of patients in research projects, e.g. as joint grant holders or co-applicants.

Medical conferences take steps to include patients in the planning and organisation. Patients participate as presenters and congress participants. The jENS congress (Congress of joint European Neonatal Societies) is one outstanding example for such congresses in Europe: Since its founding, the congress is collaborating with EFCNI and welcoming parent representatives in its audience.

In newborn health, the paradigm shift has just started: Until recently, parent organisations have often been asked to be involved in research to represent the patient/family voice only once or occasionally and often only for certain parts of a project, for example to help to obtain a grant, to give a signal of “ethical clearance”, or because it is meanwhile a “must have”. Once their consent for support is obtained, parent organisations often do not receive feedback whether a grant application was successful or later on the project outcome.

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„I am working in close collaboration with parent organisations in the area of follow-up after preterm birth. We see that especially these topics are of great value for parents and particularly those newly confronted with the situation of having a preterm infant want to know what they can do to help their baby.“

Prof Dr Dr Dieter Wolke, University of Warwick



When starting cooperation for a project, researchers and parent representatives still feel uncertain and hesitant how and when parents can be effectively involved in a research project. Both parties often feel uncomfortable in this new field of collaboration. The degree of involvement of parents is often still limited to typical tasks like dissemination or ethics rather than being extended over the entire development or life cycle.

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„During the last few years we have started to work more closely with parent organisations as well as individual parents in our research studies. This has been of great value for understanding what parents are interested in and what they need in order to be involved appropriately. Secondly, the parent organisations are skilled at communicating and at identifying the results from our research that will be of most interest and relevance for the 'end users', that is the patients and their families.“

Dr Jennifer Zeitlin, INSERM

Call to action

We call on all stakeholders involved in neonatal research to

- *Engage parent representatives throughout the whole study process (e.g. starting at defining the research questions and priorities to the study analysis, reporting and implementation of study results into clinical practice)*
- *Develop techniques which enable parents to contribute their opinion*
- *Provide training possibilities for parents and researchers to realise eye-to-eye partnership*
- *Deliver a framework that actively supports the involvement of parent representatives*

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*Despeena, born at 24 weeks
weighing 820 grams*



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About EFCNI

The European Foundation for the Care of Newborn Infants (EFCNI) is the first pan-European organisation and network to represent the interests of preterm and newborn infants and their families. It gathers together parents, healthcare experts from different disciplines, and scientists with the common goal of improving long-term health of preterm and newborn children by ensuring the best possible prevention, treatment, care, and support.

For more information, visit us at www.efcni.org

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Endorsing organisations

The Position Paper is endorsed by the following parent organisations from around the world:



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