35. Paediatric Emergency Research in the United Kingdom & Ireland (PERUKI) 311013

1. **What do you consider to be the main obstacles to recruiting children to research? How might these be overcome?**

The most common theme to arise in this question from members of Paediatric Emergency Research in the United Kingdom & Ireland (P{ERUKI) is availability of resources, whether in the form of time, funding, or personnel. Due to limited research resources, PEM staff work in environments where clinical care often takes precedence over research activities. This may be through focus on service provision and attaining clinical quality indicators, or on a more generic level with a lack of dedicated research time for physicians and nursing staff within their job plans, and lack of research training and experience for doctors in training. There is also a lack of infrastructure support for clinical researchers who wish to develop and deliver their own research in collaboration with colleagues. This is coupled with a lack of funding available to provide resource at the patient interface.

A lack of stakeholder groups for certain conditions means that these risk being sidelined in research. Clinical research within paediatrics does not have a high profile amongst practicing clinicians. Current drivers of medication research are pharmaceutical licensing expectations: there is very limited market for drugs research in children.

In addition the amount of bureaucracy and paperwork involved in many studies, especially those in which an intervention is being prospectively tested in a randomized trial, makes delivery of research extremely challenging. This latter point extends to both professionals and parents, who have a lot to take in in a short period of time. Whilst parents may be anxious, there is good evidence that they appreciate being invited to participate in research, even in the acute setting. Should they wish to do so, it is often daunting to work through the necessary forms.

These potential obstacles can only be overcome through an attitudinal and cultural shift, underpinned by the recognition of need for a strong evidence base in our clinical practice. This must be supported by a robust funding structure which translates directly to those who wish to deliver and develop high quality research. This will facilitate dedicated time, training and clinician support at all levels including provision of research nurses in research active environments at times when research is likely to be successfully delivered (often out of hours). There must be an recognition of the need for this approach within management structures, with support given to those who wish to follow this route as a career option. It is important that individuals are supported by their colleagues and be able to link with other like minded professionals. Some paediatric specialties have established a successful research culture and others should learn from

their experience. Infrastructure and capacity building within tertiary hospitals and visible University links are vital to raise the profile of research, and to ensure that academics remain engaged with the clinical community – this will allow the successful extension of research into all settings.

Seed funding from national bodies for the development of collaboratives such as PERUKI, and for site leads affiliated with such clinical studies groups, is essential. This approach will make the performance of research the norm, with the result that professionals will be more at ease discussing research, and patients and parents will accept research as a standard aspect of their care.

2. **Who should make the final decision as to whether a child participates, or continues to participate, in clinical research when parent and child disagree? What responsibilities do health professionals or researchers have in such cases? (You may wish to distinguish between children at different stages of development and/or the different ways in which disagreement may arise or be expressed.)**

This depends to some degree on the age, developmental level, understanding level and competence of the child. In younger children and those who do not display competence, the decision should lie with the parents, ideally with age-appropriate assent. The ideal for older children, and those who are deemed competent, is shared decision making. However, these situations must be approached on a case by case basis. In general, if a child does not wish to take part and the parents do, the child should not be forced to take part. This is more complex in cases where a child wishes to participate but the parents do not. In these cases parents should have the final say. It makes sense, both from an ethical standpoint, and from the point of view of the likelihood of ongoing participation in the study, that unless both parties are willing to participate, the patient should not be included in the study.

The role of the health professional is simply to explain the research and the potential benefits or risks transparently and openly. No persuasion or coercion should take place, and the clinician or researcher must not bring their own bias into the conversation. They should also identify independent groups who may be able to help with these conversations.

3. **How useful is the concept of assent? Is it helpful to distinguish between consent and assent for young people?**

The concept of assent is felt to be helpful for patients, though less so for clinicians or researchers. It explains objectively and overtly why the reasons they are being invited to participate, and what the study is about. Empowering

children from a young age to participate in their healthcare gives them a sense of autonomy and control. The same courtesy should be extended to children in research as is given in clinical care – a full, measured, age appropriate explanation of what is happening to them. In terms of processes from a researcher point of view, it is of limited use. Assent will not override consent, and it is unlikely that non-competent children will be in disagreement with parental wishes. We feel that the practice of assent, being of benefit to patients, is useful and should be continued, with the need to seek assent from children especially where no directly demonstrable benefit to participating is present.

4. **A 'shared' or 'collaborative' decision-making model is often advocated for decisions about a child's research involvement, involving the child, relevant family members and professionals. Is this a helpful approach? How might any problems arising in this model be overcome?**

This is the most common approach taken in paediatric research, and one that many of our members have experience of. We recognize that parents, children and professionals perceive situations differently, especially what may be seen as harmful or unpleasant. Taking a collaborative approach allows all parties to feel as if they have had a chance to have their views heard in relation to the study in question. It is likely to ensure better data through full participation to completion of follow up in any study, and allows any seemingly unreasonable stances to be explored. However, this model is more resource intense. It occasionally presents additional challenges or may not be possible in the acute setting due to the severity of the clinical condtion.

5. **Parents' views on whether (and how) children should be involved in decisions vary enormously both within and beyond the UK. How should the law and professionals take account of such different parenting approaches?**

The current stance should be maintained. The law should neither force people into research, nor prevent them from participating should they wish to do so. Creating or changing a legal framework generates the possibility for mis-interpretation, and we may be accused of making the process unethical by making it too difficult for children to participate. In studies where only patient information is being used, it may be suitable to legislate for an opt out rather than opt in approach. In regards to parental views, parents have a right to parent as they see fit within the constraints of acceptability in regards to the social and cultural norms. They must receive the information at an appropriate level, with full disclosure of any potential risks or benefits, and be allowed to make the decision according to their religious, cultural and personal beliefs within this framework. Failure to provide full information and acquire engagement at an

early stage will lead to unwilling volunteers and incomplete participation. As children approach the age of at which they may be deemed as competent, the balance starts to swing. As research becomes more widespread within paediatrics it is likely that parents will become used to being invited to participate.

6. **Rewards (such as vouchers) for children participating in research may be welcomed as an appropriate way of saying 'thank you', or criticised as a form of undue incentive (to either child or parent). What forms of compensation/reward/expression of gratitude for research involvement do you think acceptable, and why?**

   Participating in research should not result in a financial burden for parents or families. Transport, parking and catering costs incurred directly from research study participation should be covered. However, prospective rewards are viewed as an undue incentive. A small thank you gift, in the form of a gift voucher of small monetary value is appropriate, but this should not be mentioned at the outset, and should only be given on completion of participation so as to prevent incentivisation. It is reasonable to offer a certificate acknowledging participation, and to offer sharing of results once the study is complete.

7. **How helpful is the notion of the best interests of the child participant? How would you define 'best interests'?**

   This is a vague term which often carries no real benefit to any party as it is poorly understood, and remains a nebulous term which is difficult (impossible) to define in the current climate. In some cases it may be used to prevent rather than facilitate research, and ideally should only be used if the child is willing to participate and not in the opposite context. Every healthcare episode should carry with it the opportunity to receive the best possible healthcare. This can only be described through completion of high quality research. It is reasonable to extend this approach to say that every healthcare episode should carry with it the opportunity to be invited to participate in such a high quality research study.

8. **How can the rights and interests of individual children (potential participants in research) be balanced against the rights and interests of all children (potential beneficiaries of the knowledge gained by the research)?**

   The two go hand in hand and are interwoven, and can really only be achieved through the performance of high quality research. As long as the benefits and risks are fully understood, approval by ethics committes and consent from parents balances this well. It would be unethical to enforce recruitment into trials solely based on 'potential benefit'.

9. **Are there any situations in which you think it would be acceptable for a child to be invited to participate in clinical research when there will not be *any* personal benefit to them? If so, please give examples.**

   Healthy volunteers. For example, questionnaires or surveys, measurement of physiological parameters, or establishment of a set of normative values where no invasive testing is required.

10. **Are there any circumstances where it would be right for a research ethics committee to approve research involving risks they would usually regard as too high, if parents and young people had clearly expressed their willingness to accept these?**

    This is a controversial area in paediatric research, and a number of clinicians and researchers have different individual views. There may be some scope for this to possible. We feel that some areas in which this may be the case are in situations where patients may have a terminal condition or one for which no conventional treatment already exists. Such an approach could only ever be taken after full consultation with parents and families who have previously been in this situation to examine their views on this approach. Were a trial with these circumstances to approved, it would have to be approached very sensitively on a case by case basis.

11. **Do you think the current regulations strike the right balance between promoting clinical research in children, protecting child participants, and involving children in decisions about their own participation? What (if anything) would you like to change?**

    At the minute they often appear balanced towards making clinical research in children difficult, with multiple layers of overlapping bureaucracy. Research may be limited by concerns of upsetting children and families, without a full appraisal of whether such children and families would actually welcome the opportunity to be invited to participate in research.

12. **With limited resources, how would you decide which childhood conditions should be the priorities for research? Who should be involved in making these decisions?**

    The gold standard is via research prioritisation exercises, ideally through national research networks, as has recently been undertaken by PERUKI. These exercises should include clinicians, academics and patient groups. Lesser methods include use of national morbidity and mortality data, or identifying the most common conditions or those with high burden on the healthcare system.

13. **What responsibilities do funders, researchers and stakeholder groups have to encourage the coordination of children's clinical research?**

    They hold a fundamental responsibility and must take seriously the responsibility of ensuring high quality studies are followed through to completion with robust coordination and transparent reporting of full results. They should encourage the embedding of research in service provision and in training currciula.

14. **What responsibilities do researchers have towards child participants and parents when the study is over?**

    Research findings should be disseminated where appropriate, remembering that in some cases this must be approached sensitively as it may serve as a reminder of difficult times for the family. They must remain accessible even after the study is complete to answer any potential questions, perhaps via email. They have a fundamental responsibility to publish the full results of the study and allow full access to all data.