A qualitative feasibility study to inform Fluids in Shock (FiSh) - a pilot randomised clinical trial of fluid bolus therapy in septic shock

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AIMS

This qualitative feasibility study aimed to explore, with input from parents:

- Acceptability of the FiSh Trial, including research without prior consent (RWPC);
- Potential barriers to recruitment;
- Decision-making processes;
- Participant information materials for a pilot trial.

INTRODUCTION

The FiSh Trial proposes to evaluate whether a restrictive strategy (bolus fluid resuscitation of 10 ml/kg), compared with current recommended strategy (bolus fluid resuscitation of 20 ml/kg), is associated with improved outcomes for children presenting with presumed septic shock.

The aim of the combined FiSh feasibility and external pilot randomised clinical trial is to explore and test important key parameters needed to inform the design and ensure the successful conduct of the FiSh Trial.

DESIGN

A qualitative interview study involving parents of children who had presented to a UK Emergency Department or been admitted to a Paediatric Intensive Care Unit with severe infection in the previous three years.

PARTICIPANTS

Twenty-one parents (18 mothers, 3 fathers, 7 bereaved) were interviewed.

TABLE 1. SELECTED QUOTATIONS FROM PARENTS

Theme	Sub-theme	Example quotes
RWPC is acceptable but some initial concerns	Logical solution	*At first I was like what? You'd do that without even finding out if it was OK? And then I kind of thought about it and actually that does make sense*.
Support for FiSh but some concerns and misconceptions	Current practice is proven to be effective	*Obviously we know 20 mL/kg works… That's the thing isn't it? It's like well why are you changing it if it already works*?
	Tailored explanation is important	*I think hearing those two key points around there being limited evidence that the way we're doing it is the right way… I think that would definitely sway me to take part*.
	Unclear or missing study information	*Does it say anywhere what the bolus actually does? That might be something, 'cause I was thinking I don't really know*.
Approaching non-bereaved parents	Timing	*If I was asked this once my child was stable, I'd know he's okay… before that point I'd have probably found it quite hard to make any decisions*.
Approaching bereaved parents	Do not approach in hospital	*I don't think you should do it straight away. I don't think it should be done in hospital. It's just an overwhelming experience is all I can say*.
	Acceptability of postal 'opt out' approach	*I think the opt-out rather than the opt-in is fair because I think if it's an opt-in situation, you're going to lose the data*.

RESULTS

- All parents would have provided consent for the use of their child's data in FiSh.
- The majority were unfamiliar with RWPC, yet supported its use in FiSh.
- Parents were initially concerned about the change from currently recommended treatment; yet were reassured by explanations of the current evidence base and fluid bolus therapy.
- Parents made recommendations about the timing of the research discussion and content of participant information.
- Bereaved parents stated that recruiters should not discuss research immediately after a child's death, but supported a personalised postal 'opt-out' approach to RWPC for FiSh.

CONCLUSIONS

- Findings show that parents whose child has experienced severe infection supported the proposed FiSh Trial, including the use of RWPC.
- Parents' views informed the development of the FiSh pilot RCT protocol, participant information materials and staff training.

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