SWAT 218: Effect of providing parents with information on the use of routine data in clinical research on recruitment and retention of infants to a randomised trial

Objective of this SWAT
Primary Objective
To establish if parents are less likely to opt-out of their infant's participation in the WithHolding Enteral Feeds Around Blood Transfusion (WHEAT) trial if they are given information on the use of routine data in clinical research, in addition to the WHEAT trial specific parent information.

Secondary Objective(s)
To establish if parents are less likely to withdraw their infant from the WHEAT trial after randomisation if they are given information on the use of routine data in clinical research, in addition to the WHEAT trial specific parent information.

Study area: Recruitment, Randomisation, Retention
Sample type: Carer/Parent, Sites in a Cluster Randomised Trial
Estimated funding level needed: Very Low

Background
The admission of a baby to the neonatal unit is often unexpected and carries a significant negative emotional burden for parents.[1] This includes feelings of fear, depression, anxiety, stress and a loss of control, often compounded by questions and a lack of understanding about the health care their infant is receiving.[2, 3, 4]

The way that research information is presented and informed consent is obtained in a neonatal unit needs to understand and accommodate the challenges faced by parents.[5] However, both parents and clinicians feel strongly that parents must be involved in the decision-making for their baby, including being offered the opportunity to take part in neonatal research.[6] Multiple factors affect a parent's decision to provide consent, namely the complexity and severity of their infant's condition, the perceived harm-benefit ratio of the research as well as their relationship with the research team. Effective communications and dialogue between parents and the research team are key to ensuring that parents are able to make informed decisions about participation in neonatal research.[7]

Multiple approaches have been developed to provide parents with information about neonatal research that is clear and concise, and to ensure that the process of gaining informed consent is proportionate and appropriate. These include the use of oral assent followed by later written informed consent,[8, 9] deferred consent [10] and opt-out consent.[11]

The WHEAT trial (ISRCTN62501859) is a randomised trial that aims to determine whether withholding enteral feeds around the time of blood transfusion in preterm infants is superior to continued enteral feeding, in reducing the incidence of necrotising enterocolitis (NEC) and other adverse clinical outcomes before discharge from neonatal care. The trial aims to recruit 2167 babies within 3 years across approximately 36 NHS Trusts. It is currently underway in the UK, Australia and Canada and is using an opt-out approach to consent in the UK. Initial data collected during the first three months of recruitment in the trial, showed that out of the 127 parents approached, 23% opted-out of their infant's participation in the trial. At some participating sites, the opt-out rate has been as high as 45%. Parents do not have to provide a reason for withdrawing their infant from the trial but informal feedback from research teams highlights parental hesitancy around the word 'trial'. It is essential to identify more effective ways to engage parents, alleviate concerns and build trusting relationships with site research teams, not only to increase recruitment into the WHEAT trial, but to ensure parental understanding of research and normalise participation in neonatal clinical research.

The use of routinely recorded clinical data in randomised trials is increasing. It has a number of major benefits including efficiency and simplicity.[12] Point-of-care clinical trials describe a design methodology that integrates existing electronic health record systems [13] to allow baseline,

treatment and outcome data to be extracted directly from existing electronic records. The WHEAT trial is using such a design.

Digital multimedia has been used to facilitate written informed consent for clinical research: participant information clips, short videos that provide study-related information to potential research participants or their proxies, are cost-effective and straightforward to produce and implement.[14] There is, however, a paucity of data describing the impact of digital multimedia in trials using an opt-out approach to consent or using routinely recorded clinical data (point-of-care trials). We hypothesise that if parents are made aware of the value of using their baby's routine clinical data in clinical trials to improve neonatal care, they will be more inclined for their baby to participate in simple point-of-care trials.

Interventions and comparators
Intervention 1: A small card containing a link to a 3-minute animated video explaining the importance neonatal research and of using routinely recorded clinical data for research. This will be delivered to parents at the same time as information about the WHEAT trial is provided to them.
Intervention 2: Information about the WHEAT trial only.

Index Type: Participant Information, Method of Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Parental opt-out rate for the WHEAT trial before randomisation.
Secondary: Parental withdrawal rate from the WHEAT trial after randomisation.

Analysis plans
The primary analysis will be based on an intention-to-treat approach; participants with outcome data will be analysed in the SWAT group to which they are assigned, regardless of deviation from the protocol or procedure received. For the primary and secondary binary outcomes, risk ratios and confidence intervals will be calculated using a mixed modified Poisson model with a log link and robust variance of error, with cluster as a random effect, and adjusting for level of unit as a fixed effect. Risk differences will be calculated using a mixed binomial model with an identity link.

Possible problems in implementing this SWAT
There are no foreseen possible problems in implementing this SWAT. The intervention itself bears no cost to the Sponsor nor participating sites and can be delivered by participating site staff without additional burden or impact on local site resources.

There is no foreseen burden on parents in having to watch a short video animation at their leisure.

References
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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Christopher Gale
Contact email address: christopher.gale@imperial.ac.uk
Date of idea: 13/JUN/2023
Revisions made by:
Date of revisions: