Facilitation of Child Health Research in hospital settings; the views of nurses

Julie Brown¹, Owen Barr¹, Edel Ennis², Siobhan O’Neill², Mary Lindsay¹

¹ School of Nursing, Ulster University, L.Derry, Northern Ireland.
² School of Psychology, Ulster University, Coleraine, Northern Ireland.

Author Note

Correspondence concerning this article should be addressed to: Edel Ennis,
School of Psychology, Ulster University, Coleraine, Northern Ireland, BT52 1SA. Email:
e.ennis@ulster.ac.uk
Facilitation of Child Health Research in hospital settings; the views of nurses

ABSTRACT

Background: Child health research in clinical practice is increasing throughout the UK. Nurses and midwives facilitate access to patients, enact research study protocols and have a critical role in parental decisions to enrol children into research studies. Little is known about their perception of this process.

Aims & Objectives: To explore the views of nurses towards child health research and to identify factors influencing their willingness to facilitate it in practice.

Design: This study was a descriptive study design.

Methods: A newly designed questionnaire was completed in 2013 by 105 nurses in 3 neonatal and 2 children’s units in 2 discrete acute hospital sites.

Results: Overwhelming support for clinical research was reported. Participants were motivated to facilitate research in order to improve patient care and contribute to the evidence base; but discouraged by external organisational factors and ethical concerns. Training, education and a dedicated team to support research were considered important. Misconceptions regarding consent and the allocation of treatment were reported. Participants raised particular concerns about trials of Investigational Medicinal Product (IMP).

Conclusion: Negative views of nurses towards research, combined with a lack of knowledge of research processes, governance and ethics have the potential to threaten the success of clinical research studies.

Recommendations for clinical practice focus on three main areas; staff education, improved communication and the demonstration of managerial commitment to clinical research.
What does this paper contribute to the wider global clinical community?

- Clinical health research is increasing in volume globally.
- Whilst nurses are key stakeholders in research process in clinical practice; there is a paucity of knowledge regarding their perceptions of clinical health research.
- Through understanding of the motivators and barriers to research facilitation, involvement of clinical nursing staff in research may be fostered and thereby the successful implementation of research in practice achieved.
- This paper reports that whilst support for clinical research in the clinical nursing community is strong; there are environmental pressures and ethical concerns which must be addressed through improved education, support and managerial commitment to research.

KEYWORDS

Nurses, clinical, research, child, attitudes, extended roles in neonatal nursing, survey, research implementation
TITLE
Facilitators and barriers to the implementation of child health research; the views of nurses

INTRODUCTION
Child Health Research ensures that treatments and medicines for children are appropriate, safe and effective. Commercially funded studies have historically focussed on the adult population as these studies are more likely to yield profitable outcomes; leaving the use of off-label and unlicensed medication commonplace in the treatment of children (Royal College Paediatrics and Child Health (RCPCH) 2012). However, children are not small adults; they are a “vulnerable population with developmental, physiological and psychological differences from adults” (EU Directive 2001/20/EC 2001) and history has shown that using treatments on children, which have not been adequately tested, may lead to adverse outcomes (Caldwell et al 2004). Therefore, the ethical issues raised by involving children in the research process must be balanced against the ethics of using medication and treatments which have not been adequately tested (Kimland & Odland 2012).

Child Health Research is increasing in volume globally (Smit-Marshall 2010). This is in part due to international efforts to stimulate high quality, ethical child health research by authorities such as the European Medicines Agency (EMEA), World Health Organisation (WHO) and the Food and Drug Administration (FDA). The Best Pharmaceuticals for Children Act (BCPA), introduced in the USA in 2002, mandates paediatric studies which, supported by the Paediatric Research Equity Act (PREA 2003), has resulted in increased number of trials, increased numbers of children recruited to trials and changes to labelling of medicines (FDA 2014). The European Union Regulation (EC) 1901/2006: Medicinal Products for Paediatric Use in 2007 (Lehmann 2008) requires all companies to submit a Paediatric Investigation Plan (PIP) for all new medicinal products in the European Union which have the potential for use in children, thereby ensuring that all new medicines used in the treatment of children will be licenced prior to use.

This increasing volume of research has resulted in frontline clinical nurses expanding their practice to include the implementation of research study protocols. Nurses are advocates for their patients and are in a unique position to potentially influence how children and their families view the decision to participate in clinical
research studies. Therefore, encouraging clinical staff to become active research facilitators and promoting a positive research culture may be the key to implementing and recruiting children successfully to safe, ethical research studies.

Clinical research studies in the United Kingdom (UK) are often co-ordinated by Clinical Research Nurses (CRNs) who manage the implementation of pre-defined study protocols within their practice area. This role has become increasingly prevalent in the UK since the founding of the National Institute of Health Research (NIHR) in 2006 and the establishment of Local Clinical Research Networks (LCRN), which have provided the infrastructure for clinical research to become integrated into clinical practice within the National Health Service (NIHR 2015).

**Background**

The evidence base investigating the views of healthcare professional towards clinical research has predominantly emanated from Britain and the USA. It is limited and fast becoming outdated. It indicates that support for clinical research amongst healthcare professionals is strong (Burnett et al 2001; Singhal et al 2004; Reynolds et al 2013) and is recognised to be vital to improve work practices and to progress healthcare (Burnett et al 2001; Singhal et al 2004; Sale 2007; Augustin et al 2008; Chang 2008; AMRC 2013; Reynolds et al 2013). Nurses perceive their involvement in clinical research as a chance to develop professionally and improve patient choice (Chang 2008).

However, a survey investigating the attitudes of 563 healthcare professionals in Northern Ireland on unlicensed paediatric prescribing and paediatric clinical trials by Mukattash et al (2011), involving 65 children’s nurses, reported that only 27.7% of the nurses surveyed would be willing to “actively” participate in the facilitation of clinical research. This suggests that, despite overall reports in favour of clinical research, barriers remain to its implementation in practice.

Nurses and radiation therapists identify lack of allocated time and workload pressures as deterrents to taking on research related activities (Chang 2008; Sale 2007; Augustin et al 2008). Additional barriers include: lack of recognition, lack of dedicated research support, limited research knowledge, difficulty keeping up to date
with protocols, lack of role clarity and marginalisation by research staff (Sale 2007; Augustin et al 2008). A more recent study in a large “research active” neonatal unit in the United States reported that nurses felt that approaching families to discuss clinical research was “bombarding” them with information and overburdening them at stressful times (Reynolds et al 2013). This view was corroborated by palliative care professionals in UK hospices (Dunleavy et al 2011).

Several papers reported nurses’ attitudes towards clinical research as part of a narrative by the research team implementing the studies (Spilsbury et al 2007; Brim & Schoonover 2009; Doss et al 2009; Dunleavy et al 2011). CRNs described “hostility” from ward staff and felt that they were perceived to be “checking up” on nursing practice or ‘watching’ them. They also reported that clinical nurses have a lack of insight and understanding of research studies (Spilsbury et al 2007; Brim & Schoonover 2009). Evidence suggests that increasing age and years of practice, working in specialist practice areas and regularly reading professional journals are predictors of positive views towards clinical research (Burnett et al 2001; Chang 2008).

Much has been written about parental views of children’s clinical research (Woodgate & Yanofsky 2010; Shilling et al 2011; Elemraid et al 2013) and to a lesser extent, those of clinicians, healthcare professionals acting as Principal Investigators (Rendell et al 2007) and radiation therapists (Sale 2007; Augustin et al 2008). Few studies have examined the views of nurses who look after children in hospital towards this research, or the factors influencing their willingness to be active research facilitators. The few studies identified have focused on views of nurses towards research in specific groups of children; for example; newborns (Singhal et al 2004), premature infants (Reynolds et al 2013) and children enrolled in phase 1 cancer trials (Chang 2008); or have simply polled the support of children’s nurses for clinical research within the context of a wider study (Mukkatash et al 2011).

The literature base focuses on nurses’ views of “clinical trials”, mainly in oncology and in the adult population. Clinical trials suggest that patients are allocated to groups to “test” treatments or IMP (Investigational Medicinal Product), however clinical research is diverse and it is possible that the type of research will
influence the views of nurses and midwives towards facilitation of the study protocols. This influence has not been explored in the literature to date.

**Aims**

This study aimed to explore the views of nurses, looking after children in acute clinical settings, towards child health research and identify factors influencing their willingness to facilitate it in practice.

**Objectives**

1. To explore the views of nurses and midwives towards research involving children
2. To ascertain the willingness, or not, of nurses to facilitate clinical child health studies within their clinical practice
3. To identify the factors which encourage or impede the willingness of nurses to facilitate clinical child health research.

**METHODOLOGY**

**Study Design**

This study was a descriptive study design.

**Data Collection**

One hundred and ninety five nurses working on two children’s wards and three neonatal units in two acute hospital sites were invited to complete a paper based questionnaire. Only practice areas which have recently facilitated multicentre child health research studies for the first time, having had little or no prior research experience were included. The researcher visited each participating ward and unit invited all nurses working on these wards and units to participate. CRNs were not included in the sample. The distribution strategy was developed through consultation with Ward Managers and clinical nurses.

Each participant received a questionnaire accompanied by a covering letter, inviting him or her to take part in the research. Questionnaires were located on the ward and the ward manager was asked to remind staff at each handover that the study was ongoing and that questionnaires were available to complete. Ward clerks were informed of the study and co-ordinated the returns procedure.
Questionnaires were returned in unnamed, sealed envelopes to a sealed box in the clinical area. They were collected after a three week period by the researcher or by the identified local collaborator and returned unopened to the researcher. All responses were anonymous. Participation was voluntary and consent was implicit on completion of the questionnaire. Questionnaires were distributed between July and August 2013. Responses were received from 105 participants, who will be described in the results section. The study was approved by the Office of Research Ethics Northern Ireland and local governance approvals obtained from each site prior to commencement of the study.

Materials

Instrument design and pilot testing

The questionnaire described above was newly developed for the purposes of the current study as extensive literature searching did not identify pre-existing instruments which adequately addressed the study objectives. We developed this instrument using aspects from previously published literature/instruments in this area, from discussions with colleagues on this topic and feedback from an Expert Reference Group on a draft questionnaire. The draft questionnaire was reviewed by an “Expert Reference Group” (n=6), all of whom have experience in undertaking child health research, to assure the face and content validity of the instrument and to ensure that it adequately addressed the aims and objectives of the research. Changes to the content and presentation were made accordingly. Prior to distribution, five children’s nurses, within the sample group, were asked to complete the questionnaire and comment on clarity, content and burden of completion. Support for the validity of the questionnaire was confirmed and minor amendments were submitted for approval prior to the main study. The pilot study results were not included in the main analysis.

The questionnaire consisted of Four Sections. In Section one, demographic information was collected, including age, years of experience, education, work setting and usage of professional journals. Section Two was designed to ascertain support for, and willingness to facilitate, child health research in practice. Two open ended questions were also included concerning the motivators and discouraging factors to its facilitation. These were included in this section as the subsequent sections will examine opinions concerning the
motivators and barriers which are commonly discussed in the literature. It was wished for participants to list their main motivators and barriers to clinical research prior to them being influenced by Section Three.

Section three examined factors influencing the willingness of nurses and midwives to facilitate clinical research in general. This section consisted of a series of 22 statements to which participants were asked to grade their level of agreement on a 1-6 scale. The statements were drawn from analysis of the relevant literature, through discussion with nursing colleagues and from aspects of Funk’s work on research utilisation by nurses (Funk et al 1991). For analyses purposes, strongly disagree, disagree and slightly disagree were grouped together to indicate disagreement with the presented statement. Strongly agree, agree and slightly agree were grouped together to indicate agreement with the presented statement.

Section Four focussed on opinions concerning engagement with specific parts of the research process. It listed 10 activities that clinical staff may undertake as part of research protocols; these activities were drawn from analysis of child health research protocols and past experience of the researcher. Participants were asked to indicate their willingness to participate in the activity or not (yes/no).

Data analysis

Quantitative responses were coded and entered into SPSS 20 (IBM 2011) to obtain descriptive statistics. It was not possible to examine the influence of demographic characteristics as some group sizes were too small to allow chi square analyses. Responses to the two open-ended questions from section two were thematically analysed by the researcher (JB); with the main emergent themes collated and reported using a combination of Conventional Content Analysis (Newell & Burnard 2011) and Summative Content Analysis (Hsiu-Fang Hsieh & Shannon 2005). This preliminary analysis was presented and discussed with the project supervisors, reviewed against the data and the final themes agreed after secondary analysis.
RESULTS

Descriptive statistics
Responses were received from 105 participants, ranging in age from 21 to 60 years. The largest group of participants (n= 35; 33%) were aged between 21 and 30 years and 65.7% (n= 69) of the sample was under 40 years. The majority of participants were degree qualified (n=46; 44%), had a mean of 13.3 years post-registration (sd 9.9) and worked either in Neonatal or General Children’s settings. Midwives accounted for 14.3% (n=15) of the total sample; however 14 of the 15 midwives also held an adult nursing registration. Midwives worked exclusively in the neonatal setting, primarily using their nursing qualification. Just over half of participants reported that they regularly read professional journals (n=59; 56%)(Table 1).

[INSERT TABLE 1 ABOUT HERE]

Questionnaire psychometrics
Given the format and content of the questionnaire, section three was the only section considered appropriate for examination of psychometric properties. As a sample size of 100 or above is sufficient according to many researchers (DeWinter, Dodou & Wieringa, 2009), exploratory factor analysis using principal factor analysis was conducted to identify latent factors in the section three domain of “factors influencing the willingness of nurses and midwives to facilitate clinical research in general”. Scores were reversed on negatively phrased items. The number of factors retained was based on the scree test and identified one factor as the best solution. As would be desired, all items loaded on the factor at 0.3 or above, with loadings ranging up to 0.79. Validation of the internal consistency of the questionnaire scale for this section gave an acceptable Cronbach’s’ alpha value 0.85. These results indicate that although the current study wishes to use these items individually for information purposes, they could be used as a scale.

Nurses experience and views concerning research
Within section two, overwhelming support for clinical research was expressed, with 99% participants (n=104) stating that they supported their ward/unit’s involvement in clinical research and 96% (n=100) willing to facilitate research in practice. Nine participants offered caveats to participation including: “only if allocated
time given”, “only with training” and “only if relevant to practice”. The majority of participants reported that they had relatively little experience of participating in clinical research (80.6% of participants (n=79) had been involved in 2 or less studies).

**Research based motivators and barriers**

Based on the questionnaire presented in section 3, Table 2 shows the statements from the scale which elicited positive and negative responses. Looking at the top five\(^\d\) research motivators, it is apparent that participants value research in that they recognise the importance of developing child specific treatments, the importance of research in improving patient care, the importance of communication of research outcomes to all those involved in the process, the importance of research in the development of novel interventions and in professional development, and the importance of a dedicated research team in the implementation of clinical research study protocols. Other motivators presented but not rated as within the top five included the belief that children and their families want to be given the opportunity to participate in clinical research, the belief that there is adequate training and education given to accommodate research study protocols into daily practice, the belief that ward staff get recognition for their involvement in clinical research studies, and the belief that clinical research study protocols are presented in a way that is accessible and easy to understand.

The top five barriers to research activity included worry about not implementing the study protocol correctly, concern about overburdening families at stressful times, difficulty in keeping up to date with clinical research study protocols, legal concerns in the event of something going wrong and workload difficulties. Other barriers presented but not rated as within the top five included the belief that clinical research protocols are too complicated to understand, the belief that there is no incentive to participate in clinical research activities, the belief that the individual did not feel that they could refuse to participate in the clinical research studies being undertaken on their ward or unit, the belief that children should not be used as research participants, the belief that negative attitudes from other staff made the individual less willing to be involved in research studies, the belief that clinical research is boring and the belief that clinical research is not part of the nursing role. Overall

\(^{\dagger}\) It was necessary to list six motivators as two had the exact same frequency of endorsement.
these demonstrate that participants value clinical research and see it as an important part of child health care, however the need for training, education, managerial support and communication of research activity is highlighted.

[INSERT TABLE 2 ABOUT HERE]

**Staff views concerning motivators and barriers**

In order to ensure that the barriers and motivators presented in the questionnaire were actually representative of those most important to the sample, section 2 had two open ended questions within section wherein participants were asked to list their three main motivating and three main demotivating factors to the facilitation of research studies. It should be noted that in the actual study, these were presented prior to the structured scale in order to prevent priming. Participants (n=100) recorded 222 motivators for participation. The most frequent being: a desire to improve patient care through research (n= 38, 17.1%), to benefit the patient (n=33; 14.9%) and to contribute towards evidence based practice (n=21; 9.5%). Participants (n=88) reported 168 responses as discouraging factors to the facilitation of clinical research. The most frequently cited barriers were: time constraints (n= 34; 20.2%), additional paperwork (n=14; 8.3%) and risk of something going wrong (n=13; 7.7%). Although these were the most commonly cited, themes were examined amongst all motivators and barriers. Categories of motivators were further analysed and four themes identified; Altruistic, Individual, External and Research Motivators (Figure 1). Categories of barriers were further analysed and grouped into 4 themes; External, Ethical, Individual and Research factors (Figure 2). External Factors were the most frequently reported.

[INSERT FIGURE 1 ABOUT HERE]

[INSERT FIGURE 2 ABOUT HERE]

**Specific elements of research**

Although the research had identified motivators and barriers to the research process in general, section 4 sought to identify whether these were common to all forms of research and elements of the research process. Based on section four of the questionnaire, Table 3 outlines the frequency of endorsement of willingness to undertake each of ten individual elements of the clinical research process. Participants were most unwilling
to administer a newly developed drugs (n=34; 33.7%), talk to families about the nature and purpose of clinical research studies (n=29; 27.9%) and obtaining biological samples according to a research protocol (n=19; 18.3%) (Table 3). Participants (n=14; 13.5%) also expressed unwillingness to administer an existing drug to a child in a new formulation, delivery method or off licence as part of a research study (Table 3).

[INSERT TABLE 3 ABOUT HERE]

The open ended section at the end of section 4 wherein participants were invited to express any additional thoughts re-iterated the themes identified in the survey in general in that there was an overall willingness to engage with the research process, but that there was a need for training, education, communication, consideration of ethical concerns (e.g. parental consent, treatment equity) and the external influences of workload, time and recognition.

“If something feels unethical I wouldn’t be so keen to participate. As long as it is fair and ethical, I wouldn’t have a problem”.

“I am willing to be involved, provided I am fully informed and properly prepared/ instructed on how to carry out research”

“Carrying out new interventions/techniques in different situations than normal is good, providing adequate training/education and support for staff is given”

Participants confirmed that Investigational Medicinal Product (IMP) studies were of concern and they would only be happy to facilitate these studies if the drug “was safe” had been “well researched” and “tested previously”.

**DISCUSSION**

This study addressed the paucity of knowledge regarding nurses’ views of clinical research involving children. The views of nurses looking after hospitalised children towards clinical research involving all groups of children were examined and the factors influencing in their decision to facilitate research identified.
Overwhelming support for clinical research was expressed and the vast majority of participants, regardless of practice area, were willing to facilitate these studies within their practice. However, some participants were only willing to facilitate protocols under the proviso of specific stipulations such as training, allocated time and relevance to practice. This is congruent with the findings of Reynolds et al (2013), but contrast to the results of the 2011 study by Mukkatash et al, which identified marked disinterest in facilitating clinical research amongst children’s nurses. The nurses in our study reported that they support and are willing to facilitate research; however their responses to the statements regarding research and the free text responses suggested a more negative perspective. This suggests that whilst nurses support children’s clinical research in principle, there are barriers to its facilitation in practice.

**Views towards clinical research involving children**

The majority of participants in our study held positive views towards children being involved in clinical research. They felt that research offered access to novel therapies, improved patient care and was essential to the development of child specific treatments. The literature however reports that nurses feel that approaching patients and their families to participate in research overburdens them at already stressful times (Dunleavy 2011; Jacobson et al 2008), and that parents can be “bombarded” by research staff (Reynolds et al 2013). This was not a view supported by this study. The majority of participants disagreed that considering their child’s participation in research studies was an added stressor for parents and felt that families wanted to be given to opportunity to participate in research. This affirms the results of Shilling et al 2011, who concluded that parents were more positive about being approached to enter their child into a clinical trial than practitioners anticipated and that fears of overburdening families were unfounded.

The majority of participants in the current study felt that facilitation of research is part of their nursing role. However, it may be that facilitating clinical research is not part of the standard nursing role, rather an extension of it, which requires an understanding of clinical research ethics and professional equipoise. Implementing clinical research protocols has the potential to conflict with the nurse’s perception of key fundamentals of nursing practice (Beauchamp & Childress 2009) as they may not always be in agreement that clinical trial protocols are the best possible care for patients randomised to one treatment arm or another. This phenomenon
was confirmed in the free text responses of our study, where participants reported only being willing to facilitate research protocols if the research “benefits the child”. The benefit conferred to the participant by their involvement in research must be an unknown in the research process in order to protect the fundamental ethical principle of research equipoise. However this uncertainty has the potential to create role conflict and ethical dilemma, as has been previously documented by physicians and specialist research nurses (Easter et al 2006; Fisher et al 2011) and confirmed by the results of this study.

Factors influencing the willingness of nurses and midwives to facilitate clinical research

This study found that nurses and midwives are driven to facilitate research mainly for altruistic reasons, borne from a desire to improve care and outcomes for children and their families. This altruistic motivation has been previously documented in studies of nurses and radiation therapists (Burnett et al 2001; Sale 2007; Augustin 2008 et al; Jacobson et al 2008; Reynolds et al 2013) and augments the finding that altruism contributes to the motivation for parents to enrol their children into clinical research studies (Sammons 2009; Woodgate & Yanofsky 2010; Fisher et al 2011). This study reported additional motivators, including positive outcomes for the individual practitioner, a supportive external work environment and well designed, well conducted studies.

Barriers cited in the literature by nurses and other professionals to the facilitation of clinical research are lack of time; increased workload; lack of incentive; lack of organisational support; poor communication and feedback and lack of recognition (Sale 2007; Augustin et al 2008). These were also the most frequently cited barriers to facilitation identified in this study. Additionally, it was found that nurses were discouraged by their perceived lack of research knowledge and confidence when implementing protocols, particularly when approaching and discussing research studies with families. This corroborates the findings of the AMRC commissioned “ComRes” survey, where approximately one third of nurses surveyed were “not very, or not at all confident in discussing research with their patients” (AMRC 2013). It was also found that whilst well conducted, well designed research studies would encourage nurses to participate; poorly designed, complicated or irrelevant studies would discourage participation.
The factors identified as discouraging research facilitation were synthesised into broad themes (Figure 2), which highly correlate with the findings of studies of the barriers to research utilization amongst nurses (Kajermo et al 2010). Organisational factors such as lack of time and incentive and the increased workload associated with research studies were the most commonly reported barriers to research. This illustrates that although now dated and heavily criticised, Funk’s work remains relevant and is applicable to nurses facilitating research, not only to those utilising the nursing evidence base. Funk’s scale however, does not allow for the report of ethical concerns, nor have ethics been reported in the literature as a barrier to research utilization by nurses.

The emergence of ethics as a barrier in the current study may be explained by the fundamental difference between the nurses utilizing the results of nursing research in their practice and the implementation of clinical research. This study aimed to identify the views towards implementing pre-defined research protocols, from a range of professional disciplines, mainly medicine. The onus is not on the nurse to develop the protocols, nor utilize the findings, but to implement a research protocol to generate experimental data. The experimental nature of the research and the nurses’ perception of “risk”, potentiated by reduced research awareness and lack of education of the research process may be the driving force behind the ethical concerns expressed in this study.

Particular concerns were expressed over the implementation of IMP protocols, perhaps deemed to be the most “risky” of all research studies. Apprehension of legal and professional retributions if should problems arise was reported by the majority of participants; this has not been previously discussed in the literature. This apprehension may stem from the emphasis that is placed on nurses’ accountability. It is a fundamental principle of nursing (NMC 2015) that nurses take responsibility and answer for their actions. Following a predefined protocol, which may be experimental and carry a degree of risk, has the potential to make nurses feel that they are practicing outside their remit and thereby place themselves at risk of legal or professional reprisal.
Although not reported as a distinct “theme”, a strong emphasis was placed by participants in this study on training, education and support. Research training for clinical nursing staff currently consists of appraisal of research for academic study or training on study specific protocols. The current study has highlighted the need for training in more general research and governance procedures, in order to tackle misconceptions about the research process and ameliorate concerns about professional and legal retributions if research “goes wrong”. This in turn may improve the recruitment outcomes of clinical research, as suggested by Elemraid et al (2013).

The request and need for an accessible and dedicated research team to support, communicate and feedback results was also reported throughout the questionnaire. Communication and feedback were deemed important to avoid the “drive by” or “hit and run” research scenarios described by Darbyshire (2008).

Whilst this study was undertaken in relatively research “naïve” settings in acute hospital sites, it may be interesting to compare these views with those expressed by nurses working in large, research intensive hospitals or in health sciences research institutes. Reynolds et al (2013) surveyed 68 nurses on a busy, research active NNICU about their perceptions of clinical research. Whilst the overall perception of clinical research was positive, free text comments regarding the implementation of these studies were resoundingly negative, including the views that research “complicated the NNICU environment”, that research staff “bombarded” new mothers and that families felt confused as to where the boundary between clinical care and research lay. Therefore, whilst it may be tempting to hypothesise that increased involvement and exposure to this type of research may foster familiarity and thereby make those involved think more positively about the process, caution must be advised.

There is little in the literature to suggest that the level of academic qualification influences the perception of child health research. This was an area which we were keen to investigate within the remit of this study, however the demographic spread of the respondents did not allow for sound statistical analysis. 61% of the respondents in this study held a BSc/BSc (Hons) Nursing degree or higher academic qualification; 32.3% held a university accredited nursing diploma, which included a taught research component. Respondents holding a certificate in nursing, which has no university accreditation and therefore no taught research component were under represented in the sample (5.7% of total respondents), meaning that any differences in the views of these
respondents and those with university accreditation could not achieve statistical significance. This may be an area which warrants further investigation as the nursing becomes an increasingly academically driven workforce.

**Recent trends**

Since this study was undertaken, additional literature on the subject of child health research has emerged. The authors have decided to present these here as it was felt that the introduction should reflect the rationale for the research at the time of data gathering. The Nuffield Council on Bioethics (2015) has published a report outlining the ethical issues that must be considered when undertaking clinical research involving children. Whilst this guidance document confirms the importance of this subject and its intrinsic complexities; it does not address the fundamental issue of how these trials are being undertaken in practice.

The challenge of undertaking clinical research successfully in practice is emerging as an area of research interest in itself. Kaur *et al* (2016) surveyed clinical recruiting teams from 30 sites which facilitated the MAGNETIC trial in 2016. This was a large multicentre paediatric trial of nebulised magnesium sulphate in acute severe asthma in the United Kingdom. The survey aimed to determine the facilitators and barriers to recruitment to the MAGNETIC trial. In line with the results of our survey, reported facilitators to successful trial facilitation were a motivated and experienced research team, good communication and the presence of a dedicated Research Nurse. Barriers cited were clinical workload, staff shortages and parental concerns regarding experimental medication. The comparability between these findings and the current ones which

Another such survey was distributed to sites which participated in paediatric cardiac arrest trials involving therapeutic hypothermia (Browning *et al* 2016). Clinical paediatric intensive care nurses at 16 sites in the USA were asked about their perceptions of the trials. The majority of the nurses surveyed (77%) had positive perceptions of the trials, with institutional support and support from a dedicated study team and training cited as contributing factors to this support for the research trials. This study also suggested that education on study rational and clinical equipoise would be beneficial for clinical nurses and may increase approach/consent rates.
In addition Smith et al (2015) have outlined the experiences of nurses involved in the conduct of intensive care research using a validated data collection tool, similar to the one developed for this study. The findings again corroborated those of our study; nurses confirmed their support for clinical research and recommended the inclusion of and communication with clinical nurses in the research process and the implementation of strategies to decrease nursing workload. The current findings still extend upon these in that they examine beyond the intensive care setting.

It can be seen that trial methodology and the logistics of how to make research studies successful in practice is emerging as a current area of research interest as clinical research is fast becoming integrated into clinical practice. The results of this study sit well within the context of this emerging evidence base. Common themes are emerging from a growing evidence base, which must be addressed in order to promote buy in from clinical teams to support the increasing volume of clinical research studies being undertaken in clinical practice. In June 2017, the NMC published draft standards for the proficiency of registered nurses, which are currently under consultation. These standards propose that, at the point of registration, the registrant will be able to “demonstrate a sound understanding of research methods, ethics and governance” (NMC 2017 p.9). This may in the future allow nurses to more fully understand the processes involved in undertaking clinical health research in practice and the associated ethical and governance framework.

**Limitations**

The unique contribution of the current findings to the existing information base on this topic is to be welcomed. However, it must be acknowledged that the study data were collected in 2013 from nurses working in relatively research naive sites. Nonetheless, as was noted above, they are quite concordant with more recent findings reported from related settings. This would suggest that although the data was collected in 2013, the findings still apply. Nonetheless, these sites have now had much more exposure to clinical research in practice and repetition of the study at these sites may now produce different results. The matter of whether attitudes change with exposure is in itself is a matter for future research. Also, there are however many sites nationally and internationally which are still relatively inexperienced in facilitating clinical research, for which the results remain both representative and relevant.
This study used a novel questionnaire as no validated instrument could be identified at that time. The questionnaire drew from instruments which had previously been used and modified to make the instrument relevant to this study. The psychometrics of this questionnaire are acceptable. However, this area of study has now progressed to the development of a robust instrument (Smith et al 2015). This instrument was developed following similar procedures to the current instrument, and indeed addresses many overlapping areas in terms of personal and institutional predictors of attitudes to research. However, the current instrument does address some unique factors. For example, the current study is unique in showing that a large majority of nurses are concerned about the burden that research studies might place on a family at an already stressful time (Table 2). This is something that could easily be incorporated into training needs. Nurses also reported concerns with regard to legal implications (Table 2). Also, the current instrument is unique in terms of breaking down the specific elements of the research process and then examining willingness to engage in each element. It is recommended therefore that might further explore the potential benefits of both questionnaires, with the view to developing an instrument that would encompass all important elements of research study in this area, could be used consistently across all future studies, and could be adapted to a variety of nursing / healthcare settings.

**Conclusion**

Nurses undertaking a growing number of child health research studies support this change and are willing to facilitate it in practice. They are motivated to participate by altruistic reasons but discouraged by external and organisational barriers and ethical concerns. The “need and want” for additional training and education, not only in study protocols, but in research ethics, drug licencing and governance procedures is highlighted. The importance of a dedicated and accessible research team to communicate and feedback studies is considered vital. Reported barriers to the research process focussed on external organisational factors such as time, increased workload and lack of incentive; therefore managerial commitment to and support for research activity is essential to overcome these obstacles. By engaging clinical staff, support for clinical research could be strengthened and consequently the recruitment for and conduct of these studies may improve, resulting in more robust research outcomes.
Issues raised in this study; such as the involvement of children in research, attitudes of clinical staff towards clinical research and the realities of undertaking research in practice will be of particular interest to those undertaking clinical research with vulnerable groups and across a range of healthcare settings both nationally and internationally, as demonstrated by geographical distribution of the literature base. The production of high quality, robust data from successful child health research is beneficial to all involved in child health care.

Acknowledgements; The project was funded by the Martha McMenamin Memorial Scholarship and supported by WHSCT and NICRN (Northern Ireland Clinical Research Network).
References


Food and Drug Administration (FDA). Available at: http://www.fda.gov/Drugs [Accessed 12th November 2016]


Royal College of Paediatrics and Child Health; Commission on Child Health Research (2012). Turning the tide: Harnessing the power of child health research. London: Royal College of Paediatrics and Child Health.


World Health Organisation. Available at: http://www.who.int/en [12th November 2016]
Table 1: Demographics

<table>
<thead>
<tr>
<th>AGE (YEARS)</th>
<th>n</th>
<th>(%)</th>
<th>HIGHEST ACADEMIC QUALIFICATION</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30</td>
<td>35</td>
<td>(33.3)</td>
<td>Certificate</td>
<td>6</td>
<td>(5.7)</td>
</tr>
<tr>
<td>31-40</td>
<td>34</td>
<td>(21.4)</td>
<td>Diploma</td>
<td>34</td>
<td>(32.3)</td>
</tr>
<tr>
<td>41-50</td>
<td>27</td>
<td>(25.7)</td>
<td>Undergraduate Degree</td>
<td>46</td>
<td>(43.8)</td>
</tr>
<tr>
<td>51-60</td>
<td>9</td>
<td>(8.6)</td>
<td>Postgraduate Certificate</td>
<td>11</td>
<td>(10.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Postgraduate Diploma</td>
<td>4</td>
<td>(3.8)</td>
</tr>
<tr>
<td>YEARS QUALIFIED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>35</td>
<td>(33.7)</td>
<td>Masters</td>
<td>2</td>
<td>(1.9)</td>
</tr>
<tr>
<td>6-10</td>
<td>18</td>
<td>(17.3)</td>
<td>PhD</td>
<td>1</td>
<td>(0.95)</td>
</tr>
<tr>
<td>11-15</td>
<td>11</td>
<td>(10.6)</td>
<td>Missing</td>
<td>1</td>
<td>(0.95)</td>
</tr>
<tr>
<td>16-20</td>
<td>12</td>
<td>(11.5)</td>
<td>General Children’s</td>
<td>49</td>
<td>(46.7)</td>
</tr>
<tr>
<td>&gt;20</td>
<td>28</td>
<td>(26.9)</td>
<td>Specialist Children’s</td>
<td>3</td>
<td>(2.9)</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>(1.0)</td>
<td>Neonatal Intensive Care</td>
<td>53</td>
<td>(50.5)</td>
</tr>
<tr>
<td>PROFESSIONAL QUALIFICATION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered Nurse (Adult)</td>
<td>50</td>
<td>(47.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered Nurse (Child)</td>
<td>76</td>
<td>(72.4)</td>
<td>No</td>
<td>46</td>
<td>(43.8)</td>
</tr>
<tr>
<td>Registered Nurse (Learning Disability)</td>
<td>0</td>
<td>(0)</td>
<td>Yes</td>
<td>59</td>
<td>(56.2)</td>
</tr>
<tr>
<td>Registered Nurse (Mental Health)</td>
<td>1</td>
<td>(1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered Midwife</td>
<td>15</td>
<td>(14.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional NMC Qualification</td>
<td>13</td>
<td>(12.4)</td>
<td>0</td>
<td>32</td>
<td>(32.7)</td>
</tr>
<tr>
<td>NUMBER OF CLINICAL TRIALS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>30</td>
<td>(30.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>17</td>
<td>(17.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>11</td>
<td>(11.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>(3.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>(5.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>7</td>
<td>(6.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statements to which respondents reported positive views about research</td>
<td>% Agreement</td>
<td>Statements to which respondents reported negative views about research</td>
<td>% Agreement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-------------</td>
<td>---------------------------------------------------------------------</td>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is important to develop child specific treatments</td>
<td>99</td>
<td>I worry about not implementing the research protocol correctly</td>
<td>77</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good quality research is important as it improves patient care</td>
<td>99</td>
<td>Approaching families about clinical research studies means they feel overburdened at stressful times</td>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is important that ward staff are informed of the progress and outcomes of clinical research studies that they have been involved with</td>
<td>96</td>
<td>It is difficult to keep up to date with clinical research study protocols</td>
<td>68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical research can offer novel therapies and interventions to children, which would otherwise be unavailable to them.</td>
<td>94</td>
<td>I worry about where I stand legally and professionally if something goes wrong in a clinical research study that I have been involved in</td>
<td>63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Being involved in clinical research contributes to my professional development</td>
<td>93</td>
<td>My workload is too heavy to accommodate additional research related activities</td>
<td>59</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having a dedicated research team facilitates the implementation of clinical research study protocols</td>
<td>93</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Willingness of nurses to engage in specific research activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes</th>
<th>No</th>
<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>(% respondents)</td>
<td>(% respondents)</td>
<td>(% respondents)</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Helping to identify eligible children to participate in clinical research studies</td>
<td>93.3% (n=97)</td>
<td>6.7% (n=7)</td>
<td></td>
</tr>
<tr>
<td>Talking to families about the nature and purpose of clinical research studies</td>
<td>72.1% (n=75)</td>
<td>27.9% (n=29)</td>
<td></td>
</tr>
<tr>
<td>Taking biological samples according to a research protocol</td>
<td>81.7% (n=85)</td>
<td>18.3% (n=19)</td>
<td></td>
</tr>
<tr>
<td>Observing patients, recording information and collecting data according to a research protocol</td>
<td>98.1% (n=101)</td>
<td>1.9% (n=2)</td>
<td></td>
</tr>
<tr>
<td>Administering a newly developed drug to a child according to a research protocol</td>
<td>64.4% (n=65)</td>
<td>33.7% (n=34)</td>
<td>2% (n=2)</td>
</tr>
<tr>
<td>Administer an existing drug to a child in a new formulation, delivery method or off licence as part of a research study</td>
<td>85.6% (n=89)</td>
<td>13.5% (n=14)</td>
<td>1% (n=1)</td>
</tr>
<tr>
<td>Implementing a new intervention or technique in the treatment of a child according to a research protocol</td>
<td>93.2% (n=96)</td>
<td>5.8% (n=6)</td>
<td>1% (n=1)</td>
</tr>
<tr>
<td>Implementing an existing intervention or technique in the treatment of a child according to a research protocol</td>
<td>98.1% (n=102)</td>
<td>1% (n=1)</td>
<td>1% (n=1)</td>
</tr>
<tr>
<td>Using a new piece of equipment or device in the treatment of a child according to a research protocol</td>
<td>94.2% (n=98)</td>
<td>5.8% (n=6)</td>
<td></td>
</tr>
<tr>
<td>Using an existing piece of equipment or device in the treatment of a child according to a research protocol</td>
<td>99% (n=103)</td>
<td>1% (n=1)</td>
<td></td>
</tr>
</tbody>
</table>
Figure 1: Categorisation of the reported motivators for clinical research participation
Figure 2: Categorisation of discouraging factors to clinical research participation

External Factors
- Workload Burden
  - Time
  - Paperwork
  - Additional workload
- Lack of Support
  - Lack of Information
    - Lack of Training
    - Lack of Communication
    - Negative staff attitudes
    - Staffing level
    - No Incentive

Ethical Issues
- Risk
  - Overburdening families
  - When to obtain consent
  - Clinical status of child
  - Causing additional pain/trauma/anxiety
  - Interfering with care of other patients
- Lack of knowledge
- Lack of confidence
- No interest in study

Individual Factors

Research Factors
- IMP studies
- Research
- Complexity of protocol
- Extensive involvement
- No scientific basis
- Not relevant to practice