HHS Public Access

Author manuscript

Int J Paediatr Dent. Author manuscript; available in PMC 2016 September 01.

Published in final edited form as:

Int J Paediatr Dent. 2015 September ; 25(5): 310–316. doi:10.1111/ipd.12176.

Challenges, benefits and factors to enhance recruitment and inclusion of children in pediatric dental research

Jane A. Weintraub, DDS, MPH [Dean and Alumni Distinguished Professor] and University of North Carolina at Chapel Hill School of Dentistry, Chapel Hill, North Carolina, USA

Carol E. Breland, MPH [Research Recruitment Director]

North Carolina Translational and Clinical Sciences Institute, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

Summary

Background—Historically, children have been excluded from clinical research. Many drugs and procedures have not been tested on children. The International Conference on Harmonization and the Food and Drug Administration guidance now stress that children should be included in research unless there is a reason for exclusion. Compared to adults, recruitment of children at different life stages requires different considerations.

Objective—To review published studies and gray literature to identify pediatric recruitment strategies and develop recommendations.

Results—There is limited clinical research literature available to recommend recruitment strategies and methods for pediatric trials. Formal guidelines for reporting recruitment activities in publications are scant. Recommendations are made based on current practices regarding protocol design, obtaining consent and engaging child, parent and caregiver in research.

Conclusions—A scientific approach is needed to determine the best design for recruitment of pediatric clinical studies. Investigators should report and publish recruitment and retention strategies that facilitate this important aspect of the research process to increase transparency, efficiency and identification of the most effective methods for dental researchers.

Introduction

Historical Perspectives on Pediatric Research

As Ross and Coffey ([1]) have described, the rescue priority on a sinking ship has been women and children go first into the lifeboats. However, in medical research, until the 1990's the opposite has been true. For a long time, the health issues unique to women and children were understudied and under-funded. Children were excluded from research for a variety of reasons. The prevailing attitudes and reasons included: paternalism, that children

Corresponding Author: Jane A. Weintraub, DDS, MPH, University of North Carolina at Chapel Hill School of Dentistry, Campus Box 7450, Chapel Hill, North Carolina 27599-7450 USA. Telephone: 919-537-3236, Fax: 919-966-4049, ; Email: Jane_Weintraub@unc.edu

Conflict of Interest

The authors declare no conflict of interest.

are vulnerable and require protection, inability of children to provide informed consent for themselves, parental fear of experimentation on their children, cost, since including children in studies can be expensive, and political, since children do not vote and influence science policy ([2]). Because of the limited research conducted with children, drugs were used "off-label" for pediatric patients. Dosages were educated guesses without consideration of pharmacokinetics or the weight of the child. The term "therapeutic orphans" was coined ([3]) because many drugs released beginning in 1962 carried a clause such as, "Not to be used in children… is not recommended for use in infants and young children since few studies…"

The need to protect human subjects in research evolved over the past 70 years ([4]) beginning in response to atrocities conducted during World War II. The Nuremberg Code of Ethics, developed in 1946, called for voluntary consent of human subjects, but the code excluded children. The turning points for considering children in research were developed as part of the Declaration of Helsinki in 1964 which described ethical principles for protection for human subjects and subsequent U.S. federal regulations and guidelines developed by the National Commission in 1977, including the Belmont Report in 1978. The guidelines suggested that research should be done first on animals, then, when possible and appropriate, on adult humans, then on older children, and finally on younger children. Thus, research on children was referred to as "hand-me down" research" ([2]).

Beginning in 1983 and updated in 1991 ([4]) U.S. Federal Policy for the Protection of Human Subjects known as the "**Common Rule**" (Code of Federal Regulations (CFR) Title 45 part 46, subpart D, protections for children) was initiated and included the establishment of Institutional Review Boards (IRB) to provide oversight and approval of informed consent, and protections and policies for research with vulnerable populations- children, pregnant women, fetuses, prisoners, and mentally incompetent individuals. A major advance came in 1998, when the U.S. National Institutes of Health (NIH) promulgated guidelines on inclusion of children in (funded) research studies which indicated that children must be included in human subject research unless there are scientific and ethical reasons not to include them. Inclusion also required providing an assessment of potential risks and benefits, and obtaining informed consent from the child's parent or guardian. More recently, in 2000, the International Conference on Harmonization (ICH) guidance "ICH Harmonised Tripartite Guideline Clinical Investigation Of Medicinal Products In The Pediatric Population" ([5]) reiterated the need for testing drugs in pediatric populations. This guidance has brought forward for discussion the issue that drugs that are not tested on children put all children at risk. Thus, the balance of risk and benefit for children is shifting toward consideration of benefit to children to participate in trials.

Current Perspectives on Reporting of Recruitment Methods

The aim of this article is to review a sample of current published dental literature, general literature related to recruitment, and gray literature ([6]) to identify and gain perspectives on pediatric recruitment strategies and develop recommendations. The top ten cited articles published in the 2013 International Journal of Paediatric Dentistry (IJPD) as listed on the journal's website ([7]) were reviewed. The studies in IJPD were chosen to likely represent

higher quality papers recently published in the journal that might indicate some best practices from around the world.

Of the 10 publications listed in the IJPD ([8–17]) eight were pediatric clinical studies- seven were observational and one was a randomized clinical trial. Only one of the studies included information about how recruitment was facilitated. Study design features such as inclusion criteria, study location, time period and in some cases, sampling design were usually included. For all the studies, parental consent or parental/legal guardian consent was reported, but details about when and how were very minimal. The specific enrollment rate was reported for three studies. Except in one study of children under treatment for asthma, children with specific medical conditions were excluded or children were attending school and assumed to be healthy. In the 24-month longitudinal study by Plonka and others ([9]) that compared the effectiveness of home visits and telephone contacts to prevent early childhood caries, the study design may have encouraged recruitment. The mothers were assigned to one of the two groups, but then given the choice to belong to either group. The majority, 91%, remained in their assigned groups. Almost no information was gained from these studies about challenges to recruitment, or factors that facilitate or impede recruitment. Formal guidelines such as the CONSORT ([18]) and STROBE ([19]) guidelines for reporting and publishing clinical research have few requirements pertaining to recruitment.

Although a full literature review was not within the scope of this review, a targeted general literature search was conducted in Pub Med using the key words “child participant recruitment methods”. The search turned up 93 results on recruitment outcomes for individual trials, but few details on recruitment operations and management for dental studies.

Much information on recruitment best practices for clinical trials in general can be found in the gray literature on recruitment websites that can be applied to dental studies. From the Recruitment Services website of the North Carolina Translational and Clinical Sciences Institute (NC TraCS) ([20]), the Center for Information and Study on Clinical Research Participation (CISCRP) ([21]), and the NIH National Heart, Lung and Blood Institute website ([22]), recommendations for recruitment and retention methods are summarized below in Table 1.

Recommendations for Improving Recruitment and Retention in Pediatric Studies

Protocol Recruitment Design Strategies

Although there are some similarities, it is important to be aware that research activities differ from regular patient care. When patients receive care in a dental practice, it is perceived that they will receive accepted therapy or the current standard of care. However, when a parent or caregiver enrolls a child in a clinical trial, the visit structure and procedures as well as uncertain outcomes and benefits can generate uncertainty. Establishing trust with the parent and/or caregiver is essential.

In 2008, Marshman and Hall ([23]) published a detailed review on the shift away from research *on* children to child- centered research that includes children as essential to the research outcomes. As the authors note “it is the child who undergoes the treatment and who lives with the consequences;” thus, “research *with* children” is a methodology that should be given high consideration in protocol design.

Recruitment is a critical part of the research process. Without sufficient numbers of study participants, there is no study. Research study design benefits from a thoughtful feasibility process ([20]). Depending on how restrictive the eligibility criteria are the number of children screened may far exceed the number needed to recruit, thus substantially increasing the time needed and raising the costs to conduct the study and sometimes introducing questions about generalizability of findings. Proper budgeting for screening activities is essential. In dental research, treatment of identified oral health needs may not be included and a referral for care provided instead.

Schools can be a good venue for communicating study goals and engaging potential participants in focus groups during the design phase of the study. For some studies of young children from low-income families, U.S. government programs such as the WIC nutrition program, Early Head Start and Head Start, can be ideal settings to reach groups of children together. Building relationships and trust with the school or organization is critical, for without a good understanding of the research goals, administrators, caregivers and teachers may be reluctant to take children away from learning to participate in research. Also, they increasingly serve as gatekeepers, wanting to derive financial remunerative benefit for their organizations and schools as well as a benefit for the participating families.

Practice-based research networks (PBRN) are being used in primary care to study and understand how procedures are used in community clinical settings. The U.S. now has a national dental practice-based research network ([24]) and according to the website, “As of September 24, 2014, more than 5,500 dentists and hygienists have enrolled.” Such networks of pediatric dentists to recruit and enroll children in research are likely on the horizon if not already operating around the world.

Protocol Promotion Tactics and Approaches

The methods chosen for promoting the study set the tone for initiating consent and enrollment. In our electronic media age, the reliance on land-line telephones, flyers and other print materials is now much less common as the internet has become the preferred source for medical and research information ([21]). Thus, while print media will always have a place in communication with potential research volunteers, informational websites, smart phones with text messaging and social media such as Facebook are quickly becoming the main communication interface.

Incentives remain an important element. Unusual ideas attract attention, such as providing a custom made knitted baby hat, a unique idea used by a Winthrop University Hospital study team (Author personal communication, 2005). Other creative ideas are a baby shower for pregnant women and children’s birthday parties ([25]).

Recruiting low income racial/ethnic minority participants may pose additional challenges because of language barriers and mistrust of researchers and government institutions ([26]). Community advisory boards and community participation in the design and implementation of studies and facilitation of ongoing communication becomes especially important. The "Early Childhood Caries Collaborating Centers" in the U.S. found that participants most frequently heard about their studies in different ways. The studies located on American Indian reservations and Head Start Centers most frequently learned about them via in person field staff; for a study in a community health center near the California-Mexico border, medical and dental waiting rooms of federally qualified health centers, and in a study conducted in Boston public housing, via door-to-door recruiting.

Engaging Parents and Caregivers in the Informed Consent Process

Recruiting children for clinical research generally requires recruiting the parent or caregiver first. Often there is more than one caregiver involved, and they may not initially share the same perspectives, adding another element of recruitment challenge.

Bhatnagar and colleagues ([27]) have described how parents or caregivers may face a certain tension when deciding whether or not to enroll their child in a research study. Because it involves experimentation, parents' sense of uncertainty about the outcome is balanced against their hope for a favorable health outcome, especially if such an outcome will benefit their child. To help ease these tensions, it is important for investigators to limit risks to children who participate in studies, and to publicize findings so future children can benefit from the advances in clinical research.

Fisher and colleagues ([28]), reviewed 16 qualitative studies from five countries and summarized parents' reasons for their decision. They found that the child's health status was a critical factor. Parents of ill children were more likely to welcome innovative treatment. Parents of healthy children were more likely to be concerned about experimental risks. The desire to be a good parent and good citizen were factors in the decision-making process.

Hoberman and colleagues ([29]) identified factors modifiable by the investigators that influenced parents who consented to have their child participate in clinical research. Positive perceptions of the research team were a strong factor in obtaining consent. The purpose of the study, study design, type of interventions being tested and the study protocol are important factors. Parents are more likely to consent if there is perceived potential for enhanced care or little interference with standard care for the child and the trial had a low degree of risk.

Obtaining Informed Consent from Parents/Caregivers and Child's Assent

Parents and legal guardians give consent for infants, toddlers, and young children. However, when children achieve sufficient literacy and maturity level, generally about age six, NIH and IRBs require that researchers obtain the child's assent ([22]). Assent is interpreted that the child actively agrees to participate, and does not just fail to object to participation. It is important for children to have a part in the decision-making process. This respect for the child often encourages his/her participation. When participation may not directly benefit the

child, if it is explained that the knowledge gained may help other children, kids often want to help others ([22]).

Obtaining Adolescent Assent

There are many reasons why adolescents might not assent to participate in research, such as fear of the unknown, fear of pain, not wanting to miss school or other activities, and not wanting to be different from their peers. It is important to communicate to adolescents in language and images that resonate with them. For example, the Cystic Fibrosis Foundation website ([30]) has an excellent short video story for children ages 8–12 years old about one girl's experience joining a clinical trial.

Retaining Parent, Caregiver and Child Engagement

To ensure continuing engagement, employ friendly, smiling, caring staff members who are available for questions and concerns. Parental schedules are often a barrier to participation. When both parents are working evening and weekend hours may facilitate study visits.

Retaining Adolescent Engagement

Just as important as recruiting adolescents is retaining their consent and cooperation. Flexible scheduling helps to work around activities, and electronic apps and text messaging aid in quick communication. Share video stories about adolescents and make those available on your clinic website or screens. For example, on the NC TraCS sponsored website www.jointheconquest.org ([31]) an adolescent volunteer and his parents talk about the personal value that clinical research has given to them.

Conclusion

In conclusion, children need to be included in clinical research so the best preventive and therapeutic modalities at the proper dosages and protocols can be developed for them. It is important for dental professionals participating in these studies to be familiar with the recruitment process and factors that impede and facilitate recruitment and retention of children. Many suggestions are included based on the experience of individual investigators. At this stage of development, recruitment is more of an art than a science. The scientific evidence for what the most effective recruitment strategies are for different age groups, populations and study designs is weak in part because this research component is under-reported and current guidelines do not require it. Investigators conducting pediatric clinical research should report and publish recruitment strategies that facilitate this important aspect of the research process to increase transparency and permit identification of the most effective methods.

Acknowledgments

Part of the information in this manuscript was presented at the 2014 annual meeting of the International Association for Dental Research in Cape Town, South Africa. The project described was supported by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UL1TR001111. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

References

1. Ross LF, Coffey MJ. (Women and) children first: applicable to lifeboats? Applicable to human experimentation? Journal of health care law & policy. 2002; 6(1):14–33. [PubMed: 15017950]
2. Pearson G. Avoiding “Hand-me-down” Research: The importance of pediatric studies. AAP. 2010
3. Shirkey H. Therapeutic orphans. Pediatrics. 1999; 104(3 Pt 2):583–4. [PubMed: 10469793]
4. Sparks, J. Timeline of Laws Related to the Protection of Human Subjects 2002. [cited 2015 February 26]. Available from: http://history.nih.gov/about/timelines_laws_human.html
5. International Conference on Harmonization: Harmonised Tripartite Guideline Clinical Investigation Of Medicinal Products In The Pediatric Population 2000. [cited 2015 February 26]. Available from: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E11/Step4/E11_Guideline.pdf
6. National Institutes of Health Library. Systematic Reviews: The Literature Search - Databases and Gray Literature. [cited 2015 May 7]. Available from: http://nihlibrary.campusguides.com/c.php?g=38332&p=244522
7. International Journal of Paediatric Dentristy. Wiley Online Library; [cited 2015 February 26]. Available from: http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-263X
8. Giacaman RA, Carrera CA, Munoz-Sandoval C, Fernandez C, Cury JA. Fluoride content in toothpastes commercialized for children in Chile and discussion on professional recommendations of use. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(2):77–83.
9. Plonka KA, Pukallus ML, Barnett A, Holcombe TF, Walsh LJ, Seow WK. A controlled, longitudinal study of home visits compared to telephone contacts to prevent early childhood caries. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(1):23–31.
10. Correa-Faria P, Martins-Junior PA, Vieira-Andrade RG, Oliveira-Ferreira F, Marques LS, Ramos-Jorge ML. Developmental defects of enamel in primary teeth: prevalence and associated factors. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(3):173–9.
11. Dame-Teixeira N, Alves LS, Ardenghi TM, Susin C, Maltz M. Traumatic dental injury with treatment needs negatively affects the quality of life of Brazilian schoolchildren. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(4):266–73.
12. Davies EB, Buchanan H. An exploratory study investigating children’s perceptions of dental behavioural management techniques. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(4):297–309.
13. Ghanim A, Manton D, Bailey D, Marino R, Morgan M. Risk factors in the occurrence of molar-incisor hypomineralization amongst a group of Iraqi children. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(3):197–206.
14. Maas JR, Junior IM, Lodi CS, Delbem AC. Differences in loosely bound fluoride formation and anticaries effect of resin-based fluoride varnishes. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(3):166–72.
15. Menon I, Nagarajappa R, Ramesh G, Tak M. Parental stress as a predictor of early childhood caries among preschool children in India. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(3):160–5.
16. Pukallus ML, Plonka KA, Barnett AG, Walsh LJ, Holcombe TF, Seow WK. A randomised, controlled clinical trial comparing chlorhexidine gel and low-dose fluoride toothpaste to prevent early childhood caries. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(3):216–24.

17. Samec T, Amaechi BT, Battelino T, Krivec U, Jan J. Influence of anti-asthmatic medications on dental caries in children in Slovenia. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2013; 23(3): 188–96.
18. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010; 8:18. [PubMed: 20334633]
19. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007; 370(9596):1453–7. [PubMed: 18064739]
20. The North Carolina Translational and Clinical Sciences Institute. Research Recruitment. [cited 2015 February 26]. Available from: https://tracs.unc.edu/index.php/services/recruitment-services/strategies
21. The Center for Information & Study on Clinical Research Participation - About US. [cited 2015 February 26]. Available from: https://www.ciscrp.org/about-ciscrp/
22. The National Heart, Lung and Blood Institute. Do Children Get to Consent?. [cited 2015 February 28]. Available from: http://www.nhlbi.nih.gov/childrenandclinicalstudies/kidshavesay.php
23. Marshman Z, Hall MJ. Oral health research with children. International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children. 2008; 18(4):235–42.
24. The National Dental Practice Based Research Network. [cited 2015 February]. Available from: http://www.nationaldentalpbrn.org/index.php
25. Ramos-Gomez F, Chung LH, Gonzalez Beristain R, Santo W, Jue B, Weintraub J, et al. Recruiting and retaining pregnant women from a community health center at the US-Mexico border for the Mothers and Youth Access clinical trial. Clinical trials (London, England). 2008; 5(4):336–46.
26. Tiwari T, Casciello A, Gansky SA, Henshaw M, Ramos-Gomez F, Rasmussen M, et al. Recruitment for health disparities preventive intervention trials: the early childhood caries collaborating centers. Preventing chronic disease. 2014; 11:E133. [PubMed: 25101490]
27. Bhatnagar S, Hoberman A, Kearney DH, Shaikh N, Moxey-Mims MM, Chesney RW, et al. Development and impact of an intervention to boost recruitment in a multicenter pediatric randomized clinical trial. Clinical pediatrics. 2014; 53(2):151–7. [PubMed: 24151147]
28. Fisher HR, McKevitt C, Boaz A. Why do parents enroll their children in research: a narrative synthesis. Journal of medical ethics. 2011; 37(9):544–51. [PubMed: 21478415]
29. Hoberman A, Shaikh N, Bhatnagar S, Haralam MA, Kearney DH, Colborn DK, et al. Factors that influence parental decisions to participate in clinical research: consenters vs nonconsenters. JAMA pediatrics. 2013; 167(6):561–6. [PubMed: 23546617]
30. The Cystic Fibrosis Foundation. Learn about Clinical Trial Participation. [cited 2015 February 28]. Available from: http://www.cff.org/research/ClinicalResearch/Participate/
31. The North Carolina Translational and Clinical Sciences Institute. Join the Conquest. [cited 2015 February 28]. Available from: https://jointheconquest.org/index.php/en/

Why this paper is important to pediatric dentists

- Historically, children were not included in clinical research and many clinical decisions are still based on studies conducted in adults. Children should be elevated to the status as participants in studies and protocols designed with their needs in mind.
- Clinical studies should be designed with consideration of the potential benefits and risks to children that influence parents' enrollment decisions. Multiple strategies can be used to recruit children in different age groups and their parents.
- Investigators should report their strategies and relative effectiveness for recruiting and retaining children and their families in clinical research so the best methods can be identified. A more scientific approach to recruitment methodology should be employed and full length articles on recruitment methods should be encouraged.

Table 1

Recruitment and Retention Recommendations

Recruitment and Retention Recommendations
Protocol Recruitment Design Strategies
Build trust by communicating the research goals to the community
Select a research question perceived to be important to the community
Characterize the target population that will benefit from the research
Design trials with practicality and minimizing risk in mind
Involve the community with the design and implementation process
Incorporate a detailed recruitment plan into the formal protocol
Use focus groups to pilot test the health literacy level of study materials
Try to avoid blood draws or other invasive, uncomfortable procedures
Protocol Promotion Tactics and Approaches
Use focus groups with characteristics of target group when designing promotional materials
Create easy to understand messages that state the study goals
Employ radio, TV, print and direct mail promotions and public service announcements
Target secondary audiences such as grandparent caregivers
Use internet, social media, and text messaging communication
Create posters and flyers to display in the clinic
Introduce the topic of research during routine visits
Give incentives that are not coercive
Provide referrals for dental care, as needed
Engaging Parents and Caregivers in the Informed Consent Process
Establish trust with the parent/caregiver by building a relationship with the family
Reassure parent/caregiver that the child's well-being is paramount
Discuss the qualifications and experience of the investigators and staff members
Provide a tour of the study clinic
Always communicate in layperson's language - avoid medical and research jargon
Approach the consent process in a stepwise fashion without rushing
Address any risk concerns right away and encourage questions
Obtaining Informed Consent from Parents/Caregivers and Child's Assent
Provide clear education about the disease or condition being studied
Relay interest in improving care or outcomes for those with the disease or condition
Explain how the parent and child can be part of finding better ways to treat the condition
Explain the randomization process if applicable and the right to withdraw at any time
Demonstrate key procedures in the study protocol as applicable
Create easy to understand print material to keep and use as a reference
Obtaining Adolescent Assent

Recruitment and Retention Recommendations
Involve adolescent as a research partner
Consider limited health literacy
Have a flexible schedule
Develop electronic apps and text messaging to aid screening
Be prepared to answer challenging questions
Note that cooperation from adolescents is subject to change at a moment's notice
Parent/teenager dynamics play a large role
Adolescents do not want to be different- show them stories and studies that include adolescents
Retaining Parent, Caregiver and Child Engagement
Always maintain a pleasant, welcoming atmosphere in your research clinic
Facilitate the parent and caregiver schedules- consider weekend and evening visit hours
Provide child care for other siblings or address child care barriers
Allow time for play before the study visit
Provide simple, colorful blocks or dolls to create a relaxed, low-stress environment
Have a quiet place for mothers to breastfeed or parents to change diapers
Stock an age appropriate treasure chest from which the child may choose a small token
Provide snacks, and if needed, transportation or transportation vouchers
Retaining Adolescent Engagement
Build in contingencies for a higher than anticipated drop-out rate
Take into consideration the hectic lifestyle of most adolescents
Accommodate busy schedules, sports, enrichment activities after school and on weekends
Provide substantial snacks and age appropriate incentives
Anticipate boredom- stock up on games, videos, and internet access
Set up text messaging reminders and to communicate with participants