


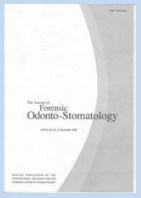

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INFORMED CONSENT IN COMMUNITY-BASED ORAL HEALTH RESEARCH

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ABSTRACT

The ethical principle of respect for persons presents multiple dimensions to stimulate debate around issues related to informed consent for participation, data management, confidentiality and privacy. The informed consent process is built on a continuum involving a comprehensive explanation of the proposed study; and the declaration of consent (the right to withdraw from at anytime from the study without any negative consequences). All research involving human participants carry a certain level of risk (physical or informational) and it is not possible for the researcher to know all the consequences of participation before a study commences. This presentation will focus around the key issues of information, consent' and competence in relation to community-based oral health research and outlines some of debates in the informed consent process.

KEYWORDS**:** Informed consent; information; confidentiality; oral health activities; risks-benefit ratio; community

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INTRODUCTION

Ethics in oral health research should be concerned with ensuring first and foremost the respect, protection and the promotion of participant's rights, however not much research related information exists in this area. The informed consent process forms part of the ethical principle that espouses to respect for persons and essentially comprises of three key elements. This includes adequate information to guide the participant into making a decision to participate in the study. Voluntariness refers to rights of the participant to withdraw at any stage of the study without any negative consequences or loss of rights and privileges. Competence refers to the individual's capacity to decide whether to participate or not. This capacity refers not only to mental competence but also takes issues around the vulnerability of participants into account.[1-5]

The informed consent process thus involves the "*ability to understand relevant information; the ability to appreciate the nature of a situation and its likely consequences; the ability to reason through the information and weigh the options logically; and the ability to communicate the choice*".[6p2] The literature indicates that participants understanding of the research process is further diminished when inadequate information is provided or when the information is highly technical, difficult to comprehend and legalistic.[6-8] Studies indicate that participants experience difficulties in really understanding the nature of their participation in a research study, the use of placebos, their right to withdrawal at any time, the right to seek alternate sources of care and the *"confusion around the dual roles of physicians and researchers"*.[6p2] This paper further extrapolates this issue to include the dual roles of oral health service providers and researchers in community-based settings such as schools.

DEBATES IN THE INFORMED CONSENT PROCESS

Several debates arise around ethical issues in community based oral health research. An ethical dilemma that could arise from the research process would be the collection of clinical data. This could include dental caries status, oral cleanliness or periodontal status. Does the researcher have an ethical obligation to refer the participant for further clinical management, should he/she require these services? How does this referral impact on the right to privacy and confidentiality? How can the researcher guarantee confidentiality for participation yet refer the participant for further management? Should the researcher thus qualify the extent to which confidentiality can be maintained?[9]

Another debate revolves around the following: should the researcher conduct a caries risk examination in geographical areas where referral patterns for further clinical management is not possible because of lack of access or availability of oral health services? Should the researcher raise awareness of oral disease status yet be unable to refer the participants for further management? Does the researcher have an obligation to provide an educative component to the research process in order to address unhealthy behavioural practices? The research process is considered a systematic enquiry through the use of scientifically valid methodologies designed to contribute to the body of knowledge in an identified field.[10] However the researcher's responsibility extends beyond the generation of data and should be held accountable for identifying further support for the participants. This could include referral mechanisms for psychosocial or educational support through health promotion efforts.[10-11] Mechanisms for referrals should be clearly articulated in the

information documents presented to the potential participants.

In qualitative research, the right to participant confidentiality, privacy and anonymity could be a challenge. Another scenario could be group focus discussions. A study does not have to be high risk or invasive to bring about social harms.[11] A breach of confidentiality concerning the participant's social status, sexual orientation, dietary practices, perceptions of oral diseases, self-care practices could all become a source of stigmatization even though the study in itself is minimal risk.[10,11] The manner in which information is generated, shared and explored can be a potential source of stress for the participants and the researcher needs to be aware of this.[10,11] It is also possible that at times information not related to the study is revealed in these focus group discussions and the researcher must be able to facilitate and balance the quality and relevance of the information provided. Further ethical dilemmas could arise should a participant decide to disclose sensitive information about him/herself or about the institution that could bring the institution into disrepute for instance, theft of tooth brushes or supplies related to the school feeding scheme programme, or more seriously, abuse at the school. The researcher would need to determine how to manage this information by balancing the rights of the individual to the legal responsibilities of the researcher.[10-12]

The participant's ability to exercise the right to withdrawal can also be difficult to achieve in some settings, for instance a school setting.[11,12] A participant could be reluctant to withdraw from a study for fear of stigmatization and ostracisation. A scenario could be where an oral hygienist is conducting a school-brushing programme as part of service delivery in a low resourced community with high levels of unmet oral health need. He or she then decides to evaluate the services as part of a research study. The school brushing programme, in this context, is already seen as a privileged contribution that is beneficial to the learners. It would be difficult for learners to refuse participation when the programme is part of the daily school activity. Other reasons could include peer pressure or the need to comply with other learners in the school, especially when the study has the support of the parents, educators and the school principal. Thus the power relations that exist between the learners and the gatekeepers and role and influence of the researcher in these settings must also be taken into account.[12]

In addition to obtaining parental consent for learners under 18 years of age, learners are required to provide assent. The rights of the child participant must be upheld even if the parent has consented but the child has refused participation.[13] The provision of adequate information on the risks-benefit ratio can be particularly challenging especially when there is possibility that this information could in fact have a negative effect on the study recruitment process. Disclosure of possible risks associated with participation could be seen as a deterrent to participation and could impact on the recruitment of study participants.[7]

It is also not possible for a researcher to know all possible risks associated with the study before the study can commence. An example of this scenario would be researchers engaging in an experimental study involving the effectiveness of fluoride mouth rinses as a caries preventive strategy. Fluoride is found naturally in low concentrations in food, beverages, fish, wine, vegetables, etc. Fluoride is also found in water obtained from boreholes and natural springs and the fluoride could be in high concentrations depending on the geographical regions. One of the known

long term side-effects of systemic exposure to fluoride is dental fluorosis and this feature ranges from a few white specks on the teeth to an irreversible breakdown and destruction of the tooth structure (mottling of enamel).[14,15] For this to occur the teeth have to be in the developmental stage, thus this side effect is primarily associated with younger children when the teeth are still developing.[14,15] It is not possible for a researcher to know the individual's total cumulative exposure to fluorides and given the debates around the long term exposure to fluoride, the researcher will not be able to conclusively outline all the possible long term effects of combined topical and systemic exposure to fluoride.

This also raises the debate around the researcher's responsibility to address the long term adverse events associated with the study. The question to be asked is: can a researcher be morally and ethically held accountable for dental fluorosis occurring in a community because of exposure to topical fluoride?

Another scenario could be the implementation of a community-based sealant programme using an experimental design. This is a clinical procedure that can be done in community settings where a resin is placed in the fissures of healthy, non-carious (not decayed) teeth. A sealant programme conducted in a community setting would not include supporting diagnostic tools such as use of radiographic examination, hence it is not possible to identify caries that cannot be seen clinically. Furthermore the placement and success of dental sealants are technique sensitive, dependent on the type of dental material used, self-care practices, the individual's caries risk profile, diet, etc. One of the disadvantages of dental sealants is the possible need for re-application.[16-18]

Hence the researcher needs to consider the extent to which post-trial care would be provided, should these dental sealants fall off. The researcher needs to identify pragmatic solutions and build this into the research and funding processes.

OBTAINING INFORMED CONSENT

Obtaining informed consent can be particularly challenging. The greater the potential risk, the greater the need for community engagement to ensure that there is community buy-in and support for the study, to alleviate any negative perceptions around the study, and promote openness and transparency. Obtaining consent from vulnerable populations must be done in a non-exploitative manner that does not compromise their safety or dignity.[2,5,7]

There is a debate on whether consent should be a once-off event or be part of a continuum.[3]
Viewing consent as a once off-process implies that the participant has provided consent to all aspects of the research process. However, the dynamic nature of the research process suggests unexpected changes can occur and it is only ethical to engage with the participant on an ongoing basis. There is also a notion that consent should be re-affirmed after the collection of data because this provides the participant with a different perspective of the study as compared with when he or she enrolled for the study.[19]

Thus the informed consent process should include information explained in simple and easy to understand format. This information should include the aims and objectives of the study, the purpose of the study, the processes involved, data collection processes, the duration of data collection, the time and venue, the possible benefits and associated risks, the mechanisms to address risk, referral patterns for further management, the costs associated with the referral process.[1,20] The researcher should also include the contact details for the researcher, supervisor where

appropriate, and a Research Ethics Committee (REC), overseeing the research process. All other funding agencies or sponsorships should be identified and stated.[1,20]

Consent is only valid if it is obtained voluntarily and without coercion. The participant should be given adequate time to consider the process, benefits and possible risks associated with participation.[1,21,22] The use of implied consent, where participation in the study is seen as a sign of consent, is deemed unacceptable. Consent should be expressed and documented as far as possible. Consent should also be obtained for different phases of a study or if data collection is occurring in multiple sittings, for instance a study involved clinical examinations, and interviews with the participants or a study involving multiple interviews with the same participant. It is imperative to ascertain who will administer the informed consent process, flexibility in the timing and considerations for re-calls or subsequent visits.[22] The researcher also needs to identify mechanisms to address the loss of time, inconvenience and expenses that could occur as a result of participation in the study. However, this must not be seen as undue inducements that could blind the participants to the potential risks associated with the study.[8-11]

Studies involving children must first demonstrate that the same research cannot be done on adults and yield the same effect and impact. The risk-benefit ratio should not only consider individual impact but how this impacts on communities of which these individuals are a part of.[23] There is need for partnerships between the individuals, communities, researchers, and institutions where these individuals are located.

The issues of how confidentiality, privacy and anonymity are maintained, must be outlined. The researcher should indicate how the results of the study would be made public. How will the participant, institutional or organizational rights to confidentiality be maintained? Will the information be de-identified or de-linked? The issue of data management, including storage and access, and its eventual disposal must be outlined. The researcher needs to identify where the data will be stored, who has access to the information, who has ownership of the data and how will the data be destroyed. It is important to note that issues of data management, including confidentiality, should extend beyond the research team and include any person that may come into contact with the data.[1-6]

The issue of future use of collected data must be addressed. Will the data be used only for research purposes? Will the data be used for educational purposes? To what extent will the use of photographs or video recordings be used? How will confidentiality and privacy be maintained with the use of photographs or video recordings? Participants should be given the right to accept or reject data gathering devices such as cameras, video and voice-recorders. Consent for use of this equipment must be obtained explicitly. What mechanisms will be in place to oversee data sharing? Will this data be annoymised or de-identified? How will issues of participant confidentiality and privacy be maintained? Does this include a review by the overseeing Research Ethics Committee?[19-23]

The researcher should identify mechanisms to address any non-disclosure of information that could occur at the start of the study. This non-disclosure could be as a result of study design (for instance a blinded study, masked study or the use of a placebo in experimental studies). The researcher should firstly provide a strong justification for non-disclosure. In the case

of experimental studies, the control group should not be exposed to an intervention that is below the acceptable standard of care. The researcher needs to identify how the participants will be informed of the reasons for non-disclosure at the end of the study and identify referral patterns for further support, if required. The feedback on the rationale for non-disclosure should include issues of potential risks or discomfort to the participants.[9-11]

Gatekeeper permission does not in any way diminish the need for participant consent. Any conditions placed by gatekeeper must be reviewed with caution, eg. access or sharing of data, because this comprise issues of confidentiality and privacy.[20] It is also possible that phrases and expressions used in the interviews can be linked to participants even though the data has been annoymised.

CONCLUSIONS

The process of obtaining informed consent is thus more than a signature on a piece of paper. It involves an intricate network of communication and collaboration based on trust.[23] Researchers in community based oral health research need to take cognizance of the ethical issues highlighted and more debate should be stimulated around this area.

REFERENCES

1. Wiles R, Heath S, Crow G, Charles V. Informed consent in social research: A literature review 2005. ESRC National Centre for Research Methods. NCRM Methods Review Papers. NCRM/001. University of Southampton. Accessed 25 July 2014. Web address: www.sociology.soton.ac.uk/Proj/Informed_Consent/litreview.rtf

2. Beauchamp TL, Childress JF. Principles of biomedical ethics. Fourth edition, Oxford University Press, 1996.

3. World Medical Association. Ethical principles for medical research involving human subjects (aka the Declaration of Helsinki) 2004. Accessed 17 March 2014. Web address: www.wma.net.

4. Kuroyanagi T. On the 2008 Revisions to the WMA Declaration of Helsinki. JMAJ 2009;52(5):293-318.

5. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical principles and guidelines for the protection of human subjects of research 1979. Accessed 28 June 2014.Web address: http://ohsr.od.nih.gov/guidelines/belmont.html

6. Taiwo OO, Kass N. Post-consent assessment of dental subjects' understanding of informed consent in oral health research in Nigeria. BMC Medical Ethics 2009, 10-11. doi :10.1186/1472-6939-10-11. Accessed 3 July 2014. Web address http://www.biomedcentral.com/1472-6939-10-11.

7. Helgesson G, Ludvigsson J, Gustafsson S. How to handle informed consent in longitudinal studies when participants have a limited understanding of the study. J Med Ethics 2005;31:670-673.

8. Fleming DA, Reynolds D. Ethical human-research protections: Not universal and not uniform. The Am J Bioeth 2008; 8(11):21-22.

9. The National Human Research Protections Advisory Committee (NHRPAC), 2002. Recommendations on Confidentiality and Research Data Protections. Accessed 15 October 2014. Website address: http://www.hhs.gov/ohrp/archive/nhrpac/documents/nhrpac14.pdf

10. World Health Organisation. Ethical issues in patient safety research. 2013 WHO Document Production Services, Geneva, Switzerland. Accessed: 15 October 2014. Website address: www.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf

11. Human Participant Studies - Risk Assessment Guide. 2014 Accessed 15 October 2014. Website address: https://member.societyforscience.org/document.doc

12. Wanat CL. Getting past the gatekeepers: difference between access and cooperation in public school research. Field Methods 2008;20(2):191–208. DOI: 10.1177/1525822X07313811. Accessed 16 May 2014. Web address: http://fmx.sagepub.com

13. Fombad CM. Protecting children's rights in social science research in Botswana: some ethical and legal dilemmas. Int Jnl Law Policy Family 2005:102-120. doi 10.1093 law/fam/ebi005.

14. Centres for Disease Control and Prevention (2001). Recommendations for using fluoride to prevent and control dental caries in the United States. Recommendations and Reports 2001/50(RR14);1-42. Accessed 19 August 2014. Web address www.cdc.gov/Mmwr/preview/mmwrhtml/rr5014a1.htm

15. Centres for Disease Control and Prevention. Community water fluoridation. 2013 CDC 24/7. Accessed 19 August 2014. Web address: www.cdc.gov/fluoridation/safety/dental_fluorosis.htm

16. Siegal MD, Miller DL, Moffat D, Goodman MS. Impact of targeted, school based dental sealant programs in reducing racial and economic disparities in sealant prevalence among schoolchildren—Ohio, 1998-1999. U.S. Centers for Disease

Control and Prevention 2001;50(34): 736-8: (accessed in April 2011. Web address: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5034a2htm
17. Kitchens DH. The economics of pit and fissure sealants in preventive dentistry: A review. J Contemporary Dent Pract 2005;6(3):95-103.
18. Hiiri A, Ahovuo-Saloranta A, Nordblad A, Makela M. Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents. Cochrane Database Systematic Review 2006;18(4):CD003067. Accessed 20 November 2011. Web address: http://jada.ada.org/content/139/3/257.full.pdf+html
19. Jesani A, Barai T. Ethical guidelines for social science research in health. The Indian National Committee for Ethics in Social Science Research in Health (NCESSRH). (Undated). Accessed on 24 July 2014. Web address: www.esocialsciences.org/Download/repecDownload.aspx?...02
20. Campbell J. Ethical Considerations with Gatekeepers. Mark Bound Nova Southeastern DCAR 7120NSU PhD. Program. 2012. Accessed on 24 July 2014.
*Web address: www.academia.edu/.../**Ethics**_in_Qualitative_Research_**Gatekeepers***
21. Health Professions Council of South Africa. Guidelines for good practice in the health care professions. General ethical guidelines for health researchers. 2008; Booklet 6, Pretoria. Accessed 18 March 2014. Web Address: http://www.hpcsa.co.za (accessed 18 March 2014).
22. Boga M, Davies A, Kamuya D, Kinyanjui SM, Kivaya E, Kombe F, Lang T, Marsh V, Mbete B, Mlamba A, Molyneux S, Mulupi S, Mwalukore S. Strengthening the informed consent process in international health research through community engagement: The KEMRI-Welcome Trust Research Programme experience. PLoS Medicine 2011,8(9):1-4
23. Cassell J, Young A. Why we should not seek individual informed consent for participation in health services research. J Med Ethics 2002;28:313-317.

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