Author's response to reviews

Title: Randomized Study to Disseminate Caries-Control Services in Dentist Offices

Authors:

David Grembowski (grem@u.washington.edu)
Charles Spiekerman (cspeker@u.washington.edu)
Michael A del Aguila (michael.del_aguila@roche.com)
Maxwell Anderson (maxscruiser@gmail.com)
Debra Reynolds (DReynolds@DeltaDentalWA.com)
Allison Ellersick (AllisonEllersick@yahoo.com)
James Foster (JsFoster@DentalDAC.com)
Leslie Choate (lchoate@everett.wednet.edu)

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Author's response to reviews: see over
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Dr. Peter Newmark  
Editor-in-Chief  
*BioMed Central*  
*BMC Oral Health*

Dear Dr. Newmark:

My co-authors and I are pleased to submit our revised manuscript, “Randomized Study to Disseminate Caries-Control Services in Dental Offices,” for consideration as a future article in *BMC Oral Health*. Thank you very much for your patience and allowing us to resubmit the article at a later date. First and foremost, we would like to thank the reviewers for their comments, which have improved the quality of our paper. Our responses to reviewer comments follow.

**Reviewer 1**

1. Introduction. Would be possible to include a simple description of dentist utilisation by children from Washington State (or US children). Probably you could get those data from your National Health Interview surveys.

We added a sentence indicating the percentage of U.S. children with private dental insurance seeing a dentist each year.

2. Introduction. Page 6. Second paragraph. I do not agree that "insufficient evidence exists for fluoride varnishes". There are some systematic reviews of fluoride varnishes (an easy search in PubMed will show them) that demonstrate a significant and high caries protection.

We updated our PubMed search and agree with this comment. The Introduction paragraphs were revised accordingly.

3. Methods, first paragraph. There is a quantitative description of sealant use, but qualitative ("rarely") of varnish use. Please, provide a quantitative figure (it could be enough an approximation or estimation) for varnish use.

An accurate quantitative figure of the number of fluoride varnish services that each office provided before the study began does not exist because dental offices were not using the WDS fluoride varnish procedure code. We changed this sentence to state that an accurate count of the fluoride varnish services does not exist for reasons described in the Discussion section: “Accurate records of dentists’ delivery of fluoride varnish did not exist before the study, and we assumed fluoride varnish was similar to other dentists in Washington state[3,8].”

4. Results. Please provide an analysis comparing those dentists accepting or not to participate in the study.

A new subsection was added to the Results section containing these comparisons.
5. Methods or Results. You should specify the percent of parents accepting their children to participate in the study.
We cannot present these results because this information was not collected in the study, mainly to reduce data collection burdens on office staff. However, anecdotal information from the intervention offices indicated high levels of parental acceptance, which is plausible because the objective of the study was to change provider behavior rather than parent or child behavior.

The randomization for this study was done at the dentist level. Our analysis is essentially based on the independent units (dentists), not the patients, thus adjustments for correlation are not necessary. The permutation method used was designed for analyzing group randomized trials such as this. The tests are based at the group level, while allowing adjustment for the individual (patient) level characteristics.

In addition, randomization and data analysis should be consistent. When the unit of randomization is the dentist/office, the unit of data analysis is the dentist/office. Whiting-O'Keefe et al (1984) note the problems that occur when patient-level data are used to make conclusions about provider behavior.

Whiting-O'Keefe QE, Henke C, Simborg DW, Choosing the correct unit of analysis in medical care experiments. Medical Care. 1984 Dec;22(12):1101-14.
Abstract: The statistical methodology of health research experiments published in Lancet, the New England Journal of Medicine, and Medical Care between 1975 and 1980 for the presence or absence of an error of experimental design and analysis was examined. The error is the result of inappropriately using patient-related observations as the unit of analysis to form conclusions about provider behavior or outcomes determined jointly by patients and providers. The error was present in 20 of 28 (71%) health care experiments addressing an issue of health provider professional performance. Its usual effect is to increase erroneously the power of an experiment to detect differences between experimental and control groups. It is likely that this type of error could be avoided by the explicit and prospective definition of hypotheses and the populations to which they are intended to pertain.

7. Methods. Analysis. I do not share the rationale to adjust three models in the analysis. This is not parsimonious. Please, consider the possibility of adjusting only one (and not three) model. This would make easier to understand your paper.
We present only one adjusted model as requested by the reviewer.

8. Tables. Please, include the standard deviation (and not only the mean) for the description of all quantitative variables.
We have added standard deviations to the tables. In the process of adding the standard deviations in Table 3, we detected incorrect (too small) averages for fluoride varnish from a preliminary computer output for some dental offices and replaced them with the correct values from our final computer output.
9. Discussion. Please provide any comment/comparison between participants/non-participants clinics.
Our response to No. 4 above compares the office characteristics of the participating and non-participating dentists, which appears in the Results section. The Discussion section contains a paragraph on this topic.

Reviewer 2

This is an interesting article which certainly highlights the great difficulties in undertaking research in primary care.

1. Abstract
Conclusion. Low dentist participation - this cannot be a conclusion as it is not based on the objectives of the study. This is opinion and as such should be in the discussion.
The intervention did not reduce children's dental fear - it recorded that the parents reported it may have reduced their children's dental fear.
We revised the conclusion of the abstract and omitted the text on low dentist participation. We agree with the reviewer’s clarification about dental fear, and this is why we used the word “may” in the original version.

2. Background
This is well written and informative. However, I do take issue with the last paragraph on the study design:-
• Part 1 is not a study on its own, it is standard procedure in any randomised study and hardly merits mentioning in this paragraph.
• Comments on dentists’ consent being an indicator of adopting technology was not an aim and is conjecture more suited to the discussion.
• The response rates are results and should not be in the introduction.
• The first sentence "our purpose ...... at risk of caries" is sufficient to describe the study.
We revised the last paragraph of the Background section, deleting most of the text but retaining the purpose statement, as recommended by the Reviewer.

3. Methods
Part 1 Dental Recruitment and Education
I have noted in the introduction this section is standard procedure and should not be called Part I.
We changed the organization of the Methods section and removed text referring to Parts 1 and 2 of the study.

The Figure 1 is unnecessary as the authors explain the randomisation and preventive intervention very clearly in the text.
We deleted Figure 1 from the paper.
Part II - not necessary to delineate this as a separate part of the study.
The division of the study into Part I and II was removed.

Page 9 - 2nd paragraph ‘Children were followed for 2 years though …’ (should be "through").
The word was corrected.

4. Results
Table 2 seems to indicate that there may be a disagreement between the dentists and the researchers on what constitutes caries risk. The researchers define ‘at risk’ for caries as ≥1 restoration or carious lesion, yet Table 2 shows only a small proportion were rated high caries risk by the control group dentists (9%), and even in the intervention group only 30% had a high caries risk. If dentists do not perceive or record a caries risk, then preventive inputs may well not be offered. Clearly the control and interventive dentists were assessing caries risk with different thresholds. Nearly half the children had no rating at all.

This comment addresses two parts of the study. The first part is the eligibility criteria for children to be included in the study, which is one restoration or carious lesion, as noted above. The second part is dentists’ perceptions of caries risk. Dentists were instructed to report caries risk as in daily practice. The study did not train dentists and office staff in the intervention and control groups to follow a specific protocol for caries risk assessment (dentists and office staff assessed caries risk as they normally do in daily practice), and the study’s eligibility criteria may be different from the dentists’ perceptions of caries risk. Therefore, our study is examining the intervention’s effect within the “real-world” of dental practice, which improves the external validity of the findings. For the offices reporting caries risk, control and intervention offices classified a similar percentage of children at low caries risk (13% vs. 12%, respectively). Control offices classified a higher percentage of children at medium risk than high risk (32% vs 9%), while intervention offices had an opposite pattern (11% medium risk vs. 30% high risk). Thus, a difference exists only at the medium-to-high threshold, which may reflect differences in how the dentists evaluated caries risk as well as differences in the oral health status of the children. Percentages might change if the caries risk data were complete. These arguments suggest that controlling for dentists’ evaluated caries risk in regression models is important when estimating intervention effects.

P15, 3rd paragraph - I am not sure it is appropriate to remove practices from the regression models in a RCT.
We agree with the reviewer’s point. However, about 300 of the study’s 689 children were enrolled in two offices, which might be contributing to the study’s results more than the other offices. Our purpose was to perform a sensitivity analysis to assess whether the main results of the study changed when the two offices were removed. We added text to this paragraph to clarify our purpose.

P16 Paragraph beginning "Parents in the intervention ..."
The paragraph should be deleted. There was no significant difference, therefore any variation could be due to chance and it is most unwise to try and suggest otherwise. This study has a problem in that it is underpowered because of the reluctance of practice owners to participate and this has made it difficult to offer
definitive results. Research of this type is difficult and the authors have
demonstrated a methodology which is sufficient, they should not be tempted to
try and suggest there are differences when it is clearly impossible to give such an
answer.
We deleted the last paragraph as recommended by the reviewer but retained the
sentence that “Parents in the intervention group also reported their children had less
dental fear than control children,” given that p=.04.

5. Discussion
I am concerned that the dentists did not use the WDS procedure code for fluoride
varnish especially as they were offered a ‘free’ product. This makes any
suggestions on the use of the varnish difficult to comment on, and as such, I am
not sure one can then discuss how dentists fitted the Kuhn’s model. It would be
more helpful to know why the practices did:
• not use fluoride varnish.
• did they prefer another system?
• or why the right code was not used?
Indeed, the views of the dentists is one key aspect which should be in the paper.
Given this was a demonstration study it is very important to hear from the key
stakeholders as to what influenced their decisions not to offer a preventive
product and whether varnish or some other fluoride system was preferred.
Of all the intervention and control offices, only two intervention offices submitted service
records with the procedure code for fluoride varnish. If the free fluoride varnish created
an incentive to not use the fluoride varnish code, we would expect the control offices to
use the fluoride code more frequently than the intervention offices, but this was not the
case. We added a sentence noting that in future studies, monitoring office coding might
increase use of the procedure code for fluoride varnish, but monitoring also may
increase the delivery of fluoride varnish in control offices.

We did not collect qualitative information from the dental offices to answer the questions
raised by the reviewer. This information is difficult to collect today because of the time
elapsed since the intervention was being delivered in the field, and because most of the
coauthors from Washington Dental Service are no longer employed there.

P17. We examined dentist and office characteristics associated with participation
in the study. There are several ‘kites’ flown here but the research did not either
ask or answer these questions and I feel a degree of prudence is required.
We revised the paragraph and removed the sentences noted here.

I think the authors should have referenced “The capitation study 2. Does
We added a sentence citing the Lennon et al paper in the Discussion section.

6. Conclusion
The low dentist participation was not investigated. There could be a myriad of
reasons for this but one cannot include a comment in the conclusion as it was not
a study objective. Conclusions are based on the aim/objectives of the study. The
main problem with the study was the small sample size and why dentists did not fill in the coding sheets appropriately.
This is a good point, and we deleted the sentence (that is referred to in Comment 6) from the Conclusions section.

Overall comment
An excellent pilot study which should focus on the problems of running such studies in primary care. The main issues are:-

1. 34% participation rate is too low to be representative of anything, as the authors admit in the last paragraph of the discussion. Thus, no generalisable conclusions can be drawn or any useful advice given.

2. No comparisons were made between the consenting and the non-consenting groups, but the authors admit that they were different in at least one important parameter.

3. No alpha level or power calculations are given so the ability of the study to demonstrate anything worthwhile is debatable. In fact, the authors also admit that the work was under powered. The only conclusion that is possible is that such studies must be larger.

4. The discussion and conclusions are largely conjecture as the authors appreciated the weaknesses in their study.

In closing, we received a notice that BioMed Central is launching a new journal, Implementation Science, and our manuscript may also be of interest to the readers of this new journal.

Thank you very much for your continued review and consideration of our manuscript. If you have any questions about the revisions, please contact me by phone or at my email address.

Sincerely,
David Grembowski, PhD
Professor and First Author

Enclosure: revised manuscript