Author's response to reviews

Title: IDEAS for a Healthy Baby: Rationale and design of a randomized controlled intervention trial of patient navigators to assist low-income pregnant women in using publicly reported pediatric quality data

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Author's response to reviews: see over
July 21, 2013

Dear Drs. Altman, Furberg, Grimshaw and Rothwell,

Thank you for the thoughtful review of our study protocol now entitled “IDEAS for a Healthy Baby - Reducing disparities in use of publicly reported quality data: study protocol for a randomized controlled trial” to better conform to the recommended format. We found the reviewer’s questions and suggestions insightful and feel the manuscript is much improved. Our responses to editor’s and reviewer’s comments are outlined below suing the following format: A – Editor/Reviewer Comment; B – our response to the comment; C – location of change in text if applicable; and D – the changes as they appear in the manuscript. We have also carefully reviewed formatting guidelines and made changes to conform to these guidelines.

This manuscript has not been submitted elsewhere previously and is not under consideration elsewhere currently. None of the authors have a conflict of interest to report and all meet the criteria for authorship.

Sincerely,

Sarah L. Goff, MD (corresponding author)

MS: 1084131162995998
IDEAS for a Healthy Baby: Reducing disparities in use of publicly reported quality data: study protocol for a randomized controlled trial

Response to Reviewer Comments

E1A. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?__________: study protocol for a randomized controlled trial.?  
1B. This has been changed as suggested.

E2A. Please remove the funding information from the title page and add it to the Acknowledgements section.  
2B. This has been moved as suggested.

E3A. Please ensure that the Trial Status section is located at the end of the manuscript, so just after the Discussion.  
3B. This has been moved as suggested.
E4A. Please move your ethical approval statement to your Methods section, it should not be in the Trial Status section.

4B. The ethical approval statement is now in the Methods section.

4C. Methods/Design, Page 6

4D. This study is approved by the Baystate Medical Center Institutional Review Board.

E5A. If applicable, please include an acknowledgement section at the end of the manuscript before the reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for all authors. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

5B. The Acknowledgement section now includes the funding source for the study and for the authors on the study who have funding.

5C. Page 19
5D. This study is supported by a grant from the Agency for Healthcare Research and Quality (1R21HS021864-01).

6A. Please also ensure that your revised manuscript conforms to the journal style (http://www.trialsjournal.com/info/instructions/). It is important that your files are correctly formatted.

6B. We have reviewed the journal style guidelines and made changes to conform to these guidelines.

Reviewer #1

1A. Revising the abstract. The objectives of the study are less clearly specified in the abstract than they are in the section entitled 'Study objectives'. I would encourage the authors to use the section in the main body of the text in the abstract too (especially for objectives 2 and 3), for greater clarity.

1B. We now use the Study Objective section from the main body of the text in the abstract as suggested.

1C. Abstract – Methods/Design

1D. The goals of this study are: to determine the efficacy of a patient navigator intervention to assist low-income pregnant women in the use of publicly available information about quality of care when choosing a pediatrician; to evaluate the relative importance of factors influencing women’s choice of pediatric practices; to evaluate the effect of the intervention on patient engagement in management of their own and their
child’s health care; and to assess variation in efficacy of the intervention for sub-groups based on parity, age, and race/ethnicity.

2A. Giving more background on the US health system and how it might shape the delivery and impact of the intervention. Trials is an international journal and many readers may not be familiar with the US health system and the authors' local context. The authors may wish to clarify the following issues:

2aA. The article states that 89% of the Baystate prenatal clinic attendees are insured through Medicaid. What are the implications of this for patients' choice of paediatric care providers (and therefore the impact of the intervention)? Are they eligible to go to any of the clinics appraised for quality by MHQP within 25 miles of Baystate? Your comments about barriers seem to suggest that insurance conditions may apply. Are you referring to the mothers on Medicaid or others? What might these restrictions be?

2aB. Based on data from the American Academy of Pediatrics Fellow’s Survey in 2000, 98% of pediatric practices in Massachusetts participated in Medicaid (publicly funded insurance) and 100% participated in SCHIP (another form of publicly funded state children’s health insurance) with 94% and 95% of practices providing services to all patients with each of these insurance sources respectively. Although we do not have current data, we polled a sample of practices within 25 miles of Baystate when developing the proposal and found all accepted Medicaid. Our concern was that some
practices that accept Medicaid patients may accept a limited number and that this might create a potential barrier. We have clarified this in the text.

2aC. Methods, Pages 6-7

2aD. The majority (89%) of the women attending the clinic are insured through Medicaid, the national public insurance available to women with no employer-based insurance and/or a low-income level. [28] Children of women who qualify for Medicaid often also qualify for this public insurance. A 2000 survey undertaken by the American Academy of Pediatric showed nearly 95% of pediatric practices in Massachusetts accepted all patients with public health insurance [29], but practices may elect to limit the number of patients they take with any type of insurance.

2bA. Does the MHQP website provide quality scores for all paediatric clinics within 25 miles of Baystate? If not, might some of your patients go to clinics without MHQP scores and how would you account for them in your analyses?

2bB. Although the majority of practices within 25 miles are reported on the MHQP website, there are some practices that had insufficient data to have stable estimates of scores. Data from patients who choose practices that do not have scores on the MHQP website will not be included in the primary outcome analysis, but will be included in analyses for secondary aims.

2bC. Analysis, Page 13
2bD. Patients who choose practices that do not appear on the MHQP website will not be included in the primary outcome analysis but will be included in secondary outcome analyses.

2cA. The authors sometimes refer to patients as 'consumers', and sometimes as 'patients'. Again, this may reflect a US understandings of a health system and appear strange to non-American readers. While it is not my place to comment on which term is more suitable, I would suggest using one term consistently throughout the article.

2cB. We have edited the manuscript to consistently use the term “patients”.

2cC. Please see changes throughout the manuscript.

3. Giving more details on the intervention

3aA. Who will deliver it and how? While the conceptual framework for the intervention is clear, the actual delivery needs further description. The protocol does not specify whether the 'patient navigator' is a person or a thing (!). If it is a person, who are they, what level of training and socio-economic background will they have? Will they be from the same background as the patients attending? Just how much influence will they be allowed to have on a patients' thinking in relation to choosing a provider of paediatric care: are they simply showing quality scores, or are they actively discussing scores and individual practices with
patients? The section on Support in Table 2 suggests that the 'navigator' will encourage mothers to think about choosing a quality provider with the same importance as other parenting decisions (e.g. Circumcision), but the main manuscript suggests that participants (patients?) will complete a worksheet with tables of scores for the practices they review, which sounds rather more involved. What will the navigators actually do in the Support phase, and how much will they be able to influence patients' choices?

3aB. We have clarified how the intervention is delivered in the text. The question about the how much navigators will be able to influence patient choices is an interesting one. Navigators do not “recommend” one practice over another but do discuss the meaning of the different scores. We anticipate that the influence the navigator has on a mothers’ choice will largely be driven by the mothers’ receptivity to the concept of quality measures as an important element in decision-making. We recognize that there may be a number of other factors (such as location) that trump quality scores, hence the careful measuring of what did matter most after mothers decide.

3aC. Methods/Design, Pages 8-9

3aD. A list of eligible patients is generated each morning. Patients are then approached in the waiting room of the prenatal clinic by one of the patient navigators and offered an opportunity to participate in the study. If interested, informed consent is obtained and baseline data collected. This may take place in a the waiting room, an exam room, or an educational office when available. Patients randomized to the intervention arm then participate in a brief in-person educational session led by the patient navigator whose
experience includes teaching small undergraduate courses. The navigator’s training for the study included developing an understanding of the methods used to develop the quality measures, use of the MHQP website and obtaining informed consent. Both the primary and secondary navigators participated in extensive rehearsal of the intervention with PI feedback prior to piloting then enrolling patients. The information sessions include the rationale for quality measurement, how quality varies among practices, and that information about variation is publicly available. The information session is followed by in-person guided use of the MHQP website with the navigator. Each of 2 guided website sessions last approximately 20 minutes and take place at two prenatal visits. The first session takes place between 20-34 weeks gestation and the second 2-6 weeks after the first session. The navigator guides the participant in use of the MHQP website on a laptop computer. There is be a standard explanation of the meaning of the quality performance measures and patient experience survey data. The patient navigator provides the same demonstration to all participants about how the website can be used to assess a practice’s performance. Following this standard intervention, patients are shown performance data for practices they would like to view within a 25-mile radius of their home. If the participant does not have any practices she wishes to view, a standard set of three area practices with high and low scores are shown as examples. Practices shown are recorded. A copy of the study informational pamphlet is given after the first guided website session and the participant is asked if they have questions about the pamphlet. During the second intervention session, the patient navigator asks if the participant had an opportunity to look at the website themselves. The navigator then invites them to look at
local pediatric practice data again and will respond to any questions about performance data for these practices. Participants may complete a worksheet during the intervention in which they fill out a table of scores on performance measures for the practices they review. Patient navigators do not recommend one practice over another but do discuss the practices’ quality scores and what the scores mean.

3bA. How much will the intervention cost? While I recognise that doing a full cost-effectiveness evaluation of the intervention may be beyond the scope of this trial, presumably any efforts to scale up the intervention if the trial is successful will require understanding (a) who can provide such an intervention – see above – and (b) how much it costs? Shouldn't documenting costs be part of this study? If the authors do not plan to do it, perhaps they could say so in the limitations section?

3bB. This is a common question with an efficacy trial. We do not plan to estimate the costs of the intervention (costs are primarily navigator time) but do plan to study in the future whether it is necessary to have a live navigator (the main cost). We also designed the intervention so that it could be administered by health care outreach workers/case managers that are being used increasingly in the United States with the advent of accountable care organizations. We have added this to the limitations as recommended.

3bC. Discussion, Page 18
3bD. Fourth, although we do not include a cost analysis for this intervention, it is possible that it may be prohibitively expensive to undertake outside of the study setting. If the intervention is successful, we plan to explore mechanisms of delivering the intervention in an affordable manner, such as using existing staff in obstetricians’ offices.

4. Power of the study to test hypotheses related to secondary objectives

4A. The study design appears adequate to test the primary hypothesis that the intervention will lead to higher mean quality scores for pediatric centres chosen by women who received the intervention compared to those in a control arm. However the ability of the study to test further hypotheses linked to the trial's secondary aims is less clear. Will the research team be able to detect significant differences in quality scores or patient experience ratings in so many sub-group analyses (parity categories; literacy; ethnicity)? This may be worth checking and specifying, and if it is possible that you will [not] have sufficient power to detect differences in sub-groups, the authors could acknowledge this in the limitations.

4B. The study is powered to test the intervention within strata defined by parity, and we have clarified this. However we are not sampling based upon literacy levels or ethnicity, and were uncertain whether participation would vary by these patient characteristics. While we intend to evaluate outcomes for subgroups defined by these characteristics, it is possible we won’t have adequate power. We have added this to the limitations.

4C. Discussion, Page 18
4D. Additionally, while the study was designed with power to detect differences within strata defined by parity, we may be underpowered to detect differences in secondary outcomes, or within subgroups of patients defined by literacy or ethnicity.

5. Issues related to the analyses for the main outcomes

5aA. What is the primary outcome of the trial? Is it the mean of two mean scores (clinical quality and patient experience) or one of these two scores? The primary outcome should be clearly stated in the abstract, in the first sentence in 'study objectives' and in the section entitled 'Primary Outcome'.

5aB. The primary outcomes are a) the mean clinical quality scores and b) the mean patient experience scores. This is clarified in the text as recommended.

5aC. Methods/Design, Page 6

5aD. The primary study outcomes are a) the mean clinical quality score and b) the mean patient experience score of the pediatric practices selected.

5bA. How often are the MHQP quality scores revised? If the trial recruitment period extends over 18 months, is it possible that the MHQP scores for individual clinics will change over time? Are the authors intending to use the MHQP score either at the time of delivery or in the neonatal period (which would make sense)? It would be good to pre-specify this.
5bB. This is an insightful question. If the practice scores should change during the course of the study, the practice scores the patients viewed in the neonatal period will be used for the analysis for those patients. Since our analysis is based on practice scores not on choosing specific practices, we do not expect that this will affect our results. We have clarified this in the analysis.

5bC. Analysis, Pages 13-14

5bD. If practice scores on the website should change during the course of the study, the scores present during the prenatal period will be used in the analysis.

5cA. Although patients attending the prenatal clinic are randomised individually, there are potential sources of clustering in the outcome data: for example, patients residing within a particular area may be more likely to access clinics within that area too, reducing the possible variability in responses/quality scores. Has any thought been given to clustering in the data for the analysis? Is the area of residence one of the maternal characteristics you would consider adjusting for in the final analyses?

5cB. This is also an insightful question, and we thank you for the suggestion. We currently attempt to address this potential issue by assessing relative importance of factors in making the decision, anticipating the proximity to home may be ranked highly. We are collecting zipcode of residence for use in identifying practices on the website closest to a patient’s home, and we can take advantage of this information to explore the impact of clustering. We have added this into the analysis section.
5cC. Analysis, Page 13

5cD. In addition we will explore the impact of clustering of women within neighborhoods defined by residential zipcode, since location of practice relative to home may have a large impact on choice of practice.