Author's response to reviews

Title: Effective Feedback to Improve Primary Care Prescribing Safety (EFIPPS) a pragmatic three-arm-cluster randomised trial: designing the intervention (clinicaltrials.gov registration NCT01602705)

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Version: 3 Date: 29 July 2014

Author's response to reviews:

Dear Editor,

Thank you for the opportunity to respond to the reviewers’ comments, and please find below a point by point response to each. We would like to thank the reviewers for their comments and taking the time to review our manuscript which we think has led to it being much improved.

With best wishes and on behalf of all co-authors,
Karen Barnett

Reviewer: Diane Dixon

Reviewer’s report:

This study describes the development of a theory based intervention to improve prescribing in general practice within Scotland. The intervention has been implemented within a three arm cluster RCT. Scotland is a leading centre for patient safety research within the UK and internationally and the trial, of which this intervention forms a part, is significant. The current paper describes the development of a theory based educational and feedback (tailored to individual GP practice performance) intervention that focusses on reducing high risk prescribing. The content of the paper is, therefore, suitable for publication within
Implementation Science and is likely to have a wide readership.

However, as the paper is currently presented I feel there is a conflation between the description of the methods and the results, which presents an opportunity for revision and the presentation of a more detailed description of the results. I have detailed comments on each of the methods and results sections below.

Methods
1. The methods section, as currently described, would benefit from some additional details. For example, how many participants were involved in each focus group during the elicitation stage of the project?

RESPONSE
The number of focus group participants has been added to the following sentence:

“An elicitation study consisting of four focus groups, each comprising between 6 and 10 health professionals, was carried out to develop the measures for the three TPB psychological constructs (attitude; subjective norms and perceived behavioural control).”

2. The elicitation study is at times described as the ‘predictive’ study. I suggest the term ‘predictive’ has a quantitative meaning that does not best fit with a qualitative method. I suggest the term ‘elicitation study’ be used throughout.

RESPONSE
The term ‘Predictive study’ used to refer to the focus groups has now been changed to ‘Elicitation study’ throughout.

3. I would have appreciated additional details of the Delphi study. It was not entirely clear whether the participants in the questionnaire study were being asked to rate their own beliefs in relation to high-risk prescribing or whether they were rating the statement in a more general sense of them being related to high-risk prescribing.

RESPONSE
Further details have been added to this section including how the GPs were identified. Participants in the Delphi Study were asked to rate each statement according to their own beliefs and how much they personally agreed or disagreed with a statement. The following sentence has been adapted to make this clear:

“GPs were asked to rate each questionnaire item, on a five-point Likert scale, their level of agreement with each statement from strongly agree to strongly disagree according to their own personal beliefs.”

4. The paper would benefit from a more detailed account of how the mapping to BCTs was done.

RESPONSE
We agree that this section was lacking in detail. This has now been extended and some description that was included in the results section has been moved to the method section to improve clarity. This section now reads as follows:

“Mapping Targeted Variables to Behaviour Change Techniques

The next stage was to map the psychology constructs within each of our two models of behaviour change (TPB, HAPA) to appropriate behaviour change techniques based on the evidence as described by Michie and colleagues (2008).[17] In this paper the authors generated an extensive list of behaviour change techniques (and definitions) from techniques published in two systematic reviews, ‘brain storming’ and a systematic search of relevant text books. Four experts judged which techniques would be effective at changing 11 theoretical constructs associated with behaviour change. The first step in the present study was to map the four psychological constructs; Attitude, Subjective Norms, PBC and Action-Planning to the corresponding constructs among the 11 that were identified by Michie et al. The next step was to list the techniques where the experts had reached consensus of ‘Agreed use’ or were ‘Uncertain’ based on the level of evidence. Techniques where there was ‘Disagreement’ among the experts or ‘Agreed non-use’ were not considered.

The feedback intervention in its entirety had been designed to represent ‘best practice’ and was informed by an expert Advisory Group. As a result, a number of the listed techniques were, to varying degrees, already being utilised in the feedback intervention. Examples of these included: Monitoring, Feedback, Provision of information regarding the behaviour/outcome, and Objects to facilitate the behaviour (e.g. support for searching in GP IT systems). The psychology informed intervention therefore had to include techniques that were not already embedded in the other components of the feedback. This was in order that any additional effectiveness of the more resource intensive (in terms of development) theory-informed intervention could be assessed.

It is also important to note that the choice of techniques were further constrained by the nature of the trial - the psychology informed intervention had to be delivered as part of the quarterly feedback to GP practices and was limited to one A4 page (a balance between the additional time cost for GPs engaging with the intervention and encouraging behaviour change). The list of behaviour change techniques are provided in Table 3.”

Results
5. Information presented in the results would be better placed in the methods section, e.g. information about the number of GPs mailed the questionnaire as part of the Delphi study.

RESPONSE
The following section of text has been moved from the result section and integrated into the methods section that discusses the Delphi Questionnaire study:
“An invitation letter to take part in the study, including a participant information leaflet and a copy of the questionnaire, was emailed to 500 randomly selected GPs from an email address list of GPs working in Scotland (excluding GPs working in the three health boards taking part in the trial). GPs were asked to rate each questionnaire item, on a five-point Likert scale, their level of agreement with each statement from strongly agree to strongly disagree according to their own personal beliefs. Completed responses were received from 48 GPs (10% response rate). The 48 GPs who completed the first questionnaire were then sent the questionnaire a second time, this time including the median, minimum and maximum response scores for each statement received in round one, and a reminder of how they had personally scored each item in the first round. GPs were asked to rescore each statement using the additional knowledge of their colleagues’ collective response. In round two, 24 of the 48 GPs responded (50% response rate). Statements were deemed to be potential candidate variables if there was a) consensus of positive agreement with the importance of a statement or b) there was evidence of significant disagreement among the GP responses (>25%; if more than 6 GPs were outliers). Questionnaire items were excluded if there was agreement that a statement was not important in relation to reviewing patient prescribing (#75%) or if more than 50% of GPs gave a neutral response.”

6. I would have like to have seen more details of the data generated by the elicitation study and the Delphi exercise. For example, a more detailed account of the statements generated by the elicitation focus groups would have been interesting, e.g. what type of barriers were identified. Similarly, how many statements reached consensus in the Delphi exercise and what was the nature of the statements that achieved consensus compared to those that did not.

7. As currently presented the results tend to describe the criteria for deciding whether or not an item was included. Whilst this information is important I was left wondering about the data generated by the elicitation study and the Delphi exercise to which these criteria were applied.

RESPONSE

The description of how the statements were scored and how consensus was met has now been moved to the methods section (see above response). To provide further information about the results of the elicitation study and the Delphi questionnaire, the following paragraphs have been added under the relevant headings within the results:-

“For example three out of the four focus groups discussed the attraction of being able to compare prescribing performance with other practices as an advantage to taking part in the intervention and reviewing patient prescribing. The fear that high risk prescribing could lead to potential harm for the practice as well as the patient, particularly if the prescribing results in a significant event, was also thought to be an important factor that would encourage GPs to review patient prescribing. The key disadvantage that was raised in the focus group discussions was the impact on GP’s time and work load. The practice pharmacist and local
GP Committees were felt to have the most influence over whether or not GP Practices would endorse the intervention. Patients currently doing well on their medication and Carers/Care Workers (regarding dementia patients) were thought to be the people most likely to oppose a change in medication. The key barriers to responding to prescribing feedback identified in the focus groups were; if the instructions provided with the feedback were confusing or there was too much information or if the message was not in keeping with current advice from secondary care. The key facilitators to responding to the prescribing feedback were if GPs believed that the feedback was important and clearly branded; if the feedback could be delivered face to face e.g. via the practice pharmacist and if the feedback is related to research and improving patient safety rather than cost effectiveness."

“Consensus was reached on 50 of the 59 statements, only 2 statements received a neutral response where more than 50% of respondents neither agreed nor disagreed with the importance of the statement and consensus was not met for seven of the 59 statements. A summary of the statements that reached consensus and those where there was disagreement are shown in Table 2. Neutral responses were received for two statements; whether the Pharmaceutical industry had an influence on whether or not GPs would review patient prescribing and whether approval from the Press was important to GPs.”

That said I feel this is an important study that has applied a clear theoretical framework for the development of an intervention to improve patient safety and has done this in a manner that should ensure the intervention (if effective) can be implemented as tested within the NHS. As such, I think Implementation Science should consider publication once the above issues have been considered by the authors.

Reviewer:Carmel Hughes
Reviewer’s report:
Most of my queries are due to lack of clarity and the sequence of material, so all are considered compulsory.

1. Abstract-I was a little confused about the order in which things were done and how the components of the intervention were selected on the basis of theory. As written in the methods section of the abstract, it appeared that part of the intervention was feedback of practice rates of high-risk prescribing had already been selected as part of the intervention in advance of the theory-informed intervention? Was feedback not part of the intervention? I would have thought that the theory work would have come first in all of these stages? And I didn’t quite follow how the intervention was embedded in the feedback. Surely feedback was part of the intervention, and this seems to be the case in the full Method section. The Results section in the abstract was hard to follow because of my queries above. I think it is partly an issuing of sequencing of material and clarity, as the ensuing Background and full Method are much easier to follow. The Abstract will need some further work as some important detail is missing (aspects around behaviour elicitation and a Delphi questionnaire) and the
sequence of material is not quite right.

RESPONSE
The abstract has now been updated to better represent the sequencing of the paper.

Background- No issues

2. Methods-I think it would be helpful to explain why activities were performed in the order that they were done. Readers may expect to see the theory aspects first, but clearly the authors have examined other trial approaches such as that of PINCER, and have opted for feedback as a central part of the intervention. This seems to be confirmed by the text which describes the intervention components of which feedback is one component.

RESPONSE
This is correct. The NHS wanted to implement a feedback designed intervention making use of the prescribing data that was available in the newPIS system. The theory informed aspect of the intervention was to ensure the feedback intervention was designed in such a way to represent best practice and was evidence based, drawing on the behaviour change literature.

The following sentence has been inserted in the first paragraph of Methods Section: Trial Design.

“The decision to implement a feedback design was driven by the intention of the NHS to use a familiar improvement method utilising the new patient level prescribing resource, newPIS, and feedback prescribing data to GP Practices to enable them to monitor their own performance.”

3. Why 5 rounds of the quarterly written feedback, and how did this work? I assume that this would involve more than 12 months?

RESPONSE
The NHS Advisory Group advised that most prescribing improvement activity happened on yearly cycles, and that feedback should be given over one year. Since the data was updated quarterly, we decided to provide five rounds of feedback (one point being that with five rounds, the fifth round of feedback is exactly one year after the first). The following sentence in the Methods Section: (2) Feedback of Performance… has been updated to allow for this explanation.

“All practices in the two treatment arms were sent prescribing feedback, with arm 3 additionally receiving the psychology informed intervention described in the next section. Based on the data available in newPIS, the Advisory Group specified that practices should be e-mailed five rounds of quarterly written feedback of their rate of high-risk prescribing to mirror most prescribing initiatives that are delivered over an approximate 12 month period (and allowing for a three month data lag in the e-prescribing information system).”
4. How did the authors discern that the Advisory Group’s recommendations were ‘theory-informed’? They give examples of such elements, but this was their interpretation.

RESPONSE
We agree that there is a degree of subjectivity in this, but the research team felt that the Advisory Group took for granted the effectiveness of some of the techniques listed by Michie et al, 2008, and therefore recommended that the design reflect these. In that sense, ‘normal practice’ appeared to be ‘theory-informed’. These are highlighted in Table 2 where we judged this to be the case. The following sentence has been added to direct readers to this information.

“For example, several members of the Advisory Group emphasised the need for educational material to provide clear advice on what action to take and the importance of having a credible messenger in terms of who signs e-mails and how feedback is branded. These behaviour change techniques are included in the extensive list of techniques provided by Michie and colleagues, 2008 and are further highlighted in table 2.[17]”

4 cont.? When discussing feedback, was it discussed in terms of behaviour change?

RESPONSE
Feedback was discussed with the aim or maximising uptake but not specifically in relation to the behaviour change and the behaviour change literature.

5. The authors justify their usage of the Theory of Planned Behaviour as it ‘has been validated and used rigorously in various health settings’. However, how did the authors know that it was the most appropriate theory to employ to affect the behaviour that they wanted to change? This also applies to the Health Action Process Approach.

6. The selection of the theories seemed to come before the identification of the target behaviours in the paper. The authors go on to describe the types of processes which might be undertaken by GPs. I had wonder if there had been any attempt to confirm these behaviours using some type of behavioural elicitation questions with GPs, and then realised that this was in the next section. I would expect this type of exercise to have taken place in advance of identifying the targeting behaviours as this is the most logical process. The order and sequence of material in this paper will need some attention.

RESPONSE
The decision to use TPB was in part, pragmatic, as we wanted to select a process that could be easily replicated if the trial was to be rolled out. From this perspective, the fact that there is a support manual for health service researchers (as a psychologist will not necessarily be involved) was advantageous. We were
aware of the general behaviours that we wanted to target (through discussions with advisory group and the GP/Pharmacist members of the study team) prior to the elicitation study but we agree other models of behaviour change could have been considered. The elicitation study was designed around the theory of planned behaviour in that the aim was to elicit from GPs and pharmacists a broad range of views regarding the three psychological constructs of the model; attitudes, subjective norms and perceived behavioural control, to responding to the intervention (so as confirmation but also to highlight any issues that we may not have considered).

HAPA was selected as the motivational phase of the model has similar constructs to TPB. We also know from the literature that a limitation of TPB is the intention/behaviour gap. HAPA was selected to provide an evidence base for a volitional phase and the inclusion of an action plan in the intervention.

The words suggesting the justification for the selection of the model have been removed from the following sentence.

“TPB is one of the more commonly used social cognition models and has been validated and used rigorously in various health settings.[21,22] While other psychological models of behaviour change could also have been considered, the TPB was selected for use in the current study due to both its evidence base, and the support available for health professionals to use this theory should the trial be rolled out at a national level. “

7. What was the sampling frame for the GPs who took part in the Delphi and how were they identified and recruited?

RESPONSE

This issue was also highlighted by the first reviewer. Please see response to comment 3. Additional information has been added to this section to describe how GPs were identified and recruited.

“An invitation letter to take part in the study, including a participant information leaflet and a copy of the questionnaire, was emailed to 500 randomly selected GPs from an email address list of GPs working in Scotland in Scotland (excluding GPs working in the three health boards taking part in the trial). GPs were asked to rate each questionnaire item, on a five-point Likert scale, their level of agreement with each statement from strongly agree to strongly disagree according to their own personal beliefs.”

8. In terms of mapping the targeted variables to BCTs, why did the authors map the TPB and HAPA to the BCTs, and not the behaviours that had been identified by the behavioural elicitation phases? Surely the latter would have been most important as these would have been the behaviours demonstrated by the GPs and therefore, the target for change?

RESPONSE

The behaviour that was being targeted was a general behaviour rather than a
specific behaviour which was to ‘respond to the feedback’. Of note was the pragmatic nature of the intervention which meant that feedback was first received by the Practice Manager rather than the GPs themselves and we had no control over how the information would be disseminated within each practice. This reflects how such feedback would be implemented in the ‘real word’, but makes it harder to specify ‘specific’ behaviours to target.

The elicitation study showed that different practices would engage in different behaviours to carry out this task but the core attitudes, beliefs about social pressures, barriers etc. around responding to prescribing feedback were consistent across practices. For this reason it was decided to design each theory informed intervention around one of the four psychological constructs that inform behaviour change. There were five rounds of feedback so the decision was made to repeat the action planning intervention as this was the only volitional component (attitude, social norms, PBC are all motivational). The results of the elicitation and Delphi study did inform the content of the interventions so that specific barriers to carrying out the behaviour were targeted in each of the four one-page interventions.

This has been explained in the relevant section of the results.

“It was evident from the elicitation study that the behaviour sequence that practices would engage in to ‘respond to the prescribing feedback’ would vary across practices. Of note, is that the pragmatic nature of the delivery of the feedback meant that the intervention would first be sent to the Practice Managers’ who would then choose how to disseminate the information to the GPs. This reflects how such feedback would be implemented in the ‘real word’, but makes it harder to identify ‘specific’ behaviours to target. Results from the Delphi study confirmed that the core attitudes, social norms, barriers and facilitating factors to responding to prescribing feedback were consistent. For this reason, the research team chose to design a behaviour change intervention for each of the four psychology constructs within the two models; attitudes (TPB), subjective norms (TPB), Perceived Behavioural Control (TPB) and Action Planning (HAPA).”

9. Results: there are aspects reported in the results that would be better in the Method e.g. the number of GPs to whom the questionnaire was emailed, the way in which the data were handled in terms of % agreed/disagreed.

RESPONSE
This point was also raised by the first reviewer (see response 5). This information has now been moved to the Methods Section.