Author's response to reviews

Title: Increasing smoking cessation care across a network of hospitals: an implementation study

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Version: 3 Date: 31 August 2015

Author's response to reviews: see over
Reviewer 1

Major compulsory Revision
1) The percentages in the results sections are inaccurate.

A typographical error was made for one percentage reported. The percentage was reported as 56.12% but should have been 56.2%. The text has been amended as outlined below.

Page 13: Slightly more than half (56.2%; n=2072) of smokers were nicotine dependent (n=560 baseline; n=1036 intervention; n=476 follow-up).

2) Explain why some wards were excluded.

Mental health, intensive care, substance detoxification or maternity patients were excluded as they have special needs likely to impact on the level of smoking care provided. The following text has been added:

Page 6: Mental health, intensive care, substance detoxification or maternity patients were excluded, based on their diagnostic codes, as they have special needs likely to impact on the level of smoking care provided.

Minor compulsory revisions

c. Background: it is unlikely that clinical treatment will reduce prevalence of smoking. However, hospital based clinical interventions for middle aged adults might reduce re-admission, complications and improve the prognosis for the patient. Clinical practice guidelines exist to treat tobacco addiction.

A Cochrane review of fifty trials found that smoking cessation programmes that begin during a hospital stay and include counselling with follow-up support for at least one month after discharge are effective in increasing smoking cessation. Such programmes are effective for hospitalised smokers regardless of the reason for admission. The addition of nicotine replacement therapy to a counselling program has been found to increase cessation rates (Cochrane 2012, Rigotti et al)

The following text has been added:
Page 4: Smoking cessation programmes that begin during a hospital stay and include counselling with follow-up support for at least one month after discharge are effective in increasing smoking cessation. Such programmes are effective regardless of the reason for admission. The addition of nicotine replacement therapy to a counselling program increases cessation rates.

d. Hospitals have both inpatient and outpatient clinics; the authors should specify that the interventions are for inpatient admissions only.

The text has now been amended as outlined below:

Page 6: All inpatient wards in all 37 general hospitals that provided medical and surgical care to adult patients received the intervention.

All inpatients other than mental health, intensive care, substance detoxification or maternity patients, that were discharged from the eight selected hospitals over a 48 month period and were recorded in the electronic medical record as being a smoker [22], an inpatient for at least 24 hours; and 18 years of age or over, were identified.

e. Why was the definition of nicotine dependence not standardized such as the use of the HSI or FTND?

The recording of nicotine dependence by clinicians is often not standardised. As the assessment of nicotine dependence was based on notation within the medical record the assessment of nicotine
dependence using standardized such as the use of the HSI or FTND was not possible. The following has been added to the text:

Page 7: As recording of nicotine dependence by clinicians is often not standardised, patients were classified as nicotine dependent if in the medical record it was recorded that they smoked more than 10 cigarettes a day, or more than 160 packs per year, or more than 3 packs per week; or within 30 minutes of waking up in the morning; or were recorded in the medical record as a “heavy” smoker) [24]. Such nicotine dependent patients constituted the study sample.

f. Why were mental health/substance/maternity excluded from the study? Also, patients with mental illness and addiction are also admitted to surgical and medical wards.

As per the response to comment 2, mental health, intensive care, substance detoxification or maternity patients were excluded as they have special needs likely to impact on the level of smoking care provided. In addition, patients with a mental illness and/or addiction were excluded based on their diagnostic codes rather than their ward of admission. The following has been added to the text:

Page 6: Mental health, intensive care, substance detoxification or maternity patients were excluded, based on their diagnostic codes, as they have special needs likely to impact on the level of smoking care provided.

g. Clarify why smokers were identified by electronic medical records and why paper records were used to assess the intervention. How does this dual system impact the implementation of this multistep intervention?

Smokers were identified by the electronic medical record as it is on this record that smoking status is routinely assessed and recorded by clinicians and/or administrative staff on admission. Further, after discharge medical coders routinely record smoking status when transferring patient paper record information to the electronic medical record. Nicotine dependent smokers were identified from the paper records and as such it aligns with the use of such paper records for the assessment of the intervention’s impact.

h. please explain why most of the hospitals were excluded from the study

All 37 general hospitals that provided medical and surgical care to adult patients received the intervention (see page 6). However, due to cost feasibility considerations, a representative sample of the hospitals that received the intervention were randomly selected to assess the impact of the intervention. The text has now been amended as outlined below:

Page 6: Further, due to cost feasibility considerations, outcome data were collected from a randomly selected representative sample of eight of the remaining 17 hospitals (47%), stratified by hospital group: Group A (1 out of 1 hospital); Group B (2 out of 4 hospitals); and Group C (5 out of 12 hospitals).

Reviewer’s report 2
This study assessed the impact of an intervention on the provision of smoking cessation care to nicotine dependent smokers across a network of hospitals. The study is interesting, but I have a significant number of concerns which are outlined below. In particular, given the time-series nature and clustering of the data (i.e. in hospitals) the use of simple regression is not appropriate. The authors may wish to consider multilevel modelling and assess for possible seasonality trends and autocorrelation. These can be adjusted for using appropriate parameters. The authors should also consider guidelines which have been published on the reporting of interventions and non-randomised trials. In particular, the description of the active ingredients of the intervention is poor. The primary outcome is not clearly specified and a flow diagram of recruitment would be helpful. In addition, it is unclear as to the methods used to randomly select a subgroup of participants, and as to why only 14% of the total possible sample were used. The
authors also only focus on dependent smokers, using arbitrary criteria. Surely all smokers are dependent but to varying degrees.

The comments above are also raised by Reviewer 2 below regarding specific sections of the manuscript. We have addressed these comments below.

Introduction

1. Guidelines around the world, including the UK and US, do not just suggest brief cessation advice but more extensive behavioural support for smokers wishing to quit. In addition, NRT is only one of three first-line therapies (also have Varenicline, Bupropion) and there are many second-line treatments. This first paragraph therefore needs to modified.

The text has been amended as outlined below:

Page 4: Such guidelines place a particular emphasis on the routine provision of cessation advice and counselling, pharmacotherapies (e.g. NRT, varenicline, bupropion) [8, 9], and offer of post discharge care [3, 5-7, 9].

2. The second paragraph needs rewording. The first sentence would make more sense if the authors said that despite the guidelines the provision of such care is suboptimal. They may then wish to refer to research on the application of evidence based practice and then go on to say that evidence exists to suggest that the provision of smoking cessation care can be improved. This would then lead on to the second sentence regarding the Joint Commission (which should be explained).

The text has been amended as outlined below (and in response to points 3, 4 and 5):

Page 4: Despite such guidelines, the provision of such care is less than optimal within US, Australia and other countries [10-16]. Intervention research has demonstrated that the provision of smoking cessation care in hospitals can be increased [10-12]. However, the demonstrated increases in care are often small or moderate and hence a significant proportion of smokers do not receive appropriate cessation care.

3. The authors need to set up from the start that they are only interested in the application of smoking cessation guidelines in hospitals. There is a vast literature on the application of guidelines generally which may be applicable but is not referenced.

The text has been amended as outlined below:

Page 4: To reduce this burden at both the individual and population levels, smoking cessation clinical practice guidelines recommend the provision of smoking cessation care to all smokers attending health services including hospitals [3-7].

4. The authors focus on the Joint Commission and so should explain and describe what this is in more detail for the international audience. Do recommendations differ relative to other countries?

The text has been amended as outlined below:

Page 4: In contrast, in the United States (US), hospital accreditation by the Joint Commission (an independent, not-for-profit organization, that accredits and certifies more than 20,500 health care organizations and programs) has been reported to be associated with an increase in the proportion of patients provided smoking cessation advice ranging from 37% to 67% in 2002 to 95% to 97% in 2008 [19].
Page 5: This is, a key gap in understanding how universal access to smoking cessation care can be achieved by all hospitals for all patients both in the US and in other countries, particularly given the lack of accreditation standards for hospital smoking cessation care in Australia and other jurisdictions.

5. The last paragraph states that the study is being conducted in Australia, but the introduction focuses on America. The authors should, as already stated, give a general overview of smoking cessation treatment around the world and then set the picture for Australia.

Page 4: Despite such guidelines, the provision of such care is less than optimal within US, Australia and other countries [10-16].

Page 5: This is, a key gap in understanding how universal access to smoking cessation care can be achieved by all hospitals for all patients both in the US and in other countries, particularly given the lack of accreditation standards for hospital smoking cessation care in Australia and other jurisdictions.

Method
Significant amendments are required for the methods section.

6. The authors should consider the use of guidelines for the reporting of interventions (e.g. there are CONSORT guidelines for RCTs).

The authors determined that the amendments to the text in response to other reviewer comments have ensured the clarity of the sampling. Further, there are no guidelines for reporting interventions using a time series design. As such, no further amendment has been made.

7. How were the hospitals randomly selected? i.e. the method of randomisation. It is unclear why 5 hospitals were group c and only 1 group A if randomisation occurred, unless it failed. Would a representative sample have included equal numbers of each?

The hospitals were selected to be representative of the hospital profile of the Local Health District. Hospitals were selected using the random digit function in Microsoft Excel. The text has been amended as outlined below:

Page 6: Further due to feasibility, outcome data were collected from a randomly selected representative sample of eight of the remaining 17 hospitals (47%), stratified by hospital group: Group A (1 out of 1 hospital); Group B (2 out of 4 hospitals); and Group C (5 out of 12 hospitals). The random digit function in Microsoft Excel was used to randomly select the hospitals.

8. Please provide details of how smoking status and demographic characteristics were assessed.

Smoking status and demographic characteristics were obtained from the electronic medical record.

The text has been amended as outlined below:

Page 10: The following patient characteristics were collected from the electronic medical record: age, gender, Aboriginal and/or Torres Strait Islander status, hospital group, and ward of discharge, length of stay, and diagnoses (smoking related/not smoking related)

9. Please state the method used to randomly select patients, not just the program. Why did you select only 14%?

Random selection used SAS version 9 statistical software by using the RANUNI function. The 14% sample was used based upon the sample size calculation which allowed us to detect a difference in smoking cessation care of between 9%-11% (page 13).
The text has been amended as outlined below:

Page 7: Random selection was conducted using SAS version 9 statistical software [23], using the RANUNI function.

10. Are these measures of nicotine dependence valid? I know time to first cigarette of the day is, but is 10 cigarettes a common cut off for nicotine dependent smokers? Are not all smokers dependent but to different degrees?

The recent report of the US Surgeon General regards tobacco dependence as a 'chronic disease with remission and relapse'. It states that nicotine use, in the form of 10 or more cigarettes a day, provides continuous neuro-exposure resulting in tolerance and physical dependence which in turn produce withdrawal symptoms. However, the recording of nicotine dependence by clinicians is often not standardised. As the assessment of nicotine dependence was based on notation within the medical record the assessment of nicotine dependence using standardized such as the use of the HSI or FTND was not possible. The following has been added to the text:

Page 7: As recording of nicotine dependence by clinicians is often not standardised, patients were classified as nicotine dependent if in the medical record it was recorded that they smoked more than 10 cigarettes a day, or more than 160 packs per year, or more than 3 packs per week; or within 30 minutes of waking up in the morning; or were recorded in the medical record as a “heavy” smoker) [24]. Such nicotine dependent patients constituted the study sample.

The description of the intervention needs to be improved. What behavioural components did it consist of e.g. goal setting, provision of social support etc. A group of researchers at UCL lead by Professor Susan Michie have developed a taxonomy of behaviour change techniques to help in the reporting of behaviour change interventions.

The intervention was based on practice guidelines, reviews of strategies to enhance the provision of smoking cessation care and practice change more generally (page 8). The description of the intervention has been enhanced in the text (not copied here because of the length of the amendment). Please see the highlighted amendments commencing Page 8.

11. What was the primary outcome of the seven reported? All guidelines recommend one primary and then secondary outcomes. The study is powered for the prior.

As all the seven outcomes are important elements of smoking cessation care, it was not deemed appropriate to select one as the primary outcome.

Analysis
12. The authors have time-series data which is multilevel in nature. Their statistical analysis is not appropriate for such types of data. Clustering needs to be accounted for using multilevel modelling, with hospital as a random effect. Given the longitudinal nature of the intervention, it is possible that there are seasonality effects, autocorrelation etc which should be accounted for.

Given there are only a small number of clusters, we believed a random/mixed effects model would be problematic as there were insufficient numbers of clusters to be confident in the estimates of the variance components. We have used a fixed effects model to account for clustering by including a fixed effect for each site and used robust sandwich variance estimators. This is an alternative approach to including site as a random effect, with the benefit that each site serves as their own control and as such accounts for all un-measured time-invariant confounders. While the data at each year are repeated cross-sectional, we explored the potential for conditional dependence and found no evidence of auto-regressive or seasonality in the deviance residuals. We have now made this more explicit in the model definition as follows:
Multiple logistic regression models assessed differences in trend between baseline and intervention; intervention and follow-up; and baseline and follow-up periods for each measure of smoking cessation care (7 models in total). Each model included fixed effects for ‘period’ (baseline as referent, intervention and follow-up), time (measured in bi-monthly increments, with six such increments taken during baseline, 12 during intervention and six during follow-up) and the interaction between period and time. The model also included fixed effect for site to account for clustering of observations, as well as the following potential patient-level confounders: patient gender, Aboriginality, age, length of hospital stay, ward class, and smoking related disease.

19. The authors have attempted a sort of post-hoc power analysis, given the sample size they anticipated to be collected. What sample size would they have required to detect an appropriate effect size. Is a 9% difference likely?

The effect size able to be detected (9%-11%) was considered as such an effect size is consistent with that found by reviews of clinical practice change generally and smoking cessation care specifically.

20. Why were there significantly more smokers during the intervention period? Were health-care professionals encouraged more to record during this period? Could this have affected the results

The baseline and follow-up periods were each of 12 months durations while the intervention period was of 24 months duration. As such, the number of smokers in the intervention period is approximately twice that of the baseline and follow-up periods.

21. There are clear differences in the profiles of smokers across the three periods. Could this have affected results? This needs to be addressed more thoroughly in the discussion.

The profile of the smokers differed significantly for ‘ward class’ and the presence of a ‘smoking related disease’ (see table 1), with no difference greater than 7% for either of these characteristics. Patient characteristics, including ‘ward class’ and the presence of a ‘smoking related disease’ were included in all logistic regression analyses that examined the impact of the intervention to account for potential confounding (see page 12).

Discussion

22. Implications and limitations of the results should be addressed in more detail

The implications and limitations section has been amended as outlined below:

Page 18: Third, not all hospitals that received the intervention were included in the evaluation component of the research due to feasibility. As such the effectiveness of the intervention within those facilities is unclear. However, the included hospitals were selected to be representative of the hospital profile within the health district. Last, a broad definition for dependence was used to identify nicotine dependent patients in the medical record and hence non-dependent smokers may have been included in the patient sample.

Page 18: This study indicated that significant gains can be made in the routine provision of some elements of smoking care in hospitals.

23. Regression analyses show associations not causation and so care needs to be taken with regards to interpretation.

Page 3: Significant gains in the provision of smoking cessation care were indicated.