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Title: A randomized controlled trial of a multifaceted clinical practice change intervention to provide comprehensive smoking cessation care in a preoperative clinic

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ABSTRACT

Background

Evidence suggests that preoperative clinics, like other hospital outpatient clinics and inpatient wards, fail to systematically provide smoking cessation care to patients having planned surgery.

Methods

The aim of the study was to assess the efficacy, acceptability and cost of a multifaceted clinical practice change intervention in increasing the provision of smoking cessation care to surgical patients. Two hundred and ten smoking patients attending a preoperative clinic at a major teaching hospital in Australia took part in the study. One hundred and twenty four patients were randomly assigned to an experimental group and 86 patients to a usual cessation care group. A multifaceted clinical practice change intervention was developed to facilitate the provision of comprehensive cessation care to experimental group patients. The intervention included the use of opinion leaders; consensus processes; computer delivered cessation care, computer generated prompts and reminders for care provision by clinic staff; staff training and performance feedback.

Results

Ninety six percent of experimental group patients received behavioural counselling and tailored self help material. Experimental group patients were significantly more likely than usual care patients to report receiving brief advice by nursing (79% vs 47%; p<.01) and anaesthetic (60% vs 39%; p<.01) staff. Experimental group patients who were nicotine dependent were also more likely to be offered preoperative nicotine replacement therapy (NRT) (82% vs 8%; p<.01), and be prescribed postoperative NRT (86% vs 0%; p<.01). The multifaceted intervention was found to be acceptable by staff.

Conclusion
A multifaceted clinical practice change intervention may be effective in improving the delivery of smoking cessation care to preoperative surgical patients.

Key words: clinical practice change, smoking cessation, tobacco, preoperative, surgical
Précis

Two hundred and ten surgical patients participated in the trial which found that a multifaceted clinical practice change intervention improved the provision of smoking cessation care, was relatively inexpensive, and was acceptable among preoperative clinic staff.
INTRODUCTION

A variety of clinical practice guidelines are available for clinicians describing efficacious smoking cessation treatments. For hospital patients, practice guidelines suggest that hospital staff provide smokers with brief cessation advice, nicotine replacement therapy (to nicotine dependent smokers) and encourage follow-up support. However, greater effectiveness may be obtained if, in addition, more comprehensive cessation care is provided [7] that includes extended cessation counselling, tailored written self-help material, and the provision of such care by multiple health care providers [4].

Despite the existence of such guidelines, evidence suggests that there is limited delivery of cessation care by clinical staff. The provision of even single elements of recommended cessation care by hospital staff appears limited, with staff not systematically assessing and documenting patient tobacco use [8,9], routinely advising or counselling smokers to quit [9-12], prescribing NRT [13,14] or providing smokers with written self help material [15].

The potential population health benefit of effective smoking cessation interventions in hospitals is lost if such practices are not incorporated into routine clinical care. Research in suggest that practice change will require strategies to overcome barriers to the provision of smoking cessation care by clinical staff such as a lack of time, knowledge and skill. The most effective interventions for modifying clinical practice includes the use of multiple strategies tailored to modify deficits in organisational support and resources, and in provider knowledge, attitudes and skills [24-26]. Strategies demonstrated to be effective in modifying these determinants include the use of opinion leaders, consensus processes, computerised support systems, reminders or prompts, educational outreach visits, and performance audit and feedback [25,27].
Within hospitals, preoperative clinics represent a particularly attractive setting to intervene with smoking patients. With up to 10% of the population undergoing surgery and anaesthesia annually, interventions within this setting have the potential to make a substantial contribution to reducing population tobacco use [18]. Furthermore, quitting smoking prior to a surgical procedure may have more immediate surgical benefits for patients, such as improved oxygen transport and delivery and improved cardiac functioning through a normalising of carbon monoxide and nicotine levels. The preoperative period may also represent a ‘teachable moment’, where smokers may be more receptive to cessation interventions [21,22]. Despite this opportunity, the provision of smoking cessation care during preoperative clinic consultations appears similarly constrained as in other hospital departments [8,23].

Given the potential benefit of comprehensive smoking cessation care in preoperative clinics a study was undertaken to address the lack of scientific investigation into the efficacy of strategies to achieve such practice change in this setting. The study aimed to assess the efficacy, acceptability and cost of a multifaceted clinical practice change intervention to facilitate the provision of comprehensive smoking cessation care to patients attending a preoperative clinic.

METHODS

Participants
The study took place in a non-cardiac preoperative clinic serving patients requiring predominantly general medical, obstetrics and gynaecological procedures, at a major teaching and referral hospital in New South Wales, Australia. Patients attending the clinic were
identified by preoperative staff as having characteristics requiring a preoperative consultation, such as poor health behaviours (heavy smoking or excessive alcohol consumption) or pre-existing disease (including Heart Palpitations, Muscular Dystrophy, Asthma or Diabetes).

All patients presenting at the clinic between May and October 2002 were eligible to participate if they were smokers, over the age of 18, were not pregnant, were not too ill to complete the study procedures, could read English, had a booked date for surgery, or had not previously been approached to participate in the study.

The trial was approved and the research procedures monitored by the University of Newcastle Human Research Ethics Committee and the Hunter Area Research Ethics Committee.

Procedure

Recruitment

A research assistant sought the consent of eligible patients. Consenting patients completed a touch-screen computerised smoking assessment program. Patients identifying themselves as current smokers were randomly allocated to either an experimental or usual care group by the computer program through a random number function. The randomisation function was programmed to allocate 60% of patients to the experimental group and 40% to the usual care control group. Such an allocation enabled a majority of patients to receive the expected benefits of the comprehensive care program. Patients or clinic staff were not blind to patients’ group allocation.

Experimental Group

The multifaceted clinical practice change intervention included the following strategies:
1. Identifying opinion leaders [25,27]

The Director of the Department of Surgery (ADS), and the Director and Nurse Unit Manager of the preoperative clinic endorsed and advocated the need for the intervention during advisory group and monthly management meetings.

2. Establishing consensus [25,27]

Consultation with staff identified a number of barriers to the provision of recommended cessation care. Staff contributed to the development of the multifaceted intervention strategies as a means of overcoming these barriers.

3. Computerised supportive systems [27]

A computer based system was developed to provide or facilitate the provision of the following elements of comprehensive smoking cessation care in an expert, standardised and time efficient manner:

a) Behavioural cessation counselling [28]

A 19 minute cessation counselling program, tailored to patient characteristics, was delivered to patients by the interactive touch-screen computer program. The program content was based on effective counselling strategies, incorporating elements of practical counselling, and both intra and extra treatment support interventions [4].

b) Brief advice, pre and postoperative NRT [29,30]

Following patient completion of the touch-screen program, written prompts were printed by the computer to facilitate clinic nurse and anaesthetist provision of brief cessation advice,
preoperative NRT (if smoke >10 cigarettes per day), and a prescription for postoperative NRT
(if smoke >10 cigarettes per day and expected ward stay of >1 day).

c) Tailored self help material [31]
Information provided by the computer program, and by patient responses to the program was
collated by the computer to produce tailored self-help materials for patients. The self help
material also provided patients with the number of a free telephone counselling service for
additional support.

4. Staff training [25,27]
During an interactive training session, nursing staff were provided with an evidenced based
rationale for the care delivery system, clinical examples, training in cessation care provision,
and printed cessation resource information. Anaesthetists attended an education session where
the importance of preoperative cessation care, the multifaceted care delivery system, and their
role in it, were detailed.

5. Care provision performance monitoring and feedback [25,27]
Data gathered by the computer program and audits of patient records were used to generate
monthly reports of cessation care provision. Bi-monthly meetings of the project team, Nursing
Unit Manager and nursing staff were held to review the feedback and develop solutions to
identified performance deficits.

Usual care group
Clinic staff had the opportunity to provide quit advice and prescribe preoperative NRT postoperative NRT to usual care group patients. The provision of such cessation care was at the discretion of clinic staff.

Data collection, procedures and measures

*Demographic and clinical characteristics*

The computer program collected information on patient demographics and tobacco use characteristics including patient age, gender, education, employment status, previous quit attempts and heaviness of smoking [32]. The diagnosis category of participants was obtained from electronic hospital records.

*Receipt of care*

The efficacy of the clinical practice change intervention was assessed in terms of the proportion of patients who received cessation care elements. Care provision data were collected by the computer program, an audit of patient medical records by a research assistant not blind to group allocation, and a 3 month telephone follow-up survey conducted by a research assistant blind to group allocation.

i) Cessation counselling

The computer recorded whether experimental group patients completed the computer delivered cessation program.

ii) Brief cessation advice
All participants were asked during the 3-month telephone follow-up survey whether nurses and anaesthetists had provided brief cessation advice. In addition, an audit of the hospitals medical records of the patient was undertaken to determine the frequency of recorded cessation advice by clinic nursing staff.

iii) Preoperative NRT
Patients who smoked more than 10 cigarettes per day were asked in the 3-month telephone follow-up survey whether they were offered preoperative NRT by clinic staff. In addition, the hospitals medical records of such patients were audited to determine the frequency of recorded offers of preoperative NRT by clinic staff.

iv) Prescribing of postoperative NRT
Anaesthetist prescription of postoperative NRT for patients who smoked more than 10 cigarettes per day and who had an expected ward stay of greater than 1 day was assessed via an audit of the hospital’s medical records.

v) Provision of tailored self-help material
The computer program recorded whether experimental group patients were provided printed tailored self-help material.

vi) Receipt of all elements of cessation care
The proportion of usual care patients provided with all the appropriate elements (up to 4) of usual cessation care (brief advice from nursing staff, brief advice from anaesthetic staff, offer of preoperative NRT, prescription for postoperative NRT) and the proportion of experimental group patients provided with all the appropriate (up to 6) cessation care elements for which
they were eligible (elements of usual cessation care in addition to computer cessation
counselling and tailored self help material) was calculated. Receipt of a care element was
defined as the provision of care indicated by data from either the telephone follow-up survey
or medical record audit.

Staff acceptability

Pen and paper questionnaires were sent to all nursing and anaesthetic staff who had worked in
the preoperative clinic over a 4 week period following the completion of the study. Five items
assessed the acceptability of providing the comprehensive cessation care elements. Each
questionnaire item required staff to indicate their level of agreement to statements on a 4 point
Likert scale ranging from strongly disagree to strongly agree.

Intervention cost

The introduction of comprehensive cessation care could be expected to incur additional costs
from 2 principal sources, the development and implementation of clinical practice change
strategies, and the delivery of cessation care elements. For both of these sources, costs were
calculated by summing the costs of staff time according to the relevant industrial award
(excluding on-costs) and goods and service costs. Staff time was calculated based on project
records and staff interviews. Goods and services costs were calculated based on normal
budgeting procedures. Research costs were not included. In addition, the estimated annual
costs of sustaining the delivery of comprehensive cessation care to patients, and the estimated
annual costs of continued provision of usual cessation care was calculated.

1. Development and implementation of clinical practice change strategies
Staff time required for clinical practice change strategies included that required for opinion leaders to advocate and endorse the initiative, for clinic staff to engage in consensus processes, attend bimonthly performance feedback meetings, pre-implementation and refresher training sessions, and the time required to collect performance feedback data from a daily audit of the medical records. Project officer costs incorporated the time to develop the care delivery protocol, attend meetings, conduct training sessions, generate performance feedback and supervise the implementation of the intervention. Goods and services costs included the cost of computer hardware and software development for the computer program.

2. Delivery of comprehensive cessation care
Staff time for the provision of cessation care included the time for staff to refer patients to the computer program, provide brief advice, preoperative NRT and prescribe NRT for patient use postoperatively. Where two measures of care delivery were available (patient report and record audit), calculation of staff time was based on medical record audit data. The cost of goods incorporated computer stock such as printer paper and toner and the cost of NRT. Service costs covered the cost of computer maintenance.

3. Sustaining comprehensive cessation care delivery
The annual cost of clinical practice change strategies to sustain care delivery are those associated with the staff time required to collect, generate and feedback quarterly performance data (based on a sample of medical records) to staff, and to attend annual refresher training sessions. Staff time required for the nursing unit manager to adopt appropriate ‘project officer’ tasks, feedback performance data, conduct training and assume responsibility of cessation care delivered by the clinical staff is also incorporated into costs. There are no goods as services costs associated with the clinical practice change strategies required to
sustain care delivery. Calculation of the annual costs for the provision of cessation care are based on the costs described in ‘delivery of cessation care’ above.

4. Ongoing delivery of usual cessation care

The annual cost of usual care was calculated based on the staff time required to provide brief advice and prescribe preoperative and postoperative NRT. Where two measures of care delivery were available, calculation of staff time was based on the measure indicating the highest prevalence of care delivery time. The cost of NRT represented goods costs. There were no service costs associated with usual care.

Analysis

Analyses were conducted using SAS version 8.2 statistical software. Chi Square (for categorical variables) and independent sample t-tests (for continuous variables) were used to assess the success of the randomisation procedure at baseline and the relationship between treatment allocation and measures of cessation care. Tests for significance were two tailed. Odds ratios with 95% confidence intervals were calculated for measures of care provision. The proportions of staff that either agreed or strongly agreed to each of the 5 acceptability statements were reported.

A cost effectiveness analysis was conducted from the point of view of a health care provider. The total annual incremental cost, and the incremental cost per smoker to provide comprehensive cessation care on an ongoing basis (excluding initial development and implementation cost) was calculated. All costs are reported in 2002 Australian dollars.
It was expected that approximately 200 smoking patients would enrol in the trial over the research period providing a total sample of 120 experimental and 80 usual care control participants per group. Allowing a 20% loss to follow-up, a sample size of 96 experimental and 64 usual care control group participants would provide 80% power to detect a 22% between group difference (50% vs 72%) on measures of care provision ($\alpha = .05$).

RESULTS

Sample

During the 6 month trial period, 1333 patients attended the preoperative clinic. Of these, 253 were identified as being ineligible by a research assistant (77 pregnant, 58 less than 18 years, 47 previously approached for participation, 24 did not have a booked surgery date, 23 too ill, 13 could not read English, and 11 were called into a clinical consultation prior randomisation). One thousand and thirty five of the remaining 1080 patients (96%) agreed to participate in the study and completed the computerised smoking assessment. Eight hundred and twenty five patients were non smokers. Eighty six of the remaining smoking patients were randomly allocated to the usual care group and 124 to the experimental group. No significant differences were detected between groups on patient characteristics including age, gender, education, employment status, previous quit attempts, heaviness of smoking or medical diagnosis categories ($p=.21 - .96$).

Data regarding the receipt of behavioural cessation counselling and tailored self help material were obtained from the computer program for all experimental group participants. Thirty participants (14%) did not provide 3 month follow-up data and 9 participants did not complete the survey items relating to anaesthetist provision of brief advice. There were no significant
differences between groups in the demographic or clinical characteristics of participants who were contacted for follow-up (p=.18 - .76). The medical records of 2 participants were not available for audit.

All 5 nurses and 10 of 13 anaesthetists completed and returned the questionnaire.

**Receipt of cessation care**

Table 1 shows the receipt of recommended cessation care elements. Over seventy five percent of experimental group patients received each appropriate element of care, with the exception of anaesthetist brief advice (60%). Experimental group patients were significantly more likely to receive each of the cessation care elements (p<.01).

**Receipt of all care elements**

Fifty percent of the experimental group received all of the appropriate elements. One experimental group patient (1%) did not receive any cessation care elements in full. In contrast 13% of usual care patients received all appropriate elements of care, 56% received just one care element and 11% did not receive any cessation care.

**Staff Acceptability**

The findings of the staff acceptability questionnaire are displayed in table 2. All aspects of care delivery were reported to be highly acceptable among nurses and anaesthetists.
Intervention cost

As can be seen in Table 3, the total cost of developing and implementing the multifaceted clinical practice change intervention and providing comprehensive cessation care to experimental group participants for the 6 month trial period was approximately $A34,171. The cost of providing comprehensive cessation care to patients over the same period was $A3,549. At $A4,568 for clinical practice change strategies and $A11,151 for the provision of comprehensive cessation care elements, the total cost of sustaining care delivery to patients based on an annual throughput of 420 smokers (double the number of smokers recruited into the trial) is $A15,719. The annual cost for the provision of usual cessation care is $A1,038. The annual incremental cost of sustaining comprehensive cessation care is $A14,681, or $A35 per smoking patient.

INSERT TABLE 3

DISCUSSION

Considerable research evidence has proven the efficacy of providing smoking cessation care to hospital patients [7]. What remains is to translate this research evidence into practice. Despite the weight of evidence, cessation care, either comprehensive or otherwise, is not routinely delivered by health care providers [8-14]. The findings of our study suggest that a multifaceted clinical practice change intervention can be effective in increasing the provision of such care. Importantly, the intervention was successful in facilitating the provision of what could be seen as best practice cessation care [4,5]. As such, the results demonstrate the feasibility of a busy outpatient clinic providing not just minimal brief cessation advice, but a comprehensive package of cessation care elements.
No reports on the efficacy of an equivalent multifaceted clinical practice change intervention in this setting could be located by the authors. Although methodological differences limit the capacity to compare the findings of this study with those in other settings, a broad comparison suggests the effect sizes obtained in this study were relatively large (21-86%). Previous studies in other settings have reported increases in the provision of care of between 2% and 27% [33-35]. In each of these cases, more limited clinical practice change strategies were implemented.

Despite the apparent success of the intervention in increasing care provision, 50% of experimental group patients did not receive all appropriate elements of cessation care. To a large extent this was due to 40% of experimental group patients reporting that their anaesthetist did not provide brief cessation advice despite this being a core aspect of anaesthetic care [8,19]. Anaesthetists were provided with a training session regarding the intervention and their role in its delivery. They did not however receive the performance feedback component of the intervention. The inclusion of performance audit feedback to anaesthetists may further improve their provision of brief advice to patients [25,27]. Research also suggests that some anaesthetists believe that they are providing redundant information if patients have already received quit advice and assistance by nursing staff [8]. A greater focus on providing the rationale and evidence for multi-provider care provision may therefore be warranted.

Previous research has identified numerous barriers to staff delivery of cessation care [16,17]. The care delivery system developed in this study was designed to address many of these
barriers. The finding that the elements of the care delivery system were acceptable to both nursing and anaesthetic staff suggests the possibility that these barriers may have been at least partially resolved. Of particular interest is the finding of a high level of staff acceptability of the computer-based elements of the system, a finding that is consistent with previous research in clinical settings which suggests that the use of touch-screen computer programs is an acceptable method of assessing patient risk behaviours and providing preventative care advice and assistance [36-38]. The true test of acceptability will lie in an assessment of care provision under normal clinic circumstances in the absence of supportive research infrastructure.

The provision of smoking cessation care, particularly multiple component interventions are established as being cost effective when compared to other medical services [39]. After the initial development and implementation of clinical practice change strategies, the delivery of comprehensive cessation care is expected to cost the preoperative clinic $15,719 annually, or $35 per patient. Research suggests that compared with non smokers, smokers incur higher charges for surgical treatment, experience longer surgical and anaesthesia time, and have an increased risk of intra-operative and postoperative complications [19,20,40]. The actual reductions in cost due to stopping smoking prior to surgery has not been reported. Further research is needed to establish whether the provision of comprehensive cessation care provides a net benefit.

There are a number of limitations to the research trial. As neither clinic staff or patients were blind to patient group allocation, a risk existed of usual care patients obtaining comprehensive cessation care elements. Such a risk was controlled by the use of the computer program as the primary determinant and provider of the major elements of such care: cessation counselling,
tailored self-help material and prompts for pre and post operative NRT. Analysis of care receipt data (Table 3) demonstrated that this control was effective as either no, or a limited proportion of usual care patients received these elements of care. In the case of brief advice by nurses and anaesthetists, relatively high proportions of usual care patients received such care. These levels appear higher than those reported elsewhere [9,11,12] and may reflect the effects of either contamination of intervention elements such as staff training, opinion leaders and concensus processes or pre-existing support by clinic staff for smoking cessation care provision. In the event that they are attributable to contamination, the already large observed effect sizes represent an underestimate of the impact of the intervention.

Second, clinic staff and patients who were aware of their group allocation may have also introduced bias into outcome assessments. While clinic staff may have felt more compelled to incorrectly document the provision of smoking cessation care in patients medical records, the use of data from both sources, the consistency of effect size and direction across both sources, and the substantial differences found between groups suggest that it is likely that an intervention effect did occur. Third, preoperative NRT was funded by the research team to be provided to experimental group patients free of charge. Provision of preoperative NRT to usual care patients incurred a cost to the clinic, a budgeting constraint that may have contributed to differences in the provision of preoperative NRT between groups. Finally, randomising patients in favour of the experimental group using a 3:2 ratio did not represent the most efficient design. However, the extent to which this randomisation schedule reduced the study’s potential to detect an intervention effect was calculated to be minimal (0.2%).
The findings of the research have considerable implications for the provision of smoking cessation care to hospital patients generally. Given its suggested efficacy, relatively low cost per smoking patient, potential for health service cost savings, and high level of staff acceptability, evaluation of the application of the clinical practice change intervention in other hospital settings appears warranted.

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