# **Decision Aid for Cigarette Smokers Scheduled for Elective Surgery**

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#### **ABSTRACT**

**Background:** Decision aids can increase patient involvement in decision-making about health care. The study goal was to develop and test a decision aid for use by clinicians in discussion options for changing smoking behavior before and after elective surgery.

**Methods:** In formative work, a decision aid was designed to facilitate patient—clinician discussion regarding three options: continue smoking, attempt a period of temporary abstinence, and attempt to quit smoking for good. A randomized, two-group pilot study was then conducted in smokers evaluated in preparation for elective surgery in a preoperative clinic to test the hypothesis that the decision aid would improve measures of decisional quality compared with usual care.

**Results:** The final decision aid consisted of three laminated cards. The front of each card included a colorful graphic describing each choice; the reverse including two to three pros and cons for each decision, a simple graphic illustrating the effects of smoking on the body, and a motivational phrase. In the randomized trial of 130 patients, the decision aid significantly (P < 0.05) improved measures of decisional quality and patient involvement in decision making (Cohen's d effect sizes of 0.76 and 1.20 for the Decisional Conflict Scale and Observing PatienT involvement In decisiON-making scale, respectively). However, the decision aid did not affect any aspect of perioperative smoking behavior, including the distribution of or adherence to choices.

**Conclusions:** Although the use of a decision aid to facilitate clinician—patient discussions regarding tobacco use around the time of surgery substantially improved measures of decisional quality, it alone did not change perioperative tobacco use behavior. (ANESTHESIOLOGY 2015; 123:18-28)

ATIENT involvement in decision-making is now widely regarded as a feature of high-quality health care. 1-5 This has increased interest in decision aids, tools designed to facilitate patient participation in decision-making about health care. 6,7 Decision aids present the available options, the relative pros and cons of each option, and the likelihood of these outcomes when pertinent. Shared decision-making increases the likelihood that decisions will reflect the informed preferences of the patient and thus maximizes patient autonomy 6,7; it remains unclear whether it may also improve adherence to the decision or downstream healthcare use or health outcomes. 7

Tobacco use is the single most important preventable cause of disease.<sup>8</sup> Clinical practice guidelines provide recommendations for clinician-provided tobacco interventions (the "5As").<sup>8</sup> These guidelines include strong, personalized recommendations to quit, regardless of patient preference. For those patients unwilling to make a quit attempt, motivational interviewing techniques are recommended to

### What We Already Know about This Topic

 Decision aids can increase patient involvement in decisionmaking about health care, but their application to perioperative counseling regarding tobacco use has not been studied

# What This Article Tells Us That Is New

In a randomized trial of 130 surgical patients, use of a decision aid consisting of laminated cards with pros and cons of continuing smoking, attempting temporary abstinence, or attempting to quit smoking improved measures of decisional quality but did not change perioperative tobacco use behavior

encourage a future attempt. Unfortunately, it has proven difficult to disseminate this approach in clinical practice, and it has shown only limited effectiveness outside experimental settings. Shared decision-making facilitated by the use of in-visit decision aids could prove to be practical tools to help clinicians discuss tobacco use with their patients as they have been shown to specifically increase

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patient involvement in the decision-making process.<sup>21–24</sup> However, there are few studies of their application to increase the involvement of patients in decisions related to their tobacco use behavior.<sup>25,26</sup>

Life events can motivate changes in smoking behavior.<sup>27</sup> One such event, the scheduling of elective surgical procedures, occurs in approximately 10 million smokers each year in the United States.<sup>28</sup> For those requiring elective surgery, smoking has immediate potential consequences, increasing the risk of several postoperative complications.<sup>29</sup> Even brief perioperative abstinence may be beneficial in reducing the levels of smoke constituents such as nicotine and carbon monoxide, 30,31 and recommendations include maintaining at least temporary abstinence from 12h before surgery until at least 1 week after surgery.<sup>32</sup> Surgery also represents a "teachable moment" for smoking cessation, as undergoing a major surgical procedure increases long-term abstinence rates, which in turn reduces the risk of cancer and other diseases.<sup>28</sup> Surgical patients who smoke face three immediate choices regarding their smoking behavior in the surgical period: (1) continue to smoke both immediately before and after surgery; (2) attempt to maintain temporary abstinence from smoking in the perioperative period; or (3) use surgery as an opportunity to quit smoking for good. Because the surgical date represents a firm point of decision, and because formative work suggests that smokers undergoing surgery are quite interested in exploring options regarding their smoking behavior,<sup>33</sup> this setting represents an excellent opportunity to explore the novel concept of using a decision aid to facilitate discussion of tobacco use between clinicians and patients who smoke.

The overall goal of this study was to develop and pilot test a decision aid to increase patient involvement in decisions regarding smoking behavior of cigarette smokers scheduled for elective surgery. After development of a decision aid in formative work, we conducted a randomized, two-group pilot study testing the hypothesis that the decision aid administered in a perioperative clinic would improve decisional quality and patient involvement in decision-making, the primary outcomes, as measured by three validated instruments. As a secondary outcome, smoking behavior in the perioperative period, including adherence to the stated decision, was also evaluated.

#### **Materials and Methods**

This study was approved by the Mayo Clinic Institutional Review Board, Rochester, Minnesota, and was prospectively registered before trial initiation (ClinicalTrials.gov ID: NCT01575119). Written informed consent was obtained both from the patients and clinicians who participated in the study. The study was conducted in the Mayo Clinic Rochester Preoperative Evaluation Center (POE). Approximately 15% of elective surgical patients undergoing a broad range of surgical procedures at Mayo Clinic Rochester are evaluated in the POE.

#### **Decision Aid Development**

We aimed to develop a decision aid to help patients scheduled for elective surgery decide whether to (1) attempt temporary abstinence around the time of surgery ("quit for a bit," from the morning of surgery until at least 1 week after the surgery), (2) make a sustained quit attempt ("quit for good"), or (3) continue smoking. We used a patient-centered approach for decision aid development based on design/ participatory action research, developed and validated by the Knowledge and Evaluation Research Unit at Mayo Clinic.34-36 It employs initial observations of current clinical encounters, initial prototype development taking into account all existing information, including evidence synthesis (based on prior work of study team members), initial prototype field testing, and then an iterative process of prototype modification and further field testing until a final version is completed. An important design parameter was the feasibility of use by clinicians who are not tobacco specialists within a typical preoperative clinical encounter.

At first, an experienced designer observed a series of nine clinical encounters involving usual discussions between clinicians and patients about smoking during the perioperative period. Clinicians included those who provide preoperative assessment services in the POE. The designer summarized and reviewed results with the rest of the study team, identifying prominent themes. An initial version of the decision aid was then designed using the team experience in creating prior complex decision aids, as more than one option was presented and each option had several potential effects potentially important to the patient. We chose not to include absolute probabilities of outcomes and how these could be modified by abstinence, as is common in many decision aids, because these vary depending on the particular surgical procedure. This initial version was formatted as a single brochure, presenting the advantages for each choice, and including detailed information regarding support available for quitting in the Mayo Clinic practice.

The same clinicians in the POE who participated in the initial information collection were briefly instructed by study team members on the use of the prototype decision aid, distributed by clinician in the course of their assessment. The designer then observed 10 clinical encounters in which the prototype was used, looking for patterns of the conversations and documenting the observed issues, problems, and challenges. The initial brochure version of the prototype, distributed by the clinician during the encounter, was felt by the designer and the clinicians to present too much information, tended to be overlooked by the patient within the other multiple brochures distributed as a part of preoperative teaching, and generated little discussion. Based on these results, the prototype was totally redesigned. Important design considerations in this prototype included (1) presenting each choice on separate, large laminated cards distinctive from other patient education materials; (2) simplifying by reducing the amount of text and eliminating description of resources to support quitting; and (3) explicating listing of both pros and cons for each choice, rather than just the pros as in earlier versions.

After observing another 15 clinical encounters, another revision of the decision aid was developed, now including a packet with printed instructions to contain the cards. The method of distribution was also changed such that the packet of cards was distributed by the personnel who brought the patient to the examination room (before the clinician evaluation). This permitted time for the patient (and accompanying people if present) to examine the cards over the typical 5 to 10 min period before the clinician entered the room.

This near-final version of the prototype was tested in a final 10 clinical encounters. These sessions were also audiotaped for further transcription and analysis. At the completion of the encounter, each patient was asked to complete the Decisional Conflict Scale and the modified COMRADE (Combined Outcome Measure for Risk communication and treAtment Decision-making Effectiveness) Scale, two existing measures

of decisional quality (described under Study Assessments). A brief interview was used to assess the areas of influence identified by patients as impacting the decision process. The providers also underwent a brief interview after the clinical encounter. Based on the results of this cycle, minor modifications were made to produce a final version of the decision aid (fig. 1), consisting of three laminated cards (approximately 14 by 24 cm) contained within a sleeve including written patient instructions for their use. The front of each card included a colorful graphic describing each choice; the reverse including two to three pros and cons for each decision, a simple graphic illustrating the effects of smoking on the body for one card, and a motivational phrase. At the conclusion of the final round of observations, both patient and clinician interviews indicated a high level of satisfaction with the decision aid. Values of the Decisional Comfort Scale (DCS) (86±8) and the COMRADE Scale  $(87 \pm 10)$  (both from a total possible score of 100) obtained in the final 10 patients observed supported these patient interview results.

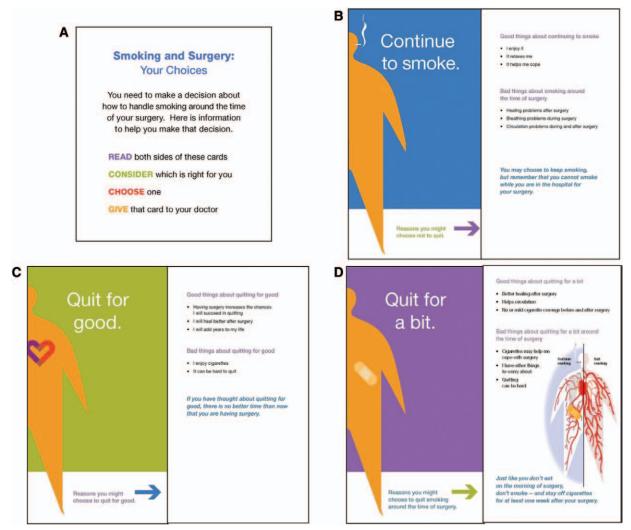


Fig. 1. Decision aid. (A) Sleeve containing the three cards. (B) Front and back of the "Continue to smoke" decision aid card. (C) Front and back of the "Quit for good" decision aid card. (D) Front and back of the "Quit for a bit" decision aid card.

#### Randomized Trial

The final decision aid was evaluated in a randomized, two-group pilot study of current cigarette smokers evaluated in the POE for elective surgery, comparing the decision aid with usual care.

Recruitment. Eligibility criteria included age 18 yr old or older and current smoking (defined as >100 cigarettes lifetime consumption and self-report of smoking either every day or some days) before surgical scheduling. During recruitment by study personnel, subjects were informed that the purpose of the study was to examine methods of how best to provide them information about smoking and surgery. The aim was to include a heterogeneous group of patients, including those who did not intend to quit smoking. Recruitment was performed on a convenience basis when the appropriate research and clinical personnel were available, including at least one clinician capable of providing each intervention condition.

Intervention Conditions. Both decision aid and usual care interventions were delivered by practicing clinicians who regularly staff the POE. These included physician assistants (n = 2), an internist (n = 1), anesthesiologists (n = 2), and anesthesiology residents (n = 19). We chose to use the usual clinical providers to deliver the decision aid, rather than study personnel, because (1) this best represents how the decision aid would be used in clinical practice; (2) the dynamics of patient interactions will likely differ between clinician and study personnel encounters; and (3) we wanted to gather feedback from providers regarding their perceptions of the decision aid in actual practice. Separate groups of clinicians delivered the decision aid (n = 18) and usual care (n = 6) to minimize the potential for contamination. The numbers in each group of clinicians were determined by the patterns of availability in the POE so that at least one from each group would be present on any given day.

All clinicians participating in the study received an approximately 15-min briefing regarding the study and provided informed consent. Those clinicians delivering the decision aid watched an 8-min video demonstrating the use of the decision aid and had an opportunity to ask questions. The total length of the briefing did not exceed 30 min for any clinician.

Patients receiving usual care received from the personnel who brought them into the examination room a standard patient education brochure in clinical use outlining the risk of smoking in the perioperative period, the benefits of quitting, and resources available to support quitting. Clinicians caring for these patients were not instructed regarding how to discuss smoking, but all incorporated advice to quit smoking as a part of their discussion per usual clinical practice in the POE.

Patients receiving the decision aid received the decision aid packet from the personnel who brought them into the examination room and who read them the instructions printed on the packet sleeve ("You need to make a decision about how

to handle smoking around the time of your surgery. Here is information to help you make that decision. Read both sides of these cards, Consider which is right for you, Choose one, and Give that card to your doctor"). A supply of the same standard patient education brochure distributed to the usual care group was made available in the rooms for use by the clinician if the patient wanted more information regarding available resources to support quitting.

**Procedure.** After enrollment, subjects were randomized to receive either the decision aid or usual care. Randomization was stratified according to anticipated type of surgery (inpatient *vs.* outpatient) using blocks of size 4, as we had previously shown that type of surgery is an important factor determining postoperative smoking behavior.<sup>37</sup> For each stratum, a randomization schedule was generated by the Mayo Clinic Division of Biostatistics. At the time of enrollment, group assignment was determined according to the appropriate stratum using sealed envelopes.

#### Study Assessments

**Baseline Measurements (Made at the Time of Enroll-ment, before Intervention).** Demographic variables assessed included gender, age, ethnicity, and educational attainment. The Controlled Preference Scale, a validated measure, <sup>38</sup> assessed the decision-making preferences regarding health-care decisions, and two single items assessed self-reported quality of life and state of health. <sup>39</sup> Assessment of smoking history included information regarding prior quit attempts, the Fagerström test for Nicotine Dependence, <sup>40</sup> and whether healthcare personnel had discussed their smoking around the time of surgery before this visit.

Patient Measurements Immediately after Intervention (in POE). Three validated measures assessed decisional quality (these and other measures are presented in the appendix). These three measures attempt to assess domains relevant to how decisions are made and satisfaction with these decisions. The 16-item Decisional Conflict Scale is the most commonly used, validated, and psychometrically characterized scale in decision aid trials, assessing uncertainty in decision-making and factors contributing to uncertainty such as feeling uninformed, being unclear about personal values and feelings unsupported, in addition to the perceived effectiveness of the decision-making process.<sup>41</sup> The COMRADE Scale seeks to assess decision-making and risk communication.<sup>42</sup> For the purpose of this study, we only assessed the risk communication domain (eight items). We did not include the decision-making domain as several items overlapped with the Decisional Conflict Scale, thus minimizing respondent burden for patients. Four additional similar items were created to specifically assess the comfort level of the patient in discussing their smoking with the clinician and scored separately (Smoking Discussion Comfort Scale). The OPTION (Observing PatienT involvement In decisiON-making) scale measures patient involvement in decision-making process. 43,44 Patient encounters were observed using video recordings. These videos were then scored by two trained observers who assign a score to each of 12 domains related to clinician—patient interaction in the decision-making process. Any discrepancies in scoring were resolved by consensus between the two observers.

Patients were also queried regarding which of the three decisions they had chosen. Four items assessed their satisfaction with the information provided regarding smoking, and five items assessed their knowledge regarding how smoking affects perioperative risk.

**Clinician Measurements Immediately after Intervention (in POE).** Immediately after delivery of the assigned intervention, clinicians were administered a seven-item Decisional Conflict Scale assessing their impressions of the patient's decision-making. 41,45 For encounters using the decision aid, as a measure of treatment fidelity, the videos of these encounters were scored by two observers regarding seven desired clinician behaviors associated with their use and four desired behaviors by the room personnel distributing the decision aid cards.

**Patient Measurements on the Morning of Surgery and 30 Days after Surgery.** At both of these times, four items assessing patient satisfaction with the discussion of smoking in the POE were administered. On the morning of surgery, patients were asked to self-report abstinence on that day, and exhaled carbon monoxide levels were measured (Micro Smokerlyzer®; coVita, USA). On day 30, self-reported abstinence from smoking for the prior 7 days (point prevalence abstinence) was sought *via* telephone contact.

# Statistical Analysis

We determined sample size based on a two-group comparison of the Decisional Conflict Scale. We hypothesized that

the decision aid group would have significantly lower decisional conflict compared to the standard intervention with an effect size of at least 0.50. Based on this assumption, a total sample size of N = 130 (65 per group) would provide statistical power (two-tailed,  $\alpha$  = 0.05) of 80% to detect a difference between groups.

For the purpose of scoring and consistency, the scoring of the Decisional Conflict Scale was reversed to form a Decisional Comfort Scale (DCS), with higher values indicating less conflict (greater comfort). As detailed in the appendix, all scores and scales were transformed to range between 0 and 100. Fisher exact test was used to compare proportions and unpaired *t* tests to compare ordinal variables. A *P* value less than 0.05 was considered to indicate statistical significance.

#### **Results**

Of the 274 patients approached for participation in the randomized trial between May 2012 and May 2013, 220 met inclusion criteria, and 130 (59% of those eligible) agreed to participate and were randomized (fig. 2). One patient randomized to usual care inadvertently received the decision aid and is not further considered, so that this report concerns 129 patients who were randomized and received the assigned intervention.

Demographic variables, smoking history, and health self-assessments were not significantly different between groups (table 1). The majority of patients received inpatient surgery, and approximately half have had some discussions with clinicians about their smoking before POE evaluation. Decision-making preferences as assessed by the Controlled Preference Scale were also similar between groups. The median time from POE evaluation to surgery was 1 day (median) (interquartile range, 1 to 2 days), with a mean of 2.6 days.

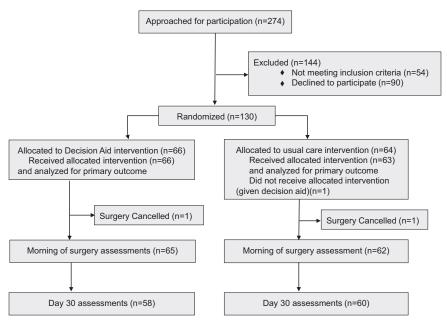


Fig. 2. Study flow diagram.

Table 1. Baseline Measures

	Usual Care (n = 63)	Decision Aid (n = 66)	<i>P</i> Value
Age (mean ± SD)	53±14	54±14	0.78
Gender (female), n (%)	36 (57)	29 (44)	0.13
Race (white), n (%)	59 (95)	57 (86)	0.14
Education (some college), n (%)	38 (62)	42 (65)	0.13
Inpatient surgery, n (%)	46 (73)	49 (74)	0.87
Cigarettes per day (mean ± SD)	15.4±9.5	15.6±9	0.88
At least one quit attempt, n (%)	58 (95)	56 (83)	0.10
FTND score (mean ± SD)	$4.6 \pm 2.2$	4.1 ± 2	0.15
Prior discussion of smoking (yes), n (%)	34 (57)	31 (48)	0.31
Quality of life* (mean ± SD)	$7.2 \pm 2.2$	$7.3 \pm 2.0$	0.78
Health status† (mean ± SD)	67±22	69±20	0.61
Controlled preference scale (mean $\pm$ SD)	$2.4 \pm 0.9$	$2.5\pm0.9$	0.55

Statistical comparisons were performed using t tests for continuous variables and Fisher exact test for proportions.

FTND = Fagerström test for Nicotine Dependence.

Video review of the encounter indicated good fidelity to intervention delivery in the decision aid group, with fidelity scores of 85 (20) (mean [SD]) and 88 (15) for room personnel and clinicians, respectively (total possible score = 100). The DCS and COMRADE scores reported by patients were significantly higher in the decision aid group (table 2), with a Cohen's d of 0.76 and 0.78, respectively, indicating a medium to large effect size. Values for each DCS subscale were significantly higher in the decision aid group. The OPTION scores, which measure patient involvement in decision-making process, were also significantly higher in the decision aid group, with a Cohen's d of 1.20, indicating a very large effect size. The DCS score reported by the clinicians delivering the interventions were also higher among those patients receiving the decision aid, with a Cohen's d of 0.49. These results indicate that the decision aid increased all measures of patient decisional quality as assessed by both patients and clinicians.

The Smoking Discussion Comfort Scale reported by patients in the POE was not significantly different between the two groups (table 2), indicating similar degrees of patient comfort with the smoking discussion as assessed immediately after the discussion. However, clarity of information and helpfulness were rated significantly higher by patients receiving the decision aid, whereas willingness to recommend to others and assessment of the amount of information presented did not differ significantly (table 3). The measure of satisfaction with the smoking discussion assessed on the morning of surgery was significantly higher in patients receiving the decision aid (81 [24] and 90 [19] for the usual care and decision aid groups, respectively; P = 0.02). However, these differences did not persist; by 30 days after surgery, satisfaction was not different between groups (84 [21] and 84 [24] for the usual care and the decision aid groups, respectively, at day 30; P = 0.90). Perioperative smoking

Table 2. Measures of Decisional Quality

	Usual Care (n = 63)	are (n = 63) Decision Aid (n = 66)	
Patients			
Decisional Comfort Scale			
Informed subscale (three items)	77 ± 17	$87 \pm 13$	0.0013
Values subscale (three items)	77 ± 17	87±13	0.0009
Support subscale (three items)	78±17	87±13	0.0068
Uncertainty subscale (three items)	76±17	$86 \pm 14$	0.0006
Effective choice subscale (four items)	$73 \pm 17$	83±12	0.0002
Total (16 items)	76±15	86±11	0.0003
COMRADE (eight items)	75±19	$88 \pm 14$	0.0013
OPTION (12 behaviors)	23±17	46±21	< 0.0001
Smoking discussion comfort scale (four items) Clinicians	75±17	77±18	0.56
Decisional comfort scale (seven items)	$74 \pm 16$	81 ± 12	0.034

All values are mean ± SD. Statistical comparisons were performed using unpaired t tests. See the appendix for description and score computations. Maximum score for all assessments is 100.

COMRADE = Combined Outcome Measure for Risk communication and treAtment Decision-making Effectiveness; OPTION = Observing PatienT involvement In decisiON-making.

<sup>\*</sup> Question: "How would you describe your quality of life?" (0 to 9). † Visual analog scale querying how good or bad is your own health today in your opinion (0 to 100).

Table 3. Satisfaction, Knowledge, and Decision

	Usual Care (n = 63)	Decision Aid (n = 66)	P Value	
Patient satisfaction				
Clarity of information (one item)	$80 \pm 23$	93±12	< 0.001	
Helpfulness (one item)	78±24	88±19	0.02	
Recommend to others (one item)	$80 \pm 24$	86±22	0.19	
Amount of information (one item)				
Too little	10 (16%)	4 (6%)	0.18	
Just right	49 (79%)	59 (89%)		
Too much	3 (5%)	3 (5%)		
Perioperative smoking knowledge (five items)	76±21	81 ± 25	0.27	
Decision*				
Continue to smoke	10 (17%)	10 (16%)	0.83	
Quit for a bit	24 (41%)	24 (38%)		
Quit for good	24 (41%)	30 (47%)		

Values are mean ± SD for continuous variables and n (%) for proportions. For the continuous acceptability items, the maximum value is 100. Statistical comparisons were performed using *t* tests for continuous variables and Fisher exact tests for proportions.

knowledge assessed in the POE did not differ significantly between groups (table 3).

The distribution of choices made by the patients at the conclusion of the interventions was not significantly different between groups (table 3). Regarding smoking behavior, the proportion of patients reporting abstinence on the morning of surgery did not differ between groups (40% and 42% in usual care and decision aid groups, respectively; P = 0.97); neither did the exhaled carbon monoxide levels (11 [10] and 10 [8] in usual care and decision aid groups, respectively; P = 0.88). When self-reported abstinence and carbon monoxide levels on the morning of surgery were analyzed according to the choice made (table 4), there were no differences in either between groups for the "quit for a bit" decision (P = 0.77 for abstinence; P = 0.38 for carbon monoxide levels), indicating that those who had received the decision aid were no more likely to adhere to this choice. The proportion of patients reported 7-day point prevalence abstinence at 30 days also did no differ between groups (34% and 32% in usual care and decision aid groups, respectively; P = 0.94). There was no difference in the proportion of patients who reported abstinence at 30 days for the "quit for good" decision (P = 0.25),

indicating that those who had received the decision aid were not more likely to adhere to this choice. No patient reported receiving assistance in maintaining abstinence.

#### **Discussion**

The main findings of this study are that (1) the decision aid developed in this study was successfully implemented with adequate fidelity by a range of clinicians after minimal training; (2) the decision aid improved all measures of decisional quality assessed by both patients and clinicians; and (3) there was no evidence that the application of the decision aid changed the distribution of choices or smoking behavior, including adherence to the stated choice.

One important part of a comprehensive approach to tobacco control is interventions to help individual smokers quit. Although tobacco treatment specialists have made important contributions, the reach of these services is limited, which has prompted efforts encouraging all clinicians to incorporate tobacco interventions into their routine clinical care. The Clinical Practice Guideline for Treating Tobacco Use and Dependence recommends that whenever patients contact the healthcare system, a systematic effort be made

Table 4. Smoking Behavior - Morning of Surgery and Day 30

	Dec	Decision Aid Intervention		Usual Care		
	Morning of	Morning of Surgery		Morning of Surgery		Day 30
Decision	Abstinence	CO (ppm)	Abstinence	Abstinence	CO (ppm)	Abstainers
Continue to smoke Quit for a bit	3/10 (30%) 11/22 (50%)	11.6±7.0 10.1±8.0	0/10 (0%) 5/22 (23%)	4/10 (40%) 13/24 (54%)	14.6±10.6 12.6±10.7	2/10 (20%) 1/23 (4%)
Quit for good	22/30 (73%)	$9.8 \pm 9.5$	13/25 (52%)	17/23 (74%)	$7.8 \pm 8.7$	15/22 (68%)

Abstainers reported as n/N (%); n = number of subjects self-reporting abstinence from smoking that day (morning of surgery) or 7-day point prevalence abstinence (day 30); N = number in each intervention group making the decision for whom the data are available at that time point. Carbon monoxide values reported as mean  $\pm$  SD.

<sup>\*</sup> Five controls and two decision aid subjects did not make a decision about their smoking or indicated multiple choices/decisions and are excluded from this analysis.

CO = carbon monoxide.

to identify tobacco users, strongly urge them to quit, and provide aid to do so.<sup>8</sup> However, this approach has proved difficult for clinicians to adopt in actual practice, including among physicians who care for surgical patients.<sup>46</sup> Barriers for clinicians to deliver the intervention include lack of time, training, and low self-efficacy.<sup>33</sup>

Current guideline recommendations are based on an advocacy approach, in which the clinician delivers strong advice to quit, which is presented as the only viable option. To support clinical counseling processes in a variety of settings, there is considerable interest in developing decision aids that can help people understand their options, consider their personal values and preferences, become involved in decision-making, and make a specific, personal choice. They are also practical tools for clinicians, as they provide a standardized approach to evidence-based practice, and do not require extensive training in counseling skills. Decision aids typically provide the probability of certain health outcomes and weight the value of an outcome according to patient preferences according to the framework of expected utility theory. 47 In our design process, we did not include quantitative outcome information, common in other decision aids, as individual risk varies widely according to surgical procedure.

Although decision support systems to help clinicians adhere to tobacco guideline recommendations have been explored, decision aids focused on patients have drawn little attention in the area of tobacco control. <sup>25,26</sup> In designing this decision aid to address perioperative tobacco use behavior, we faced unique challenges. First, this is a discussion that many patients, and clinicians, may be uncomfortable with given the stigmatization of smoking in contemporary culture and the lack of training on the part of perioperative physicians in addressing tobacco use (a theme we confirmed in design work).33 Second, addressing tobacco use is not the primary purpose of the patient visit, in contrast to the setting of several other decision aids. Finally, it could be argued that the decision aid approach is not compatible with current guideline recommendations, as this approach requires presenting the option to continue to smoke while explicitly acknowledging the advantages of this option. Unlike many settings in which clinicians may be similarly willing to support any of the available effective options, in this case the evidence clearly supports abstinence and clinicians are usually not willing to support any other option.

Nonetheless, the decision aid was successful in getting clinicians at various levels of training, including residents with little prior experience in preoperative evaluation in general or tobacco use discussions in particular, to use the aid as intended with minimal training. The decision aid successfully facilitated a conversation about smoking (as most directly reflected in the approximate doubling of the OPTION score), which in design work was identified as a major challenge. This resulted in improvements of decisional quality, with increases in each subscale of the DCS, and a robust effect size for the total score (13) that considerably

exceeded the mean effect size for 28 decision aids evaluated in a recent meta-analysis (6.2; 95% CI, 4.4 to 8.0).<sup>7</sup> The decision aid also improved measures of clarity and helpfulness, but unlike many other decision aids had no effect on knowledge,<sup>7</sup> which was relatively high in both groups, implying either a high level of prior knowledge or that the presentations were equally effective. In contrast to many prior studies of decision aids,<sup>7</sup> measures of patient satisfaction were higher on the morning of surgery, although this was not sustained 30 days after surgery. Thus, in terms of improving the quality of physician–patient conversations about smoking and measures of decisional quality, the decision aid was effective.

However, we found no evidence that use of the decision aid in isolation affected any aspect of perioperative tobacco use behavior. It did not affect the distribution of decisions among the three choices, with a high proportion of participants in both groups willing to modify their behavior in the perioperative period. This is consistent with several prior studies of other decision aids indicating that they do not consistently affect choices. Rather, effects are highly dependent on setting; for example, decision aids reduce the proportion of patients choosing major elective surgery as compared with more conservative therapy.7 The lack of effect of the decision aid on smoking behavior or patient adherence to their decision is consistent with most other studies of decision aids, which also fail to find consistent effects.<sup>7</sup> It is important to note that this study was not powered to examine smoking behavior outcomes, but even given the relatively small study size, there is little evidence for trends toward effects on smoking behavior.

Given the apparent lack of effect on smoking behavior, what then is the potential clinical utility of this decision aid? If the goal is to modify perioperative smoking behavior, these results suggest that those patients intending to maintain some period of abstinence (and > 80% made these choices) require support to succeed, as is already proven in regard to perioperative abstinence<sup>48</sup>; improving decisional quality alone is not sufficient. Nonetheless, the decision aid might be efficacious in improving the currently very low reach of tobacco interventions in surgical patients. 46 However, this would require that patients receiving the decision aid would be more amenable to tobacco interventions, which remains to be determined. If use of decision aid alone does not affect actual smoking behavior, are improvements in decisional quality and patient satisfaction of sufficient intrinsic value as a patient-centered outcome to recommend this approach, or should clinicians just follow the guideline, advocate for quitting, and avoid the appearance of sanctioning continued smoking? This study suggests that using the decision aid approach did not reduce the proportion of patients choosing some period of abstinence compared with usual advice to quit, so that at least in terms of abstinence, the decision aid approach is not inferior.

This study has several other limitations in addition to those already noted. Many clinicians delivering the decision aid were relatively inexperienced, and it is possible that efficacy would increase if provided by more experienced clinicians, although the fidelity scores among these clinicians were high. There was also not a standardized usual care intervention, and the POE has been the setting for several studies over the last 10 yr regarding perioperative tobacco control such that usual care may not be representative of general practice elsewhere. However, this factor would likely bias against finding group differences in measures of decisional quality. Finally, we did not include patients in the earliest phases of decision aid development because we had previously performed extensive formative work on smokers scheduled for elective surgery.<sup>33</sup>

In conclusion, although the use of a decision aid designed to facilitate clinician—patient discussions regarding tobacco use around the time of surgery substantially improved measures of decisional quality, in the absence of tobacco use intervention to support those who chose abstinence, it did not change perioperative tobacco use behavior, including adherence to decisions made to alter this behavior. Whether the use of the decision aid in combination with support for patients wishing to maintain some period of abstinence could affect behavior remains to be determined.

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#### Competing Interests

The authors declare no competing interests.

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# References

- Grol R: Improving the quality of medical care: Building bridges among professional pride, payer profit, and patient satisfaction. JAMA 2001; 286:2578–85
- Joosten EA, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CP, de Jong CA: Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. Psychother Psychosom 2008; 77:219–26
- 3. O'Connor AM, Wennberg JE, Legare F, Llewellyn-Thomas HA, Moulton BW, Sepucha KR, Sodano AG, King JS: Toward the 'tipping point': Decision aids and informed patient choice. Health Aff (Millwood) 2007; 26:716–25
- Say RE, Thomson R: The importance of patient preferences in treatment decisions—Challenges for doctors. BMJ 2003; 327:542-5

- Berwick DM: A user's manual for the IOM's 'Quality Chasm' report. Health Aff (Millwood) 2002; 21:80–90
- O'Connor AM, Stacey D, Entwistle V, Llewellyn-Thomas H, Rovner D, Holmes-Rovner M, Tait V, Tetroe J, Fiset V, Barry M, Jones J: Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2003; 2:CD001431
- Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L, Wu JH: Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2014; 1:CD001431
- 8. Fiore M, Jaen C, Baker T: Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline. Rockville, U.S. Department of Health and Human Services, Public Health Service. 2008
- Cummings SR, Stein MJ, Hansen B, Richard RJ, Gerbert B, Coates TJ: Smoking counseling and preventive medicine. A survey of internists in private practices and a health maintenance organization. Arch Intern Med 1989; 149:345–9
- 10. Doescher MP, Saver BG: Physicians' advice to quit smoking. The glass remains half empty. J Fam Pract 2000; 49:543–7
- 11. Easton A, Husten C, Elon L, Pederson L, Frank E: Non-primary care physicians and smoking cessation counseling: Women Physicians' Health Study. Women Health 2001; 34:15–29
- Ellerbeck EF, Ahluwalia JS, Jolicoeur DG, Gladden J, Mosier MC: Direct observation of smoking cessation activities in primary care practice. J Fam Pract 2001; 50:688–93
- Goldberg RJ, Ockene IS, Ockene JK, Merriam P, Kristeller J: Physicians' attitudes and reported practices toward smoking intervention. J Cancer Educ 1993; 8:133–9
- Jaén CR, Stange KC, Tumiel LM, Nutting P: Missed opportunities for prevention: Smoking cessation counseling and the competing demands of practice. J Fam Pract 1997; 45:348–54
- 15. Jordan TR, Dake JR, Price JH: Best practices for smoking cessation in pregnancy: Do obstetrician/gynecologists use them in practice? J Womens Health (Larchmt) 2006; 15:400–41
- Thorndike AN, Rigotti NA, Stafford RS, Singer DE: National patterns in the treatment of smokers by physicians. JAMA 1998; 279:604–8
- 17. DePue JD, Goldstein MG, Schilling A, Reiss P, Papandonatos G, Sciamanna C, Kazura A: Dissemination of the AHCPR clinical practice guideline in community health centres. Tob Control 2002; 11:329–35
- 18. Joseph AM, Arikian NJ, An LC, Nugent SM, Sloan RJ, Pieper CF; GIFT Research Group: Results of a randomized controlled trial of intervention to implement smoking guidelines in Veterans Affairs medical centers: Increased use of medications without cessation benefit. Med Care 2004; 42:1100–10
- Manfredi C, LeHew CW: Why implementation processes vary across the 5A's of the Smoking Cessation Guideline: Administrators' perspectives. Nicotine Tob Res 2008; 10:1597–607
- Piper ME, Fiore MC, Smith SS, Jorenby DE, Wilson JR, Zehner ME, Baker TB: Use of the vital sign stamp as a systematic screening tool to promote smoking cessation. Mayo Clin Proc 2003; 78:716–22
- 21. Branda ME, LeBlanc A, Shah ND, Tiedje K, Ruud K, Van Houten H, Pencille L, Kurland M, Yawn B, Montori VM: Shared decision making for patients with type 2 diabetes: A randomized trial in primary care. BMC Health Serv Res 2013; 13:301
- 22. Montori VM, Shah ND, Pencille LJ, Branda ME, Van Houten HK, Swiglo BA, Kesman RL, Tulledge-Scheitel SM, Jaeger TM, Johnson RE, Bartel GA, Melton LJ III, Wermers RA: Use of a decision aid to improve treatment decisions in osteoporosis: The osteoporosis choice randomized trial. Am J Med 2011; 124:549–56
- Mullan RJ, Montori VM, Shah ND, Christianson TJ, Bryant SC, Guyatt GH, Perestelo-Perez LI, Stroebel RJ, Yawn BP,

- Yapuncich V, Breslin MA, Pencille L, Smith SA: The diabetes mellitus medication choice decision aid: A randomized trial. Arch Intern Med 2009; 169:1560–8
- 24. Weymiller AJ, Montori VM, Jones LA, Gafni A, Guyatt GH, Bryant SC, Christianson TJ, Mullan RJ, Smith SA: Helping patients with type 2 diabetes mellitus make treatment decisions: Statin choice randomized trial. Arch Intern Med 2007; 167:1076–82
- 25. Willemsen MC, Wiebing M, van Emst A, Zeeman G: Helping smokers to decide on the use of efficacious smoking cessation methods: A randomized controlled trial of a decision aid. Addiction 2006; 101:441–9
- Cupertino AP, Richter K, Cox LS, Garrett S, Ramirez R, Mujica F, Ellerbeck EF: Feasibility of a Spanish/English computerized decision aid to facilitate smoking cessation efforts in underserved communities. J Health Care Poor Underserved 2010; 21:504–17
- McBride CM, Emmons KM, Lipkus IM: Understanding the potential of teachable moments: The case of smoking cessation. Health Educ Res 2003; 18:156–70
- Shi Y, Warner DO: Surgery as a teachable moment for smoking cessation. Anesthesiology 2010; 112:102–7
- Warner DO: Perioperative abstinence from cigarettes: Physiologic and clinical consequences. Anesthesiology 2006; 104:356–67
- Møller A, Tønnesen H: Risk reduction: Perioperative smoking intervention. Best Pract Res Clin Anaesthesiol 2006; 20:237–48
- 31. Lindström D, Sadr Azodi O, Wladis A, Tønnesen H, Linder S, Nåsell H, Ponzer S, Adami J: Effects of a perioperative smoking cessation intervention on postoperative complications: A randomized trial. Ann Surg 2008; 248:739–45
- 32. Warner DO: Helping surgical patients quit smoking: Why, when, and how. Anesth Analg 2005; 99:1766–73
- Warner DO, Klesges RC, Dale LC, Offord KP, Schroeder DR, Vickers KS, Hathaway JC: Telephone quitlines to help surgical patients quit smoking patient and provider attitudes. Am J Prev Med 2008; 35(6 Suppl):S486–93
- 34. Breslin M, Mullan RJ, Montori VM: The design of a decision aid about diabetes medications for use during the consultation with patients with type 2 diabetes. Patient Educ Couns 2008; 73:465–72
- Montori VM, Breslin M, Maleska M, Weymiller AJ: Creating a conversation: Insights from the development of a decision aid. PLoS Med 2007; 4:e233

# **Appendix: Selected Study Assessments**

# **Decisional Comfort Scale (Patients)**

- 1. I know which options are available to me for handling my smoking around the time of surgery.
- 2. I know the good things about each option.
- 3. I know the bad things about each option.
- 4. I am clear about which good things matter most to me.
- 5. I am clear about which bad things matter most.
- I am clear about which is more important to me (the good or the bad things).
- 7. I have enough support from others to make a choice.
- 8. I am choosing without pressure from others.
- 9. I have enough advice to make a choice.
- 10. I am clear about the best choice for me.
- 11. I feel sure about what to choose.
- 12. This decision is easy for me to make.
- 13. I feel I have made an informed choice.
- 14. My decision shows what is important to me.
- 15. I expect to stick with my decision.
- 16. I am satisfied with my decision.

- 36. LeBlanc A, Bodde AE, Branda ME, Yost KJ, Herrin J, Williams MD, Shah ND, Houten HV, Ruud KL, Pencille LJ, Montori VM: Translating comparative effectiveness of depression medications into practice by comparing the depression medication choice decision aid to usual care: Study protocol for a randomized controlled trial. Trials 2013; 14:127
- Warner DO, Patten CA, Ames SC, Offord K, Schroeder D: Smoking behavior and perceived stress in cigarette smokers undergoing elective surgery. Anesthesiology 2004; 100:1125–37
- 38. Degner LF, Sloan JA, Venkatesh P: The Control Preferences Scale. Can J Nurs Res 1997; 29:21–43
- 39. Rabin R, de Charro F: EQ-5D: A measure of health status from the EuroQol Group. Ann Med 2001; 33:337–43
- Fagerstrom KO, Schneider NG: Measuring nicotine dependence: A review of the Fagerstrom Tolerance Questionnaire. J Behav Med 1989; 12:159–82
- 41. O'Connor AM: Validation of a decisional conflict scale. Med Decis Making 1995; 15:25–30
- 42. Edwards A, Elwyn G, Hood K, Atwell C, Robling M, Houston H, Kinnersley P, Russell I; Study Steering Group: Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. Fam Pract 2004; 21:347–54
- 43. Elwyn G, Edwards A, Wensing M, Hood K, Atwell C, Grol R: Shared decision making: Developing the OPTION scale for measuring patient involvement. Qual Saf Health Care 2003; 12:93–9
- 44. Elwyn G, Hutchings H, Edwards A, Rapport F, Wensing M, Cheung WY, Grol R: The OPTION scale: Measuring the extent that clinicians involve patients in decision-making tasks. Health Expect 2005; 8:34–42
- 45. Légaré F, Leblanc A, Robitaille H, Turcotte S: The decisional conflict scale: Moving from the individual to the dyad level. Z Evid Fortbild Qual Gesundhwes 2012; 106:247–52
- 46. Warner DO, Sarr MG, Offord KP, Dale LC: Anesthesiologists, general surgeons, and tobacco interventions in the perioperative period. Anesth Analg 2004; 99:1766–73, table of contents
- 47. Ortendahl M: Smoking as a decision among pregnant and non-pregnant women. Addict Behav 2006; 31:1806–19
- 48. Thomsen T, Tønnesen H, Møller AM: Effect of preoperative smoking cessation interventions on postoperative complications and smoking cessation. Br J Surg 2009; 96:451–61

All items scored on a Likert scale of 0 to 4 (strongly disagree to strongly agree). All subscales and scales are summed, divided by the number of items, multiplied by 25 so that the score ranges from 0 to 100, with higher scores indicative of higher decisional comfort (lower decisional conflict). Subscales include (1) Informed subscale (items 1 to 3), a measure of how informed the respondent feels; (2) Values subscale (items 4 to 6), a measure of how personal values affect perception of risks and benefits; (3) Support subscale (items 7 to 9), a measure of how supported the respondent feels about making the decision; 4) Uncertainty subscale (items 10 to 12), a measure of how certain the respondent feels about the decision; and (5) Effect Choice subscale (items 13 to 16), a measure of whether the respondent feels they have made a good or bad decision.

#### **Decisional Comfort Scale (Clinicians)**

- I think the patient knows which options are available for him/her about how to handle their smoking around the time of surgery.
- 2. I am clear about which is more important for my patient (the benefits of quitting or the benefits of continuing to smoke).
- 3. I think the patient has enough advice to make a choice.
- 4. This decision was easy to make for this patient.

- 5. I feel the patient has made an informed choice.
- 6. I expect my patient to stick to his/her decision.
- 7. I am satisfied with this decision.

All items scored on a Likert scale of 0 to 4 (strongly disagree to strongly agree). All subscales and scales are summed, divided by the number of items, multiplied by 25 so that the score ranges from 0 to 100, with higher scores indicative of higher decisional comfort.

#### Modified COMRADE Scale (Communication Satisfaction)

- I was made aware of the different options available to handle my smoking.
- 2. I had the chance to express my opinions about the different options available.
- I had the chance to ask for as much information as I needed about the different options.
- 4. I received enough information about the choices available.
- 5. I received enough explanation of the information about the options from my doctor.
- 6. The information given to me was easy to understand.
- 7. I had a chance to decide which option I thought was best for me.
- 8. I had a chance to be involved in the decision.

All items scored on a Likert scale of 0 to 4 (strongly disagree to strongly agree). All subscales and scales are summed, divided by the number of items, multiplied by 25 so that the score ranges from 0 to 100, with higher scores indicative of higher satisfaction with communication.

#### **Smoking Discussion Comfort Scale (Patients)**

- I could easily discuss my smoking around the time of surgery again with my doctor.
- 2. I felt comfortable talking about my smoking.
- 3. I would prefer not to discuss my smoking.
- It was difficult for me to discuss my smoking.

All items scored on a Likert scale of 0 to 4 (strongly disagree to strongly agree). All subscales and scales are summed, divided by the number of items, multiplied by 25 so that the score ranges from 0 to 100, with higher scores indicative of higher degree of comfort with the conversation. Scoring of items 3 and 4 was reversed for consistency.

#### **Room Personnel Fidelity Score**

- Does the person say to the patient, "You need to make a decision"?
- 2. Does the person mention "managing smoking around the time of surgery"?
- 3. Does person instruct to talk decision over with clinician?
- 4. Does the person hand the cards to the patient at the end of the room personnel visit?

Behaviors at the time that the decision aid packets were distributed by room personnel to patients receiving the decision aids were assessed by two observers reviewing encounter videos. All "yes" answers were assigned a value of 1, and score calculated as the sum divided by the number of items and multiplied by 100 (0 to 100).

#### Clinician Fidelity Score

- 1. Was the decision aid used during the encounter?
- 2. Does the patient hand a card to the clinician?
- 3. Does the clinician provide pros and cons of the option chosen by the patient?
- 4. Does the clinician try to get at the reason for the option the patient chose?
- 5. Is there deliberation/discussion between patient and clinician regarding the different options?
- 6. Did the clinician force (or try to force) the patient to make a choice the clinician wanted?
- 7. Does the clinician ask for the patient's decision regarding smoking around the time of surgery?

Behaviors during the discussion between clinicians and patients receiving the decision aid were assessed by two observers reviewing encounter videos. All "yes" answers were assigned a value of 1 (except for item 6, where a "no" answer was assigned a value of 1), and score calculated as the sum divided by the number of items and multiplied by 100 (0 to 100).

#### Satisfaction

- 1. How would you describe the clarity of information about smoking given at this visit?
- 2. How helpful was the information about smoking given at this visit?
- 3. Would you recommend that others receive information about smoking and surgery in the same way?

All items scored on a Likert scale of 0 to 4, not to extremely, and multiplied by 25 (0 to 100).

# Perioperative Smoking Knowledge Score

- 1. Quitting smoking can improve healing after surgery.
- 2. Quitting smoking can help the circulation during surgery.
- $3. \quad \text{It is harder to quit around the time of surgery than other times}.$
- 4. Smoking increases the chances I will be nauseated after surgery.
- Most people find that quitting smoking around the time of surgery is stressful.

Correct answers (affirmative responses to items 1 and 2, negative answers for items 3 to 5) were assigned a value of 1, and score calculated as the sum divided by the number of items and multiplied by 100 (0 to 100).

# Satisfaction Score (Assessed the Morning of Surgery and 30 Days after Surgery)

- 1. I am satisfied with the discussion I had about my smoking in the preoperative clinic.
- The information I received in the preoperative clinic about how to handle my smoking around the time of surgery was useful.
- 3. I would recommend that others get information about how to handle their smoking like I did.
- 4. I am satisfied with my decision about how to handle my smoking around the time of surgery.

All items scored on a Likert scale of 0 to 4 (strongly disagree to strongly agree). All scores are summed, divided by the number of items, and multiplied by 25 so that the score ranges from 0 to 100, with higher scores indicative of higher degree of satisfaction with the conversation about smoking.