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Development of a decision aid for children faced with the decision to undergo dental treatment with sedation or general anaesthesia

Summary

Background: Decision aids are tools used to help individuals faced with difficult healthcare decisions. They help patients further understand the treatment options available and encourage the sharing of information between patients and clinicians.

Aim: To develop a decision aid for young patients faced with the decision to undergo dental treatment with inhalation sedation, intravenous sedation (IV) or general anaesthesia (GA).

Design: Qualitative interviews with dental patients (aged 10-16 years), and their parents/guardians were used to inform the content of a draft decision aid. Following further revisions, a pilot evaluation of the decision aid was conducted. Patients referred for dental treatment with sedation or GA were recruited from a UK Dental Hospital. Patients (n=15) and parents/guardians (n=13) assigned to the intervention group received the decision aid and routine clinical counselling, whereas patients (n=17) and parents/guardians (n=13) in the control group only received routine clinical counselling. Participants completed measures of knowledge, decisional conflict and dental anxiety.

Results: Knowledge scores were significantly higher for participants who received the decision aid when compared to standard care. There were no other significant differences between groups.

Conclusions: A decision aid was successfully developed and initial findings suggest such tools could be beneficial to dental sedation or GA patients and their parents/guardians. Further research is required on the use of such tools in primary care settings, with particular

attention to the impact of the decision aid on attendance and completion rates of treatment.

Background

Dental anxiety is a common problem, with recent reports suggesting that 63% of 12 year olds and 54% of 15 year olds have moderate dental anxiety, and 14% of 12 year olds and 10% of 15 year olds have extreme dental anxiety (1). The experience of dental anxiety in young people can lead to behavioural management problems, which can act as a barrier to successful dental treatment. Approaches to manage dental anxiety include the use of conscious sedation or general anaesthesia (GA). There are currently a wide variety of conscious sedation techniques available to young patients, with the three most common approaches in the UK including inhalation sedation, intravenous (IV) sedation and oral sedation. However, recent reviews of the literature suggest that no firm conclusions can be drawn when comparing the relative effectiveness of the various conscious sedation techniques with each other and with the use of general anaesthesia (2-4).

For these reasons the decision to undergo dental treatment with either sedation or GA is often dependent upon the patient's individual values. These decisions, in which there are several justifiable options each holding different benefits and risks, are referred to as 'preference sensitive' decisions (5). When such difficult decisions exist within healthcare, it is thought that the implementation of shared decision-making can be beneficial to the patient. The term, shared decision-making, refers to a collaborative process in which the patient and the healthcare practitioner work together to reach a decision which will most benefit the patient's overall well-being. The most commonly cited model of shared decision

making describes the process in relation to three separate analytical stages labelled as 'information exchange', 'deliberation' and 'deciding on treatment to implement'(6). In relation to information exchange it is proposed that the sharing of information is a bi-directional process in which patients and practitioners share all medical and personal information that is relevant to the decision-making process. When describing the deliberation stage of the process, it is suggested that the patient, clinician and others who may be involved in the decision, such as family members, should be involved. Finally, it is proposed that both the patient and clinician work together when reaching an agreement on which treatment option to implement.

One way to increase shared decision-making is through the use of tools known as patient decision aids, which include three specific features which aim to encourage active involvement in the decision-making process. Firstly, they provide further details of the healthcare decision, the options available and the costs, benefits and uncertainties associated with these options. Secondly, they encourage patients to recognise their own values attached to these various options, risks, benefits and uncertainties. Finally, they encourage the sharing of these values with the healthcare practitioner and others who may be involved in the decision-making process. A recent systematic review found that decision aids can be beneficial to patients facing a wide array of difficult healthcare decisions in terms of reducing decisional conflict, increasing knowledge and increasing participation in the decision-making process (7). It is proposed that enabling young patients to make informed, values-based choices, which are congruent with their own treatment needs, could lead to more effective management of dental anxiety and improve attendance, treatment completion rates and subsequent oral health.

Despite the increasing use of decision aids in healthcare settings, there have been very few developed for decisions within paediatric healthcare. Historically, a failure to involve the child in the decision-making process could be related to concerns over the levels of competence, with suggestions being made that children under the age of 14 may lack the necessary abilities to participate in healthcare decision-making (8). However, more recently it has been proposed that stages of development are not consistently age-related and situational factors need to be taken into account when involving children in healthcare. An important shift towards the involvement of children in matters that directly affect them linked to the introduction of the Conventions on the Rights of the Child (9). Following this, the importance of involving young patients in healthcare decisions has also been advocated on a national level, with the Department of Health in England stating that children *“should be encouraged to be active partners in decisions about their health and care, and, where possible, be able to exercise choice”* (10).

This study describes the development and piloting of a decision aid aimed at young patients and their parents/guardians faced with the decision to undergo dental treatment with inhalation sedation, IV sedation or GA.

Methods

Ethical approval for the study was obtained from the National Research Ethics Service (NRES) Committee for Yorkshire and The Humber – Sheffield (13/YH/0142). All potential participants received a patient information sheet providing details of the research

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and given at least 24 hours to consider whether or not they would like to take part in the research. Written informed consent was obtained from all participants. The decision aid was developed in accordance with the original stages provided in the International Patient Decision Aids Standards (IPDAS) background document (11). More recent guidelines have also been proposed which include some additional stages (12). However, for the purposes of the current study the original stages of the IPDAS framework were addressed using the methods detailed below (see Figure 1).

Qualitative interviews with former patients and parents/guardians

To assess the needs of patients faced with the decision to undergo dental treatment with sedation or GA (stage a) a series of qualitative interviews were undertaken with patients (aged 10-16 years) who had undergone dental treatment with sedation or GA and their parents/guardians. The themes identified as important in the decision-making process were then used to inform the content of a draft decision aid. Recruitment took place from August to December, 2013. Data saturation occurred following 12 joint interviews with patients (n=12) and parents/guardians (n=13). Patients were recruited from routine clinic appointments at the Charles Clifford Dental Hospital and the Royal Liverpool University Dental Hospital.

Expert clinician focus group and expert patient group interviews

Groups of clinicians and patients were convened to address stages b and c of the development process proposed by IPDAS. Recruitment for the expert clinician focus group took place from December, 2013 to January, 2014. Six dental experts agreed to take part in the focus group and three provided feedback on the decision aid via email. Potential

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participants were invited to take part in the study through direct contact at the Charles Clifford Dental Hospital or via email. Recruitment from routine clinical visits for the expert patient group commenced in January, 2013 and ended in February, 2014. Three patients and three parents/guardians took part.

Between-subjects pilot study

A between-subjects pilot study was conducted to address stage d of the development process proposed by IPDAS, which involves field-testing the decision aid in a clinical setting. For this stage of the study, participants were recruited from the paediatric sedation service at the Royal Liverpool University Dental Hospital. This service has a clear pathway in place, where following initial assessment, patients who are thought to potentially need sedation are referred to pre-sedation or pre-GA assessment clinic. These clinics provide a forum for further decision-making about treatment with sedation or GA. Dependent on their preferences and needs, patients then undergo treatment with either inhalation sedation, IV or GA. Due to a lack of data in the existing literature regarding paediatric dental decision aids, power analysis was impossible to undertake. For these reasons the sample size was based on the general guidance, that a total of 30 participants is appropriate when conducting a pilot study which may subsequently be used to determine the acceptable sample size of a future trial (13). Participants were recruited at their initial new patient assessment at the Royal Liverpool University Dental Hospital from May, 2014 to January, 2015. Potentially suitable participants were identified by their direct care team and were mailed a study invite letter and information sheets prior to their appointment. Suitable participants were immediately approached following their appointment and those who agreed to take part were randomly assigned to one of the two following groups:

- i) Patients and parents/guardians who were given conventional clinical counselling prior to pursuing their sedation/GA treatment choice (control group).
- ii) Patients and parents/guardians who were given the decision aid as well as clinical counselling prior to pursuing their sedation/GA treatment choice (intervention group).

Measures

In the between-subjects pilot study, patients and parents/guardians received a questionnaire including measures of decisional conflict and knowledge (see below). Patient questionnaires also included a measure of dental anxiety using the Modified Child Dental Anxiety Scale (MCDAS) (14). Patients and parents/guardians in the intervention group also received a scale relating to the acceptability of the decision aid. All participants completed and returned their questionnaires prior to their pre-sedation or pre-GA appointment. The study had originally intended to assess impact of decision aid on attendance and compliance with treatment, however due to the lack of complete data, this analysis was not feasible.

Decisional conflict

Decisional conflict is the perceived level of uncertainty regarding a healthcare decision (15). Measures of decisional conflict are frequently used throughout decision aid research, with a recent systematic review showing that 50.4% of 115 studies assessing the impact of decision aids on people facing healthcare decisions included a measure of decisional conflict (7). Decisional conflict scales have also been used to determine the

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impact of decision aids for parents/guardians making difficult healthcare decisions with or on behalf of their children (16-18). This scale consists of the following five subscales:

- Informed Subscale
- Values Clarity Subscale
- Support Subscale
- Uncertainty Subscale
- Effective Decision Subscale

Parents/guardians participating in the study received the traditional decisional conflict scale. This scale comprises 16 items with five response categories relating to each item ('strongly agrees', 'agree', 'neither agree nor disagree', 'disagree' and 'strongly disagree').

Due to concerns that younger patients would not fully understand the traditional DCS scale and limited evidence regarding the validity and reliability of the scale when used with paediatric patients, the Low Literacy Decisional Conflict Scale was used for all patients. This scale includes a total of ten items with three response categories ('yes', 'unsure' and 'no') relating to each and excludes the effective decision subscale. Scores for both parents/guardians and patients were transformed to range from 0-100, with 0 indicating no decisional conflict and a score of 100 indicating to extremely high decisional conflict. It is proposed that scores lower than 25 relate to the implementation of decisions, whereas scores higher than 37.5 are associated with delays in the decision-making process (15). Subscale scores are also transformed to range from 0-100.

Knowledge

A scale was adapted from the Knowledge questionnaire provided through the Ottawa Decision Support Framework (19), to assess patients and parents/guardians knowledge of the procedures involved with undergoing dental treatment with inhalation sedation, IV sedation and GA and the associated risks, benefits and side effects. The adapted scale consisted of 15 statements with three response categories used for the participant to indicate whether they believe the statement to be true, false or if they are unsure. Total scores ranged from 0-15. Examples of the statements included in the patient knowledge scale are listed below:

- If you have 'gas and air' you will have to wear a mask
- If you have IV sedation you will be asleep during treatment
- If you have general anesthetic you should not eat anything for six hours before the appointment

Anxiety

All patients received the Modified Child Dental Anxiety Scale (MCDAS) (14). The scale comprises eight questions used to assess dental anxiety in children and young people and participants were asked to state their feelings towards certain dental procedures such as extraction, general anaesthesia and receiving injections. Responses are measured using a five-point likert scale, where respondents use a tick box to indicate if the specific procedures included made them feel relaxed/not worried, very slightly worried, fairly worried, worried a lot or very worried. Total scores range from 8, which is associated with little or no dental anxiety to 40, which is associated with extreme dental anxiety. A recent review of the

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measures used to assess child dental anxiety report that a cut-off point of >26 defines a child as dentally anxious (20).

Analysis

Qualitative data from stages a to c were managed and analysed using framework analysis (21). Quantitative data from the pilot evaluation (stage d) were managed and analysed using IBM SPSS Statistics for Macintosh, Version 22.0 (IBM Corp., Armonk, NY, USA). Separate independent samples t-tests were used to determine the impact of the decision aid on measures of knowledge and anxiety. Due to the non-normal distribution of data, separate Mann-Whitney U tests were used to analyse the impact of the decision aid on measures of overall decisional conflict and associated sub scores.

The final stage of the development process concerned with external peer review (stage e) is addressed through the publication of this paper.

Results

Initial decision aid development

The decision aid was designed as an A4 paper booklet and the format influenced by the Ottawa Personal Decision Guide (22). The decision aid was developed to be used by patients with their parents/guardians in their own homes. However patients and parents/guardians were encouraged to bring the decision aid to the consultations to enable further discussion between themselves and the dental practitioner. The content of the

decision aid was informed by findings from the qualitative interviews and focus groups with patients, parents/guardians and clinicians and developed in accordance with the quality criteria set by IPDAS (11).

In compliance with criteria 1-3 of the IPDAS checklist (see table 1) the opening page of the decision aid included a description of the condition relating to the healthcare decision, the decision being made and the options available to the patients. Following this introduction the first stage of the decision aid lists the positive and negative features of the options available to the patient side-by-side in a question and answer table. A list of the items included in this table and the themes deriving from the qualitative data which influenced these themes can be seen in table 2.

Other key features of the decision aid include an explicit values clarification exercise and a short multiple choice quiz relating to the treatment options available. Values clarification exercises are tools used to help patients recognise their own personal values attached to the treatment options available and the related benefits, risks and uncertainties. Explicit values clarification exercises differ from implicit techniques in that they require the patient to complete an action to specify how important certain features of the decision are to them. In the current decision aid this involved patients noting down how important the negative and positive features of the decision aid were to them on a 5-point likert scale (see figure 2). Multiple choice quizzes are frequently included in decision aids to help reinforce some of the key features of the options available and also to allow patients to determine if they feel they have sufficient knowledge to make an informed decision.

Final revisions made to the decision aid following feedback from the expert clinician and patient groups included the removal of all images and changes to the language included. The removal of images related to concerns over the negative connotations attached to some images, which could bias the decision-making process. The main changes made to the language were in relation to the frequent use of terms such as 'inhalation' and 'intravenous', which some patients described as 'scary'. The final version of the decision aid is available from the first author on request.

Pilot evaluation of the decision aid

Participant characteristics

Thirty-two patients and 29 parents/guardians were recruited to the study. Data relating to the age of the parents/guardians was missing for three participants and was therefore not included in the descriptive data. Pairwise deletion was used to ensure that data from these three cases was not excluded in subsequent analyses. The mean age of the patients was 13 years (SD 1.71, range 10-16) and the mean age of parents/guardians was 43 years (SD 8.01, range 30-62). In relation to the patient group, 50% of the sample were male and 50% were female. In regards to the parent/guardian groups, 76.7% of parents/guardians recruited were female and 23.3% were male. One patient and one parent/guardian described themselves as White Irish and the remainder of the participants defined themselves as White British.

The scores for each of the measures can be seen in Table 3. All of the scales demonstrated good internal reliability in the current sample (see table 3).

Knowledge

Knowledge scores were significantly greater for patients in the intervention group in comparison to patients in the control group ($p < 0.05$) (see table 3). Significantly higher levels of knowledge were also found for parents/guardians in the intervention group when compared to the control group ($p < 0.05$) (see table 3).

Anxiety

On average, patients who received the decision aid reported lower levels of anxiety than patients in the control group. However, this difference between groups was not significant ($p > 0.05$) (see table 3).

Decisional conflict

There were no significant differences in overall decisional conflict or on any of the subscales between control groups and intervention groups for both patients and parents/guardians ($p > 0.05$) (see table 3).

Discussion

A decision aid was developed for young patients requiring dental treatment with either sedation or GA and their parents/guardians. Results from the pilot study suggested that the decision aid did increase knowledge for both patients and parents/guardians when compared to standard care, however, the decision aid had no impact upon measures of patients' dental anxiety or patient and parental decisional conflict. Furthermore, results suggested that the decision aid had no significant impact on subscales of the decisional

conflict scales relating to perceptions of being informed, levels of uncertainty, clarity of values, amount of support and whether an effective decision was made. The finding that the use of the decision aid leads to increased knowledge for both patients and parents/guardians is consistent with findings from the wider literature on the use of decision aids within healthcare. Notably, a meta-analysis included in the systematic review by Stacey and Colleagues (7) reported an overall mean difference of 13.34 (95% CI=11.17 to 15.51) in knowledge scores when comparing decision aids to routine care. However, it must be noted that none of the decision aids included in the analysis related to decisions being made within paediatric healthcare and only one study related to decisions within dentistry. In this investigation, significantly increased knowledge was associated with the use of a decision aid when compared to routine care, for patients requiring endodontic treatment (23). A previous study within paediatric dentistry, not included in the review by Stacey and colleagues (7), also found that a brief intervention consisting of videos and written information also increased recall of information for young patients aged 5-15 years (24).

Findings from the current study that suggest the decision aid failed to have a significant impact upon levels of decisional conflict, do however contrast with findings in the previous literature. Stacey and colleagues reported an overall mean difference of -6.22 (95% CI of -8.00 to -4.44) when comparing the use of decision aids to standard care, with the use of decision aids associated with reduced decisional conflict. Although, there is some previous evidence from three studies that decision aids have a limited impact on levels of decisional conflict (25-27), these studies relate solely to decisions regarding cancer treatment. It is therefore difficult to relate these findings to the current study. It should also be noted that one of these studies reported findings from a pilot study including only 30

patients (25). Therefore, it is unlikely that sufficient power was gained to accurately detect a significant effect of the decision aid.

When considering the potential impact of decision aids on anxiety, the current findings are replicated in the overall literature (7). For example, a significant reduction in anxiety within one month of a decision aid being implemented was only reported in 2 out of 23 studies included in the review by Stacey and colleagues (7). Furthermore, in relation to dentistry, a decision aid for patients undergoing endodontic treatment also reported that the use of a decision aid did not affect patients' anxiety (23). However, the fact that the measure used consisted of a single item, whose validity and reliability has yet to be established, suggests that these results should be approached with caution.

One potential explanation for the findings showing that the decision aid failed to reduce levels of anxiety or decisional conflict may relate to the suitability of the measures being used in the pilot study. For example, a systematic review of the related literature proposed that anxiety may not be an appropriate outcome measure in decision aid research, as effective decision making may actually be related to heightened anxiety. However, the inclusion of dental anxiety as an outcome in the current study would seem to be appropriate considering that sedation or GA in dentistry is frequently used to manage anxious patients. Interestingly, the MCDAS scores reported in both the intervention and control groups suggested that neither group experienced high levels of dental anxiety. Similarly, low levels of decisional conflict were also noted for all patient and parent/guardian groups. It could be argued that, as patients and family members had already had the opportunity to discuss the options available to them with their referring practitioner, they

may demonstrate less conflict at the time when the decision aid was administered. This is supported by the findings that the majority of patients and family members (81%) already held a treatment preference following recruitment.

A further explanation for the low levels of anxiety and decisional conflict demonstrated in both groups may relate to the fact that patients with higher levels of conflict and/or anxiety are less likely to attend their dental appointments, thus were less likely to be included in the study. Some support for this can be found in previous research linking heightened dental anxiety to irregular dental attendance (28). Previous treatment experience also has to be considered when analysing the levels of anxiety and conflict in the present pilot study, as a high proportion of patients and parents/guardians in the pilot study reported previous experience of treatment with sedation or GA. This is supported by findings that show previous experience of dental treatment under sedation can significantly reduce the long-term experience of dental anxiety (29). Furthermore, it is speculated that previous treatment experience under sedation or GA, either positive or negative, could lead to reduced conflict in future decision-making processes. Finally, it could be suggested that levels of anxiety may not be the primary indicator of sedation need in this patient group, with such factors as the complexity of treatment required dictating referral patterns. This explanation is supported to some degree in previous work looking at estimating the need for dental sedation, in which it was suggested that non-anxious patients could be suitable for treatment under sedation for particularly demanding treatment (30). However, when considering the wider evidence base, findings appear to suggest that dental anxiety remains the primary cause for referral for dental treatment with sedation or GA (31). Still, further

exploration of how the complexity of treatment interacts with anxiety and attendance and how this may mediate the impact of decision support tools is warranted.

This is believed to be the first study to develop a decision aid that aimed to actively involve younger patients in any decision-making process within healthcare, and as such presented some specific challenges and ethical considerations. One of these issues relates to the presentation of specific probabilities of the potential side effects and risks associated with certain treatment options. For example, specific probabilities regarding morbidity and mortality rates relating to sedation and GA were often excluded from the current decision aid due to concerns from parents and clinicians as to whether such information could cause the young patient distress and also because accurate conclusive evidence was not available. The exclusion of such information raises broader questions in relation to issues of informed consent. However, it must be recognised that decision aids should not be seen as a replacement for the standard information provided to patients and the consent processes that are already in place. Consequently, it could be argued that through introducing the issues the decision aid can actually aid clinicians in ensuring fully informed consent is gained. When considering previous reports that the relevant risks were not discussed in 30% of paediatric pre-anaesthesia consultations it is apparent that such further steps to ensure consent is fully informed should be taken throughout healthcare (32).

A number of limitations are recognised in the present study. Firstly, the pilot study lacked a within-group comparison. Consequently, by failing to measure patients outcomes at various stages of the clinical care pathway, the impact of time on measures of decisional conflict, anxiety and knowledge could not be analysed. Secondly, the study failed to

represent ethnic minority groups in both the development and pilot testing of the decision aid. This under-representation of ethnic minority groups is something that has been previously highlighted in the literature, with one study directly addressing the issue in relation to the use of a decision aid for cancer screening (33). In this instance, it was reported that ethnic minority groups can also benefit from the use of decision support interventions in relation to increased knowledge. The reasons for this under-representation of ethnic minority groups within the current research may relate to a number of factors common throughout healthcare research, including the proposal that research participation is a relatively Westernised concept (34), or the fact that interpreters were not employed, therefore excluding non-English speaking patients and family members. Ensuring the language needs of ethnic minority groups are met in future research should therefore be considered to help increase participation of ethnic minority groups. An under-representation of male participants in the parent group and the exclusion of patients aged under ten years old could also have a negative impact on the generalisability of the findings. With regards to the age range, patients younger than ten years were excluded from the study as the Royal Liverpool University Dental Hospital only referred patients ten years or over for treatment with IV sedation. Nonetheless, as patients under the age of ten years are referred for dental treatment with inhalation sedation or GA, the recruitment of younger patients in future studies is recommended to ensure the sample is representative of this patient group. Finally, the sample size included in the pilot study resulted in insufficient power to accurately detect significant differences in effect between groups. However, it should be noted that the current sample size was sufficient to address certain feasibility issues relating to the use of decision aids within paediatric dentistry and to determine accurate sample size calculations for future research through power analysis.

In conclusion, this study has shown that decision aids do offer potential to improve the experience of paediatric dental patients faced with the decision to undergo dental treatment with sedation or GA through increased knowledge of the healthcare options available. However, it is clear that further evidence is required to determine the impact of such resources throughout different stages of the patient's care pathway. It is therefore proposed that future studies should focus on the introduction of the decision aids in primary care settings, using a controlled before/after design to help aid understanding of how the decision aid may impact upon measures of anxiety and decisional conflict and how these measures may alter over time. Evidence is also required in relation to whether the impact of such resources may vary when administered during the consultation with dentist or away from the clinical setting and also how these tools will impact upon consultation length, attendance and associated expenditure. Nonetheless, this study has highlighted the fact that decision aids can be used paediatric dentistry and offer the potential to improve patients' experience of healthcare.

Why this paper is important to paediatric dentists?

- This is believed to be the first study to produce a decision aid that actively involves young people in any decision-making process relating to dental healthcare and thereby raises awareness of such resources.
- Findings from the pilot study suggest that the decision aid could be beneficial to patients faced with the decision to undergo dental treatment with sedation or GA and their parents/guardians in terms of increased knowledge of the treatment options available.

- The study highlights difficulties in the delivery and evaluation of paediatric dental decision aids in secondary care settings. These difficulties relate mainly to high rates of missed or cancelled appointments, which impact upon patients accessing such decision-making resources. These difficulties imply that further research in the use of decision aids within paediatric dentistry should focus on the delivery of such tools in primary care settings.

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Conflict of interest

The authors declare no conflict of interest.

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Figure legends

Figure 1: The stages of decision aid development proposed by IPDAS and the corresponding methods used

Figure 2: The values clarification exercise included in step 2 of the decision aid

Tables and Figures

Table 1: IPDAS 30-item checklist

Content
1. The decision aid describes the condition (health or other) related to the decision.
2. The decision aid describes the decision that needs to be considered (the index decision).
3. The decision aid lists the options (health care or other).
4. The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.
5. The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option).
6. The decision aid has information about the positive features of the options (e.g. benefits, advantages).
7. The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).
8. The information about outcomes of options (positive and negative) includes the chances they may happen.
9. The decision aid has information about what the test is designed to measure.
10. The decision aid describes possible next steps based on the test results.
11. The decision aid has information about the chances of disease being found with and without screening.
12. The decision aid has information about detection and treatment of disease that would never have caused problems if screening had not been done.
13. The decision aid presents probabilities using event rates in a defined group of

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people for a specified time.
14. The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.
15. The decision aid compares probabilities of options over the same period of time.
16. The decision aid uses the same scales in diagrams comparing options.
17. The decision aid asks people to think about which positive and negative features of the options matter most to them.
18. The decision aid makes it possible to compare the positive and negative features of the available options.
19. The decision aid shows the negative and positive features of the options with equal detail.
Development Process
20. Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.
21. The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing.
22. People who were facing the decision field tested the decision aid.
23. Field testing showed that the decision aid was acceptable to users (the general public & practitioners).
24. Field testing showed that people who were undecided felt that the information was presented in a balanced way.
25. The decision aid provides references to scientific evidence used.
26. The decision aid reports the date when it was last updated.
27. The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.
28. The decision aid (or available technical document) reports readability levels.
Effectiveness
29. There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.
30. There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.

Table 2: Original questions included in step one of the decision aid and related themes

Question included in step one	Influential theme(s)
What does it feel like?	Experience of sedation
How will it be given?	Method of administration
Will I still be awake?	Control & communication, long-term impact
Will I still need a needle in my gum?	Method of administration
Are there any side effects?	Perceived side effects and risks
Where will I have my treatment?	No associated themes
Can I eat or drink anything before?	Time
When can I go home?	Time, perceived side effects and risks
When can I go back to school?	Time

Table 3: Differences in levels of knowledge, decisional conflict and anxiety and the internal consistency of the scales used.

	Control (Mean)	Intervention (Mean)	P value	Effect size	Cronbach's alpha
Knowledge					
Patient	6.59 (3.18)	9.93 (2.97)	0.01	0.48	0.77
Parent/guardian	7.89 (3.08)	10.62 (3.31)	0.03	0.39	0.80
Overall Decisional Conflict					
Patient	20.00 (18.71)	13.00 (18.01)	0.15	0.26	0.80
Parent/guardian	18.75 (15.00)	16.23 (16.42)	0.58	0.10	0.95
Informed Subscale					
Patient	29.41 (36.58)	20.00 (31.62)	0.44	0.14	0.88
Parent/guardian	18.14 (15.66)	12.18 (13.86)	0.60	0.10	0.86
Values Clarity Subscale					
Patient	26.47 (25.72)	20.00 (33.00)	0.33	0.18	0.58
Parent/guardian	21.57 (21.05)	17.31 (18.77)	0.63	0.09	0.95
Support Subscale					
Patient	7.84 (13.33)	6.67 (12.28)	0.90	0.04	0.16
Parent/guardian	15.69 (14.40)	16.67 (20.97)	0.81	0.05	0.90
Uncertainty Subscale					
Patient	17.65 (30.32)	5 (10.35)	0.28	0.20	0.75
Parent/guardian	21.08 (22.65)	20.51 (20.30)	1.00	0.00	0.87
Effective Decision Subscale (parent/guardian only)	17.65 (15.82)	12.50 (17.49)	0.38	0.17	0.92
Dental Anxiety (patient only)	22.88 (9.21)	20.20 (7.66)	0.38	0.16	0.89

