Bulletin of Environment, Pharmacology and Life Sciences
Bull. Env. Pharmacol. Life Sci., Spl Issue [2] 2023: 563-568.

Online ISSN 2277-1808
Journal's URL:http://www.bepls.com
CODEN: BEPLAD

ORIGINAL ARTICLE **OPEN ACCESS**

A Comparative evaluation between four methods of informed consent obtained from parents regarding behaviour management of children aged between 2-8 years: An experimental clinical study

Prajkta Surryawanshi[1], Amol Patil[2], Vinaya Kumar Kulkarni[3], Santwana Tripathy[4], Pranali Shelke[1], Dr Harshada Shirsath[1]

[1]PG Students, SMBT Dental College & Hospital, Sangamner, Maharashtra
[2] Associate Professor, SMBT Dental College & Hospital, Sangamner, Maharashtra
[3] Professor & HOD, SMBT Dental College & Hospital, Sangamner, Maharashtra
[4] Assistant Professor, SMBT Dental College & Hospital, Sangamner, Maharashtra

ABSTRACT

The importance of obtaining informed consent in dentistry is increasingly recognised for moral and legal arguments which are explored. Dentists must learn to practice dentistry with attention to changing legal and societal concerns and demands. This investigation compares four methods for informing parents to gain their consent for six behavior management techniques in children. The aim of this study was to compare four methods to inform parents about child behaviour management in the children of 2-8 years. In the present experimental design, 100 children of age 2–8 years were recruited for participation. The subjects were assigned to four groups. One hundred parents were shown descriptions of six traditional behavior management techniques via one of four different presentation methods: one of two types of video presentation, an oral presentation, or a written presentation. They were asked whether they felt well informed about each technique and asked for consent to perform any one of the techniques that might be needed with their child. Analysis of variance and Turkey post hoc test was applied. Chi square and Fischer's exact test was applied. Highly statistically significant difference (p<0.001) was observed. Among four intervention methods highly statistically significant acceptability was observed with video with explanation (V2) followed by oral followed by video without explanation (V1) and written method. Overall, the video with explanation (V2) method of delivering information to parents about child behavior management techniques was the best method of ensuring that the average parent felt informed and was likely to consent.

***Key Words**: consent, behavior management, parents.*

Received 20 .11.2023 Revised 25.12.2023 Accepted 25 .01.2024

INTRODUCTION

A child must normally have the consent of a parent before they can obtain health care and advice. However, healthcare professionals are duty-bound to respect the evolving capacity and autonomy of the child and to consider the views of the child in all matters, including medical decision making. This does not imply that there is an age above which a child is automatically entitled to give consent, nor a universal age below which such consent is impossible. The issue is whether a child is capable of clearly understanding the nature and implications of any proposed treatment and is able and willing to make a decision [1].

The acceptability of paediatric dental behavior management technology recently has become a serious concern for many dentists. Although traditional management techniques such as physical restraint, conscious sedation, voice control, and the hand-over-mouth procedure are widely used and endorsed, many pediatric dentists are now concerned with legal and ethical concerns regarding these techniques. [2]

Increasingly, the acceptability of behavior management practices is being held to the reasonable patient or materiality standard. This standard requires that the dentist discuss with the patient all the information material or important to a decision to consent or not [2, 3].

The ADA Code of Ethics recommends that dentists provide information "in a manner that allows the patient to become involved in treatment decisions [5].

Pediatric dental health care providers have the opportunity to guide and support the child patient to become involved in his own health care. Young children lack the cognitive ability to participate in the informed consent discussion, but older children and adolescents who have gained experience as dental

patients may be included. Information should be provided to the patient in an age appropriate manner, and practitioners should seek assent (agreement) from the patient whenever possible [6].
The practitioner should be aware that the adult accompanying the pediatric patient may not be a legal guardian allowed by law to consent to medical procedures. Examples of such an adult include a grandparent, stepparent, noncustodial parent in instances of divorce, babysitter, or friend of the family. A child in foster care or a ward of the state may be accompanied by a caretaker who may or may not be allowed to consent to medical procedures, according to individual state law. It is advisable that the oral health care provider obtain a copy of court orders appointing a guardian to verify who is authorized to consent for medical treatment for the patient [7].
Consent for sedation, general anesthesia, or behavior guidance techniques such as protective stabilization (i.e., immobilization) should be obtained separately from consent for other procedures [8].

MATERIAL AND METHODS

One hundred parents of children reporting in the Department of Pediatric and Preventive Dentistry, SMBT Dental College and Hospital Sangamaner were recruited for participation following approval from the Institutional Review Board's Human Subjects Review Committee. All participants were literate, Hindi and Marathi speaking parents accompanying children from 2 to 8 years of age scheduled for a new patient or recall examination. Participants completed preliminary forms while seated in a large reception area. Information about dental behavior management techniques was provided in a small consultation room adjacent to the reception.
Descriptions of six traditional child behavior management techniques in pediatric dentistry were provided for parental consent:

1. Tell-show-do (TSD)
2. Nitrous oxide sedation (NO)
3. Passive restraint
4. Voice control (VC)
5. Hand-over-mouth (HOM)
6. Active/physical restraint (AR)

The descriptions of these techniques were provided by one of four methods of information delivery.
Group A- (Video method without explanation) was a videotaped depiction of each technique being used on a young patient during a live office visit, with each technique labelled, but no accompanying explanation or description.
Group B-(Oral method) Oral presentation involved a research assistant, posing as an office staff person, presenting orally the exact information contained in the written form. The written form had been memorized to avoid reading directly but the written form was present to prompt the presenter if necessary.
Group C- (Video method with explanation) was a videotaped depiction of each technique being used on a young patient during a live office visit, with each technique labeled. A dentist provided an accompanying explanation and description of each technique before it was demonstrated on the tape.
Group D-(Written method) Written presentation included the label, explanation, and description of each technique from Video 1 on office stationery to create a written form for parental consent.
Parents completed a brief demographic intake form, requesting information about the age of the child, the parent's years of education and present occupation, and their own anxiety about the child's dental visit, rated on a four-point Likert-type scale, ranging from 1 (high anxiety) to 4 (low anxiety).Each participant was approached individually in the reception area by the same research assistant and was asked to complete a brief demographic form. After this form was completed and the child had been taken in the clinic for examination, parents were told that behavior management techniques used in the clinic would be explained as part of a new program.
The parents then were assigned randomly to one of the four presentation conditions until 30 parents had been exposed to each of the four conditions. Every effort was taken to conceal the research aspect of the consent process to strengthen the legitimacy of the consent response and to ensure response validity. Participants were taken individually to the consultation room where the information was presented.
In each condition, the research assistant, explained that she would be presenting information about behavior management techniques. Participants were to indicate how much they liked each method as well as whether they would consent to the method being used with their child, if needed. Following the presentation of each technique, participants were given time to mark their approval and consent on the consent form. After the presentation, they were required to sign the form and the research assistant initiated it as a witness. At this point, parents were immediately debriefed about the nature of the

research and the reason for deception. None of the parents withdrew or changed their consent at that time.

The parent portion--presentation, data collection, and debriefing--ranged from approximately 15 min for viewing the video with explanation to approximately 10 min for a written or oral presentation, and was designed to be completed before the child finished the examination.

Fig1: Photographs' of taking questionnaire of different behavior management techniques

RESULTS

Participants were 100 children of low to middle socioeconomic status based on the Hollingshead four-factor index of social status [9]. Their previous experience with each of the dental techniques was unknown. Fisher's exact test was then used to see if consent for each individual management technique differed among the four conditions. Among four intervention methods highly statistical significant acceptability was observed with video with explanation followed by oral followed by video without explanation and written method.

Table 1: Overall comparison among four methods to inform parents about consent for behaviour management techniques in relation to Vas scale for liking the technique

	Mean	SD	One way Anova F test	P value, Significance
Group A (Video method with explanation)	**8.2**	**1.42**	**F = 48.5**	**P < 0.001****
Group B (Oral method)	**6.5**	**1.74**		
Group C (Video method without explanation)	**5.8**	**0.91**		
Group D (Written method)	**3.7**	**0.53**		

DISCUSSION

The results of this investigation extend the findings of previous investigations focused on behavior management treatment acceptability by showing how best to inform parents about behavior management technology and gain their consent. Consistent with previous research, the acceptability of a

technique was found to be closely related to willingness to consent to that technique, yet the correspondence was not perfect. More important, the manner in which parents were informed about a specific technique was a significant predictor of how informed parents felt and whether or not they consented. Because this research moves beyond treatment acceptability and looks specifically at issues of informing and gaining consent, we feel it is important in light of increasing concerns about legal liability and changing standards of practice in pediatric dentistry [10].

In this investigation, the video method with explanation of delivering information to parents about child behavior management techniques was the best method of ensuring that the average parent felt well informed and was likely to consent. Although the video method with explanation was not significantly better than all of the other methods, it consistently produced more well informed parents and more consent. In some cases, for example, oral method produced consent rates higher than the video with explanation, but both the Video method without explanation and oral were less successful at informing parents. Indeed, parents only felt well informed when viewing some of the least invasive techniques. Oral method of delivering informed consent is easy to perform, less need of equipment, but video method with explanation provides attractiveness and liability. In this investigation, the dental "staff person," rather than the dentist, informed the parents in an average of only 10 min.

Interestingly, the results suggest that the written method may be a poor alternative for gaining informed consent. The written method was as useful in producing consent as the other methods, but it was significantly worse than any other method as a means of informing parents. The fact that both the written and oral methods contained the same information suggests a problem in the transfer of that information (i.e., reading or comprehension). Although we ensured that each parent was literate prior to inclusion in the study, we did not ensure that each parent actually read every word or comprehended the written form. This may, in fact, be common with written forms. For those interested in adhering to the most rigorous informed consent scenario, these data suggest not simply handing parents a written description to read, but instead providing parents with video with explanation of the behavior management techniques typically used [10].

A study was carried out by Keith D. Alle (1995) on parents were shown descriptions of eight traditional behavior management techniques via one of four different presentation methods: one of two types of video presentation, an oral presentation, or a written presentation. They were asked whether they felt well informed about each technique and asked for consent to perform any one of the techniques that might be needed with their child. In that, the oral method of delivering information to parents about child behavior management techniques was the best method of ensuring that the average parent felt informed and was likely to consent [10].

A. Adewumi (2001) evaluated to find out to what extent children are involved in consenting to their dental care. In this study the children were asked if they understood the information given to them about their treatment. It showed that 57% of the control group felt they understood the information but this increased to 93% in the study group. This demonstrates the positive trend observed in the responses of the patients following their participation in the additional systematic consent procedure [6].

In the summary, recent calls to reexamine some traditional management procedures. The state-of-the art in managing child behavior in the dental chair is changing, and requires that dentists continue to explore the need for and development of an expanding armamentarium. Some alternatives already have preliminary research support, and these alternatives may prove to be viable, cost-effective management techniques, even for the most difficult children. Some incentive to develop alternatives has been provided by behavioral dentistry researchers, concerned about long term impact of some management techniques on dental fear. Additional incentive has been provided by dentists concerned about legal liability [11]. The results of this investigation should help all dentists make informed decisions themselves about the need for behavior management alternatives and how best to obtain informed consent.

Table 2: Pairwise comparison among four methods to inform parents about consent for behaviour management techniques

Tukey's post hoc test for pairwise comparison			
Group	Comparison Group	Mean Difference	p value, Significance
Group A (Video method with explanation) vs	Group B (Oral method)	1.7	p =0.047*
	Group C (Video method without explanation)	2.4	P =0.032*
	Group D (Written method)	4.5	P< 0.001**
Group B (Oral method) vs	Group C (Video method without explanation)	0.7	P =0.092
	Group D (Written method)	2.8	p =0.006*
Group C (Video method without explanation) vs	Group D (Written method)	2.1	P =0.019*

**p< 0.001 – highly statistical significant difference

Table 3: Comparison among four methods to inform parents about consent for behaviour management techniques on how well informed the study participants become

Well Informed Method	Acceptance Frequency (n)	Acceptance Percentage
Group A (Video method with explanation)	89/100	89%
Group B (Oral method)	72/100	72%
Group C (Video method without explanation)	64/100	64%
Group D (Written method)	31/100	31%
	Chi square test value = 24.71, p< 0.001** (highly statistical significant difference)	

CONCLUSION

The video with explanation (V2) method of delivering information to parents about child behaviour management techniques was the best method of ensuring that the average parent felt informed.

REFERENCES

1. Van Bueren G. (1995). The International Law on the Rights of the Child. Vol 35 pp 310-311. Martinus Nijhoff Publishers.
2. Allen KD, Stanley R, McPherson K: (1990). Evaluation of behavior management technology dissemination in pediatric dentistry. Pediatr Dent 12:79-82.
3. Bailey BL: (1985). Informed consent in dentistry. J Am Dent Assoc 110:709-13.
4. Miller RD: Legal issues involved in child management. In: Management of Children by Health Professionals (Proceedings of a Symposium). Healy A, Nowak AJ, Eds. Iowa City: University of Iowa Press, 1978, pp 21-24.
5. American Dental Association. Principles of Ethics & Code of Professional Conduct. With official advisory opinions revised to November 2018.
6. Adewumi A, Hector MP, King JM. (2001). Children and informed consent: A study of children's perceptions and involvement in consent to dental treatment. Br Dent J;191(5):256-9.
7. American Academy of Pediatrics Committee on Medical Liability. Consent by proxy for non-urgent pediatric care. Pediatrics 2017;139(2)
8. American Academy of Pediatric Dentistry. Behavior guidance for the pediatric dental patient. Pediatr Dent 2018;40(special issue):254-67
9. Hollingshead AB: (1975). Four factor index of social status. Working paper, Department of Sociology, Yale University, New Haven, CT.
10. Allen KD, Hodges ED, Knudsen SK. (1995). Comparing four methods to inform parents about child behavior management: how to inform for consent. Pediatric dentistry. 1;17:180.
11. Weinstein, P. (1990). Breaking the worldwide cycle of pain, fear, and avoidance: Uncovering risk factors and promoting prevention for children. *Annals of Behavioral Medicine, 12*(4), 141–147.

CITATION OF THIS ARTICLE

Prajkta Surryawanshi, Amol Patil, Vinaya Kumar Kulkarni, Santwana Tripathy, Pranali Shelke, Dr Harshada Shirsath. A comparative evaluation between four methods of informed consent obtained from parents regarding behaviour management of children aged between 2-8 years: An experimental clinical study. Bull. Env. Pharmacol. Life Sci., Spl Issue [2]: 2023: 563-568.