

Informed Consent and Disclosure of Information for Stimulant Medication: An exploratory study of teenagers', parents' and physicians' preferences for information disclosure

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ABSTRACT

Objective: This study explores the information teenagers, parents, and physicians want included in an information disclosure for stimulant medication treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Method: 30 physicians, 30 parents of youth with ADHD, and 30 youth with ADHD, ages 12-16, were surveyed about their information preferences.

Results: The majority of participants wanted general information about ADHD, and a general statement about rare risks included. With respect to specific rare risks associated with stimulant medication, half of participants wanted information about arrhythmias, seizure and stroke included. For the other rare risks, there was a range of responses across all groups.

Conclusions: About half of parents and teenagers want disclosure of cardiovascular and cerebrovascular events. Physicians cannot assume that their personal information preferences reflect that of their patients; they need to understand their patients' information needs when informing them about the benefits and risks of medications.

Key words: informed consent; stimulant medication; ADHD; information disclosure.

Introduction

Informed consent should be obtained prior to all medical interventions. Disclosure of relevant information is an essential component of informed consent. The disclosed information should specify the nature of the proposed treatment, its anticipated benefits, material risks and side effects, the alternative treatment options and the likely outcomes of not accepting treatment. (Grisso and Appelbaum 1998; Rozovsky and Rozovsky 1990; *Health Care Consent Act, 1996, S.O. 1996, C. 2, Sch. A.*)

Historically, the disclosure standard was information professionals felt should be disclosed, known as 'the professional standard of disclosure'. (Grisso and Appelbaum 1998) With court decisions, the standard evolved into 'the reasonable person standard'; the information that the reasonable person in the patient's situation would want to know to make an informed decision. (Beauchamp and Childress 2006; Dickens 2002; Grisso and Appelbaum 1998; *Reibl v Hughes, [1980] 2 S.C.R. 880.*)

Information disclosure is important for child and adolescent psychiatry because many families have concerns regarding psychoactive medications; invalid myths and assumptions need to be dispelled. Much has been written in the press regarding psychopharmacologic treatment of adolescent psychiatric

disorders. (Harris 2004a; Harris 2004b; Kirkey 2007; Kluger 2003; Schlozman 2005) possible overuse or inappropriate use of stimulant and antipsychotic medications, (Kirkey 2007; Kluger 2003; Marshall 2000; Philip 2007), and adverse side effects including the potential cardiovascular effects of stimulant medications (Food and Drug Administration 2007; Harris 2004a; Harris 2004b; Health Canada 2007; Nissen 2006). Accurate information is needed to inform families.

However, the 'reasonable person standard' has not been operationalized for the adolescent with ADHD. What information does the 'reasonable adolescent or parent' want disclosed? Early studies revealed patients wanted more information than physicians thought they wanted, particularly about treatment risks. (Faden et al. 1981) Surveys indicate that the majority of adult patients do not endorse physician discretion in information disclosure, and prefer information about all side effects to be disclosed, no matter how rare or serious. (Ziegler et al. 2001) Among adult medical patients, 80% wanted to know about side effects that occurred less frequently than 1/100,000; younger patients and those less educated wanted more information than other groups. (Ziegler et al. 2001) In contrast, among patients with rheumatoid arthritis, females, younger or more educated patients wanted more information than older or less educated individuals. (Neame et al. 2005)

Studies using non-clinical subjects reveal preferences for disclosures that explain medications' side effects, actions and impact on lifestyle. (Berry et al. 1995) Characteristics of these subjects (ie age) as well as the medication side effects (number, risk, and severity) influence the perception of disclosures. (Berry 2004; Berry et al. 2002) Younger adults are less satisfied than older adults with information disclosure, perceive risks as less likely to happen, and may be more likely to take medication. (Berry et al. 2002) Adults' risk perception is increased when the medication is intended for a young child compared to themselves. (Berry 2004) These studies suggest that the patient's age influences the perception of the information disclosure.

The present study examines the information teenagers with ADHD, parents of minors with ADHD and physicians think should be disclosed as part of the informed consent process for stimulant treatment of ADHD. This data was collected as part of a larger study in order to design an information disclosure suitable for teenagers with ADHD.

Method

Participants: Participants included physicians, parents of youth with ADHD and youth with ADHD. Physicians were child psychiatrists or pediatricians, with at least 5 years clinical experience, relevant academic publications or clinical experience with at least 10 clients per year with ADHD. Physicians were interviewed in 2004-2005.

Parents of children with ADHD and youth between 12-16 with ADHD were recruited from advertisements in physician offices, ADHD websites, and the X, a fully X affiliated teaching hospital in an urban setting. Participants recruited from X or their affiliated

child psychiatrists' office had a clinical diagnosis of ADHD based on the DSM-IV. Participants recruited from advertisements had diagnoses confirmed by either a written note from their physician or following administration of the parent module of the Diagnostic Interview Schedule for Children (Shaffer et al. 1993; Shaffer et al. 1996; Shaffer et al. 2000). Half the patients participated in 2004-05 in the first phase of a larger study on informed consent helping to develop a disclosure form. In 2008, the second half of the sample was recruited to specifically examine participants information preferences.

Procedure: Participants received a written description of the theoretical information patients should receive in order to make a treatment decision. Subjects then read a disclosure form addressing benefits and risks of stimulant medication. Subjects then rated, using a Likert scale, which additional items they felt should be included in the disclosure.

Instruments:

Disclosure The disclosure form included information about common side effects, and the potential effects on growth, tics, blood pressure and pulse, and the risk of psychosis in patients taking stimulant medication. Frequencies were represented quantitatively and qualitatively in order to ensure that participants interpreted qualitative descriptors consistently. The reading level of the disclosure form was grade 6 to ensure readability (Davis et al. 1994; Davis et al. 1990)

Questionnaire about additional information: Additional information to be included in the disclosure was evaluated using Likert style questions. (Items were rated as strongly agree, agree, neutral, disagree, strongly disagree). Additional items included more information about ADHD and its treatment, and detailed information about rare side effects obtained from a literature review. The package was pre-tested on 15 participants (2 child psychiatrists, 3 pediatricians, 5 parents, and 3 children, and 2 experts in bioethics) and revised. Data from these subjects are not included in this paper.

Socioeconomic status (SES): The Blishen Index uses parental occupational status to code for socioeconomic status SES (Blishen et al. 1987) .

Research Consent: X's Research Ethics Board approved this project. Consent was obtained from physicians, parents and consenting teenagers. Teenagers who read the consent form and said they understood it consented to study participation. Teenagers who did not state that they understood the form assented to study participation. All subjects received a monetary honorarium as compensation.

Data Analysis: Data were analyzed using statistical packages available on SPSS. Data from the original participants on whom the package was pre-tested are not included in this study report. Since not all parents and adolescents were part of dyads, paired analyses were not conducted to compare the views of parents and adolescents.

Results

Thirty physicians (15 child psychiatrists and 15 pediatricians), 30 parents, and 30 teenagers participated in this study.

Physicians mean age was 49.9 (SD=8.4), mean medical school graduation year was 1978 (SD = 8.1) and mean SES was 101.32; 62% (N=18) were male. Teenagers mean age was 13.0 (SD = 1.0), mean grade was 7.7 (SD =1), 83.3% (N=25) were male, 56.7% (N=17) were taking a stimulant medication, and 1 (3%) was taking another psychoactive medication. Parents mean age was

44.9 (SD=5.9), mean SES was 50.0 (SD=9.7), mean educational level was 16.1 years (SD=3.2) and 13% (N=4) were male. The majority of parents had completed high school 90% (N=27). Parents reported that 60% (N=18) of their youth were prescribed a stimulant medication.

The majority of parents, teenagers and physicians wanted information regarding etiology of ADHD, complications of ADHD, risk of substance abuse, drug interactions, and alternative treatments disclosed (Table 1). The majority wanted a general statement that specific rare side effects might occur included.

TABLE I PREFERENCES FOR INCLUDING THE FOLLOWING INFORMATION IN A DISCLOSURE

| Item | Agree or Strongly Agree (%(N)) | | |
|---|--------------------------------|-----------|------------|
| | Teens | Parents | Physicians |
| Many teens with ADHD have learning problems | 80.0(24) | 86.7(26) | 96.7(29) |
| Some teens with ADHD may start to feel sad | 53.3(16) | 66.7(23) | 75.9(22) |
| Without treatment, teens with ADHD may have trouble finishing schoolwork | 90.0(27) | 100.0(30) | 96.7(29) |
| Without treatment, teens with ADHD may develop behaviour problems | 76.7(23) | 93.3(28) | 80.0(24) |
| Doctors don't know exactly what causes ADHD | 60.0(18) | 86.7 (26) | 76.7(23) |
| Doctors think that ADHD is more common in some families than others | 53.3(16) | 80.0(24) | 93.3(28) |
| Doctors think ADHD is related to changes in brain chemicals | 53.3(16) | 93.3(28) | 86.7(26) |
| Brain areas that control attention may be less active in people with ADHD | 70(21) | 93.3(28) | 70.0(21) |
| The medicine acts on chemicals in the brain | 73.3(22) | 96.7(29) | 89.7(26) |
| Teens who have taken stimulants for years may feel better about themselves than those who haven't | 73.3(22) | 76.7(23) | 80.0(24) |
| It is safe to stop taking medicine on weekends or holiday | 90(27) | 89.7(26) | 79.3(23) |
| Stimulants can be abused | 76.7(23) | 90(27) | 86.7(26) |
| Teens on stimulants don't usually abuse stimulants | 70(21) | 76.7(23) | 6.7(20) |
| Stimulants should be used carefully when family members have abused drugs | 86.7(26) | 86.7(26) | 75.9(22) |
| Drug allergies can occur | 70(21) | 87(26) | 73.3(22) |
| Stimulants may interact with other medications | 93.3(28) | 96.7(29) | 73.3(22) |
| Stimulants may interact with street drugs | 73.3(22) | 93.3(28) | 83.3(25) |
| Behaviour therapy helps teens get along better | 76.6(23) | 93.3(28) | 75.9(22) |
| Behaviour therapy doesn't help teens sit still, concentrate or pay attention | 76.7(23) | 86.2(25) | 75.0(21) |
| Less than 1 kid or teen in 10,000 on stimulants gets a serious medical problem. When they happen doctors aren't sure that stimulants causes them. They report the problem to track them | 63.3(19) | 76.7(23) | 75.0(21) |

Note. 30 physicians, 30 parents, and 30 teenagers

When asked about specific rare side effects, for most of these, fewer than half of participants in each group endorsed including the side effect in a disclosure form (Table 2). However, a majority of parents and teenagers (73%) wanted the statement regarding the possibility of arrhythmias occurring when stimulant medication were prescribed included and approximately half of all parents and teenagers wanted the theoretical risk of seizures disclosed as well as the remote risk of strokes disclosed. The mean number of items endorsed by teenagers, parents and physicians was 18.17 (SD =4.5), 21.8 (SD=3.6), and 18.7 (SD=4.7) respectively; these numbers are significantly different $F(2,87\text{ df})=6.4, p=0.003$. The differences were significant only between parents and doctors and between parents and teenagers. The mean number of rare items teenagers, parents and physicians endorsed was 2.9 (SD=1.8), 3.4 (SD=2.3) and 2.0 (SD=2.4), respectively; these numbers are significantly different. $F(2,87\text{ df})=3.5, p=0.035$. Post hoc analyses reveal, significant difference only between parents and physicians. Within each group of participants, the range of items endorsed went from no items to all items endorsed.

Discussion

This exploratory study of the preferences of teenagers, parents and physicians regarding information disclosure shows similarities and differences across the groups.

The majority of parents, teenagers and physicians wanted information on etiology of ADHD, possible complications of ADHD, risk of substance abuse, drug interactions, and alternative treatments provided as well as a general statement about rare risks disclosed. In general, parents wanted more items disclosed than teenagers or physicians.

Across the specific rare risks, there was a distribution of responses with the strongest endorsement related to potential drug interactions causing arrhythmias, seizures and strokes.

TABLE II PREFERENCES FOR INCLUDING THE FOLLOWING RARE SIDE EFFECTS IN INFORMATION DISCLOSURES

| Item | | ^a Agree or ^b Disagree (%(N)) | | |
|--|---|--|----------------------|----------------------|
| | | Teens | Parents | Physicians |
| Serious problems includes: | | | | |
| a. | Inflamed blood vessels once caused a stroke. <ul style="list-style-type: none"> • Agree (%) • Disagree (%) | 50(15) 20(6) | 53.3(16) 16.7(5) | 23.3(7) 50.0(15) |
| b. | Decreased red or white blood cells <ul style="list-style-type: none"> • Agree (%) • Disagree (%) | 40(12) 10(3) | 56.7(17) 16.7(5) | 26.7(8) 46.7(14) |
| c. | Stiff muscles due to genetic disorder <ul style="list-style-type: none"> • Agree (%) • Disagree (%) | 46.7(14) 16.7(5) | 60(18) 16.7(5) | 30.0(9) 46.7(14) |
| d. | Illness in infant girl with brain problems <ul style="list-style-type: none"> • Agree (%) • Disagree (%) | 30(9) 30(9) | 33.3(10) 43.3(13) | 27. (8) 58.6(17) |
| e. | Arrhythmias when given along with other medications used to treat anxiety or depression <ul style="list-style-type: none"> • Agree (%) • Disagree (%) | 73.3 (22) 6.7(2) | 73.3(22) 13.3(4) | 46.7(14) 33.3(10) |
| f. | Stimulants can lower seizure threshold although they are not thought to cause seizures in those with or without seizures. There are only a few reported cases of seizure developing in teens with ADHD who have never experienced seizures <ul style="list-style-type: none"> • Agree (%) • Disagree (%) | 50(15) 20(6) | 66.7(20) 26.7(8) | 43.3(13) 36.7(11) |
| <i>Note.</i> ,30 physicians, 30 parents, and 30 teenagers. ^a Agree or Strongly Agree ^b Disagree or Strongly Disagree | | | | |

This study has several limitations. First, the sample is small and therefore not necessarily representative. Second, the sample has primarily younger teenagers and may not reflect the views of older teenager and their parents. Third, many subjects had used stimulant medication, their attitudes might differ from medication naïve subjects. Fourth, we did not compare clients and their treating physicians. Clients may select physicians with similar attitudes and practices to their own. Finally, the subjects were recruited at 2 points; all physicians and about half the participants were interviewed in 2004 and the remaining participated in 2008 in order to increase the sample size. The 2 groups may have had different exposures to drug related information which may alter their views on disclosure of side effects.

In addition, during this study's enrolment period, the Food and Drug Administration (FDA) reviewed information regarding cardiovascular events potentially associated with stimulant medication and recommended including this information in patient inserts. (Food and Drug Administration 2007; Nissen 2006) We cannot comment specifically about participants' views regarding this since we did not specifically enquire about this. Prior to conducting this study, our literature review had not revealed cases of sudden cardiovascular events associated with stimulant medication. Furthermore, when physicians were asked whether additional information should be included on the consent form or even on the list of additional items to include, none spontaneously suggested including this risk in the disclosure suggesting that they either were not familiar with this outcome or did not endorse disclosing it. This association has been the subject of much controversy, (Anders and Sharfstein 2006; Nissen 2006) and the FDA recommended including a black box warning and preparing patient information leaflets in an effort to inform parents and patients. (Nissen 2006) Health Canada has informed physicians of the possible association, and added a warning for stimulant medication. (Health Canada 2007) In this study participants were asked about including one cardiovascular event, arrhythmias; one cerebrovascular event (stroke), items endorsed by at least half of parents and adolescents. Thus it is likely that they would want to be informed about other possible adverse cardiovascular effects as well, in keeping with the American and Canadian recommendations. Examination of the data without the later subjects, also reveals that clients want to be told about arrhythmias, suggesting that their views were not affected by the recommendations.

Although this study is small, the findings reveal that individuals differ in their information needs particularly in terms of the rarer risks that they want disclosed. Clinicians' personal views regarding the nature of information to disclose to patients may differ from patients, just as one patients' preferences may differ from another. Physicians need to assess patients' information needs on an individual basis when providing them with information related to treatment, particularly when practicing in jurisdictions using the reasonable patient standard of disclosure. Future work should replicate these findings on larger samples and extend these findings by examining people with other mental health difficulties, as well as exploring subgroup differences. For example, are more anxious parents and their youth more likely to want more information disclosed compared to those less anxious? Are there differences between the information preferences of smaller groups, such as new immigrants, those where English is not the mother tongue,

etc. Until further data is available clarifying which subgroups have particular information preferences, physicians need to remember that their adolescent patients' perspective as well as their adolescents' parents' perspective on information disclosure may differ from each other and from their personal preferences. Physicians cannot assume that their personal information preferences reflect those of their patients. In order to help patients make informed decisions, physicians should inform patients about the benefits and risks that clients value in medical decision making.

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