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Conflicts of Interest

Are Informed Consent an Appropriate Model and Disclosure an Appropriate Remedy?

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Abstract

Conflict of interest (COI) in dentistry is typically thought to arise when a dentist's exercise of professional judgment for the sake of a patient's interest is compromised by a secondary interest such as increase of reputation or financial gain. Disclosure of conflict of interest is often recommended as a remedy to prevent the erosion of the fiduciary relationship and to permit patients to take steps to protect their own interests. Borrowing the concept of a reasonable patient from discussions of disclosure standards for informed consent, this paper offers a patient-centered definition of COI: a COI exists when the presence of a dentist's secondary interest undermines the reasonableness of a reasonable patient's reliance on his or her dentist's professional judgment. It then argues that disclosure of COI (modeled on other disclosures during informed consent) is an inadequate remedy for the breach of ethics presented by COI and an inadequate strategy to prevent harms associated with COI. It also examines research indicating that disclosure of COI has perverse effects on the informed consent process and patient decision-making, so that disclosure of COI actually inhibits patients from taking steps to protect their own welfare.

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Preventive Ethics and the Disclosure of Conflicts of Interest

Modeled on preventive dental medicine, "preventive ethics" provides an excellent approach for consideration of conflicts of interest within dentistry (Forrow et al., 1993). Preventive dental medicine is based on recognizing recurrent oral health problems and taking steps to avoid their emergence in individual patients. These steps involve examination and alteration of structural social issues and background conditions (e.g., access to dental insurance, society's changing nutritional habits, young people's development of tastes and health habits), as well as non-dyadic population-based approaches (e.g., fluoridation of water). Similarly, preventive ethics involves recognition of patterns of recurrent problems, anticipation of conflicts, and consideration of background and contextual conditions contributing to these issues. A preventive ethics approach advocates development of structural solutions in advance of problems' emergence or reemergence. This anticipatory approach involves drawing lessons from analogous situations and examination of multiple perspectives.

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dentistry may enable dental professionals to avoid or address ethical concerns in order to maintain healthy relationships with patients and colleagues. The process of informed consent, for example, may be understood in terms of preventive ethics as it is a structural, approach designed to protect patient autonomy and welfare, promote trust, and avoid future conflicts born of misunderstanding or lack of transparency. This paper explores whether disclosure of conflicts of interest (COI), modeled on informed consent's disclosure requirements and warranted by the same preventive ethics rationale, is an appropriate remedy or preventive measure to avoid the negative effects of COI in professional practice.

Typically, disclosure is thought to be the appropriate preventive ethics remedy for COI (e.g., Ozar, 2004). The American Dental Association's *Principles of Ethics and Code of Professional Conduct*, for example, requires disclosure of COI when dentists make representations in educational or scientific venues, as well as to disclose financial incentives involved in recommending particular products to patients (ADA, 2005, Sec. 5). The rationale is that if COI are disclosed to patients, then patients can incorporate that information into their informed decision making process and determine for themselves whether they feel such a conflict undermines their fiduciary relationship with their practitioner, influences the content of their provider's judgment, and threatens the quality of their care. Similarly, an audience listening to a presentation can decide whether to "discount" the accuracy of information imparted because of the potential influence of the speaker's conflicting personal interests. The assumption is that with regard to COI, disclosure—modeled on disclosure in the process of informed consent—can prevent ethical impropriety, presumably by shifting the burden of guarding against it from the practitioner to the patient.

In this paper, we argue that disclosure is not a sufficient remedy for COI. Merely informing the patient and then, in effect, letting the buyer beware is not an appropriate discharge of the dentist's fiduciary duties and does not serve to prevent the harms associated with COI. These harms include the failure of the dentist to serve his or her primary interest (i.e., his or her patient's health-related interests), erosion of the patient's reasonable trust in the fiduciary relationship and in the professional himself, and erosion of reasonable trust in and respect for the profession of dentistry. We begin by considering sources of conflict of interest as dentistry becomes increasingly commercialized. Then we present a patient-centered definition of conflict of interest and discuss the threat COI presents to the fiduciary relationship between dentist and patient. We then examine the process of informed consent to show the limitations of disclosure as a means of preventing the harms associated with COI. Finally, we discuss empirical research that indicates additional failings of disclosure as a remedy for COI.

Commercialization, Conflicts of Interest, and the Fiduciary Relationship

Conflicts of interest exist on many levels and arise from multiple sources. General dentists and specialists alike are increasingly performing procedures which traditionally were considered outside their area of expertise. A general dentist may place an orthodontic appliance or perform root canal therapy, an orthodontist may provide a teeth bleaching procedure, and some oral surgeons are now performing rhinoplasty. This blurring of activities within the practice of

dentistry has not only challenged traditional understandings of the scope of practice and standard of care which dictates an appropriate system of referrals, but also increased competition for financial gain within the dental field and across lines of dental specialization (Curtis, 2006). Conflicts of interest may increase when dentists are motivated by financial gain to limit referrals and perform an increasing number of procedures outside of (or at the outer limits of) their areas of expertise. Competition may result in a lack of collegiality, a failure to make appropriate referrals, and a system in which the patient does not always receive care from the most appropriately qualified type of professional. Thus, potential conflicts of interest abound within the profession.

Increased commercialization in dentistry, as in all branches of medicine, has the potential to place the best interests of the patient in competition with the financial interests of the care provider. Aesthetic dentistry may present a particular challenge in this area, and not merely because of the scale of the potential market. In aesthetic dentistry, the actual risk-to-benefit ratio presented by interventions depends on patients' personal values and perceptions; there is less social consensus, for example, regarding the benefit of aesthetic intervention than about the value of alleviating pain or preserving the ability to eat and speak. Especially in this more subjective, value-laden realm of aesthetic dentistry, dental professionals may find it difficult to discern whether they are primarily considering the patient's interest or their own financial gain when offering such services. Moreover, because the supply of services—the creation of possibilities of aesthetic enhancement—in large measure drives demand, the profession as a whole may be said to face a conflict of interest in advancing the frontier of possible aesthetic interventions.

Initially, it may be said that a conflict of interest arises when professional judgment regarding one's primary interest, as defined by one's professional duties, is compromised by a secondary interest (Thompson, 1993). Such secondary interests frequently include personal financial gain or increased reputation, but may include less tangible interests, such as the desire to benefit society by increasing scientific knowledge or to preserve a collegial relationship. The ADA Code anticipates the potential for financial conflicts of interest and notes that "contract obligations do not excuse dentists from their ethical duty to put the patient's welfare first" (ADA, 2005, Sec. 3). When secondary interests unduly influence the exercise of professional judgment, a conflict of interest arises. COI arise in situations in which one person relies on another to exercise judgment to act or advise on his or her behalf and that judgment is compromised by some personal interest (modified from Meyers, 2005).

We would extend this analysis and the definition of COI to argue that even when conflicting secondary interests do not actually unduly influence the professional's judgment, a COI exists when the reasonableness of the patient's reliance on his or her dentist's fulfillment of the professional, fiduciary duty to exercise judgment on his or her behalf is undermined by the presence of a conflicting secondary interest. Thus we propose a definition of COI that does not rely on an assessment of the actual motives of a particular professional or the actual influences on his or her judgment—an assessment that is frequently, if not always, impossible. Instead, our proposed definition employs an objective, reasonable person standard. A COI exists when a reasonable patient may reasonably believe that his or her dentist's exercise of professional judgment is undermined by a secondary interest. This patient-centered definition of a COI is consonant with a generally patient-centered ethic in dentistry and with the values grounding the reasonable-person standard frequently employed in interpreting the demands of the doctrine of informed consent (Berg et al., 2001). Like the reasonable-person standard in informed consent, this definition of COI relies on a socially constructed, publicly assessable view of what it is reasonable for an admittedly fictitious, normatively-defined, reasonable patient to believe.

Consider a dramatic, if rather silly example, of a menacing loan shark that specializes in making loans to dentists. Some dentists may be able to responsibly exercise professional judgment untainted by knowledge that a loan shark is arriving at the end of the month to collect money owed and plans to break the dentists' fingers if they cannot pay up. Other dentists may succumb to the perceived need for some quick cash and self-interestedly recommend cash-producing aesthetic interventions, as well as other interventions that have a high profit margin, without requisite regard for their patients' best interests. We suggest that the presence of the secondary interest in paying off the loan shark constitutes a conflict of interest for all such indebted dentists, whether or not a particular dentist is able to exercise his or her professional judgment untainted by fear for his or her fingers. The situation presents a COI because the presence of the secondary financial and safety-related interests presented by the loan shark would undermine the reasonableness of

a reasonable patient's reliance on his or her dentist's professional judgment. We need not inquire whether a particular dentist was inappropriately influenced when making a particular treatment recommendation; we need only ask whether a reasonable patient's reliance on the dentist's recommendation would be undermined if the presence of secondary interests were transparent. Reference to the reasonable patient is an attempt to employ norms distinguishing appropriate from inappropriate influences. A reasonable patient may still reasonably rely on professional judgment knowing that the professional makes "a decent living" by exercising such judgment, but may reasonably question relying on professional judgment that involves self-referral or prescription of treatments associated with higher-than-usual fees. Such social norms are admittedly fluid, but they can be publicly discussed, unlike that largely unknowable state of a practitioner's mind when he or she makes treatment recommendations.

Having adopted the notion of the reasonable person from the doctrine of informed consent, we turn now to the question of whether disclosure, modeled on the disclosure component of informed consent, is an appropriate way to address COI and prevent its negative effects on the fiduciary relationship practitioners have with their patients.

Informed Consent and Disclosure

Informed consent is not a form signed by a patient; an ethically and legally valid consent form merely documents that informed consent has taken place. Informed consent is both the autonomous action of a patient authorizing a doctor to act for his or her benefit (Faden & Beauchamp, 1986) and a norm-governed process of communication between doctor and patient that enables a patient to make an informed medical decision (Berg et al, 2001). Informed consent has two ethical goals. The first goal is to promote autonomy by allowing the patient to grant or deny access to his or her person and personal information based upon his or her own individual values and interests. The second goal is to protect patient welfare by protecting him or her from unauthorized touching and violations of bodily integrity.

Informed Consent

In dental practice, the fundamental elements of the informed-consent process are: presentation by the dentist of material information regarding an intervention, understanding of that information by the patient, who then makes a voluntary decision whether or not to consent to treatment (Berg et al, 2001). As a prerequisite to this process, the patient must be competent to consent, i.e., able to understand and appreciate the risks and benefits of the interventions, and capable of reasoning and deliberating about them (and alternative courses of action, including doing nothing), in light of the patient's own set of values (Buchanan & Brock, 1990). If the patient lacks these capacities, then a surrogate decision maker must participate in the process of informed consent on the patient's behalf.

In order to evaluate disclosure as a remedy for COI, further consideration of disclosure, understanding, and voluntary nature are pertinent. Challenges to the voluntary nature of patient decision making can take many forms. Pressure can be exerted by external factors, including other people, role constraints, and social pressures. Instead of having a root canal and crown as treatment, for example, an elderly woman may reluctantly consent to have a tooth extracted because her son tells her the crown is too expensive and not fully covered by her insurance. Internal pressures may also prevent substantially uncontrolled informed decision making. A strong need to please people may render a patient incapable of refusing unwanted procedures suggested by his or her dentist. Thus an unscrupulous practitioner who recognized this patient's quasi-pathological need to please could breach professional, fiduciary duty and take advantage of his or her inability to refuse recommended treatment.

In addition to intentional and overt manipulation, even unintended pressures within the professional-patient relationship can undermine the voluntary nature of decision making and the exercise of patient autonomy, as well as erode trust within the relationship. A well-meaning dentist might, for example, suggest to a shy young man that having his teeth whitened will make him feel more attractive and confident, and he may feel unduly pressured into consenting to a treatment that he may not otherwise want or be able to afford. Therefore, professionals must base the content and manner of their recommendations on an assessment of what degree of recommendation a reasonable person would find appropriate and resistible, as well as titrate the strength of the recommendation to the degree of benefit (or avoidance of harm) the intervention presents. Further, so far as possible, practitioners must modulate the content and manner of their recommendation to the particular informational and psychological needs of their patients; if a particular patient is known to be exceedingly deferential to authority, a practitioner may take steps

to counterbalance the patient's predisposition to accept professional recommendations unquestioningly.

Disclosure

Like voluntary nature, disclosure and understanding are necessary elements in the informed-consent process. For informed decision making, understanding is more important than disclosure; a decision is made based on what the patient understands, rather than on the information presented to him or her. Nevertheless, the bioethical and legal literatures on informed consent pay more attention to the disclosure element, presumably because concrete recommendations can be made about disclosure and because it is observable and better understood. Whether disclosure has occurred can be ascertained, while assessment of understanding remains more mysterious.

There are various ethical standards that can be used to define or guide adequate disclosure. While reliance on a professional practice standard may be invoked by practitioners to defend their disclosure practices if questioned in malpractice proceedings, this standard is ethically problematic. It gives complete discretion to a group of professionals who could choose to offer a consistently inadequate level of disclosure, instead of engaging with patients to determine what information they feel they need to make an informed decision (Berg et al, 2001).

A preferable disclosure standard is the reasonable-person standard. "Whether information is pertinent or material is...measured by the significance a reasonable person would attach to it in deciding whether to undergo a procedure" (Beauchamp & Childress, 2001, p. 82). Using this standard results in a "core disclosure" that contains these elements: the nature of the recommended procedure, its risks and benefits, alternatives to the procedure, and practitioner-specific information (Berg et al, 2001). In addition, the difficulty, length, recovery time, and pain associated with a procedure are among the things a reasonable dental patient would want to know. Regarding risks, a reasonable person would want to know their nature, magnitude or severity, and frequency. How likely are the hoped for benefits of the procedure, and are they consistent with the personal treatment goals of the patient? Among the alternatives to the recommended procedure should be the possibility of doing nothing and the risks and benefits associated with that choice.

Beyond this core information based upon what the reasonable person would need to make an informed decision, the practitioner must also offer information he or she believes would be material to the particular patient, as well as respond to the patient's questions. If a dentist knew, for example, that his or her patient was getting married in a few days, he or she should disclose that a procedure may produce a degree of facial bruising and swelling that would be visible in photographs. Or, if there is clinical evidence that acupuncture is showing promise of alleviating symptoms of temporomandibular joint dysfunction (TMJ), a patient may want to know that before consenting to surgery for TMJ, as well as the pros and cons of choosing to receive no treatment at the present time. In order to maximize the patient's ability to make an adequately informed autonomous decision, information presented should be tailored to the patient's needs. Moreover, poor hearing, limited education, and language barriers are just a few obstacles that may need to be over-

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come in order to facilitate an adequate understanding of disclosed information.

Because a patient consents not only to a treatment, but to treatment by a particular practitioner, the final informational element material to decision making is practitioner-specific information. This is also the most controversial element of disclosure (Berg et al., 2001, 61-64). Some commentators (and courts) hold that a practitioner should disclose his or her degree of training and experience performing a particular procedure, degree of training in it, and degree or rate of success with the procedure. Unusual financial incentives should also be disclosed. Patients should be made aware of situations in which treatment may be limited due to financial considerations, such as minimal reimbursements from insurance companies, as well as situations in which a procedure would result in an unusual profit for the practitioner, such as a procedure being reimbursed at an abnormally high rate. Some possible financial arrangements, like self-referral or acceptance of rebates or split fees, are considered so ethically problematic that they are to be avoided, rather than disclosed so that the patient/buyer may beware (Berg et al, 2001; ADA, 2005 Sec. 4) .

Similarly, some suggest that health-care providers should disclose any health issues or personal information which could negatively influence their performance or put their patients at risk, e.g., lack of sleep, grief, or turbulent personal relationships (Berg et al, 2001). Yet, just as it is deemed "unethical for a dentist to practice while abusing controlled substances...which impair the ability to practice" (ADA, 2005, Sec. 2), it would seem that other conditions likely to impair professional judgment ought to be similarly avoided or ought to serve as a bar to practice. It is inadequate merely to disclose them and proceed to practice.

Disclosure as an Inadequate Remedy for COI

So, what about conflicts of interest? Is their disclosure an appropriate way to prevent their negative effect on the practitioner-patient relationship, professional judgment, and patient care? We might begin by asking: what, if anything, relevantly distinguishes operating under the influence of a controlled substance, which is to be avoided categorically, from operating while influenced by secondary interests such as financial incentives or the desire to preserve a collegial relationship? One difference is that there is strong social consensus that drug and alcohol use substantially impairs judgment, including professional judgment. In contrast, reasonable people could disagree about the degree and nature of influence on professional judgment exerted by some secondary interests. Some may believe that the opportunity to gain in terms of money or reputation provides incentives for innovation and excellence, while others may see the prospect of high profit as prompting undue risk-taking (or rather, the recommendation of undue patient risk-taking). This difference might argue in favor of disclosing COI and allowing the patient to evaluate their influence on provider judgment in light of the patient's own views.

Second, while drug and alcohol use can be avoided, the presence of secondary interests is unavoidable. Dentists' desires to have friendships, feed their families, and arrive home at a reasonable hour most evenings—all of these socially acceptable interests—can conflict with the welfare of their patients in particular instances. In most cases, however, these do not unduly influence professionals' judgment. These secondary interests are the background conditions of normal life. They are expectable, anticipatable,

and even desirable; we might question the perspective of a professional whose only interest was his or her patients' welfare, his or her professional duty.

Not all influence by secondary interests can be avoided in professional practice the way the influence of controlled substances can and must be. Of course, these secondary interests associated with normal life can lead dentists to sacrifice their patient's interests; however, in most instances they do not; the need to pay a mortgage differs in its influence on professional judgment from the need to pay a loan shark. It is reasonable for patients to expect that dentists can exercise sound professional judgment in service of their patients' interests in the face of the secondary interests of normal daily life, even though in some cases some dentists will not. Even those who advocate disclosure as the remedy for COI suggest that secondary interests only have to be disclosed if they compromise the reasonableness of a patient's reliance on the professional's judgment regarding his or her welfare. To avoid every secondary interest would be impossible and undesirable; to require disclosure of every secondary interest would sap disclosure of any meaningfulness that it may be thought to have.

Furthermore, we contend that there are four reasons that disclosure is not an adequate remedy to conflicts of interest in dental practice. First, it is difficult to identify one's own COI. Second, disclosure of COI has perverse effects on practitioner behavior. Third, disclosure of COI has perverse effects on the recipient of the disclosure. Finally, relying on disclosure to remedy the negative effects of COI is conceptually unsound.

In order to disclose a conflict of interest, a dentist must first recognize it. The dentist must recognize the secondary interests that are likely to unduly influence professional judgment. The first reason that disclosure fails to remedy COI is that they are so difficult for the person possessing them to identify. If a dentist refers patients to a cousin, a not-quite-capable endodontist, because his or her mother requested it, that is a secondary interest which obviously conflicts with the primary interest, the patients' well-being. Most COI, however, are not so obvious. If a general dentist refers his or her patient's to a well-respected endodontist, who just happens to be his or her best friend, he or she may feel no discomfort, because he or she does not receive any secondary gains, other than the satisfaction of helping a friend while presumably benefiting his or her patient. Research shows that people are consistently poor at recognizing their own biases (Messick & Sentis, 1979; 1983). Even when motivated to be objective and impartial, people "deny and succumb to bias even when explicitly instructed about it," which indicates that "self-serving bias is unintentional" (Dana & Loewenstein, 2003, p. 253). Research also suggests that self-interest influences "the way individuals seek out and weigh the information on which they later base their choices when they have a stake in the outcomes" (Dana & Loewenstein, 2003). In this case, the dentist's friendship may prevent him or her from noting deterioration in the endodontist-cousin's skill or from verifying that the cousin keeps current with new techniques.

This line of research suggests that it is unconscious bias that must be reduced, and this can best be accomplished by eliminating the conflicting interests themselves, as with the prohibition of fee splitting, kickbacks for referrals, or "finder's fees" for recruiting patients to research studies. Relevant to the case at hand, instead of avoiding referrals to friends or practitioners that one likes, dentists should base their referrals on verifiable evidence of the specialist's expertise, thereby rendering friendship status irrelevant to referral practices.

The second problem with disclosure as a remedy for COI is that professionals' disclosure of a conflict of interest may have a perverse effect on their expression of judgment. In a research setting designed to simulate professionals offering advice, disclosure of the presence of COI seemed to provide the advice-givers with "strategic reason and moral license to further exaggerate their advice" (Cain et al, 2005, p. 22). These investigations suggest that practitioners who believe that a particular intervention is in the best interest of their patient may strengthen their recommendation of it to compensate for the discounting effect they anticipate their disclosure of COI will have on their patients. They may either oversell an intervention's likely benefits, or downplay its risks, or they may exaggerate their authoritative professional role (for example, by suggesting that their financial interest in a product coincides with—or affords—insider knowledge of its virtues). Both the voluntary and informed elements of informed consent may thereby be undermined.

Third, disclosure of COI may lead recipients of the disclosure to process material information in a less accurate manner. People generally believe that biased advice results from the intention to mislead (Dana & Loewenstein, 2003). Therefore, disclosure of a source of bias, a conflict of interest, may lead the advice recipient to underestimate the degree to which the professional is biased because disclosure of COI makes the professional appear more open, honest, and trustworthy (Cain et al, 2005). This may be especially true in the case of professional

recommendations, because people tend to trust their individual practitioners even when they mistrust a profession as a whole (Gibbons et al, 1998; Cain et al, 2005). Moreover, some disclosures enhance the status of professionals as authority figures by aligning them with special expertise and insider status.

The fourth reason that disclosure is an imperfect means of preventing the ill-effects of COI is that it misunderstands that ethical nature of the professional-patient relationship—its fiduciary nature. Disclosure fails to recognize and address the essentially vulnerable situation of the patient within the dental professional-patient relationship. The reason disclosure is attractive is that it purports to put the dentist and patient on a level informational and decisional field. In reality, however, the patient remains vulnerable and cannot be adequately empowered by disclosure of the COI. Indeed, how should the patient respond to such disclosure to protect his or her interests? He or she may be unable to evaluate how the secondary interests influence the provider's judgment. Yet he or she would have to understand the nature, direction, and magnitude of influence in order to know how to correct accurately for the degree of bias in the professional judgment offered. Moreover, he or she may lack financial resources to seek other professional advice or be in too much pain to do so.

These practical concerns reflect the nature of the fiduciary relationship between dentist and patient, who are inherently unequal in relevant expertise. The recommendation of disclosure as a remedy for COI fails to appreciate the inherently and unavoidable unequal nature of fiduciary relationships. Patients are dependent on their dentists for their trustworthy exercise of their professional judgment. Simply disclosing that one's professional judgment may, in fact, be influenced by secondary interests to the detriment of the patient's interest, does not make such influence ethically permissible.

Conclusion

Disclosure is thus conceptually and ethically unsound as a complete remedy for COI. While it would seem that information about the presence of a dentist's conflicting secondary interests should be material to the reasonable patient's decision making process, in fact patients typically do not make use of information about COI in ways that protect their interests or enhance their autonomous decision making. Disclosure of COI, modeled on disclosure of other material information, therefore, does not prove to be a practical remedy for COI. Disclosure's practical, and thus ethical, failings reflect its failure to take into account conceptual and ethical features of the fiduciary provider-patient relationship, most particularly the degree to which vulnerable patients must rely on their dentists to place patient welfare above other interests. ■

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