

OPIATE WRITTEN BEHAVIORAL AGREEMENTS

a case for abandonment

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ABSTRACT Written behavioral agreements (WBAs) are gaining popularity as part of the effort to manage the alarming increase in prescription drug abuse. The rationale for increased use of WBAs in managing patients with chronic pain is that they are believed to increase adherence to agreed-upon behaviors, reduce addiction to or diversion of prescription drugs, and satisfy informed consent requirements. However, there are no high-quality data to support their widespread use in any of these areas. The evidence used to support the use of WBAs is insufficient to justify their unfairness and the high risk of harm they pose to the doctor-patient relationship. Instead, we contend that WBAs are being used to provide leverage for severing relationships with some of our most challenging patients. We propose that physicians treating patients for chronic pain abandon the use of WBAs. Alternatives include open communication, detailed informed consent processes, carefully documented discussions, and most important, commitment to ongoing relationships even with difficult patients.

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The authors acknowledge funding assistance from the Richard M. Fairbanks Foundation, Indianapolis, and the Methodist Health Foundation, Indianapolis. Endowment funds from the Richard M. Fairbanks Foundation and the Methodist Health Foundation support the work of the Charles Warren Fairbanks Center for Medical Ethics, but played no direct role in the preparation of this manuscript.

The authors wish to thank Amy R. Chamness for her assistance in the preparation of the manuscript and Amanda D. Sapp for research used in preparation of the manuscript.

Perspectives in Biology and Medicine, volume 57 number 3 (summer 2014): 415–423.

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Written behavioral agreements (WBAs) came into clinical use more than 40 years ago, originally for the purpose of contracting for safety among patients expressing suicidal ideation (Drye, Goulding, and Goulding 1973). The first identified reference to the concept of contracting with suicidal patients appeared in the psychiatric literature in 1967 (Ewalt 1967). They have gained substantial popularity since then and are commonly employed across diverse medical settings, most notably in psychiatry, pain medicine, and addiction medicine.

Because of the epidemic of harm from prescription medications, especially opiates, the popularity of WBAs may be increasing (Gilson, Maurer, and Joranson 2007). In the area of pain medicine, opiate WBAs are regarded by some as part of the standard of care, and their use has been further incentivized by state medical boards and legislative efforts to minimize the escalating problem of opiate abuse (AAPM 2013; FSMB 2013).

We propose, however, that the use of WBAs should be abandoned, because of (1) a lack of evidence that they achieve their intended outcomes; (2) unfairness to patients; and (3) potential harm to the doctor-patient relationship. In some cases, they may be used inappropriately to provide leverage for severing relationships with some of our most challenging patients. In this article, we will offer evidence and argument for each of these assertions.

Authors have variously used the terms “pain contracts” and “pain agreements” to describe written documents employed in pain applications. The shift to the term *agreement* appears to have been an effort to appease many health-care professionals who were resistant to legalistic terminology (Payne et al. 2010). Passik and Kirsh (2010) argue that the term *contract* should be abandoned, since “contracts are most often used in law and business for agreements that are legally enforceable. Thus, contracts usually have legal and punitive connotations, suggesting a level of mistrust, whereas agreements imply that the parties have reached amicable arrangements that are freely accepted by all parties and are open to change” (827, 832). Here, we will use the term “written behavioral agreement” (WBA).

MAGNITUDE OF THE OPIATE ABUSE PROBLEM

Chronic pain is estimated to affect nearly 100 million adults in the United States and to cost the U.S. health-care system more than half a trillion dollars each year (NRC 2011). WBAs are thought to provide a tool for managing what has become an epidemic of harms related to misuse of prescription drugs (Collen 2009). The number of deaths from unintentional drug overdoses has been rising steadily for the past two decades, and it has become the second leading cause of accidental deaths in the United States. Overdoses of opiates now outnumber those of heroin and cocaine combined (Okie 2010).

Almost all prescription drugs involved in overdoses originally came from prescriptions (NCIPC 2011). Three-fourths of misuse can be accounted for by

such diversion (NRC 2011). Furthermore, the scope of practice-related issues and frustrations that arise from opiate prescribing—usually for patients with nonmalignant pain—is extremely significant, though less well documented.

LACK OF EVIDENCE IN ACHIEVING DESIRED OUTCOMES

If the primary goal of WBAs is to increase adherence to agreed-upon behaviors, it is helpful to examine the evidence supporting their effectiveness. A review by the Cochrane Collaboration focused on randomized controlled trials of WBAs between patients and health-care practitioners in the areas of diagnostic procedures, therapeutic regimens, and health promotion and illness prevention (Bosch-Capblanch et al. 2007). The review concluded that there was “not enough evidence available to recommend the routine use of WBAs in health services to improve patients’ adherence.” Starrels and colleagues (2010) reviewed the literature regarding both opiate WBAs and urine drug testing as means to reduce opioid misuse. All of the 11 studies that met their study inclusion criteria were observational and found to be of either fair or poor quality. The authors’ main conclusion was that relatively weak evidence supports the effectiveness of opiate WBAs in reducing opiate misuse. Dunbar and Katz’s (1996) small case series of patients with nonmalignant pain and a history of substance abuse found no correlation between a signed opiate WBA and subsequent abuse. Burchman and Pagel’s (1995) small retrospective observational study of the implementation of a formal WBA for outpatient management of chronic nonmalignant pain with opiates identified positive effects on adherence, but the study lacked explicit outcome criteria, making it difficult to draw definitive conclusions. Even the official guidelines from the American Academy of Pain Medicine do not include the goal of increased adherence, but instead include goals of documenting expectations and educating patients (Chou et al. 2009). The Federation of State Medical Board’s model policy describes the purpose of WBAs as outlining the “joint responsibilities of physician and patient” (FSMB 2013).

Although these data are inadequate to definitively determine the effectiveness of WBAs, it may be said that no high-quality data exist to support the widespread use and endorsement of WBAs by practicing clinicians and professional societies, or mandates by legislative and regulatory bodies.

PATIENT EDUCATION OR INFORMED CONSENT?

Would WBAs be better conceived of as patient education or informed consent documents? This seems unlikely, given that even *actual* written informed consent documents, such as those used in hospital and clinical settings, have been shown to be inadequate. For example, Bottrell and colleagues (2000) found that only 26% of 540 hospital informed consent documents analyzed in their study contained all four basic elements of informed consent: (1) information about the nature of the

intervention; (2) a statement of the potential risks involved; (3) a statement of the potential benefits of the intervention; and (4) alternatives to the intervention along with a statement of their potential risks and benefits (Faden and Beauchamp 1986).

However, Fishman and colleagues (2010) argue for just such an approach, stating that “it is in the patients’ best interest to have a standardized tool that is preconceived to contain all the elements of a responsible treatment agreement and that is crafted to serve the patients need for clear information and education” (14). Fishman and colleagues examined the content of “opioid contracts” analyzing every statement for its core meaning. They grouped statements into 12 major categories and into three distinct groups based on frequency: those found in greater than 90% of forms, 70–85% of forms, and less than 40% of forms. The most common categories of statements included terms of treatment, prohibited behavior, and points of termination. The moderately common categories of statements included stipulations of patients’ responsibilities, education, and rules surrounding additional treatment. The least common categories included statements of goals, emergency issues, limitations on prescriptions, legal considerations, discouraged behavior, and finally, staff behavior.

It is evident from Fishman’s analysis that WBAs do not focus on presenting the four basic requirements of informed consent, but instead contain elements far more weighted to patient prohibitions and consequences. Therefore, it is nonsensical to label WBAs as “informed consent” documents. Their actual content is not supportive of such a purpose.

UNFAIRNESS OF WRITTEN BEHAVIORAL AGREEMENTS

Despite the efforts to re-label WBAs with the friendlier term *agreement* and to move away from negative-sounding contractual language, proponents of WBAs must believe that they serve a quasi-legal function, such as specifying consequences for non-adherence or protecting physicians from legal risk. In practice, however, WBAs may more closely resemble “adhesion contracts” rather than legitimate contracts. An adhesion contract, as defined by *Black’s Law Dictionary*, is a “standard-form contract prepared by one party, to be signed by the party in a weaker position, usually a consumer who has little choice about the terms.” A legally binding and enforceable contract requires mutual agreement, as well as ample time to read and consider the terms without the presence of duress or pressure (Sacopulos and Segal 2009). By definition, the agreement should not change the nature of the physician’s duty to the patient, such as lowering the standard of care the patient receives. Generally, patients are asked to sign WBAs that are drafted by the physician or physician’s practice without the opportunity to negotiate any of the terms, and they are only given the option to sign or reject them. Although WBAs are explicitly designed to allow physicians to exit the relationship, they do not provide a proportional outlet for patients, since patients are in need of medical services that can only be obtained from a limited number of physicians who provide pain management (Collen 2009).

If WBAs were in fact contracts, they would likely not be enforceable due to being “unconscionable.” Murray (2001), quoting *Williams v. Walker-Thomas Furniture Co.* (121 U.S. App. D.C. 315, 350 F.2d 445, 449 [1965]) defines an unconscionable agreement as one with “an absence of meaningful choice on the part of one of the parties together with contract terms which are unreasonably favorable to the other party” (§96(B)(2)(b)). Due to the asymmetrical relationship between patients and physicians, Collen (2009) argues that patients, who are in a vulnerable position and desperate for help, are thereby placed in a much “weaker position” for bargaining. Furthermore, WBAs could be considered unconscionable because they are written at a level that it is not fully understood by the patient, and signed by patients under a kind of duress: under the influence of opiates or pain in the first place (Collen 2009; Prince 2010). Roskos and coauthors (2007) found that opiate WBAs “presented information at much too high a reading grade level, and with formatting characteristics that probably would make these documents difficult for the average patient to understand” (757). For example, in a preliminary study assessing how pain WBAs were used in HIV-infected patients perceived to be at high risk for opiate misuse, patients exhibited a low awareness of whether they had actually signed a WBA (Penko et al. 2012).

Finally, we could identify no direct evidence that WBAs provide any legal protection. To draw an analogy in the field of psychiatry, no-suicide contracts have been found not to protect health-care providers from malpractice liability (Bartlett 2006). Garvey and colleagues (2009) conclude that such contracts actually “may lead to adverse consequences for the clinician and the patient” (363).

POTENTIAL HARM TO THE DOCTOR-PATIENT RELATIONSHIP

The arguments used to justify the use of WBAs in mitigating improper use of opiates do not hold up to more careful scrutiny. Furthermore, WBAs may increase the level of mistrust between physicians and their patients, posing a significant risk to the doctor-patient relationship. This is a poorly studied area, and thus it is difficult to draw conclusions on the basis of empirical information. Merrill and colleagues (2002) attempted to understand the difficult relationships between illicit drug-using patients and their physicians through a qualitative and observational study of care interactions. Their main finding was that physicians and drug-using patients in a teaching hospital display mutual mistrust, especially concerning opiate prescriptions.

It is not difficult to imagine that WBAs—with their legalistic and sometimes punitive language, and with majority provisions pertaining to prohibition of patient behaviors and to the consequences of broken agreements—undermine trusting doctor-patient relationships. Whether one conceives of the doctor-patient relationship in terms of trust or covenant (Fine 2010; May 1983), we contend that WBAs immutably transform core elements of the doctor-patient relationship that contribute to trust, thereby profoundly altering the nature of the doctor-patient relationship. Buchman and Ho (2014) argue that requiring chronic pain

patients, who may already be inappropriately stigmatized, to demonstrate their trustworthiness through WBAs places a disproportionate burden on the patients to convince their physicians that their pain is real and that they deserve their pain medications. They assert that WBAs “might facilitate a misplaced ‘forced trust’ or a false sense of assurance, rather than promote the integrity of the patient–physician relationship” (675).

So what explains the rising popularity and reliance on WBAs in health-care settings? Clearly, as the problem of prescription drug abuse and related mortality has dramatically increased, public, regulatory, and legislative pressure to intervene have escalated. WBAs appear to be a concrete, measurable, and auditable step clinicians can take to demonstrate good-faith efforts to combat abuse and diversion of opiates, and their endorsement by professional societies gives them apparent validity (AAPM 2013; FSMB 2013). However, as we have argued above, the data to support their efficacy in achieving these desired outcomes is weak. Arnold and colleagues (2006) hypothesize that clinicians who treat pain with opiates inherit opiophobic values that are part of our history and culture and suggest that “Physicians need some means of security, some method to protect themselves from being duped by such patients and furthering illicit drug use, and to mitigate professional and legal liability. They need a way to ‘just say no’ to patients” (295). This explanation contains what we believe to be one of the true motivations for using WBAs.

We strongly suspect that another unstated purpose of WBAs is to provide a defensible exit strategy from relationships with some of our most challenging patients: those with chronic nonmalignant pain. In this respect, we contend that reliance on WBAs represents an abdication of our deepest ethical commitments. Clinicians may find that it is easier to use a WBA as grounds for patient dismissal than it is to live with the sense that they are providing long-term, seemingly ineffective, frustrating and challenging care to difficult patients who, by their very nature, display behaviors that undermine our trust in them. But we cannot individually or systematically undermine their opportunities to trust us. As we have shown, it is hard to argue that WBAs are consistent with our highest aspirations and honor our profoundest commitments to patients’ good. Our analysis suggests that WBAs are more about providers than about patients.

ALTERNATIVES TO WBAs

What are the alternatives to WBAs? After recognizing some of the valid objections to opioid WBAs as currently written, Savage (2010) has proposed a “patient-centered opioid treatment agreement.” But making the language of such agreements more patient-centered will not alter their function as pseudo-contracts, and it will not ameliorate their potential to damage the doctor–patient relationship.

Instead, we suggest that the eternal elements of the doctor–patient relationship can be sufficient, even in the most demanding circumstances. These elements include

caring, open, honest, and compassionate communication with patients, detailed informed consent processes, and careful documentation. Such efforts may ethically entail setting limits, including refusals to provide certain requested treatments, such as opiates. They involve what Buchman and Ho (2014) refer to “epistemic humility,” where “both the physician and patient are counting on each other in investigating a full picture of the patient’s lived experiences and determining the most appropriate care plan in the context of opioid prescription, addiction prevention, stigma and pain management” (675). Rather than dismissing a patient from one’s practice after a threshold has been violated—even without the apparent protections of a WBA—a practitioner can refuse further opiate prescriptions and instead offer to provide ongoing care and treatment, as well as other forms of analgesic therapy. To do this is to commit to an ongoing relationship.

The time has come for us to abandon WBAs and to reject the regulatory momentum to impose them on our relationships with patients. WBAs are ineffective, coercive, and harmful to the most fundamental parts of the doctor-patient relationship.

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