Bibliography


Wilson SR, Strub P, Buist AS, et al. Shared treatment decision making improves adherence and outcomes in poorly controlled asthma *Am J Respir Crit Care Med* 2010;181:566-77. ONLINE SUPPLEMENT.

Tapp H, Hebert L, Dulin MF. Comparative effectiveness of asthma interventions within a practice based research network. *BMC Health Services Research* 2011, 11:188.
SHARED DECISION-MAKING IN THE MEDICAL ENCOUNTER: WHAT DOES IT MEAN? (OR IT TAKES AT LEAST TWO TO TANGO)

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Abstract—Shared decision-making is increasingly advocated as an ideal model of treatment decision-making in the medical encounter. To date, the concept has been rather poorly and loosely defined. This paper attempts to provide greater conceptual clarity about shared treatment decision-making, identify some key characteristics of this model, and discuss measurement issues. The particular decision-making context that we focus on is potentially life threatening illnesses, where there are important decisions to be made at key points in the disease process, and several treatment options exist with different possible outcomes and substantial uncertainty. We suggest as key characteristics of shared decision-making (1) that at least two participants—physician and patient be involved; (2) that both parties share information; (3) that both parties take steps to build a consensus about the preferred treatment; and (4) that an agreement is reached on the treatment to implement. Some challenges to measuring shared decision-making are discussed as well as potential benefits of a shared decision-making model for both physicians and patients. Copyright © 1997 Elsevier Science Ltd

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INTRODUCTION

Shared decision-making is increasingly advocated as an ideal model of treatment decision-making in the medical encounter (Veatch, 1972; Brody, 1980; Quill, 1983; Brock and Wartman, 1990; Gray et al., 1990; Emanuel and Emanuel, 1992; Levine et al., 1992; Deber, 1994). Yet, it is by no means clear what shared decision-making really means or the criteria by which to judge what falls within or outside the boundaries of this model. In order to be able to evaluate the merits and limitations of a shared decision-making model it is first necessary to be clear about what the model is. To date, the concept of shared decision-making has been rather poorly and loosely defined. This leads to considerable confusion because the same conceptual label can be used to subsume different underlying philosophies and principles of physician–patient interaction. Our goal in this paper is to provide greater conceptual clarity in thinking about shared decision-making, to identify some basic characteristics of this model and to discuss measurement issues.

Improved conceptualization of shared decision-making would have several benefits. It would make more explicit what advocacy of shared decision-making means, allow for easier recognition when it does occur, and perhaps facilitate its practice by physicians and patients who have a preference for this model of joint decision-making. In so far as shared decision-making has been linked with positive patient outcomes (e.g. satisfaction and improvements in functional status), clarification of this model is clinically relevant (Egbert et al., 1964; Schulman, 1979; Greenfield et al., 1985, 1988; Brody et al., 1989; Wennberg, 1990; Mahler and Kulik, 1990; Lerman et al., 1990). Greater conceptual clarity could also guide research in this area by providing clearer direction on the types of information to be collected as relevant examples of shared and non-shared decision-making.

The increased and fairly new interest in shared decision-making derives from a number of different factors. For example, informed consent, now ethically and legally enshrined as a patient right, seems to imply at least a minimum of shared decision-making in the form of patient consent to treatment prior to any intervention (Sutherland et al., 1989). Moreover, the principle of "informed choice", i.e. disclosure of treatment alternatives rather than merely informed consent has been endorsed at several government levels in Canada and the United States (Evans, 1987; Greene, 1992; Ontario Ministry of Health, 1994; Nayfield et al., 1994).
Interest in shared decision-making also has its origins in the consumer rights movement. Here, concern with patient participation in treatment decision-making has moved well beyond informed consent to include broader principles of patient autonomy, control, and patient challenge to physician authority (Haug and Lavin, 1983; Ende et al., 1989; Charles and DeMaio, 1993; Llewellyn-Thomas, 1992, 1995). Shared decision-making is seen as a mechanism to decrease the informational and power asymmetry between doctors and patients by increasing patients' information, sense of autonomy and/or control over treatment decisions that affect their well-being (Eddy, 1990; Ryan, 1992; Emanuel and Emanuel, 1992).

A final factor is the changing nature of medical practice. During the last 20 to 30 years, there has been a dramatic shift away from acute care to chronic care and caregivers often manage illnesses or combinations of illnesses rather than cure disease. For such patients, sickness is not just a temporary status; rather, long-term and chronic illness may become a permanent part of their identity and status. In such cases, the physician–patient relationship is potentially a long-term one. The plethora of new drugs available requires that physicians work closely with such patients to develop the optimum pharmacological solution, a process that takes time, continuous monitoring and adjustment of medication types and levels. This process is likely to work best if both patients and physicians have a role in managing the illness and medication regimens.

For certain diseases, such as cancer, which are both potentially life-threatening and widely prevalent, there are key treatment decision points which may occur only once and arise early on in the course of the disease which have major consequences for the patient. Women with early stage breast cancer, for example, may be faced with the decision to have a lumpectomy versus mastectomy, and, following surgery, whether to have adjuvant chemotherapy and/or radiation. These are decisions which cannot be delayed without potentially serious implications for the health of the patient. Here shared decision-making becomes particularly important to address in the medical encounter, first, because several treatment options exist with different possible outcomes, and substantial uncertainty. Second, there is often no clear-cut right or wrong answer. Third, treatments will vary in their impact on the patient’s physical and psychological well-being (Pierce, 1993). It is this latter type of treatment decision-making context which is our focus in this paper and we use early stage breast cancer as an example of a potentially life threatening disease.

We recognize that there are different types of treatment decision-making contexts (e.g. emergency treatment, long-term monitoring of medications in the treatment of chronic disorders such as hypertension, palliative care) and that different models of treatment decision-making may be more or less appropriate or feasible in specific contexts. To discuss issues of shared decision-making in all these would be an enormous task; hence, we choose the specific decision-making context as described above as our focus for this paper.

This focus is at the micro as opposed to the macro level of analysis where, clinically, there are several treatment options available and the choice of the best treatment for a particular patient requires value judgements on the part of the patient and physician. Our paper does not address macro level economic constraints, i.e. where policy makers have decided that for certain medical conditions, there will be a limited number of treatment options available through public or third party insurers. Also, we limit the discussion of decision-making at the micro level to competent patients.

MODELS OF TREATMENT DECISION-MAKING

Shared decision-making is only one among several treatment decision-making models discussed in the literature (Veatch, 1972; Thomasma, 1983; Emanuel and Emanuel, 1992; Levine et al., 1992; Roter and Hall, 1992; Mooney and Ryan, 1993; Deber, 1994). Prominent among these are the paternalistic model, the informed decision-making model and the professional-as-agent model. Analysis of the prototype depictions of each of these models reveals some overlap in specific characteristics of each. In addition, many of these characteristics, such as information sharing, involve gradations rather than absolutes. In this paper, we want to clarify the central elements of the latter 3 models as they are portrayed in the literature, and argue that each falls short of depicting a model of shared treatment decision-making. We then identify what we see as necessary components of a model of shared decision-making, in particular, the exchange of both information and treatment preferences by both physician and patient and agreement by both parties on the treatment to implement.

On first glance, it seems easiest to differentiate the paternalistic model from shared decision-making because the former explicitly assumes a passive role for the patient in the treatment decision-making process. An early formulation of this model was Parsons’ conceptualization of the sick role. Parsons argued that the sick role carried with it certain rights and obligations for patients (Parsons, 1951). Persons granted (by physicians) the (temporary) sick role status, for example, were excused from other role-related activities such as those of family and work, but they also had an obligation to try to get well, to seek expert help, and to comply with the medical regimen (Parsons, 1951). This model clearly placed the patient in a passive, dependent role vis-à-vis the physician as expert.
In more recent depictions of the paternalistic model, the physician is seen as dominating the medical encounter and using his skills to diagnose and recommend tests and treatments for the patient. In the extreme case, “the physician authoritatively informs the patient when the intervention will be initiated” (Emanuel and Emanuel, 1992). In the less extreme, the physician will give the patient selected information and will encourage the patient to consent to what the physician considers best (Emanuel and Emanuel, 1992). The role of physician depicted in this model is guardian of the patient’s best interest. The physician does what he thinks is best for the patient, without eliciting the latter’s preferences. Patient involvement (if there is any) is limited to providing consent to the treatment advocated by the physician (Emanuel and Emanuel, 1992).

Most would agree that this is not a model of shared decision-making in any sense. Efforts to formulate alternative treatment decision-making models have arisen, in part, in reaction to the perceived prevalence of the paternalistic approach (Levine et al., 1992; Deber, 1994) which is viewed by many as inappropriate for many current treatment decision-making contexts. The extent to which this approach is currently practised by physicians is an empirical question; in emergency situations, for example, it may still be widely accepted and might, in practice, be the only feasible model for the task.

Both the informed and the physician-as-agent decision-making models derive from a recognition of informational asymmetry between patient and physician (Levine et al., 1992). As Hurley et al. (1992) note: “The crux of the information problem is that while the health care provider possesses better knowledge regarding the expected effectiveness of health care in improving health status, the individual knows best how improvements in health status affect his or her well-being” (p. 4). Technical knowledge resides in one party to the interaction—the physician, while preferences reside in the other—the patient. Yet both types of information need to be combined if effective care that leads to health status improvements valued by patients is to be provided (Hurley et al., 1992; Levine et al., 1992). In the informed model this is accomplished by increasing the patient's knowledge of the possible risks of alternative therapeutic options and their clinical effectiveness, so that patients can make decisions that reflect both their preferences and the best scientific knowledge available (Hurley et al., 1992).

The informed decision-making model incorporates the idea of information sharing (primarily from physician to patient); but we would argue that information sharing does not necessarily lead to a sharing of the treatment decision-making process. In fact, since the informed patient has overcome the problem of information deficit, presumably she is now enabled to make the treatment decision on her own. Theoretically, in this model, an informed patient no longer needs to share the treatment decision-making process because she now possesses both components (information and preferences) viewed as essential to the task (Levine et al., 1992). In this model, treatment decision-making control is clearly seen to be vested in the patient (Eddy, 1990). The physician’s role is limited to that of information exchange, communicating the needed technical or scientific knowledge to the patient (Williams, 1988; Mooney and Ryan, 1993). As noted by Emanuel and Emanuel (1992), the physician “is proscribed from giving a treatment recommendation for fear of imposing his or her will on the patient and thereby competing for the decision-making control that has been given to the patient” (p. 2225). In other words, the physician’s treatment preferences for the patient do not enter into the decision-making process.

If the paternalistic model leaves the patient outside the decision-making process, the informed model leaves the physician outside by limiting the role of the physician to one of information transfer. In the extreme case, information transfer can be done without the presence of any health care worker, for example, by the patient viewing an interactive video. We argue that unless both patient and physician share treatment preferences, a shared treatment decision-making process did not occur, no matter how much information may have been exchanged by either party.

The informed model is premised on the assumption that information is an enabling strategy, “empowering” the patient to become a more autonomous decision maker. Research has shown, however, that while patients typically express high preferences for information about their illness and its treatment (Cassileth et al., 1980; Strull et al., 1984; Beisecker, 1988; Blanchard et al., 1988; Ende et al., 1989; Lerman et al., 1990; Beisecker and Beisecker, 1990; Waterworth and Luker, 1990; Silverstein et al., 1991; Biley, 1992; Deber, 1994), their preferences for participation in treatment decision-making are much more diversely distributed (Vertinsky et al., 1974; Strull et al., 1984; Pendleton and House, 1984; Ende et al., 1989; Beisecker and Beisecker, 1990; Silverstein et al., 1991; Degner and Sloan, 1992; Ryan, 1992; Hack et al., 1994). In other words, patients want information about their medical condition and treatment options without necessarily being responsible for making treatment decisions (Ende et al., 1989; Beisecker and Beisecker, 1990; Ryan, 1992).

An informed patient may prefer to make the decision herself (or be required to do so by the physician), to share the decision-making process, or to delegate this responsibility to the physician. In Scenario 1 in the Appendix, for example, the physician clearly wants the patient to make the treatment decision. The patient, while claiming to be...
well informed, nonetheless prefers that the physician decide. Many patients faced with a serious illness, substantial uncertainty as to the outcome, and a time pressure to make a treatment decision among several competing alternatives, feel extreme psychological and/or physiological vulnerability, which may make it difficult for them to participate in treatment decision-making no matter how well informed they may feel (Gray et al., 1990; Ryan, 1992). Also, as this scenario points out, before patients can decide whether or not to share in decision-making, they must be offered the choice of participation by their physician (a point also made in a recent article by Ong et al). Other patients may wish to participate but lack a systematic way of structuring the decision-making process. In this case, efforts to promote shared decision-making may well require interventions that not only provide patients with information but also with a way of thinking about treatment decision-making that helps them focus on key issues and evaluate relevant options.

One such intervention is the treatment decision aid, ranging in type from high cost interactive videos to low cost decision boards. Several decision boards have recently been developed and tested with women with breast cancer (Levine et al., 1992; Whelan et al., 1995). They provide the patient with detailed information about her treatment choices, outcomes, the probability of these outcomes and quality of life associated with each outcome. Treatment decision aids are a form of educational intervention. But they are also aids to treatment decision-making in that they provide a way of structuring the decision-making process, and breaking it down into a number of specific and sequential steps. As Llewellyn-Thomas (1995) notes: “A distinguishing feature of a decision aid is the inclusion of exercises designed to promote clarification of the patient’s values regarding what is at stake and what it is that he or she is trying to achieve as a result of treatment” (p. 104). Decision aids are intended to provide information and to promote “self help” in the treatment decision-making process which enables the patient to more actively participate in this process, if this is her preference.

It seems fair to say that physicians such as medical oncologists who develop, test and use treatment decision-making aids are those who are already motivated to share treatment decision-making, since a primary goal of the aids is to help elicit patients’ treatment preferences. Physicians adopting the paternalistic approach are unlikely to use such aids precisely because they can help overcome traditional professional dominance over interactions in the medical encounter (Freidson, 1970; West, 1984; Hill Beuf, 1989; Waitzkin, 1991). Whelan, for example, recently reported (1995) that 97% of women with breast cancer who were assigned to a group in which the physician used a treatment decision board with information about the risks and benefits of breast irradiation following lumpectomy felt that they were offered a treatment choice compared with 70% of women in the no decision board group. To return to our main point, however, an informed patient who perceives that she has choices may still prefer not to make the treatment decision.

The professional-as-agent model is the flip side of the informed patient model of treatment decision-making. Its goal is also to resolve the informational asymmetry between physician and patient. But here, “the professional-as-agent assumes responsibility for directing the health care utilization of the patient—...as an agent trying to choose what the patient would have chosen, had she been as well-informed as the professional” (Evans, 1984, p. 75). In other words, in this model, the physician makes the treatment decision, either assuming that he knows, or having elicited the patient’s preferences for future health states, lifestyle choices etc. Both components (information and preferences) then reside in the physician, rather than the patient, and the former becomes the sole decision-maker.* Legally physicians cannot implement a treatment without at least eliciting patient consent. In practice, there may still be some physicians who assume that they know the patient’s treatment preference, and act on this without first explicitly testing this assumption. Such cases are not likely to attain public visibility unless the patient subsequently launches a legal suit, claiming violation of patient rights to informed consent.

While there have been critiques of the physician-as-agent model (Evans, 1984; Mooney and Ryan, 1993), our interest is not to take sides in this debate. Rather we argue that this model is also not necessarily one of shared decision-making. In the purest form of this model, the physician makes the treatment decision as if he had the same preferences as the patient; decision-making is again portrayed as a one-sided process. By definition, in this model the physician’s treatment preferences do not count (are excluded). The only treatment preferences that matter are those of the patient.

In summary, several models of treatment decision-making have been developed, partially in reaction to the paternalistic model. A closer examination reveals that none of these explicitly describes a process in which both physicians and patients necessarily share in decision-making, no matter how much information they share. The notion that information sharing and treatment decision-making are

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*In the agency model, the physician is usually depicted as acting as the patient’s agent, but this is not always the case. Williams, for example, defines a perfect agency relationship as one in which the physician gives the patient all the information the patient needs and the patient then makes the decision (Williams, 1988). Hence, the agency and informed models are also confused in the literature.
two separate goals in the medical encounter is beginning to be recognized in the literature on doctor–patient communication (Ong et al., 1995). In the next section we argue that for shared treatment decision-making to occur, there needs to be a two-way exchange not only of information but also of treatment preferences.

**CHARACTERISTICS OF SHARED DECISION-MAKING**

In order to specify what falls or does not fall within the boundaries of shared decision-making, it is necessary to try to identify some of its key characteristics. Characteristics are signals of identification. The characteristics we identify can be thought of as minimum or necessary criteria for classifying a physician–patient decision-making interaction as shared decision-making, i.e. necessary but not always sufficient. There may well be other characteristics that are important that we have not included. It is also important to recognize that many of these characteristics are continuous rather than dichotomous variables in recognition of the fact that shared decision-making involves gradations rather than absolutes.

*Shared decision-making involves at least two participants—the physician and patient*

The first characteristic of shared treatment decision-making is that it involves at least two participants—a clinician, who in many cases will be a physician, and a patient. This seems self-evident: as noted above, if only one person makes the decision, the process is not shared.

Frequently treatment decision-making involves more than one patient and one physician (or other health care professional) in a single or sequential medical encounter. For example, research on physician and elderly patient medical encounters increasingly focuses on triad rather than dyad relationships in recognitions that many elderly patients bring a relative or friend to the physician’s office (Rosow, 1981; Coe and Prendergast, 1985; Adelman et al., 1987; Haug and Ory, 1987; Beisecker, 1988; Haug, 1994). Both conceptual and research interest has focused on the types of coalitions that can occur in such encounters.

What this literature highlights is that family members or friends can play a variety of different roles within (or outside) the medical encounter relating to the patient’s illness, treatment selection and management.

Roles which relate specifically to the treatment decision-making process can include, for example: (1) information gatherer, recorder or interpreter; (2) coach, e.g. prompting the patient to ask the physician certain questions; (3) advisor, e.g. advising the patient which treatment option to select; (4) negotiator, e.g. advocating on the patient’s behalf regarding the timing or place of treatment or the patient priority in receiving treatment; (5) caretaker, e.g. supporting and or reinforcing the patient’s treatment decision. The involvement of family members in treatment decision-making may be particularly important with serious illnesses because of the stress engendered by the diagnosis, the uncertain outcome, and the potentially major impact of the illness trajectory and treatment management on other family members. These issues have received little attention in the shared treatment decision-making literature which focuses almost exclusively on the dyad relationship of physician and patient in the medical encounter.

When patients bring a relative or friend to a physician visit, the range and complexity of the interactional dynamics is automatically increased. In addition, the introduction of a third person enables the formation of coalitions. Coalitions (e.g. between the physician versus the patient and family member) may occur over such things as how much and what type of information is given by the physician, what is the best treatment and how and when to implement it. Studies of triad interactions between elderly patients, a family member and the physician have revealed the formation of numerous (and different) coalitions over numerous (and different) issues in a single medical encounter. However, the frequency and pattern of coalition formation is likely to vary depending on the treatment decision-making context. The triad relationship of elderly patient, physician and family member discussing treatment options for the long-term management of a chronic illness is different from the situation of a post-surgery woman with breast cancer who needs to make an important treatment decision under tight time constraints. Here, we hypothesize that fewer coalitions will be likely to occur because all parties will be motivated to reach consensus quickly on the treatment to implement so as to afford the best chance of recovery.

Also not well recognized in the literature on shared treatment decision-making is the fact that several physicians often participate in this process with a single patient. A breast cancer patient, for example, may have a family physician, surgeon, radiation oncologist, and medical oncologist, all of whom may have specific treatment preferences for the patient. For example, the surgeon may suggest a post-surgery treatment to the patient which she then has in mind when subsequently visiting the medical or radiation oncologist. If the latter presents a different treatment option, the result may be increased uncertainty and confusion for the patient. One study of patients in a cardiology unit reported that, not infrequently, five or more physicians were “making treatment decisions” about the patient’s care (Lidz et al., 1985, p. 248).

These examples suggest that limiting the conceptualization of shared decision-making to a physician–patient dyad may not, in many cases, reflect the current realities of clinical practice, where other
participants may well be involved. It misses altogether the important role that the patient's friends or family may play and the case of incompetent or seriously ill patients who require third parties to act on their behalf. There is almost no discussion in the shared decision-making literature on the implications of these situations for conceptualization and measurement of shared decision-making. Hence, we emphasize that a shared decision-making process requires at least two participants (i.e., it takes two to tango) but may often involve more than two.

Both parties (physicians and patients) take steps to participate in the process of treatment decision-making

Much attention has been focused on exploring patient preferences for participation in treatment decision-making. Over the years, several scales have been developed, with preferences for participation often conceptualized as a single continuum of the amount of participation the patient prefers (e.g., from none, to shared participation, to complete patient control or autonomy (Strull et al., 1984; Beisecker, 1988; Brody et al., 1989; Ende et al., 1989; Beisecker and Beisecker, 1990)). The terms control and autonomy are usually not defined; nor is the term participation. To some, (Strull et al., 1984) participation seems to incorporate the idea of sharing on an equal basis, but the specifics of what this really means in terms of input by both physician and patient is left unclear. Presumably, the complete patient control end of the continuum corresponds to the pure type informed model where the patient is the sole decision-maker. An implicit assumption behind much of this research seems to be that if patients express preferences, they will act in accordance with these preferences. Preferences become a proxy for behavioural intent, predictive of future behaviour.

Empirical research suggests that the link between patient preferences for participation in treatment decision-making and actual participation is not that strong. Patient preferences for information do not necessarily translate into information seeking behaviour; nor do patients who express preferences for some form of shared decision-making necessarily act on these in the medical encounter (Haug and Lavin, 1983; Beisecker, 1988; Beisecker and Beisecker, 1990; Ryan, 1992). Patient preferences for shared decision-making do not seem sufficient to make it happen in reality.*

If the majority of patients say that they have a preference for information about their illness and potential treatment options, while a much smaller number express preferences to participate in treatment decision-making, this raises some interesting questions. First, why do patients want information if it is not to be used by them instrumentally to help them make a treatment decision? We discuss this issue in the next section. Second, why do patients say that they do not want to participate in treatment decision-making and what does this preference really mean? We think that the latter is an under researched area and one that deserves much more attention because there are a variety of different possible explanations which have different implications for determining when a shared treatment decision-making process is appropriate.

First, a stated preference (e.g. a patient's stated preference not to participate in treatment decision-making) may reflect an underlying and salient personality characteristic. In this case, introducing a decision aid to help the patient structure the treatment decision-making process is unlikely to have the desired effect, because the patient simply is not motivated to take an active role in the process and prefers that the physician decide.

For other individuals, a stated preference not to participate in treatment decision-making may reflect a situationally specific response. For example, a woman faced with the diagnosis of early stage breast cancer may not want to take an active role in treatment decision-making because of perceived information or skill deficits. Here, an intervention such as a decision aid can provide information and help the patient structure the decision-making process. The intervention could, in fact, help to promote a more active treatment role preference by the patient.

In still other instances patients may express a preference for a passive role in treatment decision-making because they have learned through previous interactions that a more active stance is not well received by providers. For shared decision-making to occur, there needs to be complementary role expectations and behaviour between physician and patient around this issue. No matter how much the patient wants to participate, if the physician is not willing, then shared decision-making will not occur. Similarly, if the physician is willing but the patient is not, then the process will not be shared. It is in this sense that we emphasize that "it takes at least two to tango".

Finally, preferences for a passive role in treatment decision-making may reflect, in some instances, a cohort effect. For example, research suggests that elderly patients often prefer a more passive role in treatment decision-making than younger patients (Coe and Prendergast, 1985; Haug, 1994). This is

*Alternatively, it is possible that some patients preferring an autonomous decision-making role are constrained to share the process with their physician. In our culture, physicians have the authority to act as gatekeepers to health care. They control medical knowledge, technology, access to treatment and even norms of behaviour in the medical encounter (Ryan, 1992). At a minimum, the patient needs the physician's consent to her treatment choice in order to obtain most services.
likely to change over time as the generation of baby boomers with higher education levels and higher expectations encounter the health care system.

In summary, the patient preferences literature provides only a partial answer to the question of what role patients want to play in treatment decision-making because it fails to consider that preferences may be situationally determined, and hence, subject to change. Moreover, by limiting the conceptualization and measurement of preferences to only the patient side of the equation, it misses the important interactional dynamic with the physician which is crucial to making shared decision-making happen in reality*. By and large, physicians set the norms of interaction in the medical encounter. If the physician is not motivated to share decision-making, the patient cannot force this to happen. Her only option is to seek out another physician whose expectations about how the decision-making process should occur is similar to hers.

If preferences are not enough, then what steps do physicians and patients need to take in order to share in the treatment decision-making process? We suggest that for the physician it means first, establishing a conducive atmosphere so that the patient feels that her views about various treatment options are valued and needed (Brody, 1980). Second, it means eliciting patient preferences so that treatment options discussed are compatible with the patient’s lifestyle and values. Third, it means transferring technical information to the patient on treatment options, risks and their probable benefits in an unbiased, clear and simple a way as is possible. Fourth, physician participation would also include helping the patient conceptualize the weighing process of risks versus benefits, and asking patients questions in order to ensure that the causal assumptions (information) underlying their treatment preferences are based on fact and not misconception.

Finally, shared decision-making would also involve the physician in sharing his treatment recommendation with the patient, and/or affirming the patient’s treatment preference. The physician would need to be careful, however, not to impose his values about the best treatment onto the patient.

There may always be a danger in a shared decision-making process that the physician’s values will influence the patient, even if this is not his intent. Many patients have been socialized to think that the physician knows best, that they lack the expertise to make the treatment decision, and a trusting relationship with the physician means trusting his judgement about the most appropriate treatment, or that agreeing with the physician will result in better or more personal care.

For the patient, shared decision-making means that she must be willing to engage in the decision-making process, that is, to take responsibility for disclosing preferences, asking questions, weighing and evaluating treatment alternatives and formulating a treatment preference. This is a problem solving task that goes beyond information transfer. Scenario 2 in the Appendix depicts such a shared decision-making process. Both patient and physician discuss and evaluate treatment options and together they build a consensus. We suggest that the test of a shared decision-making process is if both parties adopt the complementary roles outlined above, and if both parties are satisfied with their level of involvement.

*This research does, however, demonstrate heterogeneity in patient preferences for participation in treatment decision-making. This in turn suggests that any attempt to define a single normative model of treatment decision-making which both physicians and patients "ought" to follow might not fit with empirical reality.

Information sharing is a prerequisite to shared decision-making

In the typical case, information sharing is a prerequisite for shared decision-making. At minimum, the physician needs to lay out treatment alternatives and their potential consequences for the patient in order to obtain informed consent. Without such information, there might be nothing for the patient to evaluate and deliberate about. As noted earlier, patients may also bring information obtained through other means to the encounter. Both patients and physicians bring both information and values; it is not simply a question of physicians bringing knowledge and patients bringing values.

As a practical problem, it is often not clear what type and amount of information patients want from physicians, or why they want it. Patients may want more information than physicians think is needed instrumentally to help distinguish the pros and cons of various treatment options. Similarly, the types of information physicians desire from patients is not always clear. Is it the patient’s full illness narrative or only those elements of the patient’s story that the physician thinks relevant to suggesting treatment options?

The physician’s primary professional obligation is to apply expertise in the treatment of patients. Time constraints, the potentially rapid course of many diseases, and financial incentives all operate to encourage physicians to complete the decision-making process as quickly as possible. In this situation it is likely that patient information is sought by the physician primarily for its instrumental use in identifying treatment options that are compatible with patient values.

The value of information about treatment alternatives, and their risks and benefits for the patient, is less well understood (Haug and Lavin, 1981; Beisecker and Beisecker, 1990; Ryan, 1992). As noted earlier, studies indicate that many patients have high preferences for information about their
illness and its management but do not engage in information seeking behaviours or in treatment decision-making. The value of information, from the patient’s perspective, does not appear to lie (or lie solely) in its potential use as an aid to decision-making. More important may be the psychological reassurance or reduced uncertainty which information is thought to provide at a time of great stress and vulnerability (Mooney and Ryan, 1993). More research is needed in order to more completely understand the value of information from the patient’s perspective.

Research evidence also suggests that when physicians infer patient preferences for information and for participation in treatment decision-making, they often fail to get them right (Strull et al., 1984; Waitzkin, 1984; Ryan, 1992). If the medical interaction is to reflect patient role preferences, these need to be made explicit by the patient either on her own initiative or elicited by the physician as part of the information exchange.

A treatment decision is made and both parties agree to the decision

Shared decision-making is usually depicted, either implicitly or explicitly as a type of decision-making process. But shared treatment decision-making can also refer to an outcome, i.e. a shared or agreed upon decision. The shared process relates to the roles that patients and physicians play and involves complementary role expectations and behaviour. Agreement between physician and patient about the treatment decision is one possible outcome of this process; others include no decision or disagreement as to the preferred treatment. In Scenario 3, for example, both the physician and the patient reveal their preferences about treatment but they cannot reach an agreement.

The test of a shared decision (as distinct from the decision-making process) is if both parties agree on the treatment option. This does not mean that both parties are necessarily convinced that this is the best possible treatment for this patient, but rather that both endorse it as the treatment to implement. The physician may feel, for example, that the patient would really be better off with another treatment but agrees to endorse the patient’s choice as part of a negotiated agreement in which the patient’s views count. Through mutual acceptance, both parties share responsibility for the final decision.

This is an important characteristic and helps to distinguish shared decision-making from other models of decision-making. In the extreme case of the paternalistic and informed models, decision-making and ultimate responsibility for the decision are clearly vested with the physician or the patient respectively, and whether the opposite party accepts the decision is not relevant. Mutual acceptance may or may not occur with other models of decision-making (paternalistic and informed) but it remains a necessary prerequisite for shared decision-making.

However, mutual acceptance does not always indicate a shared decision-making process. A paternalistic process of decision-making, for example, can result in a shared decision. How do we know when mutual agreement on the decision to implement is reached? An explicit and verbal acknowledgement provides one potential indication and can be ascertained through observation. Sometimes, the agreement may be implicit, and signified by a behavioural intent by the patient to return for treatment or by the physician to book a future treatment appointment. A verbal agreement at one point in time may not hold over time. In Scenario 4 in the Appendix, it appears that an agreement has been reached at the end of the medical encounter but, subsequently, the patient changed her mind and did not return for treatment.

SOME MEASUREMENT ISSUES

If there is confusion about what shared treatment decision-making means conceptually, then there is bound to be difficulty in measuring it empirically because of disagreement over what one is looking for as defining characteristics. We have described our ideas about this above. Even so, major methodological issues remain. For example some of the defining characteristics of a shared decision-making model overlap with those of other models and some characteristics may be present in varying degrees. Both these conditions make it difficult to establish clear boundaries or thresholds of what is inside versus outside the shared treatment decision-making box. This is particularly true for the measurement of a patient’s level of participation in treatment decision-making. For example, if a patient simply agrees to a treatment decision suggested by the physician, does this mean she participated in the treatment process? We do not think so, but the issue still remains, to what extent does the patient need to reveal and discuss treatment preferences in order for her interaction to be defined as one of shared decision-making? Also, a given medical encounter may start as one model of interaction, but evolve into something else as the encounter unfolds. This may make it difficult to precisely classify any given medical encounter as falling within one model or another.

Empirically measuring if and how patients deliberate over treatment choices and the process they use to arrive at a decision is no easy task. Observation techniques are frequently used to measure physician–patient communication more generally, using different interaction analysis systems. Many of these have been recently summarized in an article by Ong et al. (1995). These systems are
designed to identify and quantify salient features of physician–patient communication. Observation methods alone, however, have some limitations when it comes to measuring decision-making processes that occur “in the patient’s head” and may not be made explicit either through verbal or non-verbal behaviour. From what we observe, we would need to make attributions about the patient’s intentions and internal decision-making processes. For example, in Scenario 1, is the patient’s question to the physician a form of information gathering so that she can better evaluate treatment options or is she trying to get the physician to make the decision for her? Does her ultimate agreement with the physician’s recommendation reflect a thoughtful consideration of the alternatives, deference to physician authority, or reluctance to engage in the decision-making process? The same observation could yield several different stories or interpretations.

Similarly, structured questionnaires that have used a Likert type scale to measure patient preferences for actual participation in treatment decision-making in previous studies also have limitations. They simplify and structure the measurement process to such a degree that little information is gleaned about the dynamics of shared decision-making or the interactional process involved. Moreover, as noted earlier, it is often not clear how to interpret different preferences.

We think that an important area for future research is a more in-depth exploration of why patients hold different treatment preferences, and what meanings patients ascribe to these preferences. Qualitative methods such as illness narratives or semi-structured interviews seem well suited to this task for several reasons. First, they allow for an in-depth exploration and, hopefully, increased understanding of a complex process: how patients think about decision-making in general and treatment decision-making in particular. Second, they allow more freedom for the patient to structure the discourse of the interview so that the information captured reflects patients’ perspectives rather than researchers’ preconceived measurement categories. Third, with qualitative interviews it is also possible to pay much more attention to social, cultural and illness contexts which may influence patients’ views about appropriate roles in treatment decision-making. Such interviews may also be used to generate information about what patients perceive are barriers to shared decision-making and the kinds of interventions they suggest (if any) that would help them to adopt a more active treatment decision-making role.

In making the above recommendation we do not mean to suggest that qualitative methods are the only appropriate ones for studying issues related to shared decision-making. For many issues, a combination of qualitative and quantitative methods may well be appropriate. The particular methods adopted should be those most useful in generating the best information about the specific question of interest.

CONCLUSION

Because shared decision-making is increasingly advocated as an ideal treatment decision-making process, one might be tempted to try to identify explicit behaviours prescribing how to engage in this process. The ability to define specific behaviours holds appeal because it would provide a form of instructional guide, but we think it is also problematic. There is no single route to shared decision-making; some of the characteristics we describe can be met by a variety of different behaviours. Also, the physician–patient relationship is a personal, and often trusting relationship. To develop a standardized checklist of concrete and invariant steps for shared decision-making would not fit this decision-making context where the preferences of both physicians and patients can vary widely and change over time. While a checklist approach may resonate with many physicians in terms of a clinical framework of decision-making (Sackett et al., 1985), it may not resonate with patients’ models of decision-making or constructions of their illness experience. Finally, shared decision-making is in some sense a matter of perception. Similar objective states of shared decision-making (if these could be defined) might well be both perceived and valued differently by different patients.

Perhaps more important than prescribing specific behaviours would be to agree on certain fundamental principles around treatment decision-making—for example, that patients’ preferences for participation be elicited and acknowledged, that patients be given choices as to how the decision-making process will proceed, and that their choices be respected and adhered to in the physician’s behaviour.

Herein lies one of the benefits of a shared decision-making approach. It offers a potential middle choice of treatment decision-making models between two polar extremes. On the one hand, the paternalistic model is characterized by physician dominance of the decision-making process. On the other hand, the informed decision-making model seems to limit the role of the physician to one of transferring information, enhancing the patient’s ability to engage in autonomous decision-making with ultimate control but also responsibility for the treatment choice. Empirical research demonstrates that many patients, for whatever reasons, prefer not to assume full decision-making control. But many may also not like the idea of no say at all. Shared decision-making offers an intermediate alternative for both physician and patient. For the patient it offers some say without total responsibility, and for the physician, an opportunity to go beyond a role
of transferring information to also participate in, but not dominate, the decision-making process.

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REFERENCES


ments for disclosure of breast cancer treatment alternatives. Journal of the National Cancer Institute 86, 1202.

APPENDIX

A patient with newly-diagnosed early breast cancer comes to see her oncologist. The physician reaffirms the diagnosis and discusses with the patient her concerns. The physician outlines the various treatment options, the pros and cons of each, and asks the patient about her preferences for treatment, given her lifestyle and values. The patient responds that she feels knowledgeable about the disease and the pros and cons of various treatment options but can’t decide; she would prefer that the physician make the decision. The physician responds that the patient is in the worst position to judge because this decision involves placing a value on various treatment outcomes and weighing the benefits versus the risks of each option. The physician tells the patient to think it over and come back in another week with the decision. The patient comes back but still has not made a decision. Finally, the patient says: what would you do, if it was your wife? The physician says: if it was my wife, I would choose option A, but my preferences may well be different from yours. The patient replies: I will go with option A. (Scenario 1)

A patient with newly diagnosed early breast cancer comes to see her oncologist. The physician reaffirms the diagnosis and discusses with the patient her concerns. The physician outlines the various treatment options, the pros and cons of each, and asks the patient about her preference for treatment, given her lifestyle and values. The patient responds that she feels knowledgeable about the disease and the pros and cons of various treatment options. After discussing these issues at length, the patient says that she prefers option A. The physician reminds her: do you understand that with option A, as I mentioned earlier, there are a number of side effects, e.g. you will feel sick for several months. The patient responds that she understands and still prefers option A, for reasons which she reiterates. The physician agrees and says: I think that is a good choice for you. (Scenario 2)

A patient with newly diagnosed early breast cancer comes to see her oncologist. The physician reaffirms the diagnosis and discusses with the patient her concerns. The physician outlines the various treatment options, the pros and cons of each, and asks the patient about her preferences for treatment, given her lifestyle and values. The patient responds that she feels knowledgeable about the disease and the pros and cons of various treatment options. She indicates that she wants to try a new experimental treatment (A) that she has read about in a magazine. The physician responds that she does not think that this is an appropriate treatment option because its effectiveness has not been proven. The patient says that she still prefers treatment A. The physician again tries to dissuade the patient from this decision and says he cannot provide this treatment. The patient says then I will have to go elsewhere, and she leaves the physician’s office. (Scenario 3)
outlines the various treatment options, the pros and cons of each, and asks the patient which one she prefers, given her lifestyle and values. The patient responds that she feels knowledgeable about the disease and the pros and cons of various treatment options but she wants the physician to decide. The physician responds that the patient is in the best position to judge because this decision involves placing a value on various treatment outcomes and weighing the benefits versus the risks of each. The patient says, in that case, I will go with treatment A. The physician sets up the follow-up treatment visit. The patient does not return for the treatment. The physician later discovers that the patient has instead gone to another physician. (Scenario 4)
Decision-making in the physician–patient encounter: revisiting the shared treatment decision-making model

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Abstract

In this paper we revisit and add elements to our earlier conceptual framework on shared treatment decision-making within the context of different decision-making approaches in the medical encounter (Charles, C., Gafni, A., Whelan, T., 1997. Shared decision-making in the medical encounter: what does it mean? (or, it takes at least two to tango). Social Science & Medicine 44, 681–692.). This revised framework (1) explicitly identifies different analytic steps in the treatment decision-making process; (2) provides a dynamic view of treatment decision-making by recognizing that the approach adopted at the outset of a medical encounter may change as the interaction evolves; (3) identifies decision-making approaches which lie between the three predominant models (paternalistic, shared and informed) and (4) has practical applications for clinical practice, research and medical education. Rather than advocating a particular approach, we emphasize the importance of flexibility in the way that physicians structure the decision-making process so that individual differences in patient preferences can be respected. © 1999 Elsevier Science Ltd. All rights reserved.

Keywords: Treatment decision-making; Doctor–patient relationship; Communication; Breast cancer

Introduction

Although shared treatment decision-making is a concept that has gained widespread appeal to both physicians and patients in recent years, there is still confusion about what the concept means. To help clarify this issue, we published a paper which tried to define shared treatment decision-making and its key characteristics and to show how this interactional model differs from other commonly cited approaches to treatment decision-making such as the paternalistic
and the informed models (Charles et al., 1997a). The paternalistic model is by now well known and articulated (Emanuel and Emanuel, 1992; Levine et al., 1992; Beisecker and Beisecker, 1993; Deber, 1994; Coulter, 1997). Hence, we concentrated on exploring the differences between the informed and the shared models because these two labels have often been used interchangeably to describe quite different types of interaction between physician and patient in treatment decision-making.

The context for our discussion was a life threatening disease where several treatment options were available with different possible outcomes (benefits and risks or side effects), outcomes could vary in their impact on the patient’s physical and psychological well-being and outcomes in the individual case were uncertain. In this context, we argued that a shared treatment decision-making model could be identified as such by reference to four necessary characteristics (Charles et al., 1997a) as follows:

1. At a minimum, both the physician and patient are involved in the treatment decision-making process.
2. Both the physician and patient share information with each other.
3. Both the physician and the patient take steps to participate in the decision-making process by expressing treatment preferences.
4. A treatment decision is made and both the physician and patient agree on the treatment to implement.

In this paper we revisit and add elements to our conceptual framework based on further analytic thinking and our current research on the meaning of shared decision-making to women with early stage breast cancer and to physicians who specialize in this area (Charles et al., 1998). Our revised framework (1) identifies different analytic stages in the treatment decision-making process; (2) provides a dynamic view of treatment decision-making by recognizing that the approach adopted at the outset of any given physician–patient encounter may change during the course of that encounter; (3) identifies different approaches that lie in between the three predominant treatment decision-making models and (4) has practical applications for clinical practice, research and medical education. Before exploring these issues, we briefly review factors that have led to the development of new treatment decision-making models as alternatives to the traditional paternalistic approach.

The rise and fall of paternalism

Prior to the 1980s, the most prevalent approach to treatment decision-making in North America was paternalistic with physicians assuming the dominant role. Underlying this deference to professional authority were a number of assumptions. First, that for most illnesses, a single best treatment existed and that physicians generally would be well versed in the most current and valid clinical thinking. Second, physicians would not only know the best treatments available, they would consistently apply this information when selecting treatments for their own patients. Third, because of their expertise and experience, physicians were in the best position to evaluate tradeoffs between different treatments and to make the treatment decision. Fourth, because of their professional concern for the welfare of their patients, physicians had a legitimate investment in each treatment decision. This legitimation of physician control was further buttressed by professional codes of ethics which bound physicians to act in the best interests of their patients (Lomas and Contandriopoulous, 1994; Charles et al., 1997b). All of these assumptions led both physicians and patients to expect a dominant role for physicians in treatment decision-making. Status differences between physicians and patients in terms of education, income and gender also contributed to power differentials in the medical encounter.

During the 1980s and beyond, the credibility of the above assumptions began to be questioned. For an increasing number of illnesses, for example, there was no one best treatment and a more murky and complex...
decisional context evolved where different treatments had different types of tradeoffs between benefits and risks. Since the patient rather than the physician would have to live with the consequences of these tradeoffs, the assumption that physicians were in the best position to evaluate and weigh these was increasingly challenged (Eddy, 1990; Levine et al., 1992; Lomas and Lavis, 1996). At the same time, research into the quality of medical care began to focus on the effectiveness and appropriateness of a wide range of services delivered by physicians (Roos, 1984; Chassin et al., 1986, 1987b; Roos et al., 1988; Berwick, 1989; Lomas, 1990; Wennberg, 1990). The research on small area variations, for example, found consistent evidence that physician procedures for the same disease often varied considerably across small geographic areas and that these variations did not seem to be related to differences in the health status of the respective populations (Roos, 1984; Chassin et al., 1986, 1987a; Wennberg et al., 1987; Roos et al., 1988; Leape et al., 1993; Iscoe et al., 1994). Variations in treatment patterns were also found for diseases for which clinical guidelines had been developed on best practices (Lomas et al., 1989). Patient preferences may have accounted for some of this variation, but the data also suggested that either some physicians were unaware of recommended best practices for the treatment of particular diseases or that they were aware, but were not implementing the recommended guidelines.

Concern with rising health care costs in both Canada and the United States was another health policy issue focusing attention on the medical profession (Katz et al., 1998). The joining together of cost and quality concerns resulted in recommendations to make physicians more explicitly accountable to patients, the public, and in the case of the United States, to third party payers. In addition, the twin principles of caveat emptor (let the buyer beware) and consumer sovereignty gained popularity (Haug and Lavin, 1981, 1983; Charles and DeMaio, 1993), as manifested in new legislation precluding treatment implementation without informed consent and in legislation safeguarding the rights of patients to be informed about all available treatment options (Nayfield et al., 1994; Ontario Ministry of Health, 1994). These two principles were also evident in the emergent interest among both patients and physicians in developing and advocating new approaches to treatment decision-making which would incorporate a larger role for patients in the decision-making process (Brody, 1980; Quill, 1983; Thomasma, 1983; Eddy, 1990; Hughes and Larson, 1991; Emanuel and Emanuel, 1992; Ryan, 1992; Deber, 1994; Llewelyn-Thomas, 1995; Cahill, 1996; Quill and Brody, 1996; Charles et al., 1997a; Coulter, 1997; Gafni et al., 1998).

Table 1

<table>
<thead>
<tr>
<th>Models of treatment decision making</th>
<th>Analytical stages</th>
<th>Information exchange</th>
<th>Flow</th>
<th>Direction</th>
<th>Type</th>
<th>Amount</th>
<th>Deliberation</th>
<th>Deciding on treatment to implement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paternalistic</td>
<td>One way (largely)</td>
<td>Physician → patient</td>
<td>Medical</td>
<td>One way (largely)</td>
<td>Physician → patient</td>
<td>Minimum legally required</td>
<td>Physician alone or with other physicians</td>
<td>Physicians</td>
</tr>
<tr>
<td>Shared (in between approaches)</td>
<td>Two way</td>
<td>Physician → patient</td>
<td>Medical and personal</td>
<td>Two way</td>
<td>Physician → patient</td>
<td>All relevant for decision-making</td>
<td>Physician and patient</td>
<td>Physician and patient</td>
</tr>
<tr>
<td>Informed (in between approaches)</td>
<td>One way (largely)</td>
<td>Patient</td>
<td>Medical</td>
<td>All relevant for decision-making</td>
<td>Patient</td>
<td>All relevant for decision-making</td>
<td>Patient</td>
<td>Patient</td>
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* Illustration for an encounter focusing on the case of a (treating) physician-patient dyad. For more complex cases see text.
Models of treatment decision-making

Both the informed and the shared models of treatment decision-making were developed largely in reaction to the paternalistic model and to compensate for alleged flaws in the latter approach. These three models are the most prominent and widely discussed in the treatment decision-making literature. Key characteristics of each model and how they differ from one another are summarized in Table 1. In Table 1 treatment decision-making is subdivided into three analytically distinct stages, even though, in reality, these may occur together or in an iterative process. The steps are: information exchange, deliberation about treatment options and deciding on the treatment to implement. The latter is the outcome of the deliberation implement.

Information exchange

Information exchange refers to the type and amount of information exchanged between physician and patient and whether information flow is one or two way. Types of information that the physician might communicate to the patient include: the natural history of the disease, the benefits and risks (side effects) of various treatment alternatives, a description of the treatment procedure(s) to be used and community resources and information that the patient could access about her disease. These are primarily technical types of knowledge which most patients will not have. Information that the patient might reveal to the physician include: aspects of the patient’s health history, her lifestyle, her social context (e.g. work and family responsibilities and relationships), her beliefs and fears about her disease and her knowledge of various treatment options obtained from lay networks and/or other information sources. Except for the latter, these are primarily types of self-knowledge that the patient brings to the encounter and that the physician typically has no way of knowing except through direct communication with the patient in this or in prior consultations. In addition, at the outset of the encounter, either the physician, the patient, or both may exchange preferences regarding their own and each other’s role in the decision-making process. The goal of this exchange is to make explicit how each expects the decision-making process to proceed. The flow of information exchange may be one way or two way. In the paternalistic model, the exchange is largely one way and the direction is from physician to patient. At a minimum, the physician must provide the patient with legally required information on treatment options and obtain informed consent to the treatment recommended. Beyond this, the patient as depicted in this model is a passive recipient of whatever amount and type of information the physician chooses to reveal. In some cases, the physician may ask the patient about specific issues such as pain tolerance or allergies that could affect the latter’s reaction to the treatment selected by the physician. In general, this model assumes that the physician knows best and will make the best treatment decision for the patient. In addition, information exchange from patient to physician is not seen as a major prerequisite to completing this task.

In a shared decision-making model, the information exchange is two way (Charles et al., 1997a). At a minimum, the physician must inform the patient of all information that is relevant to making the decision, i.e. information about available treatment options, the benefits and risks of each and potential effects on the patient’s psychological and social well being. The patient needs to provide information to the physician on issues raised above, e.g. her values, preferences, lifestyle, beliefs and knowledge about her illness and its treatment. The first type of information exchange ensures that all relevant treatment options are on the table; the second ensures that both the physician and patient evaluate these within the context of the patient’s specific situation and needs rather than as a standard menu of options whose impact and outcomes are assumed to be similar for clinically similar patients.

In the informed model, information exchange is one way, from physician to patient. This exchange is the very crux of the model, defining the boundaries of the physician’s clinical role in decision-making. The physician in this model is assumed to be the primary source of information to the patient on medical/scientific issues about the patient’s disease and treatment options. To fulfill this role, the physician, at a minimum, needs to give the patient all relevant information from the highest quality research evidence on the benefits and risks of various treatments so that she will be enabled to make an informed decision. Beyond information transfer, the physician has no further role in the decision-making process. The remaining tasks of deliberation and decision-making are the patient’s alone. Eddy (1990, p. 442) describes the rationale for restricting physician involvement in these latter two steps as follows:

…the people whose preferences count are the patients, because they are the ones who will have to live (or die) with the outcomes. …Ideally, you and I are not even in the picture. What matters is what Mrs. Smith thinks…. It is also quite possible that Mrs. Smith’s preferences will differ from Mrs. Brown’s preferences. If so, both are correct, because ‘correct’ is defined separately for each woman. Assuming that both women are accurately informed regarding the outcomes, neither should be persuaded to change her mind.
Not only the direction of information exchange but also the amount of information exchanged can vary across decision-making models. So far, we have focused on minimum amounts for each model but have not specified outer boundaries. The amount of information that the physician could convey to the patient, for example, is, theoretically, infinite. The physician could provide detailed information on issues like the biology of the disease or detailed aspects of the molecular basis for the disease. However, in practice, the amount of information exchanged will be influenced by time and money constraints, both of which raise issues of equity and costs. Time spent by physicians with a given patient, for example, depletes the time available to them for other needy patients in their practice. This issue seems particularly salient to a shared decision-making approach. Because the information exchange is two way rather than one way, as are processes of deliberation and decision-making, this approach is likely to take more time than either the paternalistic or informed approaches, each of which requires less interaction and consensus building.

Given the importance of information transfer from physician to patient in both the shared and informed models, it is not surprising that various sorts of decision-aids have been and are being developed to help physicians communicate treatment information to patients and to present the information in a standardized way (Llewellyn-Thomas, 1995). These aids range from high technology interactive videos (Barry et al., 1995; Deber, 1996; Flood et al., 1996; Liao et al., 1996) to low technology flip charts with audio tapes (O'Connor et al., 1994). Decision boards are another form of communication aid that lie between the high and low technology options (Levine et al., 1992; Sebbar et al., 1995; Whelan et al., 1995; Elit et al., 1996). Each of these types of decision aids has been developed, for the most part, in isolation from one another and by different research teams. Although each type has its own supporters and advocates, to our knowledge, few, if any, empirical studies have been undertaken that compare the different decision aids in terms of criteria such as effectiveness, efficiency and patient satisfaction (Entwistle et al., 1998). In addition, one important role for decision-aids has received little attention. This is their potential for relationship building between the physician and patient. Exchanging information is a process which enables the physician and patient to get to know each other and to determine how well they can work together. This issue is particularly important for the patient. Through the process of information exchange, the patient has the opportunity to assess the extent to which the physician’s practice style, attitudes and behaviour will match her own expectations of and preferences for how she wants the physician to interact with her.

Building trust is one part of this process but does not capture all the important ingredients of the relationship.

In our current study of women with early stage breast cancer, for example, we found that women stressed the importance not only of finding a physician they could trust, but also one who would treat them as individuals. Patients’ assessments of these physician attributes rested, in large part, on their perceptions of the physician’s ability and willingness to contextualize the decision-making process by framing the discussion in terms of each patient’s unique background, characteristics and life experience (Charles et al., 1999).

Decision aids used within the context of the physician–patient relationship provide another piece of information for patients to use in assessing their level of compatibility and comfort with a given physician’s practice style. Some decision aids, however, can be self-administered and used outside the context of the physician/patient interaction. What effect, if any, information tools that are self-administered might have on a patient’s relationship with her physician is an issue requiring further study.

Decision aids which present scientific information to patients about treatment benefits and risks are developed to create more informed patients and to encourage evidence-based decision-making. This approach assumes that if only physicians knew how to transfer scientific information to patients in an accurate and unbiased way, the latter could be filled up (like an empty glass) with new knowledge and thereby transformed into informed and willing decision-makers. However, patients are not empty vessels. They come to the medical encounter with their own beliefs, values, fears, illness experiences and, increasingly, information about various treatment options. Moreover, patients are not so much interested in average outcomes for aggregate groups of patients as they are in knowing what this information means for themselves specifically. Patients interpret information on average treatment outcomes in order to make them personally meaningful within the decision-making context they face (Adelsård and Sachs, 1996; Turney, 1996; Charles et al., 1998). In so doing, their own values and beliefs act as filters in processing what information is allowed in and how it is understood (Williams and Calnan, 1996). In this interpretive process, the intended message to the patient may be lost, altered or transformed (Parsons and Atkinson, 1992; Whelan et al., 1995; Charles et al., 1998). Research into decision aids and other communication mechanisms that focus only on defining the specific message to be conveyed and the most appropriate means of doing so, fail to consider patient factors that might also affect how information is processed and understood. This latter type of data would be useful to clinicians who want to be part of
the deliberation process, to better understand their patients and to recognize potential differences between lay and medical world views (Mishler, 1984).

Deliberation

The deliberation stage of decision-making refers to the process of expressing and discussing treatment preferences. The minimum requirement for who is involved in this process varies across decision-making models. In the paternalistic approach, the treating physician weighs the benefits and risks of each option alone or in consultation with other physicians. The treating physician dominates the deliberation process while the patient passively listens. Physician dominance is justified by clinical judgement and experience. The label paternalistic is an apt term for this model because it evokes the image of a parent–child relationship where the authority figure (physician) has the right to decide what is best for the child (patient), even if the child disagrees (Parsons, 1951).

The treating physician may verbally communicate to the patient only the ultimate treatment decision, failing to reveal knowledge and values considered in the selection process and how these were weighted. Decision-making in this context can be completed fairly quickly if the physician feels well informed to make the decision and unrestrained by the need to have patient input into this process. Of course, the lack of patient input is precisely the reason why this model is viewed by many as undesirable.

The defining characteristic of deliberation in the shared decision-making model is its interactional nature (Charles et al., 1997a). This is both its major strength and weakness. The emphasis on interaction ensures patient input into the process; but it also makes the process more cumbersome and time consuming. Both physician and patient are assumed to have a legitimate investment in the treatment decision, the patient because her health is at stake and the physician out of concern for the patient’s welfare.

For a shared model to work, both physicians and patients have to perceive that there are treatment choices. Otherwise, there is nothing to decide (Charles et al., 1998). Patients typically face one of two alternative treatment decisional contexts. The first is a choice between two different treatments; the second is a choice between doing nothing (e.g. watchful waiting) and doing something (e.g. implementing a specific intervention such as radiation). In an earlier study, we found that women with early stage breast cancer attending a regional cancer centre for consultation re: adjuvant therapy did not perceive the latter situation as one of choice. Many women felt they had no choice but to accept the treatment offered so that they could reassure themselves that they had done everything possible to fight the disease and to alleviate the possibility of post-decision regret should the disease return. As one woman said: “Doing nothing is no choice” (Charles et al., 1998).

In a shared approach, each person needs to be willing to engage in the decision-making process by expressing treatment preferences, in addition to whatever information they exchange. Some have argued that if information is exchanged, this is sufficient to view the interaction as shared. We view information as only the first step in the overall treatment decision-making process. It is the basic building block to enable a shared process to occur but it does not, in and of itself, constitute that process.

In a shared model, the interaction process to be used to reach an agreement may be explicitly discussed at the outset of the encounter or may evolve implicitly as the interaction unfolds. The process is likely to be consensual if both parties start out fairly close together in their thinking about the preferred treatment. If they are wider apart in their views, a process of negotiation is likely to occur. Negotiating as equal partners, however, is not easy for the patient because of the inherent information and power imbalance in the relationship. Physicians, in the usual case, will have superior knowledge of the technical issues involved in treatment decision-making and perhaps years of clinical experience with similar types of patients. The physician bears the officially legitimized title of ‘expert’ while the patient may feel particularly vulnerable and frightened during the medical encounter. When education, income, culture and/or gender differences also exist between the physician and patient, the patient may feel too intimidated to freely and openly express her preferences, let alone negotiate for them with the physician. Creating a safe environment for the patient so that she feels comfortable in exploring information and expressing opinions is probably the highest challenge for physicians who want to practise a shared approach (Guadagnoli and Ward, 1998). At the other end of the patient spectrum are those who are well informed about their illness and various treatment options and who have no difficulty expressing preferences. Some of these patients may have already made the treatment decision before entering the physician’s office. If the patient’s preference is different from the physician’s and the physician is not able to change the patient’s view, then the process will become conflictual.

In a shared model, both physicians and patients are assumed to have an investment in the treatment decision. The physician can legitimately give a treatment recommendation to patients and try to persuade them to accept the recommendation. However, physicians would also have to concentrate on listening to and understanding why patients might favour a different treatment option. Perhaps the decision will be resolved
through further discussion and clarification of values, preferences and information, but perhaps not. In the latter case, physicians would have to decide whether they could endorse patients’ preferences as part of a negotiated agreement in which patients’ views count, or whether the strength of their own views of the best possible treatment for each patient would preclude endorsement of any other option. If a physician cannot, in good conscience, endorse the patient’s preference, then there is no agreement on the decision to implement even though the deliberation process was shared. In this case, the patient would have to go elsewhere and begin the process over again with another physician if she hopes to have her preferred treatment implemented (unless, of course, her preferred option was to do nothing). This example illustrates that patients face constraints in that their preferences for specific treatments can only be implemented if a physician agrees to do so. On the other hand, physicians also face constraints. A patient turned down by one physician, can make the same treatment request to another physician. A refusal from the first physician does not preclude her from receiving the desired service from the second.

Each of the above examples assumes that only two parties are involved in the decision-making process. This is the most simple case but probably not the usual case. The patient may decide to share any or all of the decision-making steps with persons other than or in addition to the physician. For example, some women with early stage breast cancer in our study of shared treatment decision-making shared the information exchange component of the process with their oncologist but consulted with family, friends or their family physician in selecting the most appropriate treatment for themselves. These latter individuals knew the patient personally and, were sought out during the deliberation and decision-making stages precisely for this reason. Including others in the decision-making process introduces additional complexity since it expands both the nature and the number of decisions to be made as well as increasing the need for co-ordination so that consultations with all persons involved can occur. In addition, some decisions require third party agreement as a necessary pre-condition for implementation. For example, a physician and patient may decide that the latter would do better being cared for at home, even though a high level of constant and close supervision is required. If there is no care-giver willing to step in and either organize or undertake this task, the decision cannot be implemented.

These examples illustrate that, in many instances, a given physician–patient interaction is only one slice of a larger decision-making process that involves others in key roles and that takes place outside the context of the medical encounter. To the extent that our conceptualizations of treatment decision-making fail to incorporate these others or to recognize their influence, they fail to capture important slices of the reality of this process. Concepts, particularly sensitizing concepts, serve as analytic guides, defining, at least initially, the boundaries of what to look for empirically to better understand a phenomenon or process of interest (Blumer, 1969; Charmaz, 1990; van den Hoonoord, 1997). If conceptualizations of treatment decision-making fail to incorporate a potential role for significant others outside the physician–patient dyad, empirical research will focus solely on this micro-system, excluding important external influences. Focusing on the physician–patient dyad may yield a lot of information about this particular slice of reality, but relatively little about the importance of this slice in the overall treatment decision-making process.

In the informed model, as noted earlier, the patient proceeds through the deliberation and decision-making process on her own. The physician’s role is limited to providing medical/scientific information that will enable her to make an informed decision. Underlying this model are two assumptions. The first is that as long as patients possess current scientific information on treatment benefits and risks, they will be able to make the best decision for themselves. The second is that physicians should not have an investment in the decision-making process or in the decision made (Eddy, 1990). To do so, would go beyond the boundaries of an appropriate clinical role because the physician might harm the patient by inadvertently steering her in a certain direction which reflects the physician’s own bias. Underlying this concern is the assumption that the interests and motivations of the physician and patient may not be the same. This consumer oriented model emphasizes patient sovereignty and patients’ rights to make independent, autonomous choices (Quill and Brody, 1996).

The view that physicians have no legitimate role to play in the discussion or recommendation of treatments may be difficult for many physicians to accept since it runs counter to decades of professional medical training and practice in which clinical experience expertise and knowledge, have been assumed to be the quintessential skills that physicians have to offer. The informed model may meet patients’ needs for autonomy in decision-making (for those who value this goal) but it may not meet the needs of physicians who want to participate in treatment decision-making and who consider this a key part of their clinical role. The identification of needs raises the issue of whose needs and goals should be served in the medical encounter: the physician’s, the patient’s or both? Few (hopefully) would argue for the physician’s needs alone. However, there may well be disagreement over the latter two options.
The use of evidence-based clinical guidelines in treatment decision-making provides a useful context within which to consider this issue. Increasingly, clinical guidelines are being developed, based on the highest quality research evidence available, to inform treatment decision-making. Underlying the evidence-based approach is an assumption that whatever treatment is shown by the evidence to be the most effective is the best treatment and the ‘rational’ choice to implement. Some physicians go further to argue that if an informed patient with an expressed desire to ‘get well’ chooses a different treatment, this choice must be the result of ‘irrational’ thinking and it is the physician’s duty to try to change the patient’s mind (Brock and Wartman, 1990). In such situations, evidence may be used by the physician to prescribe the ‘right’ treatment. Consumer sovereignty takes second place to the physician’s own belief system about what ought to determine the treatment decision. This role for evidence is not compatible with either a shared or an informed model of treatment decision-making. A role that is compatible lies in using scientific information to help create more informed patients and to enhance patient choice.

When physicians and patients have different ideas about which decision-making model should be used to structure the decision-making interaction, they are headed for conflict. Decision-making using any of the above models will be prone to setbacks if the physician and patient are not in step with each other. In our earlier paper (Charles et al., 1997a), we made the analogy that shared decision-making takes ‘two to tango’. For the two parties to dance together, the physician needs to know what kind of dance the patient prefers and the steps that this involves. Otherwise, the dance will be punctuated with false starts and missteps, creating tension between the partners and impeding their ability to work together. This analogy can be extended. For a certain type of dance, it seems appropriate that the physician take the lead (for example, in transferring technical information to patients). However, when the music changes to another type of dance, the patient may well take the lead, being more of an expert in the new steps required to fit with this particular beat (for example, patient preferences for different health states). In a shared treatment decision-making model both the physician and patient can take turns ‘leading’ specific discussions depending on which person has more expertise and experience to contribute on a given issue.

Decision on the treatment to implement

The final task in the decision-making process is choosing a treatment to implement. In the paternalistic and informed models, the decision-maker is one person; in the first case, the physician and in the second, the patient. However, in both cases the decision-maker is not totally autonomous because each faces constraints in actually implementing the decision. The physician must have the patient’s informed consent before proceeding and the patient needs the physician’s agreement to implement her preferred treatment (unless no treatment or an alternative therapy is preferred). In the shared model, both parties, through the deliberation process, work towards reaching an agreement and both parties have an investment in the ultimate decision made. The extent to which patient involvement in decision making is associated with a greater commitment to the agreed upon treatment is an important area for study.

Practical applications of the framework

Our revised and updated framework depicted in Table 1 is more flexible and incorporates a more dynamic perspective on treatment decision-making than our earlier model. We think it is also clearer in terms of practical applications for physicians and others. First, the framework provides a description of the various analytical stages in the decision-making process. The framework can be used to educate physicians about these stages and about the defining characteristics of each model. The framework also describes the general path each model follows and more specifically, behavioural expectations of both physicians and patients for implementing each model.

Second, physicians can use the framework to help explain to patients the different approaches that can be used to make treatment decisions. They can also use the framework as a tool in assessing patient preferences (as well as their own) in this regard.

Third, the framework makes explicit the possibility that not only can the decision-making approach used in one physician–patient interaction change in the next interaction, it can also change within a single interaction. For example, a physician who starts the consultation with an informed approach may need to switch mid-stream to a more shared approach if it becomes evident that the patient does not want to make the decision on her own. In this case, what started as an informed approach changes to one in which the physician takes a more active role in making the decision. Alternatively, even though a physician may be more comfortable with a paternalistic approach, a given patient may want more of a role in decision-making than the former expects or is used to. To respond to this patient’s preferences, the physician will need to move towards a shared model. The framework can help physicians identify the changes required of them to move from a particular decision-making approach adopted at the outset of a medical encounter to a
different one that better meets the needs of a specific patient in the later stages of decision-making. Said another way, a single treatment decision-making process can combine elements from different models at different stages in the overall process.

Fourth, the framework makes explicit that switching models during the encounter is easier in some circumstances than in others. In fact, some movements across models are not possible within a single interaction unless the whole process is started anew. For example, a shared model, where both the physician and patient decide on the treatment to implement requires as a precondition that two-way information exchange and deliberation have already taken place. If the physician starts the decision-making process with a paternalistic approach, the information gap would need to be filled before a switch to a more shared approach could be made.

Fifth, the framework recognizes that, in reality, there are multiple approaches that lie between the three ideal types. Starting with the paternalistic model, for example, the more that each step moves from a physician-dominated encounter to one where the patient’s input is recognized, nourished and valued, the more the model evolves into a shared approach. Similarly, as the physician’s role fades into the background in steps 2 and 3 of the decision-making process, the approach moves towards the informed model.

It would be difficult to pinpoint the exact point where one model ends and another begins. We think of the three prominent approaches discussed above as markers or anchor points that reflect the most well known and best described models, recognizing that there are many combinations in between. While each could be labeled, this would be a time-consuming and difficult task. In addition, we doubt that this would be a useful exercise since labels seem to generate normative judgements about what are ‘good’ and ‘bad’ ways of decision-making rather than focusing on the specific situational context in which one approach would be more appropriate than another. The identification in the framework, not only of general approaches to treatment decision-making but also of combinations in between increases options for physicians. It also reinforces the importance of flexibility so that physicians are able to recognize and respond to changes in patient preferences for the nature of the interaction as the decision-making process unfolds.

Sixth, identifying the interactional dynamics required of each model highlights the added ‘costs’ of engaging in shared decision-making relative to the other models. While advocates of shared decision-making have stressed the benefits of this approach in promoting patient participation and patient-centred care, few have focused on its financial costs. If shared decision-making turns out to require more time on average than other approaches in order to facilitate interaction and to build consensus, then physicians may respond by either advocating for increased fees or seeing fewer patients. However, there may also be costs for not involving patients, in the form of repeat visits, second opinions and doctor shopping. The potential system-wide policy impacts of a shared decision-making approach have not yet received much systematic research or public policy attention.

Seventh, the framework can assist in the evaluation of different components of the overall treatment decision-making process. For example, if the goal of treatment decision aids is limited to improving information transfer then the framework can be used to identify the specific decision-making stage which forms the relevant context for the evaluation. However, if the goal of decision aids goes beyond this to also incorporate relationship building within a shared decision-making approach, then the relevant evaluation context will have to be broadened. As another example, the identification of explicit and analytically distinct phases of the decision-making process makes it possible to target specific questions regarding patient satisfaction to each of these stages and to determine which contributes most to a patient’s overall satisfaction level.

Eighth, the framework can be used as an educational tool in medical training to stimulate discussion about professional orientations to and roles in treatment decision-making. For example,

1. Whose views of the meaning of shared decision-making should count: those of academics and researchers who advocate specific normative models in professional journals, or those of physicians and patients in non-academic settings whose views might be quite different?
2. Should physicians try to influence the treatment decision-making process and outcome or should the clinical role be limited to transferring relevant treatment information to the patient?
3. If a patient and her physician both prefer a paternalistic approach, is there anything ‘wrong’ with making the decision in this manner?
4. If a physician prefers that a patient make the treatment decision (the informed model), should the patient be ‘forced’ to do so, even if she does not want to?
5. Given the power, status and informational asymmetry between physician and patient, is it realistic to expect patients, even informed patients, to be able to hold their own in negotiations with physicians about treatment preferences? What steps can physicians take to create a safe environment where this can occur?
6. What is the most effective strategy available to physicians to elicit patient preferences for involvement in treatment decision-making?
Conclusion

In this paper we have revisited and expanded our earlier conceptual framework of different treatment decision-making models. We think this framework is more flexible than its predecessor and recognizes more clearly the dynamic nature of treatment decision-making. Practical applications of the framework have also been discussed. Over the course of our research we have learned that treatment decision-making is a complex process that takes place over time and can involve many individuals rather than an event that takes place at a fixed point in time and is restricted to the physician-patient dyad. Our thinking on treatment decision-making will continue to evolve as we move in an iterative process, empirically studying different aspects of this process and using the information to clarify our conceptual thinking.

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References

Flood, A.B., Wennberg, J.E., Nease, R.F., et al., 1996. The importance of patient preference in the decision to screen...


Systematic Review of the Effects of Shared Decision-Making on Patient Satisfaction, Treatment Adherence and Health Status

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Key Words
Shared decision-making · Adherence · Patient satisfaction · Quality of life · Well-being

Abstract

Background: In the last decade, the clinician-patient relationship has become more of a partnership. There is growing interest in shared decision-making (SDM) in which the clinician and patient go through all phases of the decision-making process together, share treatment preferences, and reach an agreement on treatment choice. The purpose of this review is to determine the extent, quality, and consistency of the evidence about the effectiveness of SDM. Method: This is a systematic review of randomised controlled trials (RCTs) comparing SDM interventions with non-SDM interventions. Eleven RCTs met the required criteria, and were included in this review. Results: The methodological quality of the studies included in this review was high overall. Five RCTs showed no difference between SDM and control, one RCT showed no short-term effects but showed positive longer-term effects, and five RCTs reported a positive effect of SDM on outcome measures. The two studies included of people with mental healthcare problems reported a positive effect of SDM. Conclusions: Despite the considerable interest in applying SDM clinically, little research regarding its effectiveness has been done to date. It has been argued that SDM is particularly suitable for long-term decisions, especially in the context of a chronic illness, and when the intervention contains more than one session. Our results show that under such circumstances, SDM can be an effective method of reaching a treatment agreement. Evidence for the effectiveness of SDM in the context of other types of decisions, or in general, is still inconclusive. Future studies of SDM should probably focus on long-term decisions.

Introduction

In recent decades, there has been an increasing emphasis on patient involvement in treatment decisions \[1\]. The role of the clinician is no longer an authoritarian person ‘who knows what’s right for you’. The relationship between clinician and patient has become more of a partnership \[2\]. Placing the patient at the centre of care \[3\] represents a new and important approach to improve the quality of medical care. Patient autonomy is seen as a basic value and underlying premise for the provision of healthcare itself \[4\]. Furthermore, in Europe the World Health Organisation has highlighted the need to involve patients in the development and delivery of healthcare...
and legislation has been passed in several countries aimed at strengthening the influence of patients [5].

One method of fostering these modern priorities of the clinician-patient relationship is through the process of shared decision-making (SDM). SDM is defined as an approach in which the clinician and patient go through all phases of the decision-making process together and in which they share the preference for treatment and reach an agreement on treatment choice [2, 6–8]. Forms of decision-making can be regarded as a continuum with two extremes – the ‘traditional medical model’ and the ‘informed medical model’ [2, 9, 10]. Table 1 demonstrates where SDM fits between these extremes.

Charles et al. [11] have identified necessary criteria for or characteristics of SDM. The first characteristic is that SDM involves clinician and patient. Often the treatment decision involves more than one patient and one clinician. The involvement of family members in treatment decision-making may be important. Furthermore, steps are taken to ensure that clinician and patient are both involved in the process of decision-making. Additionally, both parties take steps to build a consensus about the preferred treatment. At the very least, the clinician needs to explain the treatment alternatives and their possible consequences for the patient. The patient and clinician both bring information and values into their discussion. Finally, the patient and clinician together discuss and evaluate treatment options and together build a consensus on the treatment to implement.

Frequently, SDM studies comprise the use of decision aids. Decision aids are interventions designed to help people make specific and deliberative choices among options by providing relevant information about the options and outcomes relevant to a person’s health status [12]. A systematic review of decision aids concluded that they improve patients’ knowledge regarding treatment options and their condition [12]. Decision aids appear to have no effect on satisfaction with decision-making, anxiety, and health outcomes.

Published SDM studies have reported improvements in patient satisfaction, treatment adherence, quality of life and well-being [13] when clinicians adopt a patient-centred approach [14] and when patients are more involved and perceive greater control over their treatment choice [11, 15–17]. SDM should foster a patient-centred approach and empower patients, therefore the outcomes mentioned above are appropriate to use in assessing the effectiveness of SDM. The aim of the present systematic review was to examine the extent, quality and consistency of the published research evidence for the effectiveness of SDM with respect to these outcome variables.

**Method**

**Inclusion and Exclusion Criteria**

The review included studies that met all the following criteria: (1) studies in which a treatment decision needed to be made; (2) randomised controlled trial design; (3) involving patients aged 18
years or older faced with having to make a treatment decision; (4) comparing SDM with a control intervention, and (5) including one or more of the following outcome measures: degree of treatment adherence, patient satisfaction, well-being, and quality of life.

Excluded studies were those in which treatment decisions based on a choice between alternative treatment options did not explicitly involve shared decision-making between clinician and patient.

Search Strategy for Identification of Studies
The literature was searched with the WebSPIRS 5 search engine with the PsychINFO and Medline databases (from 1966 until July 2006). In addition, the Cochrane library, 2006, issue 2, was screened. All databases were searched from their dates of commencement. Reference lists of relevant studies were checked for further potential sources. The search was run with the following keywords: shared decision making, shared decisionmaking, shared decision-making, shared decision*, decision making*, randomised controlled trials*, adherence, patient compliance*, patient-participation*, patient satisfaction*, well-being and quality of life*. All the decision-making terms were combined with OR, and all the outcome measures were combined with the decision-making terms with AND. Only studies that were published in the English language were included.

Methodological Quality Assessment
Two reviewers (E.J. and L.D.F.) independently assessed the methodological quality of the randomised controlled trials (RCTs). The list of criteria recommended in the guidelines for systematic reviews issued by the Cochrane Back Review Group [18] was used, but adapted for this SDM review by the addition of four criteria (marked A–D in table 3). These items, key characteristics of SDM identified by Charles et al. [11], are: (A) SDM involves at least two participants – clinician and patient; (B) both parties share information; (C) both parties take steps to build a consensus about the preferred treatment, and (D) an agreement is reached on the treatment to implement.

An item was scored ‘positive’ (+) if the criterion was met, ‘negative’ (−) if it was not met, or ‘unclear’ (?) if it was not clear whether the criterion was met or not. Subsequently, all authors were consulted for additional information about the criteria that were scored ‘unclear’ in their studies. A total score was computed by counting the number of positive scores.

Results
Study Selection
The search resulted in 328 references via PsychINFO, 659 in Medline, and 373 in Cochrane Library with the keywords: shared decision*, shared decisionmaking, shared decision making and shared decision-making. These keywords in combination with satisfaction, adherence/compliance, quality of life or well-being resulted in 26 references via PsychINFO, 121 in Medline and 32 in Cochrane Library. After deleting duplicates from all the databases consulted, the search finally resulted in 137 different references.

The first selection was based on titles, keywords and abstracts, and resulted in selecting 34 studies in a single reviewer format. The other articles were not primary research studies but reviews, editorials, letters, and quality improvement reports. All 34 studies included at least two patient groups: SDM and Non-SDM. Of these 34 studies, 17 were RCTs and 17 were non-RCTs (observational, prospective cohort, cross-sectional, self-reported, exploratory, and case control studies). Of the 17 RCTs, 11 focussed on SDM and included as outcome measures adherence, patient satisfaction, quality of life or well-being. Of the six excluded RCTs, in one article [19] the patient made the treatment decision, one measured clinician satisfaction [20], and four did not explicitly involve SDM of clinician and patient and/or were based on a choice between alternative treatment options [21–24].

Study Characteristics
Characteristics of the included studies (n = 11) are shown in table 2. Nine studies involved SDM in physical healthcare: three in cancer, and the remainder in ulcer disease, ischemic heart disease, hormone replacement therapy, dentistry, and benign prostatic hypertrophy. Two studies examined the effects of SDM in mental healthcare (treatment for schizophrenia and depression).

It is important to take into account that the SDM interventions of the selected studies are heterogeneous (see also table 2). Most of the interventions used an interactive videodisc program, resulting in an individual summary of important points. A consultation with the clinician followed this program and results were discussed [25–28]. Other studies used a question/information sheet [29,30] or card ranking discussion [31] to promote patient participation in the treatment decision. In addition, general practitioners were trained in SDM skills [32] and behaviour change strategies were used to increase patient involvement [33]. Finally, two studies used SDM interventions within a treatment program [34–36].

Methodological Quality
In general, the methodological quality of the studies included in this review was high (table 3). All studies had six (>50%) or more positive scores on the validity criteria, the determined threshold for high quality [18].

Most of the studies did not include a blinded care provider (criterion 5). Furthermore, most patients were not
blinded regarding their treatment allocation (criterion 4). Most of the studies had three or four positive scores on the criteria of the key characteristics of SDM. The decision-making in all studies involved at least two parties (criterion A). However, in some studies it was not clear whether patient and clinician took steps to build a consensus (criterion C). In addition, none of the studies had a direct measure of the quality of the SDM interventions. Problems arise in interpreting studies that yielded negative results – are these results attributable to failure of effective SDM, or to poor SDM technique or application?

### Effectiveness of SDM

Five of the identified RCTs [31, 26–28, 30] reported no difference between SDM and control group on the out-

### Table 2. Study characteristics of included studies

<table>
<thead>
<tr>
<th>Population</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Follow-up</th>
<th>Results (significant outcomes between conditions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>study (first</td>
<td>condition</td>
<td>duration</td>
<td>decision aid</td>
<td>n</td>
</tr>
<tr>
<td>author)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greenfield</td>
<td>Ulcer disease</td>
<td>1985 [33]</td>
<td>Single session</td>
<td>45</td>
</tr>
<tr>
<td>Morgan</td>
<td>Ischemic heart disease</td>
<td>2000 [25]</td>
<td>Single session</td>
<td>240</td>
</tr>
<tr>
<td>Murray</td>
<td>Benign prostatic hypertrophy (primary care)</td>
<td>2001 [26]</td>
<td>Single session</td>
<td>112</td>
</tr>
<tr>
<td>Murray</td>
<td>Hormone replacement therapy (primary care)</td>
<td>2001 [27]</td>
<td>Single session</td>
<td>205</td>
</tr>
<tr>
<td>Malm</td>
<td>Schizophrenic disorders</td>
<td>2003 [34]</td>
<td>Multiple sessions</td>
<td>84</td>
</tr>
<tr>
<td>Ruland</td>
<td>Cancer</td>
<td>2003 [28]</td>
<td>Single session</td>
<td>52</td>
</tr>
<tr>
<td>Von Korff</td>
<td>Depression</td>
<td>2003 [35]; Ludman 2003 [36]</td>
<td>Multiple sessions</td>
<td>386</td>
</tr>
<tr>
<td>Edwards</td>
<td>GP patients with known atrial fibrillation, prostatism, menorrhagia or menopausal symptoms</td>
<td>2004 [31]</td>
<td>Single session</td>
<td>747</td>
</tr>
<tr>
<td>Van Roosmalen</td>
<td>BRCA 1/2 mutation carriers</td>
<td>2004 [32]</td>
<td>Multiple sessions</td>
<td>88</td>
</tr>
<tr>
<td>Johnson</td>
<td>Dentistry</td>
<td>2006 [29]</td>
<td>Single session</td>
<td>70</td>
</tr>
</tbody>
</table>
come measures. These RCTs had in common that they involved decision-making in physical healthcare. Furthermore, these studies were dealing with a single decision or measurement after one consultation. In contrast with the former studies, van Roosmalen et al. [32], although showing no short-term effects, found a positive effect in the long term. The five remaining studies [25, 26, 29, 34–36] reported improved outcomes attributable to SDM. Of these five, Malm et al. [34] and Von Korff et al. [35]/Ludman et al. [36] involved decision-making in mental healthcare.

The most frequently used outcome measure, in seven studies, was patient satisfaction. The study by Malm et al. [34] is the only RCT that showed a positive outcome for patient satisfaction. The SDM intervention in this study concerned a treatment program, in contrast to the studies that report no differences between the conditions [25, 28–31, 33]. These studies involved a single decision or measurement after one consultation.

Other outcome measures were psychological and physical well-being (e.g. quality of life, anxiety, and depression). Two [32, 35, 36] out of five studies [26, 27, 29] showed positive effects of SDM with regard to these outcome measures. Van Roosmalen et al. [32] found a positive effect with respect to well-being. The study by Von Korff et al. [35]/Ludman et al. [36] applied depression outcome measures. These studies are heterogeneous. Nevertheless, these studies involved patients making longer-term decisions and/or having chronic diseases. Another similarity between these studies is the duration of the intervention. The intervention in the study by van Roosmalen et al. [32] contains three sessions added to the treatment as usual and a 12-month intervention was used in the study by Von Korff et al. [35]/Ludman et al. [36].

One selected study had adherence as outcome measure [35, 36]. The patients in the intervention condition were significantly more likely to adhere to the medication (antidepressant) at 9- to 12-month follow-up measurement.

Finally, three selected studies [25, 29, 33] – in addition to the included outcome measures degree of treatment adherence, patient satisfaction, well-being, and quality of life – considered patient knowledge as outcome measure. The studies by Morgan et al. [25] and Johnson et al. [29] found no difference between intervention and control groups with regard to satisfaction. However, patients in the intervention group had significantly higher knowledge scores. In contrast with these studies, Greenfield et al. [33] reported that knowledge of ulcer disease was significantly greater for controls after intervention. On the other hand, this study showed that patients in the experimental group reported significantly fewer physical limitations due to ulcer disease than controls.

Table 3. Methodological quality of randomized controlled trials

<table>
<thead>
<tr>
<th>Study (first author)</th>
<th>Criteria validity/reliability</th>
<th>Criteria key characteristics of SDM</th>
<th>Total</th>
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<td>Morgan, 2000 [25]</td>
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<td>Murray, 2001 [26]</td>
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<td>Malm, 2003 [34]</td>
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<td>Edwards, 2004 [31]</td>
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<td>Johnson, 2006 [29]</td>
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</table>

1 = Adequate randomisation procedure; 2 = concealment of treatment allocation; 3 = similarity of baseline characteristics; 4 = blinding of patients; 5 = blinding of care provider; 6 = outcome assessor blinded to the intervention; 7 = co-interventions avoided or equal; 8 = compliance; 9 = withdrawal/dropout rate; 10 = similarity of timing outcome assessment; 11 = intention-to-treat analyses; A = the decision-making involves at least two parties (clinician-patient); B = both parties share the information during the intervention; C = both parties take steps to build a consensus; D = agreement is reached on the treatment to implement.

* See also van Roosmalen et al. [43]. b See also Katon et al. [44, 45]. c See also Elwyn et al. [46].
Discussion

SDM has been proposed as an important advance in modern clinical practice, and clinicians have been urged to adopt it in order to foster relationships with their patients that are more appropriate to the modern age. To our knowledge, this is the first systematic review of the effectiveness of SDM.

The methodological quality of the studies included in this review was high, and most studies included three or all four key characteristics of SDM. The two RCTs in mental healthcare scored positively on all four SDM criteria.

Limitations of the review include that it focussed only on English language publications. Furthermore, the heterogeneity of the samples, settings, and measurements might affect the generalisation of the results, although this heterogeneity also highlights the fact that SDM is a generic intervention, not dependent on the treatment setting or specialty. Moreover, a crucial point is that no study was excluded from the review on the basis of its ratings on the key characteristics of the SDM elements.

The studies with positive results are various. Studies that showed improvement in satisfaction, adherence, depression, and well-being had in common that the SDM interventions concerned treatment programs or contained more than one session. In addition, these successful studies involved patients making longer-term decisions and/or having chronic diseases, while most of the studies that did not show significant outcomes involved single or specific decisions. SDM can be regarded most appropriately as a collaborative process rather than one or two isolated events, and it is therefore not surprising that individual decisions have no significant measurable effect on factors that SDM might be expected to influence. A longer interaction between clinician and patient is perhaps necessary for patient's attitudes regarding desire for information and participation in medical decisions to manifest themselves in information-seeking behaviour [37, 38].

People with chronic illnesses (e.g. people with schizophrenia, diabetes, asthma) have to change their lifestyle and habits to improve their health status. Montori et al. [39] indicated that treatment decisions in chronic care, relative to acute care decisions, are more likely to require a more active patient role in carrying out the decision and also offer extensive chances to revisit and reverse decisions. Acute care decisions may involve minimal patient participation, are often urgent, and may be irreversible. While longer-term decisions in chronic illness usually offer much scope for patient autonomy, urgent decisions about acute care usually involve the clinician in a more paternalistic role.

In addition to the included outcome measures (degree of treatment adherence, patient satisfaction, well-being, and quality of life), increase of knowledge was often used in the selected studies. Knowledge is an important and frequently named outcome measure. Patients need to be informed about complex decisions. They need to comprehend the treatment options and their benefits and harms in order to consider and discuss these with their clinician [12]. These studies had in common that they involved single or specific decisions. However, the results of these studies were contradicting.

It is interesting that the two studies regarding mental healthcare both reported a positive effect of SDM [34–36]. Patients in mental healthcare are particularly encouraged to focus on treatment issues that might affect their lifestyle and preferences [9]. Also, both of these studies focussed on people with chronic illnesses, and it has been demonstrated that chronically ill patients who are actively involved in health decision-making are more likely to enact and adhere to health behaviours, and to engage in other health-promoting or health-maintaining behaviours [40].

Conclusions

The good-quality research identified in this review indicates that SDM can be an effective and useful way of reaching a treatment agreement when patients have to make long-term decisions. Furthermore, research shows that SDM interventions are effective when they concern single, acute decisions. Not only do the published studies reveal no benefits of SDM under such circumstances, but perhaps such benefits should not be expected in any case. Using a decision aid is unlikely to produce the benefits of SDM on its own. The wider literature on SDM indicates that SDM is often complex and usually very time consuming [13, 41]. Selecting the best treatment is not always easy. It is likely that SDM has to take place in a structured, more frequent, and longer interaction. Second, given the complex nature of SDM, it is probably appropriate for trials to include multiple outcome measures. In addition, increase of knowledge seems to be an important topic in

Joosten/DeFuentes-Merillas/de Weert/
Sensky/van der Staak/de Jong

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SDM studies. Unfortunately, results of the reviewed studies were contradictory and further research is needed to confirm the idea that SDM increases knowledge. Third, as well as assessing appropriate outcomes, it is essential for future studies to examine the process of SDM. This is important to measure the quality of the intervention. Without this, if a trial produces a negative result, it is impossible to tell whether this outcome is due to the poor quality of SDM in the study, or to the ineffectiveness of SDM in a particular context or application. In addition, investigation of the process of SDM would be expected to lead to better understanding of the key elements of SDM. Fourth, theoretic considerations suggest that SDM should be effective in decision-making with people with mental disorders [9, 10], and little research that is currently available supports this. More research is clearly needed in this area.

The available evidence indicates that SDM can be effective in the context of chronic illness and when the intervention contains more than one session. However, considering the growing clinical interest in SDM, it is surprising and disappointing how little randomised controlled studies have been published regarding its efficacy. There is therefore an urgent need for further research.

Acknowledgements

We wish to thank the authors of the original papers for their comments on this review. The Dutch Ministry of Welfare and Sports (VWS) and the Dutch Organization for Health Research and Development (ZonMW) funded this project (grant No. 985-10-018). These agencies had no role in the conduct or interpretation of the study.

References


Effects of SDM on Patient Satisfaction, Treatment Adherence and Health Status

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Shared Treatment Decision Making Improves Adherence and Outcomes in Poorly Controlled Asthma

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Rationale: Poor adherence to asthma controller medications results in poor treatment outcomes.

Objectives: To compare controller medication adherence and clinical outcomes in 612 adults with poorly controlled asthma randomized to one of two different treatment decision-making models or to usual care.

Methods: In shared decision making (SDM), nonphysician clinicians and patients negotiated a treatment regimen that accommodated patient goals and preferences. In clinician decision making, treatment was prescribed without specifically eliciting patient goals/preferences. The otherwise identical intervention protocols both provided asthma education and involved two in-person and three brief phone encounters.

Measurements and Main Results: Refill adherence was measured using continuous medication acquisition (CMA) indices—the total days' supply acquired per year divided by 365 days. Cumulative controller medication dose was measured in beclomethasone canister equivalents. In follow-up Year 1, compared with usual care, SDM resulted in: significantly better controller adherence (CMA, 0.67 vs. 0.46; P < 0.0001) and long-acting β-agonist adherence (CMA, 0.51 vs. 0.40; P = 0.0225); higher cumulative controller medication dose (canister equivalent, 10.9 vs. 5.2; P < 0.0001); significantly better clinical outcomes (asthma-related quality of life, health care use, rescue medication use, asthma control, and lung function). In Year 2, compared with usual care, SDM resulted in significantly lower rescue medication use, the sole clinical outcome available for that year. Compared with clinician decision making, SDM resulted in: significantly better controller adherence (CMA, 0.67 vs. 0.59; P = 0.03) and long-acting β-agonist adherence (CMA, 0.51 vs. 0.41; P = 0.0143); higher cumulative controller dose (CMA, 10.9 vs. 9.1; P = 0.005); and quantitatively, but not significantly, better outcomes on all clinical measures.

Conclusions: Negotiating patients' treatment decisions significantly improves adherence to asthma pharmacotherapy and clinical outcomes.

Clinical trials registered with www.clinicaltrials.gov (NCT00217945 and NCT00149526).

Keywords: randomized controlled trial; asthma control; patient–clinician communication

Among patients with asthma, and others with chronic conditions that require pharmacotherapy, only about half take their medications at therapeutically effective doses (1, 2). Estimated nonadherence rates for asthma controller medications range from 30 to 70% (3–6), including in patients with so-called difficult asthma who might appear to require treatment with still more potent medications (7). Poor adherence exacerbates airway inflammation, and may result in suboptimal asthma control, functional limitations, decreased quality of life, excess health care use, and even death (8, 9).

A recent Cochrane Review (12) of adherence studies, including those that appeared to demonstrate improved adherence to some types of medications (e.g., antihypertensives) (10, 11), found serious methodologic problems, thereby limiting any conclusions regarding intervention efficacy. Furthermore, none of the included studies focused on asthma medication adherence. Consequently, there is a general lack of evidence of effective adherence interventions targeting adults with asthma, and specifically, poorly controlled asthma.

Observational studies suggest that failure to elicit and address patients’ individual circumstances and goals/preferences regarding their regimen may contribute to treatment nonadherence (13). Asthma treatment guidelines recommend that clinicians consider patients’ treatment goals, but little is known about clinician adherence to these recommendations or the effects of their doing so (8).

Charles and colleagues (14, 15) hypothesized that a shared treatment decision-making (SDM) process, in which the patient...
has actively participated, will result in a greater commitment and adherence to the selected regimen than to a regimen selected by the physician alone. The authors described four key defining features of the SDM model, namely, that both clinician and patient: (1) share relevant information; (2) express treatment preferences; (3) deliberate the options; and (4) agree on the treatment to implement.

There is a paucity of strong evidence from appropriately controlled trials that supports the inference from observational studies that SDM regarding treatment of a chronic disease (in which self-management is essential) actually results in patients accepting and adhering to the regimen and improves both treatment adherence and disease outcomes (16, 17). Although a recent review of SDM by Joosten and colleagues (18) identified 11 randomized controlled trials that met at least one of Charles and colleagues’ criteria, none concerned asthma, and nearly half involved a one-time treatment decision, rather than decisions typical of chronic disease management. Furthermore, only one included medication adherence as an outcome, and none investigated clinical outcomes, other than a limited measure of patient well being. Although Joosten and colleagues noted the potential effectiveness of the SDM process, they recommended additional research that should include multiple clinical outcomes.

Better Outcomes of Asthma Treatment (BOAT) was a three-arm, multisite, randomized, controlled trial in 612 patients with poorly controlled asthma. The two experimental intervention arms were designed in the context of asthma care management, which refers to a period of targeted review of asthma treatment and control and asthma self-management education by a nonphysician health professional. The primary hypothesis was that patients with poorly controlled asthma who received care management using an SDM approach would exhibit greater adherence to controller medications, better asthma-related quality of life, and lower health care utilization for acute symptoms than patients who received usual care (no asthma care management). A contingent secondary hypothesis was that, given a demonstrated benefit over usual care, patients who participated in SDM would demonstrate better outcomes than patients who received the identical care management, except that treatment was determined by the care manager and physician alone (clinician decision making [CDM]). Secondary clinical outcomes included short-acting β-agonist (SABA) use, lung function, and asthma control.

Some results presented here have been previously reported in the form of abstracts based on preliminary results (19–23).

METHODS

The study has been approved annually by the institutional review boards of the Kaiser Foundation Research Institute in Oakland, California, and of the Kaiser Permanente (KP) Center for Health Research in Portland, Oregon, and Honolulu, Hawaii. Substantial additional information about the study methods and timeline are available in the online supplement.

Patient Recruitment and Eligibility Criteria

The target population was patients whose asthma was not well controlled, and whose adherence to their asthma regimen was likely to be inadequate. KP members, aged 18–70 years, with evidence suggestive of poorly controlled asthma, were identified at five clinical sites using computerized records of overuse of rescue medications (a controller/[controller + rescue medication] ratio ≤0.5 and at least three β-agonist dispensings in the past year) or a recent asthma-related emergency department (ED) visit or hospitalization. Exclusion criteria included intermittent asthma (brief exacerbations or symptoms less than once/wk), primary diagnosis of chronic obstructive pulmonary disease or emphysema, insufficient pulmonary function reversibility (for ex-/current smokers and those without regular controller use), regular use of oral corticosteroids, and current asthma care management.

Spirometry. Spirometry was performed at enrollment using standardized research methods (24) and equipment that met American Thoracic Society standards.

Randomization

A computer-based adaptive randomization algorithm (25) was used to ensure concealment from randomization staff and better-than-chance balance among the three groups on age (18–34, 35–50, and 51–70 yr), sex, race/ethnicity, hospitalization in the prior two years (yes/no), and frequency of asthma controller use in the past week (none, 1–3, ≥4 d).

Intervention Protocol

The SDM and CDM interventions were identical in format, content, and all patient education handouts and worksheets, except for the process by which treatment was decided.

Format. Session 1 of the intervention is outlined in Figure 1, highlighting the unique features of the SDM and CDM protocols. In session 2 (~1 mo after session 1), and in three brief phone calls 3, 6, and 9 months later, patient progress was assessed and medications were adjusted, as necessary, using the assigned care management approach. Except as noted subsequently here, both protocols used identical standardized interventionist scripts and materials.

The patient’s asthma history was elicited using a standardized patient information form, the patient’s level of asthma control was classified, and asthma education was provided. Once treatment was negotiated (SDM) or decided (CDM), patients were instructed in the correct use of the relevant inhaler medication devices using methods previously shown by this team to improve inhaler technique and eliminate common usage errors (26, 27). At the end of session 1, a written asthma management and action plan was created, and potential barriers to medication adherence were elicited and addressed using motivational interviewing techniques (28). Any subsequent changes made at session 2 or in a follow-up phone call were documented in the plan.

Treatment decision process. In the CDM model, the care manager prescribed an appropriate regimen based on the patient’s level of asthma control, and explained that decision to the patient. The SDM model implemented the four key defining features described by Charles and colleagues (14, 15). The care manager elicited the patient’s goals for treatment and relative priorities regarding symptom control, regimen convenience, avoidance of side effects, and cost. The patient was then shown a list of the full range of regimen options for all levels of asthma severity, based on the then-current national asthma guidelines (29) and KP pharmacopeia. These options differed with respect to the number and type(s) of medications, dosing, and schedule. Using a simple worksheet, the patient and clinician then compared the pros and cons of all of the options the patient wished to consider, which included the option of continuing the patient’s current de facto regimen (i.e., how they were using their current asthma medications) to arrive at a treatment that best accommodated the patient’s and care manager’s goals.

For both groups, a SABA was always prescribed for rescue use as needed. If indicated, treatment of allergic rhinitis and/or gastro-esophageal reflux disease was prescribed (CDM) or negotiated (SDM).

Care Manager Training and Intervention Quality Control

A total of 16 KP nurses, respiratory therapists, and pharmacists, as well as nurse practitioners and physician assistants, most of whom already served as asthma care managers, were recruited to serve as study care managers and assigned to the SDM or CDM program. SDM and CDM care managers were trained separately and worked independently.

For quality control purposes, audiotapes of both sessions of 10% of the patients were scored on a detailed performance checklist to determine whether the two protocols were delivered as intended. In addition, patients were given a stamped postcard to return to the research office after session 1 to report their perceived role in the treatment decision.
Coordination with Patient’s Physician

Care managers documented each encounter in the patient’s chart, where it also was available to the patient’s physician. The care managers discussed their recommendations with the physician if they or the physician had any questions about the new regimen. For care managers who were not licensed to prescribe, the physician reviewed and wrote the prescription.

Usual Care Control Condition

Usual asthma care at KP medical centers was based on a stepped-care approach to pharmacotherapy with the aim of long-term asthma control, as recommended by the National Asthma Education Prevention Program’s Expert Panel Report 2 (29). At some KP sites, physicians also had the option to refer patients to an asthma care management program, typically of less than 6 months’ duration, in which a licensed health professional (nonphysician) provided asthma education and addressed adherence and other medication use and self-management issues in a manner similar to, but less structured than, the CDM intervention. However, asthma care management was neither a required aspect of usual care nor necessarily available at all BOAT sites, and current participation in that program was an exclusion criterion for the study. Once enrolled in BOAT, usual care and SDM or CDM patients (after the intervention phase) still had access to KP’s existing care management services, if available, based on their physician’s referral.

Outcome Data

Pharmacy data. Medication acquisition data were extracted from KP dispensing records for 1 year prerandomization and 2 years post-randomization. Fill/refill adherence was measured using a continuous medication acquisition (CMA) index for each year, calculated as the total days’ supply acquired in a given year divided by 365 days (30–32). The index represents the proportion of the prescribed medication supply acquired by the patient during each 365-day period, and may potentially overestimate, but not underestimate, actual use.

Acquisition indices were calculated separately for: (1) all asthma controllers (inhaled corticosteroids [ICS], leukotriene modifiers, cro-
molybdenum, and theophylline); (2) for ICS alone; and (3) for long-acting β-agonists (LABAs). Combination ICS-LABA medications (i.e., fluticasone-salmeterol) contributed to both the ICS and LABA index calculations.

A second pharmacy measure, beclomethasone dipropionate canister equivalents, was the estimated total number of canisters of beclomethasone to which the asthma controller medications dispensed in a given year were equivalent (i.e., equipotent in terms of their anti-inflammatory effectiveness). Per the method of Schatz and colleagues (33), each dispensing of a controller medication (excluding theophylline), in any form or quantity, was assigned a weight representing its equivalent in fractional or multiple canisters of beclomethasone 80 μg. The weighted values were summed for each patient for each 365-day period to obtain a cumulative measure of controller medication dose dispensed.

A third pharmacy measure—an clinical outcome—used a separate set of weights to standardize the amounts of all SABAs dispensed in terms of their bronchodilator effectiveness in canisters of albuterol, regardless of SABA type and delivery mode. The weights were summed to obtain the total number of albuterol canister equivalents acquired by the patient in each study year.

Other outcomes. The primary clinical outcomes were asthma-related quality of life and asthma health care utilization. Asthma-related quality of life for the prior 2 weeks was assessed by patient self-report at baseline and follow-up Year 1. Asthma control in the preceding 4 weeks was assessed using the four-item Asthma Therapy Assessment Questionnaire (ATAQ) (35). Lung function measures included FEV1 (forced expiratory volume in 1 second), in any form or quantity, was assigned a weight representing its equivalent in fractional or multiple canisters of beclomethasone 80 μg. The weighted values were summed for each patient for each 365-day period to obtain a cumulative measure of controller medication dose dispensed.

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Other outcomes. The primary clinical outcomes were asthma-related quality of life and asthma health care utilization. Asthma-related quality of life for the prior 2 weeks was assessed by patient self-report at baseline and follow-up Year 1, using the five-item Symptom Subscale of the Quality of Life Questionnaire (34). Health care utilization data included the date, diagnoses, facility, and service (ED, hospital in-patient, urgent care, or out-patient department) of all visits to KP or contracted facility, including visits with International Classification of Diseases, Ninth Revision code prefix 493. These data were extracted from KP databases for 1 year prerandomization and 1 year postrandomization to calculate the annual asthma-related visit rate for each patient. BOAT intervention sessions were not included in these rates.

In addition to SABA use (see above), secondary clinical outcomes included self-reported asthma control and lung function measured at baseline and follow-up Year 1. Asthma control in the preceding 4 weeks was assessed using the four-item Asthma Therapy Assessment Questionnaire (ATAQ) (35). Lung function measures included FEV1 expressed as percent of the predicted value based on age-, sex-, and race-specific norms (36), and the ratio of FEV1 to FEV6, expressed as a percentage.

Statistical Analysis

For each outcome, the primary hypothesis was that patients who participated in SDM would demonstrate a significant advantage relative to patients under usual care. The statistical significance of the secondary hypothesis, that SDM would demonstrate an advantage over CDM, was considered only if the primary null hypothesis was rejected. Given the conditional sequence of the hypotheses, no adjustment for multiple comparisons was needed to preserve the type I error rate of the secondary comparison (SDM vs. CDM) at the α of 0.05. Because BOAT was designed to test an SDM model, there were no a priori hypotheses regarding differences between the CD and usual care groups; however, results of these comparisons are informative and are presented for completeness.

Multivariable generalized linear regression analysis was used to estimate the intervention effect on each outcome (except ATAQ) at follow-up, controlling for the baseline value of that outcome, site, and the randomization balancing variables. To estimate the odds ratios of having well-controlled asthma (ATAQ score = 0) at follow-up Year 1 relative to usual care, multivariable logistic regression analysis was used. Baseline estimated, overall and by group, are presented without adjustment for any other variable. Missing data were not imputed: baseline and follow-up analyses were restricted to those patients with complete data for the analytic model variables at both time points.

The ratings scores of the care managers, patients, and quality control evaluator regarding the treatment decision process were compared using the Wilcoxon test. Group differences in patient characteristics and asthma medication regimens were tested using either χ2 tests or t tests. All group differences were tested using a two-sided α of 0.05, and all analyses used SAS software version 9.2 (37).

RESULTS

Recruitment

Initially, 5,414 patients were identified as being potentially eligible (Figure 2), of whom 2,534 were contactable and provided informed consent for preliminary eligibility screening (38). The final sample size was 612 (n = 204/group): Honolulu, n = 114; Oakland/Richmond, n = 180; Portland, n = 196; and San Francisco, n = 122. At the Year 1 follow-up clinic visit, 551 patients completed the patient assessment and lung function tests. Baseline and follow-up pharmacy and utilization data were extracted for all patients from existing clinical/administrative records.

Baseline Characteristics

As intended by the selection procedures and eligibility criteria, the sample consisted primarily of persons whose asthma, at baseline, was poorly or very poorly controlled (83.9%) (Table 1) when classified based on symptoms, rescue medication use, and lung function per guidelines of the Global Initiative for Asthma (39).

Intervention Process

Length and quality. Session 1 lasted an average of 77 (±17) minutes for the CDM group and 106 (±22) minutes for the SDM group. Session 2 averaged 31 (±18) minutes and 32 (±19) minutes, respectively. The follow-up phone contacts together averaged 30 (±25) minutes per patient for the CDM group and 35 (±25) minutes per patient for the SDM group. Intervention fidelity was high (see the online supplement).

Intervention cost estimate. Using KP salary guidelines, an average $54 per-hour rate for care manager salary and benefits (~$12,000/yr) was assumed and applied to the average length of the intervention sessions and follow-up telephone contacts, plus an average estimated 20 minutes additional time per patient for documentation and visit reminders. The estimated cost per patient treated was $174 using the SDM model (~3.2 h) and $142 using the CDM model (~2.6 h), a cost difference of $32.

Treatment decisions. At the conclusion of session 1, there were no differences in the proportions of the SDM and CDM groups whose regimen included an ICS or who were prescribed a LABA or allergic rhinitis medication (Table 2). However, for about 13% more SDM patients than CDM patients, the decision process resulted in selection of a higher dose fluticasone propionate preparation (220 μg) rather than the higher strength beclomethasone dipropionate (80 μg). KP’s formulary-preferred ICS, or than the lower-dose fluticasone propionate preparation (110 μg).

Medication Acquisition

Controller use. During the prerandomization year, approximately 18% of patients did not acquire any controller medication, and overall adherence, per CMA values, was very poor. In follow-up Year 1, the adjusted mean acquisition index for all controller medications was significantly higher in the SDM group (CMA, 0.67) compared with both the usual care (CMA, 0.46; P < 0.0001) and CDM groups (CMA, 0.59; P = 0.029) (Figure 3A), and also significantly higher in the CDM than in the usual care group (0.59 vs. 0.46; P = 0.0008). Similarly, in follow-up Year 1, the adjusted mean index for ICS alone was significantly higher in the SDM group (CMA, 0.59) than in both the usual care (CMA, 0.37; P < 0.0001) and CDM groups (CMA, 0.52; P = 0.017), and significantly higher in the CDM than in the usual care group (0.52 vs. 0.37; P < 0.0001).

In follow-up Year 2, the SDM group’s adjusted mean CMA indices for all controllers, and for ICS separately, remained...
higher than at baseline, but were no longer significantly higher than the usual care or CDM groups’ values (Figure 3A).

**Controller regimen anti-inflammatory potency.** In follow-up Year 1, the SDM group acquired more than twice as many beclomethasone canister equivalents than the usual care group (10.9 vs. 5.2; \( P < 0.0001 \)), and also significantly more than the CDM group (10.9 vs. 9.1; \( P < 0.005 \); Figure 3B). The difference between CDM and usual care was also significant (9.1 vs. 5.2; \( P < 0.0001 \)). In follow-up Year 2, the adjusted mean canister equivalents acquired by the SDM group remained greater than its baseline value (7.1 vs. 4.9), and continued to be significantly greater than those of the usual care (mean, 4.6; \( P = 0.00225 \)) and CDM groups (mean, 5.8; \( P = 0.04 \); Figure 3B). There was no longer a significant difference between CDM and usual care.

**LABA use.** In the prerandomization year, 22.2% of the patients acquired a LABA at least once, and 11.0% of those prescribed a LABA acquired an ICS-LABA combination. In follow-up Year 1, the adjusted mean canister equivalents acquired by the SDM group remained greater than its baseline value (7.1 vs. 4.9), and continued to be significantly greater than those of the usual care (mean, 4.6; \( P = 0.00225 \)) and CDM groups (mean, 5.8; \( P = 0.04 \); Figure 3B). There was no longer a significant difference between CDM and usual care.

**Clinical Outcomes**

**Asthma-related quality of life.** At follow-up Year 1, both the SDM (mean, 5.5) and CDM groups (mean, 5.4) had significantly higher adjusted mean symptom subscale scores than the usual care group (mean, 5.1) with no significant difference between the CDM and usual care groups. For those on a LABA in follow-up Year 2, the adjusted mean LABA acquisition index was significantly higher in the SDM group (CMA, 0.51) than either the usual care (CMA, 0.40; \( P = 0.0225 \)) or CDM groups (CMA, 0.41; \( P = 0.0143 \); Figure 3C), with no significant difference between the CDM and usual care groups. Patients in the SDM group also continued to be significantly more likely to acquire a LABA at least once than patients under usual care (Table 3), and significantly more likely to use a combination ICS-LABA preparation than patients under usual care.

**Figure 2.** Case progress through the Better Outcomes of Asthma Treatment (BOAT) study: identification, eligibility determination, initial assessment, randomization, intervention, and follow up. Patients were identified as potentially eligible based on their recent hospitalization or emergency department visit and a medication ratio of \( \geq 0.50 \), indicating an overuse of rescue medication. Not contactable includes patients whose primary care physicians (PCPs) were not notified, PCP did not respond, PCP did not assent, letters were not sent/received, or calls were not successfully completed. Non-screenable patients were not screened for multiple reasons, including disinterest in participating in the study. Includes persons who passively refused by failing to keep two or more enrollment appointments. Reasons for ineligibility include failure to meet spirometry criterion and other psycho-social and medical prerandomization exclusion criteria (e.g., drug rehabilitation or currently receiving asthma care management, etc.). Excludes five post-randomization exclusions for previously undiscovered behavioral/mental health problems: shared decision making (SDM), \( n = 1 \); clinician decision making (CDM), \( n = 4 \).
than usual care (7.1 vs. 8.1; \( P < 0.002 \)) (Figure 4B), but not significantly greater odds than the usual care group. The SDM group also had greater odds of no control problems than the usual care group (odds ratio, 1.6; 95% confidence intervals [CIs], 1.1–2.4; \( P = 0.006 \)). * SDM group, \( n = 191 \); CDM group, \( n = 185 \).

**Includes single preparations (salmeterol and formoterol) and ICS-LABA combination preparations (fluticasone-salmeterol 100, fluticasone-salmeterol 250, and fluticasone-salmeterol 500).**

**Definition of abbreviations:** CDM – clinician decision making; ICS – inhaled corticosteroid; GERD – gastroesophageal reflux disease; LABA – long-acting \( \beta \)-agonist; N/A – not applicable; SABA – short-acting \( \beta \)-agonist; SDM – shared decision making.

### TABLE 2. BASED OUTCOMES OF ASTHMA TREATMENT PARTICIPANTS, BY GROUP

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>UC</th>
<th>CDM</th>
<th>SDM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age, years*</td>
<td>45.1 ± 12.4</td>
<td>46.9 ± 12.1</td>
<td>45.7 ± 13.3</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>117 (57.4)</td>
<td>114 (55.9)</td>
<td>115 (56.4)</td>
</tr>
<tr>
<td>Male</td>
<td>87 (42.6)</td>
<td>90 (44.1)</td>
<td>89 (43.6)</td>
</tr>
<tr>
<td>Ethnicity*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>127 (62.3)</td>
<td>124 (60.8)</td>
<td>128 (62.8)</td>
</tr>
<tr>
<td>African American</td>
<td>30 (14.7)</td>
<td>34 (16.7)</td>
<td>32 (15.7)</td>
</tr>
<tr>
<td>Asian</td>
<td>22 (10.8)</td>
<td>18 (8.8)</td>
<td>20 (9.8)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>8 (3.9)</td>
<td>9 (4.4)</td>
<td>9 (4.4)</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>17 (8.3)</td>
<td>16 (7.8)</td>
<td>15 (7.4)</td>
</tr>
<tr>
<td>American Indian</td>
<td>0 (0.0)</td>
<td>3 (1.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school diploma</td>
<td>6 (2.9)</td>
<td>2 (1.0)</td>
<td>6 (2.9)</td>
</tr>
<tr>
<td>High school diploma/some college</td>
<td>116 (56.9)</td>
<td>132 (65.0)</td>
<td>114 (55.9)</td>
</tr>
<tr>
<td>4-yr college degree or higher education</td>
<td>82 (40.2)</td>
<td>69 (34.0)</td>
<td>84 (41.1)</td>
</tr>
<tr>
<td>Family income &gt;$40,000/yr</td>
<td>134 (69.1)</td>
<td>139 (70.9)</td>
<td>133 (66.8)</td>
</tr>
<tr>
<td>Ever told by doctor they had COPD</td>
<td>11 (5.4)</td>
<td>14 (6.9)</td>
<td>4 (2.0)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>33 (16.2)</td>
<td>33 (16.2)</td>
<td>31 (15.2)</td>
</tr>
<tr>
<td><strong>Asthma characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level of control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very poorly controlled</td>
<td>85 (42.1)</td>
<td>82 (40.2)</td>
<td>79 (38.7)</td>
</tr>
<tr>
<td>Poorly controlled</td>
<td>83 (41.1)</td>
<td>87 (42.7)</td>
<td>96 (47.1)</td>
</tr>
<tr>
<td>Moderately well controlled</td>
<td>29 (14.4)</td>
<td>24 (11.8)</td>
<td>17 (8.3)</td>
</tr>
<tr>
<td>Well controlled</td>
<td>5 (2.5)</td>
<td>11 (5.4)</td>
<td>12 (5.9)</td>
</tr>
<tr>
<td>Asthma controller medication use*</td>
<td>None</td>
<td>50 (24.5)</td>
<td>43 (21.4)</td>
</tr>
<tr>
<td>1–3 d/wk</td>
<td>38 (18.6)</td>
<td>44 (21.6)</td>
<td>41 (20.1)</td>
</tr>
<tr>
<td>&gt;4 d/wk</td>
<td>116 (56.9)</td>
<td>117 (57.4)</td>
<td>114 (55.9)</td>
</tr>
<tr>
<td>Hospitalized for asthma in past 2 yr*</td>
<td>76 (37.3)</td>
<td>69 (33.8)</td>
<td>71 (34.8)</td>
</tr>
<tr>
<td>Daytime symptom frequency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1/wk</td>
<td>11 (5.4)</td>
<td>12 (5.9)</td>
<td>14 (6.9)</td>
</tr>
<tr>
<td>&gt;1/wk but &lt;daily</td>
<td>111 (54.4)</td>
<td>114 (55.9)</td>
<td>101 (49.5)</td>
</tr>
<tr>
<td>Daily</td>
<td>82 (40.2)</td>
<td>78 (38.2)</td>
<td>89 (43.6)</td>
</tr>
<tr>
<td>Nocturnal symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2×/mo</td>
<td>113 (55.4)</td>
<td>116 (56.9)</td>
<td>114 (55.9)</td>
</tr>
<tr>
<td>&gt;2×/mo but &lt;5×/mo</td>
<td>22 (10.8)</td>
<td>24 (11.8)</td>
<td>29 (14.2)</td>
</tr>
<tr>
<td>&gt;5×/mo</td>
<td>69 (33.8)</td>
<td>64 (31.4)</td>
<td>61 (29.9)</td>
</tr>
<tr>
<td>FEV1% predicted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;80%</td>
<td>76 (37.6)</td>
<td>79 (38.7)</td>
<td>70 (34.3)</td>
</tr>
<tr>
<td>60–80%</td>
<td>62 (30.7)</td>
<td>65 (31.9)</td>
<td>78 (38.2)</td>
</tr>
<tr>
<td>&lt;60%</td>
<td>64 (31.7)</td>
<td>60 (29.4)</td>
<td>56 (27.5)</td>
</tr>
</tbody>
</table>

**Definition of abbreviations:** CDM – clinician decision making; COPD – chronic obstructive pulmonary disease; SDM – shared decision making; UC – usual care. Values are expressed as \( n \) (%). * Randomization balancing variable.

### TABLE 2. PRESCRIBED MEDICATIONS AT THE END OF SESSION 1, BY GROUP

<table>
<thead>
<tr>
<th>Medication</th>
<th>CDM* ( n ) (%)</th>
<th>SDM* ( n ) (%)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any controller*</td>
<td>181 (97.8)</td>
<td>186 (97.4)</td>
<td>1.08</td>
</tr>
<tr>
<td>Any ICS</td>
<td>178 (96.6)</td>
<td>181 (94.8)</td>
<td>0.50</td>
</tr>
<tr>
<td>Beclomethasone 80</td>
<td>108 (60.7)</td>
<td>90 (49.7)</td>
<td>0.032</td>
</tr>
<tr>
<td>Fluticasone 220</td>
<td>53 (29.8)</td>
<td>78 (43.1)</td>
<td></td>
</tr>
<tr>
<td>Other ICS*</td>
<td>17 (9.6)</td>
<td>13 (7.2)</td>
<td></td>
</tr>
<tr>
<td>LABA**</td>
<td>91 (49.2)</td>
<td>92 (48.2)</td>
<td>0.84</td>
</tr>
<tr>
<td>SABA</td>
<td>185 (100.0)</td>
<td>191 (100.0)</td>
<td>N/A</td>
</tr>
<tr>
<td>Allergic rhinitis medication</td>
<td>48 (26.0)</td>
<td>39 (20.4)</td>
<td>0.20</td>
</tr>
<tr>
<td>GERD medication</td>
<td>5 (2.7)</td>
<td>0 (0.0)</td>
<td>0.028</td>
</tr>
</tbody>
</table>

**Definition of abbreviations:** CDM – clinician decision making; ICS – inhaled corticosteroid; GERD – gastroesophageal reflux disease; LABA – long-acting \( \beta \)-agonist; N/A – not applicable; SABA – short-acting \( \beta \)-agonist; SDM – shared decision making.

**Randomization balancing variable.**

**Including flovent 220 preparations in combination with a LABA.**

**Includes ICS-LABA combination, budesonide, aerodil, beclomethasone 400, fluticasone 110, and beclomethasone with strength unspecified \( n = 2 \).**

**Includes single preparations (salmeterol and formoterol) and ICS-LABA combination preparations (fluticasone-salmeterol 100, fluticasone-salmeterol 250, and fluticasone-salmeterol 500).**

**Any controller† includes ICSs, leukotriene modifiers, and theophylline, but not LABAs. No patients in this sample were prescribed oral prednisone for daily/alternate day use.**

**Fisher’s exact test for cell sizes \( <5 \).**

**Values estimated from Pearson’s \( x^2 \).**

**DISCUSSION**

On the postcards mailed back after session 1, patients in the SDM group anonymously rated their influence on the treatment selection as being approximately the same as the care manager’s influence (mean rating, 3.1 on the five-point scale), but with neither being more influential than the other. The ratings of patients in the SDM group were significantly different from those in the CDM group, with the latter feeling that their care managers had a greater influence (mean, 2.5 ± 0.9; \( P < 0.0001 \)) than they themselves did.

**Patient-Perceived Roles in Treatment Decision Making**

On the postcards mailed back after session 1, patients in the SDM group anonymously rated their influence on the treatment selection as being approximately the same as the care manager’s influence (mean rating, 3.1 ± 0.6 on the five-point scale), but with neither being more influential than the other. The ratings of patients in the SDM group were significantly different from those in the CDM group, with the latter feeling that their care managers had a greater influence (mean, 2.5 ± 0.9; \( P < 0.0001 \)) than they themselves did.
who experienced either usual care or who received care management in which the clinician played the primary role in choosing the treatment regimen. By virtue of both (1) their greater fill refill adherence and (2) the pattern of their regimen choices, patients in the SDM group also acquired a significantly higher average daily dose of asthma controller medication (a larger number of beclomethasone canister equivalents) than either patients under usual care or active control patients. Additionally, patients who shared in making treatment decisions had significantly better clinical outcomes on all six measures—asthma-related quality of life, asthma health care utilization, use of rescue medication, lung function, and the likelihood of well-controlled asthma—compared with those receiving usual care. Although the SDM approach, and its behavioral and regimen changes it induced, were not associated with significantly better clinical outcomes compared with the CDM approach, the differences were consistently in a direction favoring SDM on both objectively measured and patient-reported outcomes. Furthermore, the clinician decision model only resulted in significantly better clinical outcomes compared with usual care.
care on four of the six clinical outcomes, and not in significantly less SABA use or a higher FEV$_{1}$/FEV$_{6}$ ratio. Only among patients in the SDM group was SABA use (the only clinical outcome available for the second follow-up year) significantly lower than that of usual care in follow-up Year 2.

The greater advantage of the SDM than the CDM model over usual care, as well as the greater persistence of its effectiveness in reducing SABA use, support a treatment preference for the SDM approach. However, a rigorous, long-term cost-benefit analysis is required to determine whether these clinical benefits are accompanied by cost savings that offset the cost of the CDM or the additional cost of the SDM intervention.

There was no evidence that the SDM approach resulted in a significant proportion of patients avoiding corticosteroids or electing inadequate doses. In fact, patient involvement resulted in higher proportions receiving the highest-dose fluticasone (220 μg) over the highest-dose beclomethasone (80 μg), and the combination ICS-LABA over separate preparations. Both tendencies appeared to be due to the greater convenience of the regimen (i.e., the need for fewer puffs of fluticasone [220 μg/d] than beclomethasone [80 μg/d] to achieve an equipotent dose), and the convenience of a single inhaler in the case of the combination preparation. Without the patient’s active involvement, the CDM care managers tended to choose the formulary-recommended ICS and separate ICS and LABA preparations.

Significance of Findings

An SDM approach is consistent with the concept of patient-centered care, and this study demonstrates that it is an important component with significant potential to not only change patient behavior through increased adherence, but also to improve clinical outcomes. The present findings have significant implications for asthma treatment and research, and potentially for the treatment of a wide range of other chronic conditions.

The findings also provide previously unavailable information on the average degree of clinical improvement, on a range of outcome measures, that is associated with a specific average increase in the cumulative annual ICS dose. This finding may help in evaluating the clinical importance of other interventions directed at improving medication adherence that may lack some or all of the clinical outcome measures obtained in the present trial.

The observation of a mean improvement in the quality of life score of 0.40 points, attributable to the SDM model, is less than the putative 0.50 minimal clinically important difference on that measure (40). However, questions exist regarding the methodology used to establish that minimal clinically important difference value (41, 42). The fact that the SDM group reported significantly higher quality of life at follow up, and that more than 70% of the group experienced a score improvement of greater than 0.50 points, is additional evidence that the clinical benefits of the intervention were evident to the patients.

Methodological significance. Concern with the quality of clinician–patient communication dates back at least 4 decades (43). Until now, observational studies have been the norm. Few controlled experimental studies have been conducted of modifications in communication around the treatment decision process, as distinct from other aspects of clinician–patient communication, and none of those that have been conducted concerned asthma. Most have emphasized one-time or acute treatment decisions, rather than the ongoing decisions associated with chronic conditions. Previous research also has generally focused on patient satisfaction, and has shown little evidence of significantly changing patient behavior or improving clinical outcomes. Furthermore, lack of assessment of the quality of the interventions, as delivered, has severely limited the interpretability of the largely negative trials (16).

Attributing the observed adherence, regimen potency, and clinical benefits to the patients’ active participation in their treatment decisions is justified because the SDM and CDM interventions were identical in all respects, except the treatment

![Figure 3. (Continued).](image)

| Table 3. Pre- and Postrandomization Percentage of Patients Dispensed a Long-Acting β-Agonist, by Group |
|---|---|---|---|---|---|
| Dispensed a LABA* | UC | CDM | SDM | P Value$^{1}$ |
| Pre-randomization $^{2}$ | | | | |
| Yes | 52 (25.5) | 44 (21.6) | 40 (19.6) | SDM-UC: P = 0.16 |
| No | 152 (74.5) | 160 (78.4) | 164 (80.4) | SDM-CDM: P = 0.35 |
| Follow-up Year 1 $^{2}$ | | | | |
| Yes | 59 (28.9) | 108 (52.9) | 112 (54.9) | SDM-UC: P < 0.0001 |
| No | 145 (71.1) | 96 (47.1) | 92 (45.1) | SDM-CDM: P = 0.77 |
| Follow-up Year 2 | | | | |
| Yes | 63 (30.9) | 90 (44.1) | 93 (45.6) | SDM-UC: P = 0.006 |
| No | 141 (69.1) | 114 (55.9) | 111 (54.4) | SDM-CDM: P = 0.77 |

Definition of abbreviations: CDM = clinician decision making; LABA = long-acting β-agonist; SDM = shared decision making; UC = usual care.
* Includes fluticasone-salmeterol 100, fluticasone-salmeterol 250, fluticasone-salmeterol 300, salmeterol, and formoterol.
$^{1}$ P values estimated from Pearson’s χ².
$^{2}$ UC = 204; CDM = 204; SDM = 204.
decision process. This experimental difference was also reflected in the perception of those in the SDM group that they had a greater role in the treatment decisions than did the patients in the CDM group. Previous controlled trials of SDM have given insufficient attention to the choice of the control condition. Joosten and colleagues' review (18) did not consider the appropriateness of the control condition as a design criterion; most studies reviewed simply compared their intervention to the current standard of care. Without an active control for features of the intervention other than the treatment decision process (e.g., providing patient education), it is difficult to know the extent to which any positive results are attributable specifically to the patient’s involvement in the treatment choice. The contribution of the BOAT study is enhanced by the existence of such a control, which allowed the elucidation of the unique contribution of the shared decision process itself.

**Asthma care management.** The target population of patients with poorly controlled asthma was a specific subset of patients with asthma within a very large managed health care system that had a long-standing commitment to high-quality asthma care management.
care, education of patients with asthma, and physician adherence to asthma treatment guidelines, and that, at some sites, offered asthma care management as an optional part of usual medical care. Virtually all of these patients had medication benefits with modest copayments that varied with the provisions of their insurance plans. Nevertheless, in the baseline year, these patients had acquired only about one-third of the days’ supply of medication that had been prescribed for them, and were experiencing frequent symptoms and activity limitations. Nearly one-fifth were not using an asthma controller at all. Our findings reveal that care management using a clinician decision model was clearly beneficial in terms of medication adherence and many clinical outcomes, and suggest that the likelihood of achieving the hoped-for benefits, and their magnitude, is increased by specifically involving the patient in the choice of treatment.

Need for ongoing reinforcement. The fall-off in asthma controller adherence/acquisition that was observed during follow-up Year 2 in both care management conditions is not surprising, and suggests that further follow up and reinforcement may be important to sustain the benefits of a shared decision process and of care management in general. For both models, the interventions typically occurred very early in follow-up Year 1, with no external reinforcement of the intervention processes after the patients’ 9-month follow-up intervention phone calls.

Primary care providers and other clinicians at KP who may have seen patients subsequently had no access to the intervention materials, and hence were very unlikely to have used a comparable shared treatment decision approach. Patients in both care management conditions were also less likely than patients under usual care to have asthma-related medical visits during follow-up Year 1, which would also reduce the opportunity for reinforcement.

The fall-off in adherence may also suggest that, having experienced a clinical benefit in Year 1, patients began to “step down” their therapy on their own. There is a need for further investigation into the pattern and causes of the decline in medication adherence over time, and whether periodic review by a care manager or physician can sustain both adherence and clinical benefits.

**Intervention cost versus benefits.** Compared with usual care, in follow-up Year 1 the SDM care management intervention increased the total days’ supply of controller medication acquired by the patient by an average of 77 days and by 9.6 beclomethasone canister equivalents, increased the quality of life score by 0.4 points, decreased asthma-related physician visits per year by 0.4 visits, reduced albuterol acquisition by 1.6 canister equivalents, increased the FEV1:FEV6 ratio by an average of 2.8 percentage points, and doubled the likelihood of having well controlled asthma. Although the SDM intervention required a per-patient investment of $174 for care manager time, and resulted in some increase in cost to the patient and health care system for medications, it also resulted in decreased costs for asthma-related provider visits. The study was not
powered to detect specific differences in the more costly ED visits and hospitalizations; hence, any cost savings in this regard are unknown, and should be the focus of future research.

Strengths
The SDM intervention included all four defining features of the SDM model (mutual information sharing, expressing treatment preferences, discussing the options, and agreeing on treatment). The study design tested the hypothesized benefits of this model in a randomized, controlled trial with a very strong active, as well as a passive, control group. Care managers’ adherence to their respective intervention protocols was objectively assessed, and confirmed the fidelity of intervention delivery, and it was documented that the interventions resulted in differing perceptions of patients’ own influence on the treatment decisions.

Other strengths include the use of objective measures of medication acquisition and refill adherence and health care utilization, available for all patients during follow up, high-quality spirometry, and multiple validated patient-centered measures.

Limitations
As an initial efficacy trial, this study was not powered to detect differences in ED visits or hospitalization rates—the most costly types of utilization; hence, a true cost–benefit analysis was not performed. The results of this study are also limited to adult patients; it remains to be determined whether the effects of a shared decision process can be generalized to pediatric patients (i.e., treatment decisions made by parents on their child’s behalf). Finally, in settings in which different treatment options have more pronounced differential cost implications for patients (e.g., non–managed care organizations), or in which asthma management guidelines support different patterns of medication usage (e.g., greater use of combination products), the priorities of adult patients may be more or less consonant with clinician recommendations than was observed here.

Although pharmacy dispensing data were obtained for both follow-up years, the inability to continue active follow-up and to extract health care utilization data through follow-up Year 2 is a modest limitation. However, even a 1-year follow-up of multiple behavioral, clinical, and health care utilization outcomes greatly exceeds the duration of most previous studies.

Conclusions
An SDM approach to the selection of asthma pharmacotherapy, in the context of asthma care management, is efficacious in improving both medication adherence and clinical outcomes. An appropriately powered study to determine the cost-effectiveness of this approach is warranted, as are further studies of the effectiveness of this approach in patients with other poorly controlled chronic diseases and in both younger and older patients.

Conflict of Interest Statement: S.R.W. received up to $1,000 from Asthmatix, Inc., for consulting related to assessment of patient-centered outcomes of bronchial spirometry, and multiple validated patient-centered measures. T.T.G. received $1,000 from trade show speaker fees. T.T.G. also received $10,000 from the University of Maryland School of Medicine, and $1,000 from Novartis, for participation in a meeting that involved the discussion of medication acquisition and refill adherence and health care utilization.


Other members of the Better Outcomes of Asthma Treatment (BOAT) Study Group: Faith Bocobo, M.D., Don German, M.D., and Alaina Poon, Pharm.D., the Permanente Medical Group (San Francisco, CA); Myungoc Nguyen, M.D., the Permanente Medical Group (Oakland, CA); John Hoehne, M.D., the Permanente Medical Group (Richmond, CA); Nancy Beiley, Ph.D., Palo Alto Medical Foundation (Palo Alto, CA); Christine Fukumoto, M.D., Hawaii Permanente Medical Group (Honolulu, HI); and Joan Holup, M.A., the Kaiser Permanente Center for Health Research (Portland, OR).

References
Online Data Supplement

Shared treatment decision-making improves adherence and outcomes in poorly controlled asthma

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Philip W. Lavori, PhD
Jodi Lapidus, PhD
William M. Vollmer, PhD
and the BOAT Study Group
METHODS

The study has been reviewed and approved annually since 2002 by the IRBs of the Kaiser Foundation Research Institute in Oakland, Calif., and of the Kaiser Permanente Center for Health Research in Portland, Ore., and Honolulu, Hawaii. Randomization occurred from January 2003 to January 2005; final extraction of two years’ follow-up pharmacy dispensing data occurred in mid-2007.

Patient Recruitment and Eligibility Criteria

More than 5,000 Kaiser Permanente (KP) members aged 18-70 years were identified at Portland, Honolulu, and San Francisco, Oakland, and Richmond, Calif. KP clinical sites (estimated aggregate patient population 3.8 million) through asthma registries as having some evidence suggesting asthma that was not well controlled, specifically, pharmacy evidence of overuse of rescue medications relative to asthma controllers, and/or a recent asthma-related emergency department (ED) visit or hospitalization. Of the 4,285 that were contactable, 2,534 provided informed consent and were screened in person; the remaining 1,751 could not be screened for multiple reasons including disinterest in participating. The in-person screening yielded 1,170 who met the basic eligibility criteria. Six hundred and twelve ultimately also met the study criteria for reversibility of airway obstruction and were randomized and completed the study. See Figure 2 in the manuscript for the CONSORT diagram showing the detailed recruitment process.

Exclusion criteria included intermittent asthma, recent asthma-related hospitalization (past 3 months), primary diagnosis of chronic obstructive pulmonary disease or emphysema, insufficient pulmonary function reversibility, regular use of oral corticosteroids, current enrollment in a KP asthma care management program, pregnancy, hospitalization during the
preceding three months, inability to speak/understand English, use of a non-KP pharmacy, 
expectation of dropping/losing KP membership during the study, or inability to meet baseline 
data collection requirements.

**Spirometry.** To be fully eligible, a 12% increase in FEV1 pre- to post- bronchodilator 
had to be demonstrated by all patients who did not use a controller medication regularly. Current 
or ex-smokers who regularly used a controller were required to exhibit at least an 8% increase. 
There was no reversibility criterion for never-smokers who regularly used a controller.

**Informed Consent Procedures**

All potentially eligible participants gave informed consent prior to the baseline 
assessment and lung function testing. Brief operational descriptions of all three study arms were provided in the informed consent document; the two experimental group descriptions specified what the participants and care managers would do but did not use labels (e.g., shared decision making) in these descriptions.

**Randomization**

A computer-based adaptive randomization algorithm was used to ensure better than 
chance balance, within site, among the three experimental groups. Five balancing variables were used: age (18-34, 35-50, 51-70 years), gender, race/ethnicity (White/Caucasian, African- 
American, Hispanic, Asian, Pacific Islander, American Indian/Alaska Native), hospitalization in the two years preceding enrollment (yes/no), and frequency of asthma controller use in the past week (none, 1-3, ≥4 days).

The assignment probabilities were set equal (1/3:1/3:1/3) for the first 15 randomizations at each site and were equal thereafter whenever no net group assignment imbalance existed (after summing the marginal imbalance scores across the five dimensions). When an imbalance did


exist such that there was one smallest group, the assignment probabilities were 6/8 for the smallest and 1/8 for each of the other two. When the two smallest groups were tied, the assignment probabilities were 3/8 for the two smallest and 2/8 for the largest group. These probabilities tended to offset the direction of imbalance, following Efron’s rationale.\textsuperscript{E2}

Allocation was concealed from staff randomizing patients. Randomization was implemented by having a designated, non-blinded research staff member at the site enter the relevant patient descriptors into the randomization module on the BOAT website, which immediately performed the randomization, stored the result, and returned the patient’s study assignment for implementation of the experimental assignment as indicated (e.g., referral to the designated care manager). All other study personnel, with the exception of the care managers, were blinded to patient’s study assignment.

**Compensation**

BOAT patients were not compensated by free access to medication, nor were they provided with any financial incentive for participation in the intervention sessions. Patients were provided with a modest incentive for completion of the study assessments at baseline and follow-up. All KP Northern California (KPNC) patients received $30 if they completed both baseline assessments; those at KP Portland and Hawaii received BOAT-logo hip/bum/fanny packs (per differing policies of the respective IRBs about incentives for participation in research assessments). Once randomized, KPNC patients received $35 for each follow-up assessment (at the Year 1 and Year 2 follow-up visits) with a $25 bonus for completing both; KP Portland and Hawaii patients received inexpensive BOAT-logo items (magnet, pens, etc.) for completing the assessment at follow-up Year 1. Follow-up retention was high and comparable at all sites (see Figure 2 in the manuscript for the CONSORT diagram).
Intervention Development

Intervention development had several critical goals: 1) to create two distinct care management approaches – one representing an operational definition of “shared decision making” (SDM) and the other an operational definition of “clinician decision making” (CDM); 2) to give patients in both groups a comparable understanding of asthma and the basis of its medical treatment; 3) to include specific activities in the SDM protocol to elicit the patient’s goals and priorities, present the various possible treatment regimens and their relative merits (in terms of control of inflammation, side effects, convenience, and cost to the patient), and ensure that the patient and clinician discussed and compared the various regimens relative to the patient’s priorities in order to arrive at a treatment decision to which both agreed; and 4) to train care managers (interventionists) with diverse professional and clinical backgrounds and personal styles to implement their assigned intervention (either SDM or CDM) in a consistent manner.

Prior to drafting the protocols, BOAT intervention development staff and co-investigators observed patient encounters with asthma care managers already employed in the KP system in order to determine how care management was being implemented per national and KP guidelines, assess the variations among care managers, and determine the extent to which any elements of structured shared decision-making were already a part of their approach. The BOAT International Advisory Group also provided input on the shared decision model and on issues that needed to be considered to operationalize this model. Drafts of the interventions were prepared and reviewed by several care managers and study medical advisors (pulmonary, allergy, or general internal medicine specialists). Care managers then pre-tested the interventions with 28 patients similar to those to be recruited into the clinical trial. These encounters were either observed by developers or audio-taped with a subsequent review by the development team.
Multiple rounds of revision and pre-testing occurred until satisfactory versions of the scripts were obtained.

**Intervention Protocol**

**Format.** The final SDM and CDM protocols were identical in format and in most components ([Figure 1](#) in the manuscript). Both involved two in-person visits with an asthma care manager (Session 1, intended to take 50-60 minutes; Session 2, typically held one month later, approximately 20-30 minutes), plus three brief follow-up phone calls at approximately 3-month intervals. Both protocols involved:

- a detailed asthma history;
- education about asthma and assessment of the patient’s understanding;
- explanation of how asthma control can be objectively determined from symptoms and lung function;
- comparison of this objective assessment of asthma control based on lung function test results and reported symptoms (the dial as shown in [Figure E-1](#) with the patient’s initial perception of their asthma control (using the same dial without the objective symptom and lung function criteria);
- explanation of what the patient’s current level of control, given the particular asthma treatment regimen the patient has been implementing, implies about the severity of their asthma ([Figure E-2](#));
- explanation of severity and control as the basis for medical treatment and of the rationale for an emphasis on controllers and minimal use of rescue medications;
- instruction on proper technique for use of inhalers/spacers;
o preparation of a written *Asthma Management and Action Plan* at the end of Session 1 based upon the regimen selected;

o establishment of a follow-up plan to evaluate and adjust the regimen, as necessary, at Session 2 (after the patient had implemented the plan for approximately one month) and in succeeding 3-, 6-, and 9-month follow-up telephone calls from the care manager to the patient.

As highlighted in Figure 1 in the manuscript, in the SDM protocol the patient’s goals and preferences regarding treatment, and any barriers they might confront in implementing treatment, were specifically elicited and taken into account in negotiating the treatment regimen (see Treatment decision process below). This was not done in the CDM protocol. The CDM care manager’s goal was to prescribe treatment following medication guidelines and encourage the patient to carry out that treatment.

The intervention protocols were in the form of “scripts” used by the care managers to structure their interaction with the patient. They included the use of the following visual aids/worksheets: 1) *Patient Information Form* for gathering data from the patient regarding recent asthma symptoms, perceptions of control, medication use, alternative treatments used, environmental triggers, and, in the case of the SDM intervention, patient goals for treatment and priorities regarding factors that were important to the patient (control, convenience, side effects, and cost); 2) *Asthma Controllers/Relievers*, a poster with pictures of actual medication delivery devices to help patients identify their asthma medications; 3) *How to Use Your Inhaler/Inhaler Skills Checklist* form (double-sided); 4) *Your Lungs and Asthma*, a poster with illustrations and key teaching points; 5) *How Well Controlled is Your Asthma*, a pictorial dial with segments defining each level of control (Figure E-1); 6) *Asthma Severity Classification*, a chart depicting
a 3-step process for assessing asthma severity in currently medicated patients, based on the National Asthma Education and Prevention Program’s (NAEPP) Expert Panel Report-2 consensus guidelines.\textsuperscript{E5} Care managers subsequently used the patient’s asthma severity classification to discuss treatment recommendations, per prescribing guidelines (Figure E-2); 7) an Asthma Management and Action Plan filled out for the patient at the end of the session; and 8) four 1-page Weekly Asthma Diary forms.

The SDM intervention used one additional resource, the Medication Planner worksheet (Figure E-3; see further description of its use in Treatment decision process below).

**Treatment options.** Identical treatment guidelines for asthma of different levels of severity were given to all the care managers (both SDM and CDM). All treatment regimens listed were consistent with the severity-based guidelines from the National Asthma Education and Prevention Program’s Expert Panel Report-2 and the KP system-wide guidelines and pharmacopeia. The various regimens were constructed from four different inhaled corticosteroids (ICS) (beclomethasone, fluticasone, budesonide, and flunisolide), either alone or in conjunction with another controller (a leukotriene modifier or theophylline) or a long acting beta-agonist (LABA). Options that involved a LABA always included an ICS, either separately or as a combined ICS-LABA preparation. For ICSs, different strengths and dosing regimen options (number of puffs and frequency – once or twice daily) were included as appropriate to each level of severity. Regimens roughly similar in the degree of control they offered were clustered on the list, and the clusters were ordered from those offering most to those offering least control. For treatment of mild persistent asthma, 11 treatment options were listed; for moderate persistent asthma, 33 options; and for severe persistent asthma, seven options – a total of 51 options altogether, encompassing most of the logical possibilities.
The treatment guidelines also included treatment recommendations for allergic rhinitis or gastroesophageal reflux disease where relevant, and suggested the option of a prescription for oral prednisone for the patient to have on hand in the event they experienced severe symptoms. Additionally, all regimen options included a short acting beta-agonist (SABA) prescribed for use as a rescue medication, as needed. For patients who reported exercise-induced asthma, the regimen could include the use of a SABA prior to exercise.

*Treatment decision process.* The treatment guidelines described above were used in different ways in the two intervention conditions. CDM care managers were given a form containing guidelines for prescribing, with options grouped by the severity of asthma to which they were appropriate. They explained to the patients that their treatment recommendation was based on the level of control of the patient’s asthma in relation to their current regimen, but they did not show the form to the patient or discuss alternatives regimens unless stimulated to do so by the patient. They also explored barriers to the implementation of treatment and encouraged the patient to adopt the prescribed regimen. The CDM care managers were instructed to answer any patient questions, but neither encouraged nor discouraged questions about alternate medications.

SDM care managers, on the other hand, discussed multiple treatment options with the patient in light of the individual’s goals and preferences. Control of inflammation, convenience, avoidance of side effects, cost, and any other considerations mentioned by the patient were listed, in the order of their priority for the patient, in the first column of the *Medication Planner.* The form presenting the full range of treatment options for asthma was shown to the patient. These differed in the nature of the medication and medication combination options, range of dosages, and schedule. Those options the patient wished to consider were entered at the top of
each succeeding column of the Planner. In all cases, the first treatment option listed on the Planner was the *de facto* regimen, i.e., for the patient to make no change and to continue to use or not use their current medications as they were. This very frequently meant a regimen that was not appropriate to the severity of their asthma or its current level of control. At least two alternative regimens, or as many as the patient wished to consider, were always considered from among the full range of options available. The patient and clinician then compared the pros and cons of each option in light of the patient’s goals and priorities, noting these pros and cons in the appropriate cells of the Planner and discussing these until the patient and care manager came to a joint decision.

It was apparent when a patient wanted to consider a treatment option that was not consistent with guideline recommendations because of the way the options were categorized on that form (by severity level and the nature of the medication(s), and the care manager would have pointed this out, as appropriate, by indicating that the option provided less potential to control the asthma than other options, or that it offered a greater level of control but also potentially greater risk of side effects and/or less convenience (e.g., due to increased dosing requirements for the same effect). Sharing such evaluative information was part of the clinician’s professional contribution to the discussion. The patient’s contribution was in sharing their own goals and preferences and evaluating the information provided. If a patient chose a potentially very inadequate or dangerous regimen, a procedure was in place to have them sign a form indicating they were aware of this, but this was rarely necessary.

Patients did not receive free access to medication. All prescribed medications were based on the KP pharmacopeia and costs were discussed per the individual patient’s KP membership plan (e.g., medication co-pay), which varied depending on their plan’s medication benefits.
During the session, the patient’s costs for different regimens could be accessed electronically by the clinician.

Further information on the SDM and CDM protocols is available from the corresponding author.

**Interventionist Training**

To be eligible to be a care manager, individuals had to be licensed, non-physician health professionals. BOAT recruited nurses (n=3), respiratory therapists (n=3), and pharmacists (n=7), nurse practitioners (n=1) and physician assistants (n=2), most of whom also served as care managers within the KP system, for total of 16 BOAT interventionists. Care managers’ professional discipline was not related to the number of patients they saw, and patient assignment to a specific care manager, within site and experimental group (SDM or CDM), was unrelated to either patient or care manager characteristics: 38 patients saw care managers who were nurses, 121 saw respiratory therapists, 114 saw pharmacists, 38 saw the nurse practitioner, and 64 saw a physician assistant.

Assignment of care managers to the SDM or CDM conditions was done purposively to achieve the best possible overall balance between the two conditions in terms of disciplinary backgrounds and amount of clinical experience. Care managers assigned to SDM and those assigned to CDM were trained separately and saw only the protocol for their assigned condition. Assignments of care managers to SDM or CDM were not strictly random because of the inherent limitations on the availability of appropriately credentialed clinicians who had requisite experience in adult asthma management (including in most cases, experience in asthma care management) and who were employed and available for the amount of time required to see the numbers of study participants at a given clinical site. Initially, five SDM and five CDM care
managers were trained. The initial 1-day small group training session included a general introduction to the BOAT study and an overview of the assigned intervention protocol; practice of the successive segments of the intervention (including demonstrations by the development team); and instruction on the use of spirometry results in the classification of asthma severity (ASB). This was followed by individual trainee practice with real or simulated patients, observation and subsequent debriefing by the development team; and instructions on the plan and procedures for pilot tests with four real patients in their home clinics. Each session with these four patients was tape recorded and reviewed against a checklist by the primary intervention developer/QC evaluator. Detailed feedback was given to each care manager on each session with a practice patient. After four initial patients, and when performance was deemed acceptable, the care manager was certified as ready to see study participants.

Subsequently, intervention QC procedures were implemented, with a review of audiotapes and ongoing individual feedback to the care managers. Monthly conference calls were held with the care managers assigned to a given experimental condition to discuss their experiences, provide reinforcement, identify any general problems or situations not explicitly covered in the existing protocols, and develop common solutions, which were subsequently documented by issuing formal supplements to the SDM and/or CDM protocols, as appropriate. A total of 11 supplements were issued. Some supplements were required when special patient circumstances were encountered for the first time and others were occasioned by external factors such as changes to the system’s formulary, medication availability, or release of new information about potential side effects. No supplements were required after the initial months of intervention implementation.
Personnel changes and the addition of a third and fourth clinical site in Northern California required training six additional care managers individually. The pattern of training and the training activities were essentially the same as described above. In total, six SDM and 10 CDM care managers were trained. The larger number of CDM than SDM care managers was due to the additional sites as well as unanticipated staff turnover (position changes within KP, spouse job relocation, family medical leave, etc.). In cases where care managers had limitations on their scope of practice, arrangements were made to have proposed prescriptions reviewed and signed by a KP study physician.

**Communication with primary care provider (PCP).** Communication and coordination of care between the care manager and patients’ PCPs throughout the BOAT trial was facilitated by the fact that all clinical contacts at KP, including those with the care managers, are documented in the patient’s chart and the basic facts regarding the patient’s regimen and clinical encounters were available in KP’s electronic database and accessible to the patient’s physicians and other authorized individuals involved in the patient’s care.

There was no intent that the patient’s physicians be fully blinded to intervention assignment, nor obviously could the care manager be blinded to the assignment of those patients assigned to him/her. Care managers were blinded to both the participation and study assignments of other patients, however. The patient’s physicians could see documentation of care management encounters in the patient’s record if and when they had occasion to view that record during the trial. They were not specifically informed which patients were enrolled or which had been assigned was to the SDM or CDM arms, or whether a given care manager was using the SDM or CDM protocol, but it is possible that they became aware of this if they had any question about the basis for a proposed treatment change for which the care manager was
seeking approval. Both SDM and CDM care managers sought approval for such changes, when required by the nature of the change and what was permitted by the individual care manager’s professional scope of practice with regard to prescribing new medications or adjusting dosages per protocol.

**Usual Care Control Condition**

Usual asthma care at the BOAT KP medical centers was based on a stepped-care approach to pharmacotherapy with the aim of long-term asthma control, as described by the NAEPP’s Expert Panel Report-2.\(^5\) Specific prescribing guidelines are also based on the NAEPP recommendations as well as the KP formulary.

As part of usual asthma care, KP physicians have the option to refer patients for specialized care by an allergist or pulmonary specialist and/or to refer patients to an adult asthma care management program, but the availability at specific sites varies and is subject to resource limitations. Consequently, the asthma care management program is not an integral part of the medical consultations occurring in the course of usual care. Where available, the program is based on physician-referral only and is an intensive 6-month program in which a non-physician advanced health care professional (usually a respiratory therapist, nurse, or clinical pharmacist; not a physician) provides education about asthma and works with the patient to improve treatment adherence, and identify and resolve any other barriers to attaining asthma control. Care managers are trained to provide asthma education and to use motivational interviewing and other strategies to identify and address barriers to regimen adherence. They can adjust treatment by protocol within KP asthma guidelines and in consultation with the patient’s physician.

All care managers – both in the existing KP program and BOAT interventions – documented each visit and phone contact in the patient’s chart, where it was available to the
patient’s physician. The care managers discussed their recommendations with the physician if they or the physician had any questions about the patient’s new regimen. For those care managers whose scope of practice did not allow independent prescribing, the physician approved and wrote the prescription.

**Intervention Quality Control (QC) Procedures**

Session 1 and Session 2 were audio-taped for approximately 10% of each care manager’s patients (the first four and, subsequently, every ninth patient). Ratings based on these taped sessions were used for ongoing QC and feedback to the care managers throughout the trial, but especially during the initial learning period. One study group co-author (NLB) evaluated all taped sessions. A second QC rater evaluated 32 randomly selected Session 1 tapes – four from each of the eight care managers (four SDM and four CDM) who saw the greatest number of study patients. For both protocols, the *Adherence to Protocol Summary Score* and *Decision Roles Score* scales were used to evaluate protocol adherence and the patient’s and care manager’s roles in the treatment decision. The raters scored each protocol element, and gave an overall adherence summary rating for the five major protocol sections (Set the Stage, Gather Information, Provide Education, Discuss Treatment, and Wrap Up).

The *Adherence to Protocol Summary Score* (APSS) was calculated as the mean of the five summary ratings for the major sections of the Session 1 protocol. Each section summary rating scale was anchored at the end points: 1=‘Inadequate’ and 5=‘Word for word (without reading).’ If both protocols were delivered as intended, mean scores across care managers would be approximately 5 with no group difference.

The *Decision Roles Score* reflected the relative contribution of care manager and patient to treatment decisions. After each patient encounter, both the care manager and patient rated
their individual role on a five point scale: [Decision made] 1= ‘By the care manager alone,’ 2= ‘Mostly by the care manager,’ 3= ‘By the patient and care manager equally,’ 4= ‘Mostly by the patient,’ or 5= ‘By the patient alone.’ If the interventions were delivered as intended, the SDM and CDM groups would have systematically different decision role ratings – with SDM encounters being rated $\geq 3$ and CDM encounters rated between 1 and 2.

**Evaluation by care manager.** Following each session, all care managers entered into the BOAT data collection website any regimen changes or new treatment decisions reached, as well as their evaluation of their own and the patient’s relative contribution to those decisions.

**Evaluation by patient.** At the close of each session, the patient was given a pre-addressed, stamped postcard to mail to the local research coordinating center with a rating of his/her own and the care manager’s relative contribution to the treatment decisions. The postcard asked “Who made the decisions in your meeting with the care manager about what your asthma treatment would be” and answers were recorded on a 5-point scale from 5=“I alone made the decision” to 3= “The care manager and I participated equally in making the decision,” to 1=“The care manager alone made the decision.” The postcard contained only the participant’s study ID number, no identifying information, and was not seen by the care manager.

**Further validation of the QC rater’s scoring.** The purpose of the QC validation by the second rater was to determine the general extent to which the ratings were consistent with those of the primary QC rater with regard to the SDM and CDM care managers’ adherence to their respective protocols and the relative contribution of the care manager and patient to treatment decisions in SDM vs. CDM encounters.

**Results of intervention QC procedures**
Protocol adherence. The protocol adherence scores assigned by the QC rater were high (SDM=4.0, CDM=3.9) and did not differ significantly between the two groups ($P=0.47$). A value near 4.0 indicates that all of the intended topics were covered, virtually all of them completely and thoroughly, that the interventionist followed the intervention script closely and covered topics in the prescribed sequence, that the handouts and other teaching aides/worksheets were used appropriately, and that accurate information was given in response to participant questions.

Roles of patients and care managers in treatment decisions. The QC evaluator’s ratings of the audio-taped encounters provided evidence that both the SDM and CDM protocols were delivered as intended. Patients, care managers, and the evaluator all accorded the patient a significantly greater influence on the treatment decisions in SDM than CDM sessions; all $p<0.0001$). The mean decision role scores for SDM patients, as assigned by care managers, the patients, and the QC evaluator, all were $\geq 3.0$, meaning that the SDM patients were consistently viewed as having an equal or somewhat greater influence on treatment selection than the care managers, with neither having a dominant influence on the decision. In contrast, for CDM sessions, all three felt that the patient had less influence on the treatment decisions than did the care manager (mean rating=2.5).

Further validation of the QC rater’s scoring. The association between the QC and a second raters’ evaluations of protocol adherence was moderately strong (SDM Spearman $Rho=0.50$, CDM $Rho=0.55$; combined groups $Rho=0.48$, $P=0.005$); for their decision role ratings, the combined association was very strong (SDM $Rho=0.36$, CDM $Rho=0.27$; combined $Rho=0.79$, $P<0.0001$). A correlation coefficient was the appropriate metric since the APSS is a quasi-continuous score (i.e., the average of five 5-point ratings). The fact that the correlation
using the ratings from both SDM and CDM sessions was substantially larger than the individual
group correlations was due to the much larger variance in decision role ratings when the two
experimental groups were combined, which reflects the intended differences between the SDM
and CDM groups.

Data Collection

Baseline and Year 1 follow-up data for all patients were obtained by patient interview,
lung function testing, and data extraction from KP pharmacy and health care utilization records.
Pharmacy dispensing data were available at all sites for follow-up Year 2. However, due to
resource limitations, it was not possible to extract health care utilization data for all patients for
the follow-up Year 2, since in Hawaii, this extraction required manual chart review.

Patient Characteristics

The patient questionnaire was administered via interview at the pre-randomization and
Year 1 follow-up clinic visits. Trained interviewers administered all questionnaires for the study
to avoid problems associated with low literacy. It collected information on sex, age, basic
demographic characteristics, currently prescribed asthma medications, including their prescribed
dosages and schedules, the patient’s use of their prescribed daily controller medication, daytime
and nocturnal asthma symptoms, and whether or not the patient had been hospitalized in the past
year.

Asthma-related quality of life. Asthma-related quality of life was assessed using the 5-
item symptom sub-scale of the Juniper Mini Asthma Quality of Life Questionnaire (MAQLQ) at
pre-randomization and 12-months post-randomization. The symptom sub-scale included:
shortness of breath, bothered by coughing, chest tightness or heaviness, difficulty sleeping, and
chest wheeze. Each item on the MAQLQ was asked by the interviewer relative to the last two
weeks, with response choices ranging from 1=maximum impairment to 7=no impairment.

It has previously been asserted by the developers of the AQLQ that a group means
difference of > 0.50 points is the minimal difference in order to conclude that a clinical benefit
has been demonstrated. However, more recent research suggests that the methodology by which
the minimal clinically important difference was determined is subject to serious question, and
that smaller group differences may indeed be clinically important. Members of the
development team have also modified their approach to focus on the magnitude of changes at the
individual patient level, and hence the proportion of patients whose scale scores changed by
more than a specific criterion amount.

**Asthma control.** Asthma control was self-reported using the Asthma Therapy
Assessment Questionnaire (ATAQ), a four-item questionnaire that assesses level of asthma
control in the past four weeks. Interviewers asked respondents to rate whether they had or did
not have problems on each of four dimensions (self-perception of asthma control, nighttime
awakening due to asthma symptoms, lost time at work due to asthma, and use of asthma reliever
medications). The total number of problems reported yielded scores between 0=no control
problems and 4=four control problems. At follow-up, few participants had ATAQ scores over 1,
so the 4-point scale was collapsed into binary form corresponding to an ATAQ score of 0 versus
scores of 1 through 4.

**Asthma regimen and severity and control classification.** During the pre-randomization
clinic visits, each patient’s regimen (medications and the dosages and schedules on which they
were actually being taken) was classified as to the asthma severity for which that regimen would
be appropriately prescribed (see Figure E-2), per the Global Initiative on Asthma guidelines.
This regimen was termed the *de facto* regimen and was not necessarily – and in many instances was clearly not – the regimen as prescribed by the patient’s physician. For example, a patient who only used rescue medications and not his prescribed daily controller would be classified as having a *de facto* regimen appropriate to mild intermittent asthma.

In a small proportion of cases, patients reported taking medications on a regimen or schedule that did not exactly match any of the standard guidelines-recommended regimens (e.g., taking fewer puffs per day of an ICS than would be appropriate for a patient with Moderate Persistent asthma, but also taking a LABA) or else the strength of the preparation was missing. In these cases, an appropriate intermediate regimen was defined (e.g., a regimen between mild and moderate or between moderate and severe).

The criteria and algorithm for determining the level of asthma control were based on the reported frequency of nighttime and daytime symptoms and the FEV₁ percent predicted value from baseline spirometry (see Figure E-1). When the level of control implied by participant’s symptoms differed from the level of control implied by the FEV₁, the lower of the two levels of control was used, as is recommended in the guidelines.

**Lung Function**

Lung function was assessed at the pre-randomization and Year 1 follow-up clinic visits per standardized research spirometry methods¹⁸,¹⁹,²⁰ using equipment that met or exceeded American Thoracic Society requirements (SensorMedic 1022 or OMI 2000, 8 liter dry rolling seal spirometer with a digital electronic assembly). This system employs software that determines the acceptability and reproducibility of each maneuver during the testing session and alerts the technician to possible problems (e.g., slow initiation of the maneuver, early cessation of airflow, coughing). Spirometry was performed before and 20 minutes after four puffs (200µg).
of albuterol, a SABA. Pulmonary function parameters included: 1) forced expiratory volume in 1 second (FEV$_1$) expressed as percent predicted relative to age, gender, using race-specific norms; and 2) the ratio of FEV$_1$ to forced expiratory volume in 6 seconds (FEV$_6$), expressed as a percentage (FEV$_1$/FEV$_6$).

Technicians received two days of small group or individual training consisting of basic didactic instruction, demonstrations, and observed practice until they could perform acceptable maneuvers. At their home sites they performed additional tests on volunteers. These data were transmitted to the pulmonary function reading center at LDS Hospital in Salt Lake City, UT (Dr. R. Jensen), for evaluation. Research assistants who met criterion performance in terms of the quality of their maneuvers were certified to perform study spirometry.

Spirometry quality was monitored by the pulmonary function reading center at the LDS Hospital in Salt Lake City, UT. Each maneuver from each participant session was graded (A = 4.0, B = 3.0, etc.), and the best, reproducible maneuver for each participant was used in the analysis. Scores were summarized by technician across participants and provided the basis for additional training, correction or reinforcement as needed.

**Verifying KP membership**

KP membership was verified for each patient for each study year to ensure that the estimates of medication adherence and health care utilization for each year were accurate. A comparison of KP membership records with pharmacy dispensing and medical visit records revealed that, even after eliminating apparent “gaps” in membership of two months or less, most patients who still appeared to have membership during the BOAT study period were still receiving medical care and filling prescriptions at KP facilities, suggesting some unreliability in the electronic membership records. Furthermore, using KP electronic records, a sensitivity
analysis was conducted in which we compared the results of the multivariate analytic model predicting the groups’ mean CMA values for patients with at least 11 months apparent membership with the results when the small proportion of patients with less than 11 months membership was included. The difference in results was negligible. Consequently, a decision was made to consider the full 365-day observation period for the pre-randomization and follow-up year(s) for all patients when calculating medication adherence, regimen potency, and health care utilization rates.

**Intervention Process and QC Outcomes**

Data on the SDM and CDM patients’ asthma regimens as a result of the intervention were available from their Asthma Management and Action Plan. Information from the care managers’ Post-Session Report forms, completed after each in-person encounter and follow-up phone call, included the starting and ending times of the encounter, any additions, deletions, or other changes made in the patient’s regimen during the session, and the care manager’s rating of the relative contributions made by the care manager and the patient to the treatment decisions. A similar rating was requested of the patient using the postcard described earlier.
REFERENCES


How well controlled is your asthma?

- **Well Controlled**
  - Symptoms less than weekly
  - Brief asthma episodes
  - Nighttime symptoms no more than twice a month
  - Normal lung function between episodes

- **Moderately Well Controlled**
  - Symptoms more than once a week but not daily
  - Nighttime symptoms more than twice a month but not weekly
  - Normal lung function between episodes

- **Poorly Controlled**
  - Symptoms daily
  - Asthma episodes may affect activity & sleep
  - Nighttime symptoms weekly or more often
  - FEV1 40-60% of predicted OR
  - PEF 40-60% of personal best

- **Very Poorly Controlled**
  - Symptoms daily
  - Frequent asthma episodes
  - Frequent nighttime asthma symptoms
  - FEV1 ≤ 40% predicted OR
  - PEF ≤ 50% of personal best
## Medication Planner

<table>
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<tr>
<th>Features that matter to me</th>
<th>Current Plan</th>
<th>Option 1</th>
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Comparative effectiveness of asthma interventions within a practice based research network

Tapp et al.
Comparative effectiveness of asthma interventions within a practice based research network

Hazel Tapp¹, Lisa Hebert²* and Michael Dulin¹

Abstract

Background: Asthma is a chronic lung disease that affects more than 23 million people in the United States, including 7 million children. Asthma is a difficult to manage chronic condition associated with disparities in health outcomes, poor medical compliance, and high healthcare costs. The research network coordinating this project includes hospitals, urgent care centers, and outpatient clinics within Carolinas Healthcare System that share a common electronic medical record and billing system allowing for rapid collection of clinical and demographic data. This study investigates the impact of three interventions on clinical outcomes for patients with asthma. Interventions are: an integrated approach to care that incorporates asthma management based on the chronic care model; a shared decision making intervention for asthma patients in underserved or disadvantaged populations; and a school based care approach that examines the efficacy of school-based programs to impact asthma outcomes including effectiveness of linkages between schools and the healthcare providers.

Methods/Design: This study will include 95 Practices, 171 schools, and over 30,000 asthmatic patients. Five groups (A-E) will be evaluated to determine the effectiveness of three interventions. Group A is the usual care control group without electronic medical record (EMR). Group B practices are a second control group that has an EMR with decision support, asthma action plans, and population reports at baseline. A time delay design during year one converts practices in Group B to group C after receiving the integrated approach to care intervention. Four practices within Group C will receive the shared decision making intervention (and become group D). Group E will receive a school based care intervention through case management within the schools. A centralized database will be created with the goal of facilitating comparative effectiveness research on asthma outcomes specifically for this study. Patient and community level analysis will include results from patient surveys, focus groups, and asthma patient density mapping. Community variables such as income and housing density will be mapped for comparison. Outcomes to be measured are reduced hospitalizations and emergency department visits; improved adherence to medication; improved quality of life; reduced school absenteeism; improved self-efficacy and improved school performance.

Discussion: Identifying new mechanisms that improve the delivery of asthma care is an important step towards advancing patient outcomes, avoiding preventable Emergency Department visits and hospitalizations, while simultaneously reducing overall healthcare costs.

Keywords: asthma, comparative effectiveness research, shared decision making, integrated approach to care

Background Significance

Asthma is a chronic lung disease that affects more than 23 million people in the United States, including approximately 7 million children [1,2] The burden of asthma in the U.S. is high, accounting annually for 2 million emergency department visits, 504,000 hospitalizations, 13.6 million physician office visits, and over 4,200 deaths while resulting in $15 billion in direct medical costs [3-5]

In North Carolina during 2007, the lifetime prevalence of asthma in adults was 12.1%, impacting over 800,000 individuals [6] The prevalence of asthma was disproportionately higher in African American and Native
American populations as well as low income populations [7]. Asthma prevalence for the state also reached 17.8% in children under the age of 17 [7]. Unfortunately, not only is asthma prevalence increasing in the Carolinas, but many patients suffering with asthma lack adequate control of their symptoms. Indeed, over 50% of adults noted asthma symptoms more than once per week and 21% had daily symptoms [7]. This resulted in one-third of adults losing at least one day of work because of their asthma over the prior 12 months, and 24% of asthma patients having at least one Emergency Department (ED) or urgent care visit related to their asthma during this same period of time [7]. Rates of ED utilization for asthma management were also almost 200% higher for minority children than non-minority children.

Our state’s asthmatic patients also frequently lack a usual source of care, and 45% of asthmatics went without a visit to their regular physician over the past year [7]. Patients with asthma also report a lower quality of life, with 18% of all asthmatic patients rating their health overall as poor [6]. Hospitalization rates are also higher for asthmatic patients and a significant health expense for the state. Over $88 million was spent on hospitalizations for asthma in 2004 costing on average $8,259 per hospital stay.

The 2009 Institute of Medicine (IOM) report identified two priorities in the need for comparative effectiveness research on asthma including the need to study an integrated approach to care and shared decision making [8]. The agency for healthcare quality and research (AHRQ) has also placed asthma on the priority list of conditions for comparative effectiveness research with particular interest in impacting populations that are low-income, minority groups, women, children, elderly individuals, and individuals with special health care needs, such as those who live in inner-city and rural areas. This attention to asthma is related to the burden of the disease on the U.S. population, disparities on outcomes for asthmatic patients, and the lack of knowledge of how to improve adherence to medications and subsequently improve asthma outcomes [9-17]. Gaps in our knowledge of the optimal medical management and predictors of asthma outcomes (including environmental triggers) are also present and need to be addressed by comparative effectiveness studies [18-24].

Potential solutions include more comprehensive asthma management strategies that build upon existing successes in the development of integrated care systems; special emphasis on targeting high-risk populations; the use of self-management and shared decision making approaches to care; and school-based interventions that can be linked with primary care providers.

The National Asthma Education and Prevention Program (NAEPP) asthma guidelines emphasize that the goal for optimal asthma control is to reduce both impairment and risk, and recommend a stepwise approach to pharmacotherapy [25,26]. Measurement of asthma control can be complex, encompassing physical examination, objective tests, and patient history [26]. Well-controlled asthma is characterized by: experience of symptoms and use of a rescue medication twice a week or less, no early morning or nighttime awakenings, no limitations on activities of daily living, normal forced expiratory volume in 1 second (FEV1) or peak expiratory flow (PEF) test results, and controlled asthma as determined by physician and patient assessments [27].

Prevention and reduction of asthma exacerbations are key to reducing risk associated with asthma. NAEPP guidelines define asthma exacerbation as an “acute or sub-acute episode of progressively worsening shortness of breath, cough, wheezing, and chest tightness—or some combination of these symptoms” [25]. Although most asthma exacerbations are treated in an outpatient setting, they present considerable difficulty for patients, including increased healthcare utilization, lost work productivity, school absences and increased healthcare costs [28].

One individualized behavioral approach to asthma disease management is the use of an asthma action plan, developed through asthma education activities to increase a patient’s knowledge and skills with regard to asthma control [25,29-31]. The National Institute of Allergy and Infectious Diseases (NIAID) inner-city asthma studies program found that a home-based approach tailored to an individual child’s specific risk factors provided a more effective intervention strategy, especially with the inclusion of a written asthma action plan [32,33].

Methods/Design
This study received ethics approval from the Institutional Review Board of Carolinas HealthCare System.

Description of all interventions
This study will include 95 Practices, 171 schools, and over 30,700 asthmatic patients. The interventions to be compared will include (Figure 1, Table 1): Group A: control practices providing usual care; Group B: control practices with a centralized electronic medical record (EMR), decision support tools, and population management tools; Group C: intervention practices have all the tools of Group B, but use an integrated system based on the Chronic Care Model to improve asthma outcomes; Group D: intervention practices will have all tools available to Group C with the addition of implementation of a shared decision making approach to care; and Group
Three main interventions are planned:

1) **An integrated approach to care (IAC) for asthma management**

Here our objective is to compare the effectiveness of an integrated approach to asthma management based on the chronic care model (CCM) with a non-integrated episodic care model (usual care control). This model based on the CCM, includes decision support, an electronic Asthma Action Plan, population management tools, training in the practice redesign and rapid cycle process improvement by a quality improvement coach, and linkages to community resources. This approach will be compared to control practices (A) and practices that receive the tools without training with a coach (B).

2) **A Shared Decision Making (SDM) approach**

The objective is to compare the effectiveness of a combined shared decision making and IAC approach (C) with the integrated approach alone and with usual care (control). This model is based on the successful intervention developed by Wilson and colleagues that...
changes the dialog between patients and physicians to positively impact patient medication compliance and asthma self-management. This model will be implemented in select practices that have already implemented the IAC approach to determine if additional benefit can be gained using SDM. Practices receiving the SDM intervention also primarily serve disadvantaged populations including the uninsured, Medicaid patients, disabled Medicare patients, and minority groups.

3) A School-Based Care (SBC) Approach

Here our objective is to compare the effectiveness of a school-based approach to care with the integrated approach to care and with and without the shared decision making approach to care and against the control. This intervention will provide an electronic data capture system to a robust CDC funded school-based intervention to assist with evaluation and to link the school-based care team with primary care providers. This system has identified almost 8,500 asthmatic children who will be a part of this intervention. Outcomes for children will be compared to children in control practices as well as practices in the IAC and SDM approach.

Clinical Outcomes

The major clinical outcomes goals are: reduced hospitalizations and emergency department visits; improved adherence to medication; improve quality of life; reduced school absenteeism; improved self-efficacy and improved school performance. Associated quality goals are to improve percentage of patients with persistent asthma who are prescribed a controller medication; and those with asthma who receive a flu vaccination. Quality goals will be measured by the percentage of patients who reach the goal out of all patients identified with the disease. The three interventions that will be undertaken each have the potential to impact these goals. The data collected for the evaluation of the three approaches to asthma management will also be leveraged to identify other important variables that impact asthma outcomes including: pharmaceutical management, co-morbidities (Tobacco Use/Exposure, GERD, Allergic Rhinitis, Obesity, Sleep Apnea), patient demographics (age, sex, race/ethnicity, insurance status), and community level variables (neighborhood quality of life, build environment and transportation elements, pollution sources, and housing density).

Setting

The research network coordinating this project (The Mecklenburg Area Partnership for Primary Care Research, MAPPR) includes the hospitals, urgent care centers, and outpatient clinics within Carolinas Healthcare System (CHS) that share a common Electronic Medical Record (EMR) and billing system allowing for rapid collection of clinical and demographic data (Figure 2). This vertically integrated hospital system provides care to over 1.2 million patients including over 38,000 patients with a diagnosis of asthma. Between 2008 and 2009, these patients were responsible for almost 17,500 hospitalizations and 68,000 clinic visits. The research network includes a group of ambulatory clinics that together provide over 85% of care to the uninsured

Table 1 Asthmatic Patients Seen in the CHS System 2008

<table>
<thead>
<tr>
<th>Description</th>
<th>Number of Patients</th>
<th>Number of Clinic Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Unique Patients with an Asthma Diagnosis</td>
<td>38,634</td>
<td>77,582</td>
</tr>
<tr>
<td>African American Race</td>
<td>14,168</td>
<td>34,551</td>
</tr>
<tr>
<td>Hispanic Ethnicity</td>
<td>2,043</td>
<td>4,596</td>
</tr>
<tr>
<td>Age &lt; 18</td>
<td>110,058</td>
<td>21,357</td>
</tr>
<tr>
<td>Number within Mecklenburg County</td>
<td>16,458</td>
<td>41,961</td>
</tr>
<tr>
<td>Uninsured, Medicaid, or Medicare</td>
<td>13,564</td>
<td>31,022</td>
</tr>
<tr>
<td>Number of Hospitalizations for Asthma</td>
<td>10,321</td>
<td>NA</td>
</tr>
<tr>
<td>Number Emergency Room Visits</td>
<td>30,121</td>
<td>NA</td>
</tr>
<tr>
<td>CHS School Children with Asthma</td>
<td>8,500</td>
<td>NA</td>
</tr>
</tbody>
</table>

Figure 2 Map of North and South Carolina Showing the Scope of Carolinas Healthcare System (CHS) Each county shaded in green is home to a CHS facility including the 32 hospitals and 95 clinics that will take part in this project.
patients within the surrounding community. Inclusion of the 92,000 patients who receive care within these clinics allows the evaluation of the effectiveness of interventions for asthma management within a large population of poor and/or underserved community members. The MAPPR network includes the Mecklenburg County Health Department and the county school system (Charlotte Mecklenburg Schools, CMS). Indeed, CHS employs the 121 school nurses who assist with management of children with asthma in the school setting.

Development of the Intervention

The approach is to implement the three separate but interrelated interventions across the community. The primary intervention, the integrated approach to asthma management, has been implemented in 10 practices, and through this project will be deployed in 65 additional practices. In addition, an active federally funded school-based system of care will be enhanced through this project allowing improved evaluation and comparison of outcomes between the school’s system of care and other intervention as well as allowing the creation of a school to healthcare provider link.

Database Development

The overall strategy for this study is to create a centralized database for evaluation of comparative effectiveness of five different groups for management of asthma patients. The new database will draw information from the Carolinas Healthcare Systems billing and clinical databases, Medicaid claims data, school system data, chart abstraction, community level datasets, patient surveys and focus groups.

A centralized database will be created with the goal of facilitating comparative effectiveness research on asthma outcomes specifically for this study. The database named ACER (Asthma Comparative Effectiveness Research Database) will be setup using Microsoft SQL Server 2005 (Redmond, WA) and designed to support SAS (SAS Institute, Cary, NC) that is the standard analysis software used within the institution. The data will flow from 8 different sources including: the healthcare system’s billing data, the healthcare system’s clinical data, school data from the Institute for Social Capital, school nurse data, Medicaid claims data, patient level data (from surveys and focus groups), and community level data from the Center for Metropolitan Studies (Figure 3).

Any patient that has had a diagnosis of asthma recorded for billing purposes at any visit throughout the system since 2008 will be identified for the study as having asthma. This system recorded 38,634 unique patients for 2008 resulting in 77,582 visits to primary care practices. The unique medical records for each of these patients will be identified and the healthcare utilizations for these patients will be monitored prospectively through the course of the study. Additional data elements drawn from this dataset include patient demographics (age, gender, sex, race/ethnicity, and insurance type) as well as concurrent diagnoses.

For this study, clinical data from the EMR will be drawn from 75 of the study clinics (65 clinics in Group B and 10 clinics in Group C). All patients with asthma will be identified from billing data and the same unique medical record number will be used to pull these patient’s clinical data. Data elements that can be pulled include: Tobacco Use/Exposure, assessment of daytime/nighttime symptoms, controller medication for persistent asthma, action plan given/updated and flu vaccine up to date.

The clinics in this study that are not connected to the EMR will be used as control practices. Clinical data from these clinics is abstracted from charts by the CHS quality team and will be ongoing during the 3 years of this study for comparison. Data collection will occur on a quarterly basis and will include: Tobacco Use/Exposure, assessment of daytime/nighttime symptoms, controller medication for persistent asthma, action plan given/updated, and flu vaccine up to date.

A local not for profit institute has been working with the Charlotte Mecklenburg School System for the past 4 years to store data for community-wide research. The Institute stores data on school absenteeism and school performance including End of Grade testing results. The school data will be added to the ACER server for the study to examine changes in school performance and absenteeism that are related to the study interventions.

The management of children with asthma within the school system through school-based nurses has enormous potential to improve asthma outcomes. This study will support the development of an electronic data capture system for school nurses. Data elements collected will include clinical measures including peak flows, asthma medications utilization, and the Asthma Action Plan.

The North Carolina Medicaid System is one of the most successful in the country in terms of providing high quality of care at a low cost [34]. This system, Community Care Partners of North Carolina, works by incentivizing primary care physicians to provide preventive care through the assistance of case managers [35]. CCPGM and Carolinas Healthcare System have a data sharing system allowing access to data for the Medicaid patients with asthma. The data are collected electronically and includes health services utilization (hospitalizations, ED and clinic visits) and data on medication compliance (prescriptions filled). These data are sent to CHS on a monthly basis and will continue to be shared for this study. Data for Medicaid will be matched based
on patient name and birth date and entered into the ACER database for analysis.

**Patient Level Data**

Patient level data will be collected using direct patient surveys, focus groups, and information exchange during the community forums.

**Surveys**

Depending on patient age, the patient survey will include the Mini Asthma Quality of Life Questionnaire (Mini-AQLQ) or Mini Pediatric Asthma Quality of Life Questionnaire (Mini-PAQLQ), the Asthma Therapy Assessment Questionnaire (ATAQ) and 2 additional five-point scale questions added by the research team. The Mini AQLQ (5 items) will be licensed from QOLteck (West Sussex, UK) and used to collect data from all patients that are 17 years and older where this survey has been validated [36]. The Mini PAQLQ will also be licensed from QOLteck, and this 13 question instrument will be used to assess quality of life in children between the ages of 7 and 17. The 5 point ATAQ questionnaire will be used to evaluate the effectiveness of asthma management for all patients. The pediatric version will be administered for children age 5-17 and adult version for patients age 17 and older [37]. The final questions are identical to those used by Wilson and colleagues to measure the patient’s perceptions of a shared decision making approach and asthma self-efficacy [37-39]. These questions will ask about the patients’ perceptions of the quality of care they received and the influence they had versus the medical team in the development of their treatment plan. The final survey will include 12 questions for adults and 20 questions for children under the age of 17 which will be printed on a single page for mailing.

Surveys will be mailed to a randomly selected group of asthma patients who receive care within the 95 clinics.
followed for this study every 6 months with the aim of collecting 100 surveys from each of the 5 groups at each time point. Patients will be incentivized to complete the survey with a $10 gift card for participation. Five of the clinics in this study are part of a network that provides care to disadvantaged patients including the uninsured, low-income minority populations, the indigent, disabled Medicare, and Medicaid patients. These populations tend to have frequent address changes and lower rates of literacy, resulting in lower rates of participation with mailed surveys. This group is of key importance for this research study and 4 of these 5 clinics have been targeted to receive additional interventions to improve asthma outcomes. Patients that complete the survey on-site will be provided with a $10 gift card to reimburse them for the time required to participate.

All survey data will be added to the ACER database on a weekly basis. Online survey results will be collected using Survey Monkey (http://SurveyMonkey.com) and this data with the patient identifier and date of completion will be downloaded and transferred into ACER. Mailed surveys will be compiled by the research team and manually added to the database. In addition, the date that the survey was mailed and returned will be included for surveys returned by mail. If a survey is completed both online and via the mail, the mailed version will be discarded.

**Focus Groups**

Qualitative data will be collected through focus groups performed with patients (or their parents for children under age 17) and providers from each of the 5 groups throughout the study. Each focus group will have between 8-10 participants and will occur at baseline and every 6 months to collect qualitative information about the study. There will also be a focus group once every 1-3 months to evaluate the process and the monthly asthma meetings. There will be no recruitment for these, as the participants will be the regular attendees from the monthly asthma meetings (i.e. providers, key personnel from the clinic). A focus group guide for these sessions has been developed by the research team. Groups B-E will be asked to provide feedback about their perceptions of the study and its impact on their ability to receive or provide high quality asthma care. Particular interest will be focused in these groups on soliciting critical feedback about the project to be used for process improvement. Clinics in Group A will also be asked to participate, but these groups will be asked more general questions about their management of asthma patients and how they hope to improve care for asthma patients in the future. Focus group data will be analyzed and provided back to all participating practices and research team. Data from focus groups will be identified only by practice and no individual data from the focus groups will be collected. Focus group data will not be added to the centralized ACER database.

**Community Level Data**

Through MAPPR’s affiliation with the University of North Carolina at Charlotte, UNCC, and Center for Metropolitan Studies, geocoded data will be made available for this study showing: housing density, neighborhood quality of life, pollution sources, transportation and built environment elements, race/ethnicity, and household income. These data have been developed by the center or purchased from Claritas (New York, NY). We will geocode patient addresses for the ACER database which will allow the research team to examine and map asthma outcomes compared with other community level variables. One example of this technique can be seen in Figure 4, where patients with an asthma diagnosis within the clinic system for underserved or disadvantaged patients are mapped across Mecklenburg County. These maps can quickly be compared to other community-level data that will be shared by the Center for Metropolitan Studies.

**Analysis**

**Intervention Effectiveness Analysis**

Comparisons between each group (A-E) and within Group E will be performed by statistical tests of regression model parameters. Specifically, we will generate a separate regression model for each of the six clinical measures and both quality measures (Table 2). Comparison groups will be defined as factors in the model. Propensity score methods will be used to control for differences in pharmaceutical management, patient demographics, co-morbidities, and community level variables between groups. Since Group E is not independent of Groups A-D, we will test for significant interactions between Group E and the other groups. A secondary analysis of the data will be performed to examine other important variables that impact asthma outcomes. This includes pharmaceutical management, co-morbidities (Tobacco Use/Exposure, GERD, Allergic Rhinitis, Obesity, Sleep Apnea), patient demographics (age, sex, race/ethnicity, insurance status), and community level variables (neighborhood quality of life, build environment and transportation elements, pollution sources, and housing density). In this analysis, we will build a regression model for each of the 6 clinical outcomes and use pharmaceutical management, patient demographics, co-morbidities, and community level variables as predictors. Regression tree methods will be used to help understand the potentially complicated interactions between these predictor variables. In both the primary and secondary analyses, linear mixed effects models will be used to account for practice-level effects within intervention group.
Cost Analysis

The basic form of our analysis is that of a follow up study with three years of analysis. We will construct measures of service use and costs, by category of service as well as for all services combined, expressing all these measures in per-time-period terms for comparability across groups. This will permit comparison among groups to identify the effects of the intervention on health disparities, for example. Each of these dependent variables (use and cost, by service category) is specific to a calendar year. Thus the basic unit of analysis is the person-year of use or cost. We will use regression analysis to estimate the mean difference in outcome variables between groups, where the groups are identified by a dummy variable to examine effects of the integrated approach to asthma management based on the chronic care model (CCM), while holding constant other factors, and, in a more detailed analysis, by a set of dummy variables to examine the effects of the group interventions B through E, as compared with the control group A receiving usual care. Interactions between the dummy variable(s) and dummy variables indicating race/ethnicity will identify the effect of the CCM on health disparities. Cost savings to be achieved have the potential to be substantial, especially for the costs of hospitalization,
which is a major cost driver. For example, using nationally representative data [40] we found that, among persons ages 19-64, the adjusted rate of preventable hospitalization for asthma for African American women was 2.2 times as great as that for non-Hispanic white women, while the comparable adjusted difference for men was 4.2 times as great. In this same age range, the adjusted rate for women was 2.2 times as great for Hispanics as for non-Hispanics, while among men the rate was 3.3 times as great for Hispanics.

Differences were much larger among those ages 65 and older, with rates 6 times higher than whites among men for African Americans, and over 8 times higher for Hispanics. Thus, even a modest reduction in the disparities of preventable hospitalization attributable to asthma affecting African Americans and Hispanics will substantially reduce total costs. Of course, in addition to reducing disparities in preventable hospitalization for African Americans and Hispanics, the intervention is likely to reduce preventable hospitalization related to asthma for all persons in the intervention groups.

Discussion

Identifying new mechanisms that improve the delivery of asthma care is an important step towards advancing patient outcomes, avoiding preventable Emergency Department visits and hospitalizations, while simultaneously reducing overall healthcare costs. The wide range of patient types with asthma (e.g., pediatrics vs. adults) as well as the varying degree of severity of the disease makes it difficult for a single approach to work universally. In addition, variation in primary care clinics and providers makes it challenging to implement new practices and concepts around asthma management such as shared decision making. To overcome these limitations, this study was designed with multiple interventions and two control groups. Perhaps most importantly, the shared decision making component of the intervention was designed to be developed and implemented using participatory methods to ensure broad uptake and dissemination.

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Authors’ contributions

All authors made significant contributions to the conception and design of this study and read and approved the final manuscript. HT and MD drafted the manuscript.

Competing interests

The authors declare that they have no competing interests.

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References

1. What is asthma?. [http://www.nhlbi.nih.gov/health/dci/Diseases/Asthma/Asthma_Whatis.html].

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