Personalized Disclosure by Information-on-Demand:
Attending to Patients’ Needs in the Informed Consent Process

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Introduction: Impediments to Informed Consent

In an explicit attempt to reduce physician paternalism and encourage patient participation in making health care decisions, the informed consent doctrine has become a foundational precept in medical ethics and health law. The underlying ethical principle on which informed consent rests — autonomy — embodies the idea that as rational moral agents, patients should be in command of decisions that relate to their bodies and lives. The corollary obligation of physicians — to respect and facilitate patient autonomy — is reflected in the rules that have been created to implement consent procedures, especially those requiring disclosure of relevant information.

However, there are many practical impediments to patient self-determination in health care decision-making. Well-meaning physicians often lack the time to live up to the ideal of facilitating genuine, informed deliberation with and by their patients, and many lack the motivation or skill to do so successfully. Even when physicians are willing and able to undertake a personalized interaction, many patients lack the necessary health literacy and numeracy to comprehend physicians’ disclosures, and studies of cognitive heuristics and other behavioral impediments to “rational” decision-making have cast doubt on patients’ capacity to understand the disclosed information and make choices that accurately reflect their preferences and further their aspirations.

Still, even if these practical impediments to informed patient decision-making were successfully addressed, there is another obstacle at the very heart of the informed consent doctrine — the lack of patient control over the flow of information.

Physicians have the information patients need to make educated decisions, whereas patients generally do not. The accepted remedy (in ethics and the law) for this information asymmetry problem is mandated disclosure of specified information by the physician. Some states have adopted the “reasonable patient” standard in determining the nature and amount of information that should be provided to patients by their doctors (“what would a reasonable patient need to know to make a decision?”), while others adhere to the “reasonable physician” standard (“what information would a reasonable physician convey to her patient prior to treatment?”).

Whatever the standard of information disclosure, the underlying assumption is that given the information, the reasonable patient will be able to identify the information that is relevant to her choice and will be in a position to make a decision aligned with her values and goals (i.e., she will “know what to do”). In many cases, though, the patient may not know which information is truly material to her decision, especially when presented with exhaustive information. We refer to this as the “relevance problem” — patients need assistance in acquiring, interpreting, and filter-
ing information in a way that best fits their personal needs — i.e., they need information that is relevant and helpful to them, and that clarifies the nature of the choice rather than obscuring it. This is one reason why the achievement of genuine “informed consent” is often characterized as a process rather than an event. Unfortunately, the idealized process of informed decision-making is not often realized in practice. Instead, for reasons we describe below, meaningful dialogue between doctors and patients has all too often been displaced by a stylized ritual of reading and signing a form.

The Ritual of Informed Consent

Most agree that the commonplace ritual of informed consent — focused as it is on the presentation and signing of a consent form — has many flaws. Viewed from the patient’s perspective, what should be an iterative, personalized process of receiving and absorbing information and seeking clarification or further information has become standardized and inflexible, as physicians attempt to comply with a duty to inform all patients in a generic, “reasonable” manner. As a result, some patients may be under-informed, while others are overwhelmed, distracted from what is important to them (which could be quite different than what a “reasonable patient” would want to know), or unable to exercise a right not to know. One might say, in response, that the interests of both parties — physicians as well as patients — have to be taken into account in formulating rules for information disclosure. A requirement for individualized or “subjectively” tailored disclosures would leave physicians without any practical way of avoiding liability for failing to predict what information any given patient would want to know. Indeed, for just this reason, courts have explicitly rejected the “subjective patient” standard of disclosure that focuses on individual patients’ needs for information in favor of the “reasonable patient” standard.

When the problem is viewed in this way, a standardized disclosure might be seen as a logical feature of the law’s effort to formulate a predictable rule. However, the current approach has by no means eliminated the risk of physician liability for failure to obtain informed consent. To the contrary, many physicians are still uncertain what is expected of them, even in states that accept the “reasonable physician” standard. Even when standardized disclosures have been endorsed by professional bodies or risk management experts, courts have occasionally ruled that the patient was entitled to other information. Consequently, the failure to disclose information relevant to a given patient in those cases amounts to a failure to obtain informed consent, thereby creating indeterminacy and unpredictability and shaking professional confidence in the value of the consent process. As a result, some physicians act defensively, bombarding their patients with exhaustive information (“overkill”), which still may not meet a given patient’s needs; or despairing of patients’ understanding such an extensive disclosure, they choose to disclose some minimal amount of information, thereby exposing themselves to liability if that information is retrospectively determined to be insufficient. Uncertainty is also heightened by variations in patient presentations (e.g., co-morbid disorders, concurrent treatments, unusual patterns of symptoms, degree of medical literacy) that make standard disclosures (such as those recommended by professional associations) inapplicable or inadequate at the time of the medical interaction.

In sum, obtaining the patient’s informed consent has tended to become a generic, impersonalized ritual, in which physicians are obeying an ethico-legal decree of uncertain scope (“be certain to inform your patient”), and often acting defensively, and in which patients lack control over the flow of information, leaving them at risk both for being under-informed relative to their decisional needs and of receiving more information than they need or desire. This surfeit of unwanted information can distract them from the relevant issues, leave them unduly worried about miniscule risks, and possibly lead to decisions contrary to their real wishes. This is all the more disturbing because preoccupation with the “legal sufficiency of the disclosure” makes physicians cynical about the whole exercise (often awkwardly and revealingly called “consenting” the patient), and undermines the ethical aspiration of achieving a constructive and meaningful dialogue with the patient about the patient’s wishes and needs.

Importantly, legal claims of inadequate informed consent are made in retrospect, when the unwanted outcome has already transpired. At this stage, it is harder to ascertain what level of specification would have altered the patient’s decision, thus making it difficult for physicians to counter patients’ claims that patients would have chosen a different course of action, if only the information had been available. Judges and juries, like everyone else, are influenced by a strong “hindsight bias” — i.e., the tendency to believe that since a risk materialized, if told about it in advance, the patient would have chosen differently. The imposition of liability in these cases has significant financial consequences, both in respect to damages awarded to plaintiffs in malpractice cases and the subsequent impact on practitioners’ insurance premiums.

The question addressed in this article is whether an alternative paradigm of informed consent could
achieve a constructive fit between the flow of information and each patient’s actual informational needs while also providing greater legal protection for physicians.

The approach we are proposing might be described, in shorthand form, as “information on demand” (IOD). The fundamental idea is that patients should be able to tailor the disclosure process to their own values and informational needs.

**Achieving Personalized Disclosure**

We aim to shift genuine control over the informational process to patients, and to facilitate a personalized process by overcoming both the information asymmetry problem and the relevance problem. By personalizing the process of seeking and receiving information, our proposal would allow patients to specify their desire for information in a prospective manner. This approach rests on recognition that people differ in their level of risk aversion, inclination to immerse themselves in medical information, medical literacy, feelings of self-efficacy, and desire to rely on others to make important decisions, and that these individual differences may be embedded in strong cultural influences (be they idiosyncratic or group-based). The law of informed consent should be shaped to reflect these variations rather than to ignore them. Consider, for example, a physician’s use of video images of a proposed medical procedure to supplement the written description, a tool that a patient might welcome or, to the contrary find upsetting. Clearly physicians should not be required by law to use any particular method for informing the patient and should take their lead from the patient him- or herself. The approach we are proposing might be described, in shorthand form, as “information on demand” (IOD). The fundamental idea is that patients should be able to tailor the disclosure process to their own values and informational needs.

We acknowledge significant variations in practices among physicians and specialties regarding the ways in which the formality of obtaining consent is integrated into patient-physician interactions. In some practice settings, the physician may discuss the diagnosis, treatment alternatives, and recommended course of action in general terms before any written disclosures or documents are provided. In others, the physician may review the consent form with the patient as the entirety of the disclosure process. In still others, the physician may convey the recommended course of treatment without significant discussion and hand the patient written materials to review or rely on another clinician or staff member to go over the form. What we are proposing is compatible with — and should improve the consequences of — any of these sequences.

We focus in this article on consent processes for major procedures, such as surgery, which usually involve the use of a formal process of disclosure and written consent. However, if proven to be useful in this context, our suggested approach could be modified and introduced to other areas of health care, including consent to medical research.

A key feature of our approach is a concerted effort to elicit from patients an expression of their overall preference for information and their desire for specificity. This aims to put the patient in the driver’s seat, rather than leaving the physician with the responsibility of deciding how much to disclose, resulting in either too little disclosure (often rooted in paternalism) or flooding a patient with exhaustive information of no material interest to her (often rooted in legal defensiveness). Recognizing that not every practitioner or facility will be able to implement a fully individualized disclosure process immediately, we suggest a two-stage model by means of which the goal of optimizing disclosure to patients can be achieved.

**Stage 1: A Transitional Step Forward**

The first stage of implementing a more patient-centered model of information disclosure is a transitional step that would shift the legal and ethical paradigm in the direction of patient control. Under a re-adjusted formula for obtaining informed consent, the patient would be expected to signal his or her desire for information as a prelude to the disclosure process. It might be helpful to consider the analogy of walking through customs at international airports, where passengers self-identify their status by selecting the aisle through which they pass: green (nothing to declare) or red (carrying items on which customs duty must be paid). Similarly, patients during this transitional phase would be asked to pronounce their need for information: (1) a green aisle (basic information is offered such as the nature of procedure/treatment, the reasons it is being performed, when the patient can return to work, and the consequences that would be expected to
impact the patient’s life); (2) a blue aisle (where more information is provided, including major/significant risks of the proposed treatment defined by severity and frequency, and about alternatives); and (3) a red aisle (extensive information is provided, including items that only a small number of patients might find relevant).

**Standardized Disclosures**

Stratification of patients under the proposed approach will require different standardized disclosures for each medical procedure for each “aisle” that the patient might choose. Although this is admittedly a challenging task, it should not be too burdensome to extract the material information in each category from existing consent forms. Seen as a collaborative effort to empower patients, all stakeholders should be involved in this task, including medical professionals to provide accurate content, patient advocates to assure accessibility (e.g., readability at an 8th grade level) and comprehension, and health law specialists to advise about compatibility with legal requirements in the relevant jurisdiction.

Disclosure according to these three options could be embodied in physicians’ discussions with patients, written or other materials provided to them, and consent forms as well. Of course, a patient may inquire at any time about a topic not included in the required disclosure for the “aisle” she has selected. When that happens, the physician must provide accurate information in answer to the question, irrespective of the path chosen. It would be legally sensible to make the blue aisle (essentially the “reasonable patient” standard) the default, but the patient should be told this at the outset and given the choice to ask for more (red) or less (green). This would assure continuity with existing law and would reflect what most patients probably want (a proposition that can be tested).

One item on the list of disclosures (alternatives) seems especially thorny. As indicated in Table 1, the “basic” disclosure (the green aisle) would include a description of the proposed procedure, the reason for it, and certain expected consequences, but would not initially include a presentation of alternatives to the recommended procedure, which would be described in the intermediate disclosure (the blue aisle). However, under our proposal, patients who choose the first (green) tier would be asked if they want to receive information about alternatives and, if so, they would be described. Prompting this option offers a guarantee that the existence of alternatives, even if not detailed information about them, would be known to all patients.

From the physician’s standpoint, the advantages of a personalized process can be realized only if the choices made by the patient regarding the desired specificity of disclosure are binding — at least when consent is being retroactively challenged. That is, once a patient has stated his preferences and the procedure has taken place, he may no longer argue in court that the informed consent process was inadequate in that it failed to provide him with the information he needed. He cannot claim in retrospect that his personal degree of risk-aversion is different from that signaled by the choices for information disclosure he has made. In

<table>
<thead>
<tr>
<th>Table 1</th>
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<tbody>
<tr>
<td><strong>IOD (Information on Demand)</strong></td>
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<tr>
<th>Type of information</th>
<th>Green: Basic Information</th>
<th>Blue: Intermediate Information (Green plus*)</th>
<th>Red: Extensive Information (Green and Blue plus*)</th>
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<td>Ramifications</td>
<td>Preserves the “right not-to-know” certain medical information, especially the risks of treatment. Minimum content of the disclosure will depend on state law</td>
<td>Should be generally compatible with either the professional standard or the reasonable patient standard</td>
<td>Resembles exhaustive IC protocols currently in use that are designed to minimize liability exposure</td>
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other words, the consent transaction will be personalized, while providing both parties the assurance that the current informational exchange meets the patient’s needs. It bears emphasis, though, that the interactive process should give patients the option of switching from the green or blue aisles to the blue or red ones, where the choice clearly implicates personal values that the physician is in no position to discern, such as in early laryngeal cancer, which can be treated by surgery or by radiotherapy, with similar survival rates (over 90%), but with very different impacts on the patient’s life. However, if the patient chooses to delegate decision-making authority to an agent, then the responsibility for dealing with the patient’s denial and discomfort in relation to the consequences of the recommended treatment and the alternatives would rest with the agent, not the physician.

Stage 1 of a more personalized disclosure offers genuine advantages: (1) it is an important step toward an individually tailored process rather than a generic one; (2) it increases patients’ control over the process, thus being patient-centered, as opposed to physician-centered (i.e., defensive), with possible positive ramifications for the patient-physician relationship; and (3) it provides greater legal certainty, with downstream savings in legal costs and actuarial exposure.

respectively. However, once an aisle is selected, the burden is shifted to the patient to request a change. Moreover, it remains a physician’s obligation to tell the patient that more information is available if the latter wants it (“Just tell me what else you’d like to know.”).

Waiver of Right to Be Informed
Would it be permissible to honor a patient’s request to waive the right to be informed altogether (“I don’t need to hear that stuff. Just go ahead with the procedure.”)? Although strong ethical arguments can be made on the both sides, we believe that a minimum set of information should be disclosed to the patient or, if the patient declines, to the patient’s designated agent. We acknowledge that informed consent law traditionally has recognized a patient’s right to waive disclosure of information. But allowing such waiver is based on the idea that some patients may rationally choose not to know the risks they face if that information would be disturbing to them. Under our model, the patient’s desire “not to know” would be accommodated by allowing her either to select the green aisle or to delegate decision-making authority to an agent. If the patient chooses to retain legal authority to consent to the proposed treatment, then we believe that this choice entails the responsibility to confront the emotional discomfort that comes along with making a consequential decision. Examples include information relating to inevitable consequences of undergoing the proposed treatment — e.g., the way the treatment will impact a patient physically (you will lose your hair, you cannot have babies) — as opposed to potential risks, disclosure of which can be waived by selecting the green aisle. We are also inclined to include the description of alternatives to the recommended treatment in the minimum disclosure in those contexts.

Summary
In summary, Stage 1 of a more personalized disclosure offers genuine advantages: (1) it is an important step toward an individually tailored process rather than a generic one; (2) it increases patients’ control over the process, thus being patient-centered, as opposed to physician-centered (i.e., defensive), with possible positive ramifications for the patient-physician relationship; and (3) it provides greater legal certainty, with downstream savings in legal costs and actuarial exposure.

Stage 2: Fully Individualized Disclosure
Advances in information technology will eventually facilitate a highly personalized solution to the problem of individualizing consent disclosure through interactive software. For example, once a physician has proposed a particular course of treatment to the patient and has explained the rationale for doing so in general terms, the physician might provide the patient with a CD, flash drive, or the link to an Internet website that includes particularized information about the recommended treatment and alternatives. For present purposes, we assume that the patient (or an agent designated by the patient or acting on behalf of a patient lacking decisional capacity) has the cognitive ability to navigate her way through an interactive teaching program. The teaching (software) program would not only allow individuals to specify their level of interest in the medical information, but would pro-
vide hypertext links with various levels of specification that would enable patients to obtain information-on-demand (IOD), based on their individual interests. Much as museum visitors who rent an audio-guide can elect whether to hear more detail about a large number of topics related to the exhibition they are viewing, patients too would have a similar degree of flexibility and control.

Use of information technology will allow control over the flow of information as well as multiple opportunities to review the information and enhance comprehension. Additionally, there is a substantial opportunity to examine the application of developing technologies to the understanding side of the equation. A software program can be written in such a way that after completing the educational module associated with the disclosure, patients could take a mini-test (readability at an 8th grade level) to assess whether they had sufficient understanding of the procedure (and possibly the risks, benefits, and alternatives). If a patient consistently “fails” such a test, it might signal a need for legally effective decision-making authority to be assumed by an adequately informed surrogate decision maker.

After the patient proceeds through such a personalized disclosure process, the “transcript” of the patient’s requests for information would be available to both the patient and the physician. A personal interaction with the physician regarding any unanswered questions can then ensue, followed by the formal indication of consent. This approach is intended to preserve the personal quality of the patient-physician relationship, but it also serves an important legal purpose. If a patient claims in a legal action after the fact that “I should have received additional information,” the transcript will show whether his claim is backed by his actual behavior. If it shows that he did not open clearly identified hypertext links related to the risks that materialized when given an opportunity to do so, the mismatch between his claimed interest in more information and his revealed choices would support a strong inference that he decided that the information was not relevant to him, and (if unrebutted) would sever the causal link necessary for a finding of negligence in informed consent litigation.

It appears that experiments with interactive software for informed consent are already underway. However, a fully developed information technology (IT) modality for achieving personalized disclosure of this sort is probably several years away. Research will be required to assure that the program is user-friendly, to reduce the risk that patients will overlook important information, and to optimize patient understanding of the alternative courses of action. In addition, mecha-

nisms will need to be available to allow physicians to “fine-tune” the disclosures, and the substantial barriers to use IT in medical practice will have to be overcome. In the meantime, however, the “transitional solution” outlined above — admittedly a small step, but one that reflects a serious effort to achieve greater patient control over the flow of information during the consent process — can be implemented.

**Addressing Possible Objections**

The personalized process enables the patient to identify and select the informational sets she cares about (for example, inevitable consequences as opposed to potential risks, frequent side effects as opposed to more remote chances of complications), and to receive answers to her individual concerns. Under a well-designed computer-assisted process, the “relevance problem” is solved completely by the patient’s continuing opportunity to demand and probe the available information to ascertain its applicability to her situation. Under our transition proposal, it is solved categorically, albeit less completely. Thus, the content of each category of information (mainly about risks or alternatives) for every procedure would have to be formulated for all three aisles.

Skeptics might claim that, particularly during the transitional stage, what we propose harbors the potential for resurrecting or reinforcing (as many feel it never died...) medical paternalism — i.e., by allowing patients to select options short of “full disclosure,” we will be encouraging them to rely on the judgment of their physicians by rendering them incapable of independent choice. This concern is exacerbated by the prospect that information-seeking behavior will be strongly related to social status and education: patients who are relatively uneducated, uninformed, unsophisticated, poor, socially vulnerable, and intimidated by the medical system are likely to receive the least amount of information, while patients with a higher degree of health literacy and socio-economic position will seek and receive the highest level of information.

We take these concerns very seriously, but we offer two responses. First, our proposal offers a better option than the current ritualized practice which is not really designed to promote choice. Moreover, it does not make the disparities in practice any worse than they now are and, to the contrary, provides a platform for closing the health literacy gap in the long run through advances in information technology. Indeed, broad doubts about the prospects for patient empowerment overlook the documented transformation that has already occurred in the acquisition of medical information by internet-empowered health consumers.
As consumers of other kinds of goods and services, patients are frequently expected to identify the level of information they need and want. Therefore, in the interaction that we envision, patients are asked proactively to specify the information they require.

Second, we envision a consensus-based process for developing the standardized disclosures during both phases of implementation — an approach that should counteract concerns about professional dominance or about bridging the literacy and numeracy divide. Standardized disclosure in each set should be developed through collaborations among patients, relevant providers, educators, and other stakeholders. There is no material reason for that educational task to be undertaken solely by the medical profession or health care organizations. Such a collaborative effort would require time, resources, and professional commitment. We therefore envision an incremental process that allows the gradual creation of disclosure in distinct areas of surgery, which in turn can provide reliable demonstration projects.

Another point of concern could be that patients might be defeated, rather than empowered by the personalized approach — i.e., they might be overwhelmed even in the transitional stage by having to make a choice about the level of information that they want. Implementation of a computer-based disclosure process with multiple hyperlinks could exacerbate that reaction. Although we cannot rule out the possibility that some patients may react this way, we suspect that the number will not be large. But we would encourage attention to this possible adverse effect as these approaches are tested. Of course, as a way of controlling their anxiety, some patients may revert to the risk-averse default position of “exhaustive information” as a protective stance, thus demanding the highest level of information and clicking on every hypertext option. However, this concern does not seem to be a disadvantage, as even if it materializes, it reflects patients’ choices and respects their right to obtain more information. Moreover, for many practice settings, this level of disclosure is what occurs today, often in response to perceived legal requirements. As compared with current practice, our approach clearly expands the range of patients’ choices rather than contracting it.

Two related concerns are whether our suggested approaches will freeze attempts to generate better or higher quality information for patients, as physicians avoid the effort involved in updating disclosures and whether our proposal negatively depersonalizes doctor-patient relationships. We acknowledge that these concerns must be addressed in a serious manner, mak-

Our modest aim is to lay down a new paradigm of information on demand, designed to empower patients, enhance legal certainty, and achieve greater congruence between the information patients want and the information they receive. It is possible that this approach could also promote more meaningful patient-physician interactions in many cases, a desirable outcome that has been difficult to achieve by other means.

The Path Ahead
Will personalized disclosure eliminate informed consent litigation? Convincing courts and/or legislatures to accept this approach will admittedly be a challenge, since it would reframe legal doctrine that has evolved for more than five decades. It is possible that our transitional proposal could be implemented by the courts as a refinement of existing doctrine. However, implementation of a computer-assisted modality for personalizing disclosure may require legislative action in some states to resolve doubts about the legal effect of failing to seek additional information. Given the
legislative interest in various “malpractice reforms,” achieving the legal changes necessary to make this proposal work may have a more sanguine future than anticipated at first sight. Whether such efforts should be undertaken will depend on “proof of concept” through substantial behavioral research. Our modest aim is to lay down a new paradigm of information on demand, designed to empower patients, enhance legal certainty, and achieve greater congruence between the information patients want and the information they receive. It is possible that this approach could also promote more meaningful patient-physician interactions in many cases, a desirable outcome that has been difficult to achieve by other means.

References


14. For example, Wilson-Toby v. Beshkin, 72 A.D. 3d 810, 898 N.Y.S.2d 633 (2010). (Although consent forms advised the plaintiff generally that cosmetic breast surgery would result in permanent scarring, the court ruled that “consent forms signed by the plaintiff ‘do not establish, as a matter of law, that the scarring that the plaintiff actually experienced as a result of the procedure was, in its nature and in its extent, consistent with the type of scarring that, prior to the procedure, the plaintiff had been told to consider as being among the reasonably foreseeable risks of the proposed procedure, or that a reasonable, fully informed person in the plaintiff’s position would have undergone the procedure despite the existence of such risk.’” [citation omitted]).


18. S. D. Halpern, A. Shaked, R. D. Hasz, and A. L. Caplan, “Informing Candidates for Solid-Organ Transplantation about Donor Risk Factors,” New England Journal of Medicine 358, no. 26 (2008): 2832-2837. (“This policy should outline specific aspects of transplantation that should be disclosed during the consent process... to allow patients to make a dichotomous choice to accept or decline all nonstandard organs as a group, and eliminate the practice of organ-specific consent. In particular, we believe UNOS should abandon its current recommendation that patients be notified when organs are offered from donors with behavioral risk factors.” These phrases support the need to refrain from providing ‘all’ information.


23. A federal judge recently struck down a key provision of Texas’ new law requiring doctors to show pregnant women images


28. See Hall et al., supra note 25: “... at the same time that the IC process appears to empower patient participation, it may overwhelm some patients with more information than they want. Fully 85% of patients arrived in the clinic wanting to know as many details as possible about their health status, but after the clinic visit, only 25% continued to report this preference. At the same time, the proportion of patients preferring as few details as possible increased from 0% to 36%. These preliminary findings may warrant reconsidering the amount of detail disclosed in the iMed documents and the IC process.”