

PEER-REVIEWED CME ARTICLE

The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm

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Abstract

In this paper, we examine the limits of informed consent with particular focus on ways in which various factors can overwhelm decision-making capacity. We introduce *overwhelm* as a phenomenon commonly experienced by patients in clinical settings and distinguish between emotional overwhelm and informational overload. We argue that in these situations, a clinician's primary duty is prevention of harm and suggest ways in which clinicians can discharge this obligation. To illustrate our argument, we consider the clinical application of genetic sequencing testing, which involves scientific and technical information that can compromise the understanding and decisional capacity of most patients. Finally, we consider and rebut objections that this could lead to paternalism.

Introduction

As clinical medicine and translational science have evolved over the past several decades, medical ethics has faced the challenge of keeping pace with the development and clinical application of new therapies and technologies. In this paper, we propose a categorical rethinking of the [doctrine of informed consent](#) in specific clinical contexts. In a sense, informed consent is the victim of its own success: we suggest that informed consent has become so central and important to the way clinicians practice that they may fail to recognize situations in which patients' ability to provide informed consent may be compromised. We introduce the concept of the overwhelmed patient, reflecting on different ways in which patients' ability to provide informed consent may be compromised, and invoke the need to protect patients as a countervailing ethical obligation. We then provide suggestions for how clinicians can prevent patients from becoming overwhelmed, either emotionally or cognitively: emotionally overwhelmed

patients need support, and informationally overwhelmed patients need alternate models of medical decision making. No doubt, informed consent is a valuable way in which clinicians attempt to discharge their obligation to [respect patient autonomy](#). But clinicians also have other ethical obligations, including beneficence and nonmaleficence; we argue that informed consent is not the appropriate way to discharge all of a clinician's ethical obligations in all clinical situations. Specifically, we will argue that in situations in which patients potentially can be overwhelmed, clinicians have the obligation to take steps to prevent them from becoming overwhelmed, or at the very least to prevent harm that may result from emotional overwhelm or informational overload.

Informed Consent and Autonomy

When talking about informed consent, one should distinguish between research and clinical care. There is a difference between the role of investigator and the role of clinician, and between physician-patient and investigator-participant relationships [1, 2]. Although the ideas we explore in this essay could be relevant to either research or clinical contexts, we will focus on clinical contexts—specifically, the implications of our ideas for informed consent for clinical care in situations in which informed consent may not be an appropriate approach to decision making.

A recent essay brought this set of concerns to the fore. Reflecting on informed consent in the case of whole genome sequencing, Parens argues that “informed consent is meant to protect people from being coerced into decisions that someone else thought were in their—or the state’s—best interest” [3]. Nevertheless, Parens observes a “drifting away” from informed consent in genetic sequencing testing, which he views as unfortunate if we consider what is at stake in informed consent: respect for persons. Parens does acknowledge that we shouldn't just remain committed to informed consent because it is traditional but argues that if we move away from informed consent, we should have good reasons to do so. A mere “drifting away” would be ethically troubling, as it would put respect for persons at risk.

We agree with Parens's sentiments. Respect for persons and the accompanying doctrine of informed consent are cornerstones in bioethics. But are there perhaps good reasons to move away from informed consent in the field of whole genome sequencing tests and, as we are suggesting, instead focus on protecting patients? We contend that there may be: in the context of whole genome sequencing, informed consent may be impossible, and a clinician needs to shift towards preventing harm.

Our thinking informed by Parens's essay prompts us to make a suggestion some might find unsettling. In their fervor to respect the autonomy of patients, some clinicians approach every biomedical intervention and test without questioning the doctrine of informed consent. This means that clinicians engage patients in discussions of the benefits and risks of interventions and tests and expect an informed decision from the

patient. In the right contexts this is appropriate. The problem is that informed consent is not always possible. There are some contexts in which the nature of the information is such that the patient's understanding and capacity for decision making are overwhelmed, making informed consent impossible. Besides the duty to respect a patient's autonomy, a clinician has a host of other ethical obligations to her patient. Notably, these include the duty of preventing harm. For example, a patient whose decision-making capacity is compromised or who is overwhelmed may be at risk of making decisions harmful to him- or herself without even realizing it. Such a patient is also at risk of the harm of having her values compromised, as a patient with compromised decisional capacity may make a choice that is actually not in keeping with her values.

If patient autonomy is not feasible, the clinician's other ethical commitments remain in place and should still be discharged. Given the primacy of the ethical injunction to avoid patient harm, we therefore argue that in situations in which informed consent is not feasible because a patient's decision-making capacity is overwhelmed, a clinician should consider shifting from prioritizing informed consent to protecting her patient.

Overwhelm and Information Overload

The claim we defend is a simple one: there are medical situations in which the information involved in making a decision is of such a nature that the decision-making capacity of a patient is overwhelmed by the sheer complexity or volume of information at hand. In such cases a patient cannot attain the understanding necessary for informed decision making, and informed consent is therefore not possible. We will support our thesis regarding informational overload by focusing specifically on the area of clinical [whole genome sequencing](#)—i.e., identification of an individual's entire genome, enabling the identification and interaction of multiple genetic variants—as distinct from genetic testing, which tests for specific genetic variants.

We will first present ethical considerations regarding informed consent. Next, we will present three sets of factors that can burden the capacity of a patient to provide informed consent for a specific decision—patient, communication, and information factors—and argue that these factors may in some circumstances make it impossible for a patient to provide informed consent. We will then discuss emotional overwhelm and informational overload and consider how being overwhelmed affects informed consent. Our interest in this essay is mainly in informational overload; we will therefore consider whole genome sequencing as an example in which informational factors overwhelm a patient's decision-making capacity. Finally, we will offer suggestions as to how the duty to protect patients from harm can be discharged when informed consent is not possible because of emotional overwhelm or informational overload.

Informed Consent and Capacity

Informed consent happens when a patient authorizes a medical procedure or intervention based on understanding of the risks, benefits, and alternatives [4, 5]. This process assures respect for the free decisions of autonomous individuals, a duty that derives from the moral principle of [respect for persons](#). A valid process of informed consent requires four things: voluntariness (the decision is free from coercion or undue influences), disclosure (the clinician's sharing of information relevant to the patient's decision), understanding (appreciating the risks, benefits, and nature of the procedure), and capacity (the ability to engage in reasoned deliberation, comparing the risks and benefits of the procedure with personal life goals) [4, 5].

Informed consent can be compromised when any of these elements is lacking. For example, if a decision is not voluntary but is instead made under duress from a clinician, family member, or other third party, it is not informed consent. Similarly, if a patient [lacks capacity](#) to engage in reasoned decision making, informed consent is not possible. In other words, for informed consent to achieve the goal of respecting persons, each of these components needs to be present.

Capacity can be thought of as a sliding scale, rather than an all-or-nothing phenomenon [4]. A patient may have the capacity to make some decisions but not others. On a sliding scale, the higher the stakes of the decision and the more nuanced the information involved in making the decision, the higher the threshold for considering a patient to have capacity. For high-stakes, life-or-death decisions with complex medical information, a high threshold for capacity would be required. This means that a patient would be required to demonstrate a greater ability to process and reason about the complex information involved than is needed for less demanding or lower-stakes decisions. For example, if a person refused a life-saving surgical procedure for which the risks are negligible and refusal would result in certain death, the threshold for accepting a refusal of surgery as an informed and autonomous refusal is quite high. A surgeon faced with such a patient would want to go to great lengths to ensure that the patient truly understands the choice and its implications, and that these match the patient's life goals and values, to ensure that the patient's refusal is an autonomous choice. If the patient was a 15-year-old who said that she didn't want a surgical scar and therefore refused surgery, the threshold for capacity has likely not been met.

In situations in which patients clearly do not have the capacity to make informed decisions, clinicians do not continue to seek informed consent from their patients. In an emergency, when someone is unconscious, a clinician might presume consent and administer emergency treatment. In some other cases, a [surrogate decision maker](#) is sought to decide on behalf of the patient. For minors, who have not yet developed the cognitive skills required for understanding and deliberation, parents make decisions on behalf of their children, according to the perceived best interests of their children. One

could argue that in these situations clinicians are making protection of the patient the primary ethical consideration. In an emergency involving an unconscious patient, protecting the patient against harm supersedes the obligation to obtain informed consent for procedures that would otherwise require informed consent. If a patient lacks capacity, a surrogate decision maker provides physician oversight and thereby potentially diminishes harm from physician biases. Typically, surrogates are also asked to verbalize the values of the incapacitated patient to the best of their abilities, ensuring that a patient is protected from the harm of having his or her values overlooked in the provision of care.

These arguments are based on considerations of patient protection and do not accord with the model of informed consent, which is justified by respect for autonomy. More obviously, in surrogate decision making for children, autonomy is less important than doing what is best for the child. The driving force for decision making is not an informed consent process but a decision-making process that seeks the best outcome for the child [6]. When it comes to adults, the ethical values underlying surrogate decision making are respect for self-determination and concern for the patient's well-being [7]. The ideal is a [substituted judgment process](#) in which the surrogate illuminates the prior wishes of the incapacitated patient [7]. However, this is not always possible, and, even when it is possible, it can be an imperfect process [7]. Ideal substituted judgment obviates the need for including other measures, such as weighing the welfare of the patient. For example, if the patient's prior wishes are not known, the surrogate is encouraged to resort to the best interest standard, which is purely based on considerations of patient welfare [7]. Our point is that surrogate decision making is not purely based in autonomy, as is the case with a dyadic informed consent process (the traditional informed consent process between two parties, clinician and patient); other ethical values such as the welfare of the patient are also relevant in the process of surrogate decision making. Surrogate decision making moves away from the ideal of informed consent towards valorizing protection of the patient. This is appropriate; in these situations informed consent is not feasible, and given the primacy of the ethical obligation to do no harm, a clinician should focus on her obligation to protect her patient rather than fixating on informed consent.

Three Variables Influencing Capacity: The Sliding Scale of Capacity and Its Consequences

There are three broad sets of variables that influence capacity.

Patient-related factors. One set of variables is patient related. In the most obvious case, a patient who is unconscious lacks capacity to make even the most basic decisions. A patient who is under the influence of alcohol or hallucinogenic drugs may lack capacity for most decisions. Very young children lack the capacity to make medical decisions. But there are also more subtle cases in which it is unclear to what extent capacity is

influenced by patient-related factors. Some patients may not have the educational attainment or intellectual ability to understand the choices before them if the choices are scientifically complex. Language and cultural barriers may also impose limits on capacity. In some medical situations, it could be that such patients have a significant enough challenge in understanding that it should alert a physician to potentially diminished capacity.

To make this even more complex, let us imagine these factors as a sliding scale. On the one end, there are patient factors that completely preclude capacity and, on the other, patient factors that burden capacity but do not make it impossible. So, on one end of the sliding scale we have unconscious patients that can make no decisions and, on the other, patients with no clinically relevant limit to their cognitive ability to understand. In between we have persons with varying degrees of patient-related factors influencing their capacity.

The emotional burden of the illness experience and consequent cognitive overload, which may affect the patient's decisional capacity, is a patient-related factor that is alluded to in the bioethics literature, but is nowhere fully explored. For example, Appelbaum writes, "When fear or anxiety appears to be interfering with a patient's ability to attend to and process information, introducing a known and trusted confidant or adviser to the consent process may permit the patient to make competent judgments" [8]. If additional relational support does not solve the problem, Appelbaum argues that a surrogate decision maker should be sought [4]. It goes without saying that the use of a surrogate decision maker should be reserved for instances in which a patient's decision-making capacity is compromised to the point she cannot engage in medical decision making regarding the issue at hand. Surrogates are not the same as supportive confidants, and clinicians should distinguish between these. A confidant aids in decision making and shores the patient up against overwhelm, while the patient retains authority to authorize medical treatments. A surrogate makes decisions on behalf of the patient, and the surrogate authorizes medical treatments. Surrogates are only used when the patient cannot make decisions for herself.

Information-related factors. If decisional capacity is on a sliding scale, the more complex, scientifically advanced, and intellectually demanding information becomes, the higher the threshold for capacity of patients to provide consent. Some types of medical information (e.g., risk) contain probability estimates that require training to understand fully and tax the ability of patients to understand and deliberate.

We would argue that if the sliding scale of decisional capacity holds for patient factors, it also holds for information factors. On one end of the scale is comprehensible, straightforward information on a procedure and its risks and benefits that is clear and easily understandable. As we move up the sliding scale, the information becomes more

voluminous and more complex; the burden on capacity becomes higher. If we keep going up the scale, at some point we encounter information that people who ordinarily have capacity to make their own decisions find impossible to fully understand. Of course, we may still find exceptions here: a medical expert or molecular geneticist may still have the cognitive ability to understand and engage information at these very high levels. But for most patients, full understanding—and truly informed consent—will be impossible.

Communication-related factors. Clinicians' skill and method in [communicating complex medical information](#) to patients has been shown to influence the understanding that patients attain [9, 10]. For example, making use of decision aids, extending the decisional timeframe, and communicating complex concepts in digestible chunks can aid patient understanding [9, 10]. Alternatively, it is not hard to see that dumping an indigestible barrage of complex information on a patient would challenge her understanding. The clinician's capacity to communicate complex information is therefore an important variable that impinges on decisional capacity. It is thus important that clinicians have skill and expertise related to communicating information, facilitating understanding, and reducing the effects of emotional overload. We recommend that the learning of such skills be routinely incorporated in clinical training across all medical disciplines and that these skills be reinforced by specialized [communications training](#) for practicing clinicians.

Of course, combinations of patient and information factors may interact and influence capacity synergistically—think of a patient with a language barrier and low level of education who is faced with risk and benefit information that includes complex scientific concepts and probability estimates.

Our argument is therefore a simple one. Informed consent depends on capacity. Capacity can be influenced by patient factors, information factors, and communication factors. Upon reflection, it seems possible that certain types of information overwhelm the decisional capacity of patients who have no patient factors impacting their capacity. That is, it may be possible that some types of information render a competent patient unable to provide truly informed consent. In such situations, patients are in effect incapacitated for that decision.

Introducing the Concepts of *Overwhelm* and *Informational Overload*

We suggest that there are at least two ways in which a patient can be overwhelmed so that obtaining informed consent is not feasible.

Emotional overwhelm. First, a patient may be emotionally overwhelmed by the illness experience and by the implications and complexity of decisions she is now faced with. We will refer to this idea as *emotional overwhelm*. Being emotionally overwhelmed may make informed consent more difficult and would require the clinician to take extra steps to ensure that an autonomous choice has been reached through an informed consent

process. Informed consent may still be possible in this case but is more difficult to attain as the patient's ability to make decisions is taxed. In such cases, the clinician must make an extra effort to ensure the integrity of the informed consent process by taking steps that may protect patients against the effects of emotional overwhelm. Consider the following:

- Enabling the patient to be supported by family or loved ones.
- Using a multidisciplinary approach, enabling the patient to be supported by various members of the care team.
- Extending the decisional timeframe, delivering news in a skillful and incremental way, and using decision aids [9].

Such steps may assist an informed consent process and ultimately allow true informed consent in the case of the emotionally overwhelmed patient.

Information overload. A patient's ability to provide informed consent may also be overwhelmed by the complexity, uncertainty, or volume of information involved in the decision, as may occur with the emergence of newer technologies such as whole genome sequencing [10]. Informational overload is present when the information required to provide informed consent is of such complexity, volume, or uncertainty that it makes it impossible for a patient to make an informed choice because the decision-making capacity of the patient is overwhelmed; the patient is in effect incapacitated for the decision in question.

We suggest that in these circumstances a clinician focus on the countervailing ethical obligation of protecting her patient against harm. There are cases in which informed consent is from the outset not possible because of informational overload, in which no amount of bulwarking against being informationally or emotionally overwhelmed can facilitate reaching true informed consent. What incapacitates the patient is the information itself. There may not necessarily be any patient- or communication-related factors that impinge on decision making. We are not advocating that clinicians evaluate patients for informational overload in the provision of general clinical care; informational overload is situational, related to the information itself, and not patient-specific. Instead, we recommend that clinicians be aware of certain clinical situations in which informational overload is unavoidable, and that specific steps be put in place to protect patients in such situations.

Possible Alternate Approaches to Attain Informed Decision Making

How should clinicians respond to such situations?

Surrogate decision making. One possible solution to the problem of informed consent when decisional capacity is compromised is to seek a surrogate decision maker. However, in situations of informational overload, this may not solve the problem. If the information has inherent qualities that would overwhelm a reasonable patient, it is likely

to also overwhelm a surrogate. Unless the surrogate decision maker is a content expert who also understands the values of the patient, a surrogate decision maker will not solve the problem of informed consent. Surrogate decision making may, however, be useful for the emotionally overwhelmed patient who remains unable to provide informed consent despite additional support [4].

Shared decision making. Another possible solution is to make use of shared decision making (SDM) [11, 12]. This approach relies on deliberation between clinician and patient regarding available health care choices, taking the best evidence into account [11]. The clinician actively involves the patient and elicits patient values [11]. The goal of SDM is often stated as helping patients arrive at informed decisions that respect what matters most to them [11].

It is not clear, however, that SDM will be successful in facilitating informed decisions when an informed consent process has failed. SDM as a tool for informed decision making is at its core dependent on the patient understanding the options presented and being able to describe the preferred option. Understanding and deliberating about what is at stake for each option is a key component of this use of SDM. Therefore, if the medical information is so complex that it overloads the patient's decision-making capacity, SDM is unlikely to achieve informed decision making. But if a patient is emotionally overwhelmed by the illness experience and all that accompanies it, a process of SDM and support for the patient may eventually facilitate informed decision making.

We believe that SDM cannot in fact facilitate obtaining informed consent in medical situations in which informational overload is present and that the primary goal of SDM in these situations is not informed decision making. Instead, we believe that SDM represents a move away from an informed consent process towards protecting patients. We submit that the true primary goal of SDM is not informed consent but to make treatment decisions that are in keeping with medical evidence and standards and also consistent with a patient's values [12]. In SDM, the clinician advances recommendations based on her understanding of the patient's expressed values, incorporating the clinician's obligations of avoiding harm and providing benefit to her patient [11, 12]. SDM protects the patient in two ways. The clinician respects the patient's personhood by eliciting and taking into account the patient's values during care planning but also protects the patient against harm by advancing recommendations in keeping with the best evidence. Resorting to SDM, in our view, acknowledges that informed consent is not the correct tool for certain complex medical situations and that considerations of patient protection are paramount.

Thus, if SDM is used as a tool to facilitate informed decision making, we suggest that it will not reach its stated goal when informational overload is present. If, however, SDM is seen as a patient protection tool with the goal of eliciting and taking into account patient

values during care planning, we fully support its use. We maintain that in circumstances in which patients' capacity is overwhelmed, clinicians should shift their focus from obtaining informed consent to protecting the interests of the patient. It is important to note that the patient only lacks capacity for this decision and not for others. Capacity is decision-specific. Therefore, it is only in terms of a particular decision for which informational overload makes informed consent impossible that the clinician should focus on protecting the patient. This conclusion has far-reaching implications for decision making about genetic sequencing tests.

Whole Genome Sequencing: Revisiting and Building on Parens's Argument

Whole genome sequencing is entering the field of precision medicine [13]. It is generally accepted that the routine incorporation of whole genome sequencing in clinical care is inevitable and a positive development in health care in the near future [13, 14], one that will lead to exciting new diagnostic and therapeutic options [13, 14].

The problem with whole genome sequencing is that these tests return mountains of information, including a multitude of incidental findings [14]. Such findings may include higher risk for certain diseases and early diagnosis of a presently asymptomatic disorder [14]. Interpreting the implications of these incidental findings is quite complex, and it is recommended that medical decision making be done in conjunction with a clinical geneticist [14]. Such incidental findings can lead to harm, which has implications for the use of whole genome sequencing tests [14, 15].

The incidental findings may trigger additional tests, each of which carries its own risks of harm [16]. In particular, some of the incidental findings will be false positives—incorrectly indicating that a patient has a given condition—triggering unnecessary testing, cost, and anxiety [16]. Genome sequencing tests may also return results that have [implications for close family members](#), triggering testing for these family members, which may cause distress to the patient and family [17]. Another potential harm is that the Genetic Information Nondiscrimination Act of 2008 does not prevent insurance providers from obtaining and using the results of a genetic test in calculating payments to insured persons for claims, although it does not allow them to require genetic tests prior to issuing insurance [18]. It cannot be predicted prior to the test whether a genome sequencing test will reveal the kind of information that may put a patient at risk of receiving lower insurance pay-outs. It is true that all medical information can be used by insurance companies in this way, so in a sense whole genome sequence testing is not distinct from other medical testing. However, given the sheer amount and complexity of information returned by genome sequencing and the vast potential for returning medically relevant incidental findings, the possible implications for insurance pay-outs from having a whole genome test are a valid concern.

The potential harms of a whole genome sequencing test are therefore substantial, leading some to suggest that an informed consent process should accompany genomic testing [14, 15]. Considering the challenges posed to informed consent by incidental findings that arise in the course of genome sequencing tests [19], Appelbaum and colleagues argue that the magnitude and implications of the potential incidental findings are sufficiently great to preclude a traditional informed consent discussion. Accordingly, Appelbaum et al. suggest that alternate models of informed consent be used for these tests [19]. These options all aim to address the inherent difficulty in different ways, but each has problems. One model is telling a patient that there may be incidental findings and then obtaining consent for the release of specific actionable incidental findings if they occur. Another is making the return of certain categories of incidental findings a condition of testing. These two options impinge on the very autonomous choice they seek to protect; limiting autonomy to ensure respect for autonomy is a strange way of ensuring respect for persons. Lastly, consent could be outsourced to a third party—send a patient to an expert who will deal with the consent process and the return of incidental findings, but this is not really a solution. Although it is highly advisable and good practice to involve genetic experts in decision making and in discussions with patients, the risk of informational overload still remains. Thus, even if a third party has superior content knowledge, the information itself may still overwhelm a patient's ability to provide consent according to the traditional informed consent model.

The challenges posed to informed consent are an ongoing focus of study of the National Institutes of Health (NIH) National Human Genome Research Institute. One of the institute's working groups is tasked with developing new and creative approaches to informed consent in clinical genetic sequencing and with developing standardized consent language [20]. But given the inherently complex informational factors that may overwhelm patient capacity, we argue that informed consent is inherently not possible and that an alternative model be invoked in dealing with clinical genetic sequencing. Is it not better simply to admit that informed consent is not possible, given the type and scope of the information pertinent to the test?

Koenig offers a solution that we find much more appealing [21]. In responding to Appelbaum et al.'s article [19], she argues that informed consent has become the equivalent of a fetish in biomedical research. When an issue arises in protecting research subjects, the answer is always "more consent." This, Koenig argues, is strange because there are definite limits to informed consent, particularly in the area of genetic testing, and because a growing body of research shows that there is a large disparity between the ideal of informed consent and what happens in practice in "informed consent" discussions [21-23]. Although Koenig's comments are focused on research, they are just as applicable to clinical care contexts. Koenig's proposed solution for the genetic sequencing challenge is intriguing: governance of consent. In this model, a patient consents to a decision-making process involving others. The return of actionable

incidental findings is discussed by a group of persons, including experts and community members; this group debates how the information should be handled and returned. The patient provides informed consent to have a group of this sort deliberate on her behalf about whether and how incidental findings would be returned. Koenig argues that this procedure respects patient values and autonomy, while also protecting patients from harms that might result from the volume of unexpected incidental findings associated with whole genome screening tests [21].

A number of things are attractive about Koenig's proposed solution, which could help us think more critically about how physicians can help patients with information overload. One is that it still draws on the decision-making capacity of the patient. Even though the patient may lack capacity to provide informed consent, she may have the capacity to consent to an alternate decision-making process. In clinical practice, this solution translates to offering a patient a number of different ways in which decisions can be made with regard to return of actionable findings. This process respects the personhood of patients in that they provide consent to the extent they are able and express their values in doing so.

At the same time, this process removes any fears that clinicians are "hiding something" or acting in ways that are unjustifiably paternalistic. It provides oversight of clinicians: a clinician has to verbalize his or her recommendation and plan to the community of peers or other deliberative community identified by the patient. But, most importantly, this solution also takes seriously the problem posed by the nature of the information and protects patients, in a morally responsible way, from being overwhelmed. Recognizing that the patient is incapacitated due to information factors, the clinician invokes an alternative to informed consent that protects the patient's interests while respecting her autonomy as far as possible. We would argue that Koenig's model of "consent to be governed" is quite consistent with the ethical goal of protecting patients.

Protecting Patients

We have argued that the complex nature of the information involved in whole genome sequencing can overwhelm the decision-making capacity of patients, making informed consent impossible. Given the impossibility of informed consent and the potential harms associated with genomic testing, we have argued that clinicians should focus on protecting patients from harm. Here we offer some suggestions on how this could be done. These suggestions would be of benefit in cases of informational and emotional overload. Suggestions 1-3 apply specifically to the context of whole genome sequencing, the quintessential example of a clinical situation in which informational overload may occur, and suggestions 4-7 should be considered in all cases of overwhelmed decisional capacity.

1. If there are no clear benefits to a genetic test, it should not be offered to patients. There should be a clear indication as to why a test is necessary and a clear

benefit that outweighs potential harm before a test is done. If patients request a genetic test for a reason that does not meet these criteria, clinicians should discourage them from pursuing testing. This is not a new idea, but we emphasize it as important in contexts in which patients may become overwhelmed.

2. Extend the decisional timeframe. If a test is indicated and the patient needs to make a decision as to whether to undergo the test, clinicians should encourage the patient to take time to deliberate over the decision. Given the complexity of the information, we suggest that a decision should not be made within the confines of a 15-minute doctor's appointment. Rather, as much time as is needed to arrive at a good decision should be taken. We recognize that this recommendation is also not new; current genome testing practice standards recommend the involvement of a genetic expert and taking sufficient time in deliberation [14, 15]. We emphasize that this recommendation is an important one and that primary care clinicians should not engage in genomic testing without appropriate support and without taking an appropriate decisional timeframe into account.
3. If a test is clinically indicated, consider using an alternate model of decision making and consent. One such example is governance of consent as presented by Koenig [21]. Another possibility is to involve patients in a deliberative democracy process, such as a "community jury" [24]. In prostate-specific antigen (PSA) screening, it has been shown that involving patients in a community jury deliberative process increases understanding and retention of information and perhaps makes individual decision making easier [24]. This is a process in which patients deliberate with peers who face the same decisions regarding choices, with the support of content experts [24]. Perhaps some version of such a group deliberative process among peers can be helpful for some patients faced with possible whole genome testing. In clinical practice, this would amount to a clinician being transparent about the fact that informed consent is not possible in this complex situation and offering her patient different ways to make genomic testing decisions. Options offered could include assistance from the hospital ethics committee, a community jury process, or the patient deferring to the clinician. The patient therefore consents to a way in which decisions will be made while at the same time avoiding informational overload. Not only does this process respect and protect the patient, but it also facilitates realization of other values inherent to the practice of medicine, such as transparency, building of trust, and relationship-centered care.
4. Encourage relational support from family or friends when complex decisions are at stake. When patients face complex information, sharing decision making with family or friends can help them process it [25].
5. In clinical situations in which patients may be at risk of overwhelm, consider using an SDM approach instead of a traditional informed consent approach. Indeed, for decisions such as prostate cancer screening with PSA, many experts

recommend the use of an SDM approach [26, 27]. The SDM approach we advocate has the goal of making medical decisions that are in keeping with medical evidence and standards and are also consistent with a patient's values. The clinician advances recommendations based on the best medical evidence and on her understanding of the patient's values. This decision-making process requires open communication, establishment of a relationship, and exploring the patient's values. It is vital that clinicians develop the necessary skills to employ such an approach, and we suggest that clinicians receive training in SDM approaches both during their education years and while in practice.

6. Consider sharing information in digestible, progressive chunks, and on a need-to-know basis. This means only sharing what is necessary for prevention of serious harms and tailoring information in a way that protects a patient from being overwhelmed and from a potentially harmful choice. If complex information is presented all at once, it may increase the risk of informational overload and thus increase the risk of a harmful choice [25].
7. Because sharing information in chunks risks leaving clinician bias unchecked, we recommend that clinicians work with a support mechanism in place, such as consulting with an ethics committee. The clinician would voice her reasoning to the committee, which would provide assistance in guiding decisions on what information to share with the patient—including which options to strongly recommend and prioritize—and also compensate for inherent clinician biases. This is an important step in protecting a patient against harm when a high-stakes medical decision involves substantial informational complexity.
8. We recommend that all clinicians undergo communications training aimed at developing skills related to facilitating understanding, communicating information, and providing support to patients. Such types of training for clinicians have been shown to improve patient satisfaction, improve physician empathy, facilitate the formation of meaningful patient-clinician relationships, and decrease clinician burnout [28, 29]. Indeed, these outcomes show the importance of communications training in equipping clinicians with skills necessary to support patient decision making and prevent or respond to informational overload or emotional overwhelm. We recommend that communications training be included in clinical education programs across the board and be reinforced when clinicians are in practice. Since clinicians' ability to communicate may impinge on a patient's capacity to make a decision, clinicians' communication skills should be optimal.

The Charge of Paternalism

Some may object that we are arguing for a form of [paternalism](#), contending that we think doctors know what is best for patients better than patients themselves do. Some may even accuse us of arguing for a return to the old days of "doctor knows best": the poor patients don't know what they need or want, so it is the job of the clinician to protect

them from themselves. In this way, the objector would argue, we are advancing an argument for the kind of paternalism that modern medicine has rightfully repudiated.

Our response is twofold. Firstly, these arguments should not be construed as an argument for paternalism because paternalism happens when a clinician overrides the autonomy of a patient, claiming that this is done in the patient's best interests [30]. We are arguing for no such thing. Our argument is that there are some situations in which autonomous decision making is not possible—for example, when the patient is overwhelmed. In these situations, there is no autonomous choice and no autonomy to override. Thus, our argument is not an argument for paternalism but instead an argument for an ethical safety net in cases in which autonomy is limited.

Secondly, the arguments we presented are meant to highlight some of the limitations of informed consent and not to justify paternalistic actions. It is simply the case that informed consent does not work in all medical situations and can in fact subvert the very ethical principles it is meant to protect. In such situations clinicians need other tools to ensure that their ethical obligations are fulfilled. The arguments we have offered are meant to move us along towards the development of such tools.

Conclusion

We have argued that threats to patient capacity are found in informational factors, patient factors, and communication factors. These place limits on the attainment and use of informed consent. We have argued that these limitations apply in the case of genetic sequencing, making informed consent impossible, and have suggested ways of protecting patients from harm when using these tests.

Continued insistence on using an informed consent process when it is not appropriate deflects from other important ethical obligations, such as avoidance of harm. We urge clinicians to be aware of the two different senses in which a patient can be overwhelmed and to protect overwhelmed patients from harm. There should not be a continued insistence on obtaining informed consent from the overwhelmed patient and, instead, steps should be taken to provide the assistance that patients in these situations require.

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