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Reply to Walker: Ensuring Understanding and Intelligibility in Informed Consent

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1 Introduction

In a recent and exciting article on informed consent, Tom Walker develops a proposal that, if shown to be right, would be extremely helpful and welcomed by those involved in matters of informed consent.[1] Essentially, he suggests making a division between (a) the information that doctors and researchers must ensure is understood by patients and research participants, and (b) that which doctors and researchers only need to disclose.[2] He then argues that, as a result of accepting this division, (1) the demands on doctors and researchers will be reduced, since they will only need to ensure understanding on the part of patients or research participants of a fraction of the items currently required for informed consent; and that (2) the empirical evidence showing that some of the information required for informed consent is not understood may be far less worrying than it otherwise might seem.

I will argue that neither (1) nor (2) obtain: accepting Walker's recommendation will have the counterproductive effect of increasing the burden on doctors and researchers in a majority of cases, and it will also make the empirical evidence more problematic for informed consent, given his views on the information which only need be disclosed by doctors and researchers.

[1] Tom Walker, "Informed Consent and the Requirement to Ensure Understanding," *Journal of Applied Philosophy*, Vol. 29, No. 1, 2012. Unless otherwise stated, references are to this article.

[2] Given the scope of this reply, I will not develop either theoretical or historical aspects of the notion of informed consent, other than those relevant to my discussion of Walker's article. For recent discussions of informed consent, see inter alia Neil C. Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007); Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 6th edn. (Oxford: Oxford University Press, 2009), chapter 4; Franklin G. Miller and Alan Wertheimer, eds., *The Ethics of Consent: Theory and Practice* (Oxford: Oxford University Press, 2010).

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When discussing work on informed consent, we should not underestimate the possible speed with which some proposals of this nature are sometimes implemented, particularly when compared to other areas of applied ethics. Ethics committees tend to have a significant degree of autonomy or discretion in approving informed consent practices. Moreover, members of these committees, who generally have an academic background, are potentially receptive to conceptual innovations of the sort that can be disseminated through articles such as the one published by Walker. In this context, it is significant that Walker's proposal, if successful, would allow for a very attractive practical implementation that could bring about a dramatic change in the way informed consent is practiced. Furthermore, my discussion of Walker's article will bring to the fore the challenges that a proposal of this kind will have to face in relation to any division of labor concerning the different types of information required to obtain informed consent.

2 Walker on Ensuring Understanding and Disclosing Information

2.1 Distinction Between Consent at All and Informed Choice

Walker's starting point is the uncontroversial and pertinent observation that for consent to count as informed on the part of patients and research participants with regards to treatments and participation in research projects, respectively, two trends have increased the demands to be met: the types of information required have substantially augmented and, whereas initially the information had to be disclosed, doctors and researchers must now ensure that it is understood (p. 50). As a result of this, two practical problems present themselves: first, obviously, obtaining informed consent has become more taxing for doctors and researchers, since not only is the list of items to cover longer, but they have to ensure that the information is understood rather than simply disclosed; and second, owing to research on informed consent, there is empirical evidence that suggests that not all the information provided is understood by patients and research participants (p. 50).

Walker seeks to address the practical problems just discussed by showing that while (a) there are types of information that certainly need to be *understood* by patients and research participants, and so doctors and researchers must ensure that this is the case, (b) there are other types of information that *only* need to be *disclosed*, with the implication that there is *no obligation to ensure* that they have been *understood*.

The distinction between information (a) and (b) is, in turn, supported by Walker's distinction between consent at all, on the one hand, and informed choice about such consent, on the other:

> When considering what information is needed for informed consent we might be concerned with what information a person would need in order to *consent at all* — that is, with what information is such that without it someone could not consent to take part in the research or to being treated. … I will argue that when it comes to this information doctors and researchers ought to ensure that

> their patients and research participants have understood it before obtaining their consent. A very different type of enquiry that we might be engaged in is that of determining what information a person needs in order to make an *informed choice about whether or not to consent* to treatment or to being part of a research project. (p. 51, my emphasis)

Once we come to see the difference between consent at all[3] and informed choice about consent, we can alleviate the two practical problems described above: one, having to ensure understanding of increasingly long lists of types of information; and two, the skepticism, based on empirical evidence, that such understanding is really taking place.

With regards to the first problem, the list of types of information required for informed consent will not be any shorter, but the number of items from it about which there is the need to ensure understanding will certainly decrease: this will remove onerous and unwarranted demands on doctors and researchers (p. 51). Walker even goes as far as suggesting a two-list system: one list with information needed for consent (and which requires that understanding be ensured) and the other with information needed to make an informed choice about whether or not to consent (and which only requires disclosure).

As for the second problem, since making an informed choice about consent does not require that all the information be understood, but only disclosed, "it may well be that the empirical evidence is less problematic than it at first seems" (p. 51).

2.2 Information to be Disclosed but Not Necessarily Understood

I will now turn to Walker's proposal that a significant percentage of the items that go on the lists of required information for informed consent must be disclosed but that there is no obligation that they should be understood and, therefore, no reason to ensure that patients and research participants understand them. There are two key aspects of Walker's view on this issue that I want to explain here. First of all, I will develop the basis for his distinction between the information that must be understood and that which only needs to be disclosed. Then I will present his contention that doctors and researchers, rather than merely having no obligation to ensure understanding, have a *prima facie obligation not to ensure understanding* of the types of information that only need to be disclosed.

Firstly, Walker argues that there is information needed for patients or research participants to consent at all. Such consent is required to render permissible an act that otherwise would be morally (and possibly legally) impermissible (p. 53). Often, such consent involves consent to an action: what the doctor or researcher is going to do to the patient or research participant. The information required for such consent must be understood. For instance, in order to consent, patients and research participants unavoidably need to understand whether their bodies are going to be

[3] In the remainder of this paper I will use indistinguishably the terms "consent at all" and "consent." There should be no confusion with "informed consent," since I will never drop the word "informed" in this phrase.

touched or cut (through surgery), or whether they will suffer side effects as a result of treatment or participation in the research project.

By contrast, there are other aspects of treatments and research projects that are only needed by the patients and research participants to make an informed choice and so they only need to be disclosed. Examples of these types of information would be who is funding the research project, the institutional affiliation of the researchers and where the results will be published; even the benefits of a treatment typically fall in this category, for patients do not need to know these benefits in order to consent, but rather so that they can make an informed choice about whether to consent (pp. 53–55, 59–60).

Walker remains neutral regarding the debate on how to determine the standard that should guide the nature and extent of the information that needs to be disclosed for consent to be informed (pp. 55–56). The important point is that such an obligation does exist and he doesn't need to be any more precise.

Moreover, Walker sensibly argues that there will be variations concerning what different patients and research participants find relevant in order to arrive at an informed choice owing to their different beliefs and values (p. 55). Therefore, it follows that "requiring that doctors and researchers ensure that all the information they disclose [to allow for an informed choice] is understood would require them to ensure that irrelevant information is understood" (p. 57).

Secondly, Walker contends that there is a prima facie obligation to precisely avoid ensuring understanding of information that is not necessary for consent, but that is only relevant for making an informed choice; well understood from the previous point is that it might *only* be *potentially* relevant and that, depending on the person, it might not be relevant at all.

Following Walker's example, let's imagine that a research participant does not feel that whoever is funding the research project has any bearing on her decision as to whether or not to participate in the research project. If the researchers were to ensure that she has understood the section on funding of the disclosed information, they would have to prevail over her decision to skip that section: she would have to go back and read it properly. According to Walker, this amounts to a *failure to respect the autonomy* of the research participant: the judgment of the research participant would be substituted by that of the researcher with regards to what is relevant to making an informed choice about participating in the research project (pp. 57–59). Walker thinks that the failure on the part of doctors and researchers to respect the autonomy of patients or research participants is of a very serious tenor: he compares it to failure to respect autonomy in cases where either information is withheld or treatment is decided upon without consulting the patient. I will criticize Walker's characterization of this obligation in Sect. 4.

What then is the epistemic obligation of doctors and researchers concerning the information to be disclosed so that patients and research participants can make an informed choice? After all, although as discussed above different people will find different bits of information relevant, those bits that are relevant to them might be critical to their deciding whether or not to undergo treatment or be part of a research exercise. Obviously, simply disclosing the information will not be enough; as Walker argues "providing information in a form that they cannot understand will

not satisfy these obligations" (p. 59). Therefore, the requirement is for the disclosed information to be *intelligible*. Importantly, some of the patients or research participants may well need to understand some or all of the information disclosed prior to deciding whether or not it is relevant for their informed choice, whereas others might prefer to skim or skip sections based on prior judgments about their relevance (p. 57). Hence, one could argue that having the freedom to decide which bits of the disclosed information are relevant implies that all the information disclosed is going to be laid out in an understandable form.

3 Empirical Evidence Concerning Lack of Understanding

In this section I will focus on Walker's claim that the empirical evidence showing that patients and research participants do not understand some of the information that they are given to obtain informed consent is far less worrying than might appear at first. According to him, so long as the potentially misunderstood information belongs to (b) the information that only needs to be disclosed, rather than (a) that which requires doctors and researchers to ensure understanding, evidence that such information is not understood "does not directly show that there is a problem with the consent obtained" (p. 60).

In what follows, I will show that Walker's argument fails: not only does the empirical evidence not become less damaging for information (b), but it is actually more damaging for information (b) than it is for information (a), if one accepts Walker's own thinking on both.

The concern stemming from empirical evidence applies to both information (a) and (b): Walker does not say otherwise, nor does his argument hinge upon the evidence affecting information (a) and (b) differently. Now, according to Walker, doctors and researchers have the obligation to ensure that information (a) is understood. Therefore, in Walker's view, doctors and researchers have every reason to take steps to assess whether or not information (a) has been understood; moreover, if it hasn't, they ought to remedy that state of affairs.

This is clearly not the case for the information that only needs to be disclosed. Here, the epistemic worry applies equally, but the normative demands are very different: Walker contends that not only is there no obligation to ensure understanding of this type of information, but actually there is a prima facie obligation *not* to ensure such understanding on pain of failing to respect the autonomy of patients and research participants. So, for information (b) doctors and researchers might have as much reason to worry that it might not be understood as they do for information (a); however, for information (b) they have a mandate not to take any extra steps to check whether or not this is the case, since this might mean failing to respect the autonomy of patients and research participants by, for example, having them look at a piece of information that they had chosen to skip. This would be the case even in less taxing approaches where a small percentage of the patients or research participants are examined about their understanding of information (b). An informed consent set-up where only that information (b) considered relevant by each patient or research participant is checked seems

wholly unrealistic in most cases; in any event, Walker never suggests anything of the sort.

Walker has argued that information (a) is more important than information (b). And, to be clear, I am happy to grant him this point. But he has never defended that *only* information (a) is necessary to obtain informed consent. Indeed, his proposal is that *from all the information* required to obtain informed consent, we should distinguish between information (a) and (b), not that we should keep information (a) and leave out (b). Therefore, failure to understand some of the information that only needs to be disclosed does amount to *failure to obtain informed consent* if that information is deemed relevant for making an informed choice by the patient or research participant. Hence, the intelligibility demands on the information to be disclosed remain very high indeed, since failure to make this information available in an understandable form implies *potential failure* to meet the requirement of informed consent. Such failure might be less bad than failure to understand the information necessary to consent at all, but still it is a morally unacceptable failure on the part of doctors and researchers: they must work under the assumption that all the information might be required to be intelligible by one patient or research participant or another, and so they have the obligation to make intelligible all the information to be disclosed; not to do so would amount to accepting the possibility that a percentage of the consent obtained is not *truly informed* consent.

In view of this, it is hard to understand Walker's relaxation of the demands for intelligibility, when he states that

> information about risks is something that for many people is relevant to making an informed choice about whether or not to agree to take part in research. As we have seen a researcher's obligations here are to disclose information. Whilst potentially relevant, evidence that research participants do not understand the risks *does not directly tell us whether researchers have fulfilled these obligations*, and so does not directly show that there is a problem with the consent obtained. What would be relevant here is evidence about whether or not researchers are providing the information in an *understandable form*, or whether there are ways of providing the information that would be *easier to understand*. (p. 60, my emphasis)

True, the empirical evidence does not show that some of the informed consents obtained are not truly informed. It does show, however, that there is a reasonable chance that at least some aren't, since there is a reasonable chance that at least some (perhaps many) of the research participants will find the information about risks relevant to making an informed choice about their participation in the research project. Therefore, it would seem morally irresponsible for a researcher to design a project aware of the possibility, based on empirical evidence, that a percentage of the participants will fail to provide truly informed consent; to admit that this epistemic problem is *potentially* relevant does not diminish the severity of the problem. This point, of course, applies equally to any other problematic information besides risks. Furthermore, I find it hard to comprehend how empirical evidence about the understanding of information (or rather the lack of it) is going to be

substantially different from empirical evidence about information being provided in an understandable form.

In any case, Walker's conclusion is that given the different motivation to ensure understanding (i.e., the obligation that patients and research participants must understand the information necessary to consent), on the one hand, and to disclose information (i.e., the obligation that the patient must be able to make an informed choice), on the other, evidence of misunderstanding concerning the latter "may not be as problematic as has been thought for the idea that we need informed consent" (p. 61). He fails to see that albeit less problematic, the choice about treatment or research participation will not be informed and hence *informed* consent will not be obtained: it might be a lesser failure, but still an inadmissible one.

Importantly, Walker's contention puts doctors and researchers in the impossible position of, on the basis of empirical evidence, worrying that some of the information required to make an informed choice won't be understood, but at the same time having a prima facie obligation not to, for instance, put in place procedures to assess whether it has been understood, since this would run the risk of not respecting the autonomy of their patients and research participants.

4 The Failure to Respect Autonomy

I will now briefly discuss Walker's contention that doctors and researchers have a prima facie obligation not to ensure understanding of the types of information that should only be disclosed because doing otherwise would imply a failure to respect the autonomy of patients or research participants. The following quotation captures very well Walker's view with regards to the nature and severity of such a failure:

> [R]equiring doctors and researchers to ensure understanding would, if taken seriously, also be to require them to ensure that their patients or research participants do not make decisions using processes such as skipping or skimming sections of the information provided. … [(i)] In doing this the doctor or researcher substitutes the judgment of someone else (his own judgment or that of the person drawing up the guidelines) about how to make a decision given the information provided for the judgment of the patient or research participant him or herself. This kind of substitution, however, is a failure to respect the patient's or research participant's autonomy. [(ii)] As such it is a failure of the same type as that which would occur if a researcher were to withhold information about the risks of taking part in an experiment because the researcher judges it would not be important. [(iii)] It is also the same kind of failure that would occur if a doctor were to decide that someone should have treatment without consulting them. In all these cases what is happening is that the doctor or researcher substitutes their judgment for that of the other person. (p. 58)

In one sense, it may well be that failures (i), (ii) and (iii) are all of the same kind, since in all the cases the (actual or potential) judgment of the patient or research participant is wrongly overridden by that of the doctor or researcher. But, in another

sense, failures (i), (ii) and (iii) are conspicuously different; so much so that it is misleading to maintain that they are of the same type, as they may be in one sense, without qualifying such a claim by outlining in what ways they are not: it leads one to believe that failure (i), wrong as it may be, is more severe than it actually is.

The point can effectively be made by using Walker's own division between (a) information that is required to *consent at all* and (b) information that is required to make an *informed choice* about consent. Failure (iii), to decide on treatment without consultation, would certainly mean withholding information (a). Failure (ii), to withhold information about risks, may mean withholding either information (a) or (b), since knowing about risks can be necessary for either consent or for making an informed choice about whether to consent.[4] In stark contrast to failures (ii) and (iii), failure (i) would not have the consequence of depriving the patient or research participant of any information necessary to either consent or make an informed choice. Therefore, and critically in the present discussion, failures (ii) and (iii) would have the consequence that *informed consent had not been obtained*; that is not the case for failure (i).

I conclude that, properly qualified, failure to respect the patients' or research participants' autonomy in relation to what they have decided is irrelevant information for making an informed choice, while to be avoided, is less worrying than Walker seems to think. It follows that the obligation not to ensure understanding of information that need only be disclosed has a lesser normative force than if failures (i), (ii) and (iii) are thought of as being of the same kind. A lowering of the normative strength of such obligation might make less problematic instances in which this obligation is not respected on account of a greater benefit stemming from not fulfilling it (p. 58; see the next section for a discussion of this point). It might also mean that the problems discussed in the previous section resulting in part from the obligation not to ensure understanding of information only to be disclosed, while still pressing, are less pronounced. Nonetheless, Walker's proposal, even if thus amended, continues to postulate a prima facie obligation not to ensure understanding for this type of information.

5 Ensuring Understanding

In this section, I will engage with Walker's proposal to attenuate the effect of the current combined trends of enlarging the list of types of information needed for informed consent, on the one hand, and ensuring that this information is understood rather than simply disclosed, on the other. Walker believes that these two trends unnecessarily burden doctors and researchers. His suggestion consists in dividing the information typically required for informed consent into (a) that which needs to be understood (because it is required for there to be consent at all) and (b) that which only needs to be disclosed (because it is required to make an informed choice

[4] While it is true that there will be cases where certain information about risks will not be necessary for either information (a) or (b), the important consideration is that there will certainly be cases where it will be, and that is all I need to make my argument here.

about consent). I will argue that Walker, in trying to secure a salient and clear-cut distinction between information (a) and (b), makes the obligation to ensure the understanding of information (a) too strong and rigid. As a result of this, instead of ameliorating the demands on doctors and researchers, Walker's strategy in many cases will actually increase them. Moreover, his proposal promotes a drastically different treatment of information (a) and (b) in practice, which I believe is not helpful.

5.1 Exceptions to the Demand to Ensure Understanding

Despite Walker's general claim, discussed in the previous section, that doctors and researchers must not ensure understanding of information that should only be disclosed, he is happy to grant that there are plausible exceptions to this obligation. So there might be

> reasons that mean that doctors or researchers in a particular case have a *prima facie* obligation to ensure that the information [to be only disclosed] has been understood. It might, for example, be that understanding that information would benefit a particular patient. In that case what would be needed is to decide whether that benefit justifies disrespecting their autonomy. Alternatively, it might be that greater understanding would enable a more autonomous decision to be made. In that case, if there is an obligation for doctors or researchers to promote their patients' or research participants' autonomy … then it would need to be determined whether promoting future autonomy in this way would justify failing to respect the patient's or research participant's current autonomy. (p. 58)

By contrast, Walker does not discuss any plausible exceptions to the obligation to ensure understanding of information that is required for there to be consent at all. Therefore, a natural implicit reading of Walker, given the moral and epistemic demands placed on such information, is that there aren't in fact any. But I believe that such exceptions exist and that, moreover, our thinking about how to deal with them is very similar to that outlined by Walker in the quotation above with respect to the information that need only be disclosed.

Let's think about the following case: a doctor tells a patient that he is suffering from a very serious illness and there is a 90% chance that he will die within a year unless he undergoes surgery; moreover, there is a 50% chance of death as a result of the surgery, but if the surgery is successful there is a 50% chance of him living more than three years longer. Then the doctor asks the patient whether he has understood what he has been told and whether he wants any further clarification. The patient assents to the first question and declines the offer of further explanation.

There is no doubt that this is the kind of information needed for there to be consent at all on the part of the patient. But the reaction of the patient does not seem to be anywhere near what Walker requires to satisfy the condition that the patient's understanding has been ensured: Walker thinks that in many cases the patient's saying so (by, for instance, signing a form) won't be enough and argues that the doctor or researcher should take active steps to ensure that the information needed

for consent has been understood (pp. 52–53). Since information about risks features prominently in the empirical work that provokes skepticism about the understanding of information by patients and research participants, in the case under discussion the doctor seems to have every reason not to stop at the patient's answer, but to ensure understanding by other means: for instance, by asking him questions that will show whether or not he has understood the information just given; or by asking him to explain it in his own words. The worry is obvious: either option has the potential to cause considerable distress to the patient and may seem cruel to him and his relatives. There might be other options, but I doubt that they would really ensure understanding of the information about the risks without exposing the patient to psychological suffering; after all, he is already in a very vulnerable and stressful situation.

What is the answer to the conflicting obligations of ensuring understanding by the patient and avoiding, if at all possible, psychological harm? The same answer that Walker has provided for the conflicting obligations of ensuring and not ensuring understanding of information that should only be disclosed: doctors and researchers have to weigh the conflicting moral obligations and take what they judge to be the best course of action. Let's say, *ex hypothesi*, that there is good empirical evidence that, in disclosing risks in a manner and setting such as those in the example described above, 1 to 2% of adults do not understand them. In the absence of any verbal or non-verbal cues that reveal a comprehension problem, the doctor might think it unnecessary to go beyond the patient's assent to the question of whether he has understood the information. But say that the percentage were 20%; then the doctor might think otherwise. Unfortunately, in many cases empirical evidence won't provide templates that mimic real-life cases this closely, whether involving risks or otherwise. In those situations, doctors will have to use their best judgment regarding whether or not to take positive action to ensure understanding or passively accept the succinct assent of the patient.

The corollary of this case is that the obligation to ensure understanding with regards to information needed for consent, just as is the case with the obligation not to ensure understanding with regards to the information needed to make an informed choice, can (and will) have exceptions. I believe that it is important to acknowledge this possibility. As in the example discussed above, exceptions might be made in consideration of the psychological well-being of the patient or research participant, or by a combination of such concerns for the patient and a low likelihood of misunderstanding on his part. There might be other motives for making exceptions, including not wanting to place a burden on either doctors or researchers, or patients or research participants, that might be judged as unreasonable in view of the small benefits to be had in relation to the risk of misunderstanding of the information in question.

5.2 The Practical Requirement to Take Extra Steps to Ensure Understanding

I believe that Walker's views on what ensuring understanding entails would have in practice the consequence of unnecessarily burdening doctors and researchers, and patients and research participants. He argues that

> the patient or research participant must understand information that is necessary for someone to be able to consent if the doctor or researcher is to have the consent she needs. For this reason *she can only be sure* that she has consent if *she takes steps to ensure* that this information has been understood. (p. 53, my emphasis)

On the evidence of this passage, Walker thinks that the obligation to have the patient understand the information necessary to consent at all can only be fulfilled if such understanding is ensured by some positive course of action; moreover, ensuring such understanding will *always* involve taking steps to such effect, otherwise one cannot be sure. To be fair, in another passage he contends that "in many cases," rather than always, such steps will be needed (p. 52). As for the meaning of the "steps" required to ensure understanding, Walker does not go into much detail and he is perfectly entitled not to, since it is neither the focus of his article nor an issue that can be solved easily, given the wide variety of medical and research settings. But what he does clarify is that such steps are to be understood as going beyond "simply obtaining a statement from the patient or research participant that he understands the information" (p. 52).

In any case, one might very well wonder what those steps to ensure understanding might consist of in practice; this is particularly pertinent since a very attractive feature of Walker's proposal is the possibility of a practical implementation that will significantly reduce the work required to obtain informed consent. Efforts to ensure that information has been understood can take a variety of forms. One likely method might be to implement some kind of systematic individualized assessment or checking procedure to ensure that the information has been understood by each and every one of the patients or research participants. However, it seems obvious that in many cases such measures will result in very taxing and impractical demands on researchers, perhaps leading them to either significantly redesign or even abandon research projects. In some medical settings, such an approach might be highly problematic for doctors and patients (as seen in the example discussed above) or very onerous for the medical personnel.

Alternatively, research on informed consent can "piggy-back" on the research project whose informed consent practices are the object of concern; or such research can be done in conjunction with informed consent procedures for a given medical treatment. Again, while feasible in some contexts, the severe difficulties associated with these strategies are well known: from having a detrimental effect on participation in the main research study, to simply having enough numbers to do the piggy-back study, through the increased burden placed on researchers or medical personnel.[5]

By and large, the chief impact of informed consent research has consisted in making doctors and researchers aware of the shortcomings of their informed consent designs: publications can easily be read and discussed by those designing informed consent procedures, as well as by those approving them. With this approach, to ensure understanding means to design the right delivery of the information by taking advantage of our current knowledge of these matters, including empirical evidence.

[5] Philip J. Candilis and Charles W. Lidz, "Advances in Informed Consent Research," in Miller and Wertheimer, op. cit., pp. 330–331.

However, this approach is at odds with what Walker proposes on two counts. Firstly, it does not seem to fulfill his requirement to go beyond the assent of patients and research participants. It simply will not amount to taking steps to ensure understanding as prescribed by Walker, since in the end the assurance of understanding will come from the assent provided by the patient or research participant, in the absence of any clues to question such assent.

Secondly, and crucially, this approach greatly dilutes the practical import of his distinction between (a) the information that must be understood for there to be consent at all and (b) that which must only be disclosed to make an informed choice about consent. For, as discussed in Sect. 3, while it might be less important than information (a), information (b) still is essential for informed consent to be obtained and, therefore, doctors and researchers must ensure that all of the information (b) is rendered in an intelligible fashion.

So it seems that in many cases, perhaps most often, the requirements regarding information (a) and (b) will come to the same thing: that the information is laid out in an understandable way. Of course, should there be a suspicion that patients or research participants do not understand information needed to consent, actions should be taken to remedy this situation, including measures such as assessing the understanding of the information, or doing research to better identify and comprehend the potential failures. Nonetheless, if the same suspicion arose with respect to information required to make an informed choice, although the case might be less problematic, it still would be unacceptable not to take steps to rectify the matter, as shown in Sect. 3. It might well be that such suspicion justifies overriding the patient's or research participant's autonomy to ignore part of the information required to make an informed choice. Again, for practical purposes, the division of information into that which must be understood and that which must only be disclosed does not seem anywhere near as relevant and clear-cut as Walker contends.

In sum, my concern here is that, with respect to the information necessary to consent at all, Walker is endorsing a *blanket obligation* to take steps that go beyond rendering the information in an intelligible fashion. Furthermore, it worries me that the empirical evidence alluded to by him is being used as an unqualified and general motivation to endorse this blanket obligation. While empirical work on informed consent is extremely valuable and must be seriously considered, it is far from being uncontroversial.[6] At any rate, I believe that the responsible and realistic approach by doctors and researchers is to be aware of such research and to design the informed consent provisions accordingly, while paying careful attention to any signs that some part of the information is not being understood.

6 Conclusion

I have argued that Walker's proposal to divide the information required to obtain informed consent into two different groups is counterproductive for his original aims of reducing the burden on doctors and researchers, and attenuating the worries

[6] See Candilis and Lidz, op. cit., for a recent review of empirical work on informed consent.

stemming from experimental evidence on patients' and research participants' lack of understanding of the information used for informed consent. To make this division salient and clear-cut, he first develops an overly demanding account of doctors' and researchers' obligations to ensure the understanding of the information needed for there to be consent at all, and second, advocates a too rigid view of the obligation of doctors and researchers to simply disclose (and not ensure understanding of) information required to make an informed choice.

I have suggested that, in many cases, the obligation to ensure the understanding of information necessary to consent at all can be considered to have been fulfilled by an informed consent design that takes into account the best available knowledge and resources, obviously including empirical research, concerning the intelligibility of information required for informed consent. While I certainly agree with taking extra positive steps to ensure understanding when it is thought necessary by doctors and researchers, I believe that it is a mistake to endorse a blanket obligation (or something close to it) to take such steps in relation to information that must be understood for there to be consent at all: this would unnecessarily burden doctors and researchers.

Walker maintains that doctors and researchers have a prima facie moral obligation not to ensure the understanding of the information relevant to making an informed choice. I have pointed out that this view has the unfortunate consequence of making more troubling the empirical evidence to the effect that patients and research participants do not understand some of the information used in obtaining informed consent. Doctors and researchers will be faced with the dilemma of worrying that some of the information required to make an informed choice won't be understood, but at the same time having a prima facie obligation not to take steps to assess whether it has been understood on pain of not respecting the autonomy of their patients and research participants.

In sum, it does not seem a good idea to divide the information required for informed consent into two lists, one with high demands concerning understanding and the other with only an obligation of intelligible disclosure. In many cases, the best course of action will be to use current knowledge about intelligibility of information in informed consent settings to produce the best possible layout of *all* the information necessary for informed consent. In addition, a thoughtful use of different approaches to assess understanding and remedy the lack of it should be encouraged, but not just for information necessary for there to be consent at all, but also for information relevant to making an informed choice; in both cases, the extra steps to be taken, of whatever nature, may have to be weighed against a number of considerations, both moral and practical. A far more flexible model then emerges, with a degree of continuity and fluidity in the treatment of all the information required for informed consent that clearly departs from Walker's proposal.[7]

[7] I would like to thank an anonymous referee for helpful comments on a previous version of this article.