

# The role of authentic choices in medical consent

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By

Alexander J Villafranca

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## **I. Abstract**

This dissertation investigates whether the “authenticity” of a patient’s choice (i.e. its correspondence with important markers of the patient’s identity), should be part of a model of valid medical consent. This research question was addressed across three manuscripts using philosophical and empirical methods. Manuscript one is a philosophical manuscript defending my thesis that the standard model of valid consent may be improved by including the “authenticity” of a patient’s choice as an additive condition, thereby forming what I call the “authenticity-informed model of valid consent”. In this manuscript, I present seven procedural practices stemming from this new model. I argue that these practices should be considered for inclusion in the existing procedural recommendations of the Canadian Medical Protective Association (CMPA), which draw heavily from the standard model. The new practices could help physicians to i) more accurately evaluate the decisional capacity of patients; ii) more accurately evaluate the autonomy of patient choices, and iii) better support the psychological and physical well-being of patients. I also created vignettes to assess empirically whether the end goal of promoting authentic and autonomous patient choices would have instrumental value above choices that are solely autonomous. In manuscript two, I introduce the use of pretesting to evaluate and enhance the rigor of vignettes studies used in empirical ethics research. This manuscript includes an illustrative example of how data collected through a respondent debriefing procedure can be used to measure numerous desirable vignette characteristics. Manuscript three uses the vignettes to evaluate the instrumental value of shifting from a choice that is solely autonomous to one that is both authentic and autonomous in a single, but consequential, clinical scenario. This study confirms that shifting from a solely autonomous choice to an authentic and autonomous choice can substantially decrease anticipated decisional

regret and increase both anticipated decisional satisfaction and compliance with postoperative instructions. In conclusion, there are plausible reasons to believe that adding authenticity may improve the standard model of valid consent and its associated procedural practices.

Consequently, consideration should be given to modifying the procedural recommendations of the CMPA to reflect the addition of authenticity.

## **II. Acknowledgements**

Author James Allen once wrote that “no duty is more urgent than that of returning thanks”. I take great enjoyment in fulfilling this duty to the many people who have helped me during the course of my PhD program. I am not one for generic acknowledgements, so I have tailored many of my statements to the intended person. Third parties may not fully understand the context of these comments, but I hope that they will take my word that any inside references or jokes are indeed profound and hilarious, respectively.

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With gratitude to you all,

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### **III. Dedication**

This dissertation is dedicated to the memory of both T and S. When examined over a wide enough timescale, all lives contain elements of tragedy. And yet, there is something especially senseless and frustrating about death at an early age. The information theory of the self states that a person is a pattern of information, as reflected in the connections between neurons in the brain. As one person influences you, the patterns of information in your brain begin to mirror those found in the brain of the person who influenced you. While both of you saw me toil on this effort, regrettably neither of you lived to see me complete it. However, I find solace and encouragement in the idea that your influence- part messy and imperfect, part edifying and ensouling- remains as an imprint on my brain, visible to those who are straining under the right kind of light.

A.

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## **VII. Contribution of authors**

This dissertation contains three manuscripts for submission to peer reviewed journals. The title of each manuscript is listed as follows:

1. The role of authenticity in medical consent.
2. Using pretesting to improve the quality of vignette studies.
3. Should we promote patient choices that are both autonomous and authentic? A vignette study of layperson reactions to authentic and inauthentic choices.

These manuscripts are included as Chapters 2, 3, and 4 in the present document, respectively. I was the primary author of all three manuscripts. For each manuscript, I was responsible for the study conception and design, literature reviews, and any data collection, analysis, reduction, and interpretation of findings. I also wrote the first drafts and revised them based on feedback from my committee.

## A. Chapter 1: General Introduction

### *Theme of the dissertation*

This dissertation addresses whether the authenticity of patient choices should be included in a model of valid consent in the medical context. It does this by arguing in favour of, and in some cases empirically testing, the potential benefits and drawbacks of such an inclusion. It also proposes procedural practices to reflect this inclusion.

### *Research objectives*

The specific objectives for each manuscript in this dissertation are as follows.

**Manuscript 1-** This philosophical manuscript defends the thesis that the standard model of valid consent could be improved by including the “authenticity” of a patient’s choice as an additive condition, thereby forming what I call the “authenticity-informed model of valid consent”.

**Manuscript 2 -** This methodological manuscript provides an introduction to the use of pretesting to evaluate and improve the quality of vignettes used in empirical ethics research. As part of this, it illustrates how I used pretesting to ensure that the vignettes used in manuscript 3 have construct validity. The illustrative example used in this manuscript was then applied in manuscript 3.

**Manuscript 3-** This manuscript empirically evaluates the instrumental value of shifting from a choice that is solely autonomous to one that is both authentic and autonomous. Study outcomes include respondent anticipated decisional regret, satisfaction, and compliance with postoperative instructions.

### *Rationale for the dissertation*

For healthcare providers to perform a medical procedure on a competent patient in an ethical manner, either the patient or a designated decision-maker must first provide valid consent [1]. In 1986, Ruth Faden and Thomas Beauchamp [2] presented an influential model of valid consent applying to the clinical and research contexts, hereafter referred to as the standard model. The primary goal of this model is to “enable potential subjects and patients to make autonomous decisions” [2] p.284, and to differentiate between autonomous and non-autonomous agents, to whom physicians have different moral duties [2] p. 288.

Faden and Beauchamp propose that in one sense, an informed (i.e. valid) consent is a “special kind of autonomous choice (or action)” (p. 277), where a patient “authorizes a professional...to initiate a medical plan for the patient” [2] (p.278). They also identify individually necessary conditions for autonomous (i.e. valid) consent, stating that choices must be informed, voluntary, and made by a patient who has sufficient decisional capacity [2,3].

The standard model asserts that there is a second sense of the term “informed consent”

(sometimes called “effective consent”), which is:

...a legally or institutionally effective authorization by a patient. Such an authorization is effective because it has been obtained through procedures that satisfy the rules and requirements defining a specific institutional practice in health care or in research [2] p.280.

These procedures typically involve guiding and restricting the actions of physicians [2] p.277 & 280. While the procedural practices that an organization recommends are motivated in part out of concern for respecting patient autonomy, they are also motivated by other factors such as the effect that consent requirements have on institutional functioning and on the autonomy of clinicians [2] p. 285 & p.330. For instance, the procedural practices might try to avoid placing

undue burden on the physician's time or excessively limit their professional autonomy, even if doing so would further facilitate patient autonomy.

The standard consent model forms the basis for the procedural practice recommendations developed by the Canadian Medical Protective Association (CMPA) [4–6]. These recommendations state that “The consent must have been voluntary, the patient must have had the capacity to consent and the patient must have been properly informed” [6]. The CMPA indicates that their guide to consent is a “practical guide for physicians in their day-to-day dealings with patients” [6], thereby representing a form of effective consent.

The procedural recommendations of the CMPA are important in Canada since the agency provides medical liability protection, medical-legal advice, legal assistance, and continuing medical education to all practicing physicians and residents in Canada [7]. Its membership list contains nearly 98 thousand physicians [8]. In 2017 alone, its website was visited over 1.2 million times, and it provided formal legal advice to almost 22 thousand physicians in this same year [8]. Thus, the CMPA's influence on physician behaviour is significant, and its advice on procedural practice carries weight.

The authenticity of patient choices, broadly defined as coherence with important markers of a patient's identity, is not included as part of either the standard model of valid consent, or the procedural practices of the CMPA. This lack of inclusion exists despite recognition by Faden and Beauchamp that authenticity is “the leading candidate for a position as an additional condition” for autonomous choice (and therefore valid consent) [2]. Omitting authenticity from the standard model is not congruent with the importance of the concept within our society, which recognizes authenticity as a broader ideal and as a useful criterion to evaluate people's choices. Advice commonly given to individuals who are facing a difficult decision include vague appeals to

authentic choice, such as the recommendation that they should choose options that would be “true to him or herself”. As a society, we teach our children to value authentic action by presenting them with books and movies whose protagonists learn to develop, accept and act consistently with their values, goals, and/or past behaviors [9–12]. The popularity and ubiquity of authenticity has led influential philosopher Charles Taylor to proclaim that we are currently living in the “age of authenticity” [13] (p.48), with cultural and theological commentators accepting and echoing his sentiment [14,15].

Many academics have also taken an interest in the concept of authenticity, including those in the fields of philosophy, psychology, and health services research. Existential philosophers such as Jean-Paul Sartre popularized this concept in the mid-20<sup>th</sup> century, with their efforts eventually leading philosopher Storm Heter to call authenticity “the chief existential virtue” [16]. In the analytic philosophical tradition, authenticity has substantially influenced autonomy theory [2,17–19], with an important model of autonomous choice, the “authenticity model”, giving the concept special consideration [2,20]. These autonomy theorists typically hold that “the modern picture of the ideal person is a picture of an independent, self-directed individual whose actions clearly manifest what he or she really is” (12) and that “our decisions are worth protecting if they are somehow rooted in our values and overall commitments and objectives” (13).

Concurrently, psychologists have studied authenticity as a characteristic of an agent (i.e. trait authenticity) [21–25] and as a psychological state of mind (i.e. state authenticity) [26–29].

Lastly, as part of its “goal of improving the efficiency and effectiveness of health professionals and the health care system” [30], many health services researchers have examined different approaches and tools aimed at improving interactions between healthcare providers and patients. This includes broader movements in medicine, such as patient-centered care [31–33] and shared



decision-making [34–37], as well as specialized tools such as value assessment questionnaires [38–41] and decisional aids [42–44]. While these tools are intended in part to support the goals of the standard model of valid consent, they also aim to assist patients by clarifying their values and matching medical choices to their values and/or preferences. For instance, one goal of patient-centred care is to more closely align patient choices with their stated preferences, beliefs, and/or values [45,46]. This shows a concern for the correspondence of the patient’s choice with at least several markers of the patient’s identity (e.g. values, preferences).

In summary, the intuitive appeal of authenticity is shared across multiple academic fields, as evidenced by their attempts to explicate the concept, empirically investigate its applications, or incorporate different senses of the concept into existing theories and frameworks. The widespread appeal and perceived importance of authenticity make it a reasonable candidate to consider for inclusion in a model of valid consent.

The next three sections of the introduction will provide separate rationales for each of the three manuscripts included in this dissertation. The manuscripts support each other by informing each other’s methods or arguments. The methodological manuscript enabled me to develop rigorous vignettes to use in the empirical study, thereby increasing the rigor of the inferences made. The empirical manuscript roots at least several of the philosophical arguments in rigorous empirical data, thereby strengthening and supporting the philosophical paper.

### ***Rationale for the philosophical manuscript***

The philosophical manuscript is a logical extension of previous philosophical work. Some philosophers have considered adding authenticity to the standard model of informed consent and have provided reasons for and against such a proposal [2,3,17,47–49]. However, typically they have considered adding authenticity as a necessary condition for valid consent, which may

encourage physician paternalism. Several philosophers have argued that including authenticity in the informed consent process could facilitate the assessment of the decisional capacity of the patient, or the autonomy of the patient's choice [48–50]. However, these possible benefits have not been thoroughly described in terms of the types of situations where these benefits could apply, and the types of misclassifications of patients and choices that would most likely be prevented. In addition, it would be useful to link the benefits of preventing such misclassifications with the clinician's duties to respect patient autonomy and to act beneficently (both of which are moral principles that, when followed, tend to produce good outcomes for the patient). Finally, it would be useful to describe how the authenticity of patient choices could be incorporated into the procedural practices of the CMPA. This would involve proposing procedural practices to reflect the addition of authenticity and providing physicians with sample questions and statements to use in order to achieve the recommended practices. The philosophical manuscript addresses each of these gaps.

### ***Rationale for the methodological manuscript***

The empirical manuscript involves a vignette study. In order to ensure that this study generated valid inferences, the vignettes needed to be rigorously developed. Upon reviewing the vignette literature, numerous authors reported concerns regarding the quality of the research in empirical ethics [51–55]. While a recent consensus initiative aimed to develop standards of practice in bioethics research [56], its recommendations do not provide specific guidance regarding vignette development or integration. In addition, with notable exceptions [55,57–59], I found relatively few articles focusing on the proper use of vignettes in empirical ethics research, and none focusing on arguably the most flexible and inexpensive tool to improve the quality of survey

research - pretesting. This presents an opportunity to synthesize and disseminate useful information to an audience of researchers that is currently under scrutiny.

The relationship between the methodological manuscript and the empirical manuscript is iterative. The methodological manuscript presents an introduction to the use of pretesting in empirical ethics research. This information was used to develop a pretesting procedure for the vignettes we used in the empirical manuscript. However, some of the data generated by the vignette pretesting was included in the last part of the methodological manuscript as an illustrative example. In particular, it was demonstrated how data generated from a respondent debriefing procedure could help to evaluate and improve vignette construct validity and other desirable characteristics. This iterative procedure served the dual purposes of improving the rigor of the vignettes used in this dissertation while bringing a tool that is extremely useful for vignette development to the attention of empirical ethics researchers.

### ***Rationale for the empirical manuscript***

The need for the empirical manuscript is justified by 1) the ethical perspective I have adopted; and 2) the scarcity of empirical data supporting the arguments being made in the philosophical manuscript.

In this dissertation, I have adopted the philosophical perspective of a rule consequentialist, who “elects rules solely in terms of the goodness of their consequences and then claims that these rules determine which kinds of acts are morally wrong” (23). In particular, I am adopting the perspective of a rule-utilitarian, who considers the “aggregate well-being or welfare” (23) that would be created through the widespread adoption of a rule. To justify the adoption of the “rule” that authentic choices should be included in a model of valid consent, an appeal to the popularity of authenticity is insufficient. Instead, arguments and evidence must be presented to support the

idea that its inclusion would result in consequences that contribute to aggregate well-being (at least under some circumstances). This would give authentic choices “instrumental value”, as they would be “a means to, or causally contribute to, some-thing that is intrinsically valuable” [60], with the wellbeing of persons being the intrinsically valuable “thing”. By “intrinsic value”, philosophers typically mean “the worth something has for its own sake” [61]. Thus, the ethical perspective that I have adopted requires an appeal to consequences, which the empirical paper helps to establish scientifically.

In the philosophical manuscript, I claim that the end goal of increasing the number of patient choices that are both authentic and autonomous would result in greater decisional satisfaction, less decisional regret, and greater compliance with postoperative activity restrictions. Previous literature cannot directly support these claims, and thus, they are tested in the empirical manuscript.

The rationale for selecting these three indicators of the instrumental value of patient choices was based in part on their importance and their ubiquity in health services research. In the context of medical decision-making, the focus is often on “patient-centred outcomes” or “patient-important outcomes” [62–64]. As the names imply, this focus shifts away from more basic physiological measures toward “outcomes that matter to patients” and that are “tied to the patient’s perspective” [62] (p.123). These include various markers of patient affect, quality of life, and the presence of important adverse events and complications (e.g. respiratory failure, death, pain, etc.) [63,64]. In vignette studies that focus on medical decision-making, frequently examined patient-important outcomes include decisional regret and satisfaction with the decision-making process [65–67]. In addition, compliance with medical treatments is often examined, as it can predict adverse events caused by patient non-compliance [68,69].

These outcomes are important. Patient satisfaction (regarding either the decision-making process or the outcomes of medical care) is a useful indicator of the quality of patient care [70] and is thought to be “perhaps the most commonly used patient centred outcome measure” [71] (p.114). It has also been linked, both theoretically and empirically, to compliance with medical treatment [67,72]. In privatized healthcare systems, as well as those with mixed funding, medical treatment is often considered a “consumer driven industry” [73], where “patient satisfaction is important...because the patient has the power to walk away and seek another provider” [62] (p.128). In this context, patient satisfaction metrics can influence institutional market share and allegiance to healthcare providers [72], and are used to secure approval, funding, and bonuses from certifying bodies and health systems [74,75]. Collectively therefore, patient satisfaction can have substantial economic consequences to clinicians and institutions in privatized healthcare sectors [62]. Patient satisfaction is also important in publicly funded systems such as Canada, due to increasing trends to publicize patient satisfaction scores for hospitals<sup>1</sup> and individual healthcare providers, which could ultimately affect the reputation of these institutions and clinicians.

Regret negatively affects the well-being of the agent who is experiencing the emotion. Acutely, it is a painful and adverse emotional state [76,77] that individuals are motivated to anticipate and avoid [78,79]. In the postoperative context, greater decisional regret scores are correlated with higher patient anxiety [80], lower quality of life [79,81], and greater symptoms of depression [82].

A lack of compliance with treatments and post-treatment lifestyle modifications has been

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<sup>1</sup> For instance, see the Hospital Report Research Collaborative at <http://www.hospitalreport.ca>

identified as an important problem in healthcare, with non-compliance ranging from 4-50%, depending on the clinical population and the specific instruction in question [83–87]. Non-compliance places patients at risk of experiencing side-effects of treatment without the accompanying benefits [83]. In many scenarios, such as surgical recoveries and life-sustaining treatments, a single instance of non-compliance with treatment could have dire physical and psychological consequences to the patient due to treatment or surgical failure. Consequently, all three outcomes merit attention.

## **Conclusion**

In summary, the philosophical manuscript builds on previous work by arguing in favour of a model of valid consent that includes the authenticity of patient choices as an additive condition. It also presents procedural practices to reflect this inclusion. The empirical manuscript tests several important claims that are made in the philosophical paper using a vignette study. In order to ensure that the vignettes used in the empirical study were rigorous, a thorough pretest was conducted, which is described in part within the methodological manuscript. This manuscript also provides an introduction to the use of pretesting in empirical bioethics research, thereby addressing a substantial gap in the guiding methodological literature.

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## **B. Chapter 2: The role of authenticity in medical consent**

Alexander Villafranca, Arthur Schafer (critical editing)

### ***1. Introduction***

In this paper, I argue that the “authenticity” of a patient’s choice should be considered as an additive condition to the standard model of valid consent in the medical context, forming what I call the “authenticity-informed model of valid consent”. The paper consists of six sections. In the first section, I describe the standard model of valid consent, which is rooted in the work of Ruth Faden and Tom Beauchamp (1,2). This model asserts that a patient’s consent is valid when it is informed, voluntary, and when the patient has adequate decisional capacity. In the second section, I describe the Canadian Medical Protective Association’s (CMPA) important view of effective consent, which is heavily influenced by the standard model. The procedural recommendations of the CMPA are important, since the agency provides medical liability protection, medical-legal advice, legal assistance, and continuing medical education to all practicing physicians and residents in Canada. Given its influence and connection to the standard model, the recommended procedural practices of the CMPA are the main target of my criticisms. In the third section, I describe the authenticity-informed model of valid consent, which involves including authenticity as an additive condition to the standard model. I also propose seven procedural practices to implement this addition. In the fourth section, I illustrate two deficiencies of the standard model compared to the authenticity-informed model. The first deficiency is that the standard model results in less accurate judgments about the decisional capacity of patients. The second deficiency of the standard model is that it results in less accurate judgments about the autonomy of choices by competent patients. These misclassifications could lead to a less satisfactory fulfilment of the physician’s duties to respect patient autonomy and to act beneficently toward the patient. I argue that the procedural practices derived from the

authenticity-informed model could help to avoid these misclassifications. In the fifth section, I describe a third deficiency of the standard model - that in some instances it is likely to do a less satisfactory job of supporting the psychological well-being of patients than the authenticity-informed model. This is especially true when the patient is choosing between an autonomous choice that would limit the authentic activities in which the patient can partake and prevent participation in their most authentic activities, and an autonomous and authentic action that would not. In the final section, I describe what may be the most important criticism of the authenticity-informed model of valid consent; that this approach would increase physician paternalism. I acknowledge the risk but contend that it can be minimized by the elements of my proposed model and procedural practices. I conclude that the authenticity-informed model could better facilitate the physician's duties to act beneficently and to respect patient autonomy when compared to the standard model. I also conclude that the seven procedural practices I propose should be considered for inclusion in the CMPA guidelines.

## *2. The standard model of valid consent*

For healthcare providers to perform a medical procedure on a competent patient in an ethical manner, either the patient or a designated decision-maker must first provide valid consent (3). In 1986, Ruth Faden and Thomas Beauchamp (1) presented an influential model of valid consent, which could be called the standard model. The primary goal of this model is to “enable potential subjects and patients to make autonomous decisions” (1) p.284, and to differentiate between autonomous and non-autonomous agents, to whom physicians have different moral duties (1) p. 288.

Faden and Beauchamp propose that in one sense, an informed (i.e. valid) consent is a “special kind of autonomous choice (or action)” (p. 277), where a patient “authorizes a professional...to initiate a medical plan for the patient” (1) (p.278). They also identify three individually necessary conditions for autonomous [i.e. valid] consent: “autonomous authorization is given if a patient or subject [acts] with (1) substantial understanding and (2) in substantial absence of control by others (3) intentionally” (1) p. 278.

In describing adequate understanding, they mention: 1) an accurate interpretation of what is said; 2) an abstract understanding of the relevant information; 3) an appreciation of how the consequences will affect the patient’s life and well-being; and 4) the absence of demonstrably false beliefs.

Originally, Faden and Beauchamp preferred the term “substantial absence of control by others” or “substantial non-control” over the term “voluntariness”, due to their assessment that the latter term was vague and ambiguous (1) p.257. The term “substantial absence of control by others” or “non-control” was limited to external constraints on action, such as coercion and manipulation (1) p.337. However, the term “voluntariness” gained popular usage despite this rejection, and ultimately Beauchamp and a group of collaborators revisited the concept in several 2011 papers (2,4). As a result, their view of valid consent was refined in such a way that the condition of “intentionality” merged with an expanded version of “non-control”, with this composite being re-labelled as “voluntariness”. In addition, this use of “voluntariness” as a composite term was expanded to include not only external constraints on action, but also internal ones, such as addiction, dementia, personality disorders, and brain damage.

In the work of Faden and Beauchamp, adequate decisional capacity is not a necessary condition for valid consent, but rather, a necessary condition for autonomous *agents*: “Competence is

analysed... in terms of criteria of autonomous persons, as distinct from autonomous actions.”

p.274. However, it still plays a critical role in the model, by “serve [ing] a gatekeeper function by identifying persons from whom it is appropriate to obtain informed consents” (1) p.274.

Notably, the standard model does not include the “authenticity” of the patient’s choice as a necessary or other condition for valid consent. This exclusion was motivated by concerns that adding authenticity to the model could increase the incidence of unjustifiably paternalistic actions toward patients. In a later work, Beauchamp and colleagues revisited the issue when expanding their condition of “non-control” into the condition of “voluntariness”. They considered adding “authenticity” as a necessary condition of “voluntariness”, but again rejected the idea for similar reasons.

In summary, valid consent according to the standard model requires that a patient’s choice be informed, voluntary, and be made by a patient with adequate decisional capacity.

### ***3. Effective consent and recommended procedural practices***

The standard model asserts that there is a second sense of the term “informed consent”

(sometimes called “effective consent”), which is:

...a legally or institutionally effective authorization by a patient. Such an authorization is effective because it has been obtained through procedures that satisfy the rules and requirements defining a specific institutional practice in health care or in research (1) p.280.

These procedures typically involve restricting and guiding the actions of physicians (1) p.277 & 280. While the procedural practices that an organization recommends are partially based on a concern for respecting patient autonomy, they are also typically motivated by concerns such as

fairness to clinicians, the effect of consent requirements on institutional functioning, etc. (1) p. 285 & p.330.

The standard model forms the basis for the procedural practice recommendations developed by the Canadian Medical Protective Association (CMPA), which are disseminated to “medical students, trainees, and medical faculty” (5) through both their “Good Practices Guide” educational modules (6), and their report “Consent: a guide for Canadian physicians” (7). Both resources endorse the standard model: “The consent must have been voluntary, the patient must have had the capacity to consent and the patient must have been properly informed” (7). The CMPA indicates that their guide to consent is a “practical guide for physicians in their day-to-day dealings with patients” (7) - thereby representing a form of effective consent.

In Canada, the procedural recommendations of the CMPA are important, since the agency provides medical liability protection, medical-legal advice, legal assistance, and continuing medical education to all practicing physicians and residents in Canada (8). Its membership list contains nearly 98 thousand physicians (9). In 2017 alone, its website was visited over 1.2 million times, and it provided formal legal advice to almost 22 thousand physicians (9). Thus, the CMPA’s influence on physician behaviour is significant, and its advice on procedural practice carries weight.

None of the procedural practices of the CMPA directly addresses authenticity. The physician is most encouraged to tailor the procedures to the current identity of the patient when informing them. First, citing legal precedent (Reibl vs. Hughs, 1980), they recommend physicians use the “reasonable person” standard as a guide to determining the amount and type of information



provided to the patient (7,10).<sup>2</sup> The CMPA provides further guidance regarding the information that should be disclosed in order to fulfil the reasonable person standard. This includes “an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available.... The physician should disclose to the patient the nature of the proposed treatment, its gravity, any material risks and any special risks relating to the specific treatment in question” (7). The CMPA also specifies that uncertainties regarding the diagnosis, prognosis, or successes and harms of the different treatment options should be specified, with particular concern to avoid the impression that the success of the treatment is guaranteed (11).

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<sup>2</sup> This is in contrast with at least two other disclosure standards that have been used and advocated for in the past. The first of these is the “professional standard”, where a physician should disclose what a “reasonable physician of ordinary skill would disclose in the same or similar circumstances” (11) pg.24. This is sometimes seen as the least stringent disclosure standard, as patients tend to want more information than physicians have typically offered in the past (11). It also seems strange to base the disclosure standard on what physicians prefer to disclose, since the patient typically has the greatest stake in the decision.

The second competing standard is the “subjective” or “individual” standard of disclosure, where a physician “must provide information that the individual patient would find pertinent to the discussion.” (11) pg. 25, regardless of whether a “reasonable person” would find it pertinent. This standard requires considerable knowledge about the patient. As a legal standard, it places physicians at an increased legal risk, since patients who experienced an extremely rare and relatively minor complication (which physicians would not usually be required to disclose under the “reasonable person” standard) could claim that they would have altered their decision if they had been provided this missing information. The veracity of such statements would be difficult to assess.

To their credit, the CMPA go slightly beyond the reasonable person standard and encourage physicians to individualize the information provided to patients. First, they make a point of telling physicians that “the patient must be given the opportunity to ask questions” (7) and that physicians “are expected to answer patients' questions as honestly and completely as they can” (11). This provides the patient an opportunity to gain additional information that they find relevant, even if the “reasonable person” would find it irrelevant. The CMPA also stipulates that physicians should disclose “material risks”, with the “particular circumstances of the patient [being] an important determinant of materiality” (7). Finally, the CMPA asserts that the “consent discussion extends to what the physician knows or should know a particular patient would deem relevant to making a decision” (11). Unfortunately, it is unclear exactly what the physician is expected to know about his or her patients. The CMPA provides an example of a violin player contemplating hand surgery but fail to mention whether the violin playing is the patient’s vocation, life passion, or hobby. Thus, the centrality of this fact to the patient’s life and the questions that led to its uncovering are unclear.

#### 4. *The “authenticity-informed model of valid consent”*

To understand the limitations of the standard model (and the procedural practices derived from this model by the CMPA) it must be compared to an alternative. The alternative I propose, the “authenticity-informed model of valid consent”, is a model that includes authenticity as an additive condition for valid consent. By “additive condition”, I mean that authenticity in patient choices would be something that should be promoted because it enhances the validity of consent to the extent that it is present, but has no minimum degree that is either necessary or sufficient for the consent to be considered adequately valid. Thus, no amount of authenticity could compensate for a lack of autonomy in achieving valid consent. This account is motivated in part by the deficiencies of the standard model. However, it is also motivated by the view adopted by many autonomy theorists that “the modern picture of the ideal person is a picture of an independent, self-directed individual whose actions clearly manifest what he or she really is” (12) and that “our decisions are worth protecting if they are somehow rooted in our values and overall commitments and objectives” (13).

Newman and Smith assert that “despite a great deal of academic interest in this concept, to date, the precise meaning of the term, authenticity, has remained somewhat elusive” (14). In introducing the topic of authenticity, Nick Smyth warns: “it is probably fair to say that no one conception of authenticity enjoys widespread acceptance by contemporary philosophers” (15). This conceptual confusion has led other philosophers to conclude that the term “authenticity” is either vague (16) or ambiguous (17). I make no claim that I have solved this conceptual controversy. I instead simply adopt the broad view that authentic choices are those that have some degree of consistency with markers of a patient’s current identity. A person’s past behaviour/choices, plans (especially significant and/or long-term plans), stated values, and ideal

self are all useful indicators of a person's current identity. By "ideal self", I mean the type of person the patient aspires to be, in terms of personal traits, values, behaviours, and lifestyle. The congruence of a person's choice with any one of these have been proposed as candidate definitions of "authentic choice" (1,18–20), with several accounts mentioning more than one indicator as criteria (18,19). These definitions are similar, in the sense that they are all non-hierarchical (21) but coherentist (22), and non-substantive (23,24).

Hierarchical accounts require that the patient in question reflects on their given choice/desire/action and then chooses to endorse it (or at least fail to repudiate it) relative to some criteria (25,26). Initially, the focus of hierarchical models was on evaluating the authenticity of desires and defining authentic desires as those that were consistent with the person's second-order desires. An example will clarify these concepts. Imagine a patient who wants to have a plastic surgery to improve his physical appearance. This desire would be his "first-order desire". Also, imagine that upon reflection, this same man is disgusted by his desire for plastic surgery, seeing it as a sign of vanity and weakness, and therefore wishes that he did not have the desire for surgery. This would be his "second-order desire". Since the two desires are not congruent (i.e. he does not want to want the surgery), the desire for the surgery would be considered inauthentic. While the initial focus was on the authenticity of desires, the object of evaluation could be shifted to choices. Some hierarchical models will also put stipulations on how this identification with the first-order desire can come about, with identifications caused by manipulation, coercion, or other undue influence being rejected (27). With hierarchical accounts, the second-order preference/desire is considered more central to the patient's identity than the first-order aspects of the self. My account of authenticity is largely non-hierarchical, because I view patient choices as one aspect of the self and judge the authenticity of these choices relative

to other, equally important aspects of the self, such as past behaviour/choices, stated values, long-term plans, or the patient's description of their ideal self. This is more in line with the broader category of "*coherentist*" accounts, where the choice is authentic when it "coheres with (is in harmony with) some mental state that represents her point of view on the action [or choice]" (22). What exactly that mental state would be depends on the specific account in question (22), but candidates traditionally include markers of the individual's current identity, such as future plans (28) or character traits (29). My account is also similar to "*integrationist*" accounts that either completely avoid or minimize ordering aspects of the self into a hierarchical arrangement (13), in the sense that my account aspires towards choices that cohere with a self that has all the aforementioned markers well-integrated and providing non-conflicting information.

The inclusion of each of these markers of the patient's current identity is useful, as they have different temporal orientations- one marker focuses on the patient's past (i.e. past behaviour), one marker focuses on the present (i.e. current values), and several focus on the patient's future (i.e. plans, ideal self). However, discrepancies between how the patient has acted in the past and how they plan or aspire to act can lead to conflicting information about the authenticity of the choice. In these situations, the account of authenticity defended in this paper would make an appeal to hierarchical endorsement. For instance, imagine that the patient who wanted plastic surgery had done so in the past (indicating congruence with past action), but the act of getting plastic surgery was not consistent with the type of person he aspired to be (i.e. one that displayed high levels of self-acceptance and an acceptance of the aging process). In this instance, we might ask the patient the following question: "Which do you identify with more in this situation- your past behaviour, or the person that you aspire to be?" In some cases, the incongruence with the

ideal self may be small and inconsequential enough that the patient identifies more with past behaviour. In other cases, the incongruence may be adequately significant for the patient to repudiate his past behaviour and identify more with his ideal self. In a third set of cases, the patient may find a way of modifying their aspirations or reframing their past in a way that eliminates the discrepancy. This process ensures that the assessment is informed by the past actions of the patient, while still allowing the patient the freedom to grow and modify their identity based on new experiences and insights<sup>3</sup>.

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<sup>3</sup> This raises the question of whether a patient could have an “authentic conversion” from his or her past actions. A full analysis of this issue is beyond the scope of the paper, but I have some preliminary thoughts. Differentiating authentic conversions from inauthentic identity changes could prove difficult in practice. However, it could also present us with an opportunity. Later I will argue that an inauthentic choice could be an indicator of a lack of voluntariness or decisional capacity. Similarly, incongruence within the self could be an indicator of the same problems as they apply to the patient (agent). Values, plans, and an ideal self that has been abruptly changed could be a marker that the patient is being unduly influenced (via coercion, manipulation, bribery, etc.). Looking out for controlling influences of any kind would be essential to detecting this situation. If the patient’s plans and ideal self are not delusional and are somewhat coherent could be a sign that the conversion was authentic and not due to a lack of competence. If the patient were able to describe the process of how he or she reached their new understanding, this could provide us with evidence that the conversion was competent. In the absence of evidence that the autonomy of the patient has been compromised, I think that relying on the second-order judgements of the patient are the least bad option (as imperfect a solution as this is). If we fear that the plans and ideal self being described are a passing fancy, we might suggest that the patient take additional time to consider these newfound plans, and to share them with loved ones to acquire more feedback.

A similar means of adjudication could be used in sorting through the concurrent presence of multiple conflicting or competing values, plans, and ideal selves. In the complete absence of such higher order preferences, a patient might default to looking at the number of aspects of the self to which each choice corresponds, as well as the strength of each correspondence, and use these as evidence of the authenticity of each choice. For instance, suppose that the patient identified equally with all markers of his current identity. If the choice to have the plastic surgery was only somewhat consistent with past behaviour, while the choice to avoid the plastic surgery was highly consistent with his ideal self, plans, and stated values, the evidence of authenticity for the latter action would be stronger based on the number and strength of the consistencies. The goal of these appeals to second order endorsements is to integrate conflicting markers of the self or identify the aspects of the self that are most critical to the patient. In the absence of higher order preferences, the goal would be to encourage choices that cohere most strongly to the largest coherent set of identity markers. This bears the influence of Laura Ekstrom's coherentist account of autonomy, where the "true self" (or I would be more apt to say, a more plausible set of identity markers) "includes those beliefs and preferences which cohere together; that coherence itself gives them authorization." (13)

Substantive accounts of "authenticity" require that authentic choices meet a criterion that is not specific to the agent in question (23,24). Candidates for such a criterion vary widely (30–32). The "moral adequacy" view would consider a choice authentic if it met an ethical standard. The "transparency" view would consider a choice authentic if it and/or the motivations behind it were transparently disclosed to a third party, such as the clinician or individuals who the patient trusts. The "sincerity" view would consider a choice authentic if it was made with sincere intent. The "aesthetic" view would consider a choice authentic if it exemplified an aesthetic that was

considered valuable. The exact aesthetic considered valuable varies substantially between accounts of authenticity, but could include living one's life with a spirit of non-conformity, spirituality, simplicity, rebelliousness, environmental conscientiousness, etc. (30,31) In contrast, my non-substantive account allows each person to have their own personal criterion against which the authenticity of their choice can be judged (i.e. the choice is compared to the patient's *own* values, ideal self, past actions, etc.). I am thus arguing for the inclusion of "authenticity" in a broad, non-substantive, and largely non-hierarchical sense.

Before outlining the procedural practices and possible questions and statements that a physician could use to promote authenticity, it will be helpful to make several clarifying distinctions. For instance, imagine the case of Julie, a pro-life activist who works as a professor at a liberal arts college. She faces an unwanted pregnancy that originated from a short-term relationship with an abusive partner, and in response, she is choosing to have an abortion. The authenticity of Julie's choice (relative to each marker of her current identity) could be evaluated on several levels. At one level, the authenticity of the medical choice itself could be evaluated, based on the content of the choice, but independent of its consequences to Julie. In some instances, the simple act of choosing a treatment may be highly inauthentic for some patients. If Julie is choosing to have an abortion while continuing to hold her previous beliefs and values about abortion, her choice would be inauthentic (even if this act had either no consequences or beneficial consequences to Julie), since it goes against her deeply held beliefs. At a second level, the authenticity of Julie's choice could be evaluated based on its consequences to her, such as the type of lifestyle it would allow, the effect it will have on her psychological wellbeing, and the impact it would have on her relationships. For instance, Julie does not plan to have children, places little value on starting a family or being a mother and would prefer to focus her attention on having a fulfilling career.



Most of Julie's friends and family are pro-choice and would therefore be supportive of her decision. In fact, many of them would come to find a deeper empathy and respect for Julie because of this action. In addition, this act would prevent the abusive ex-boyfriend from having an excuse to remain involved in Julie's life. During their relationship, he acted as a barrier to Julie's future plans, and influenced her in a manner that distanced her from her ideal self (by bringing out the worst in her). In this sense, the choice to have an abortion might be viewed as highly authentic. Sometimes the lines will blur between these two levels of analysis, such as when treatments are either continuous or repetitive (e.g. taking a pill each day, going to dialysis each week, remaining on a ventilator, etc.), since these treatments have ongoing consequences for the lifestyle of the patient. At a third level, the authenticity of the medical choice could be evaluated based on the way the patient arrived at the choice. For instance, suppose that Julie is typically a cautious person who approaches important decisions methodically and with considerable reflection. In this case, however, she arrived at her choice quickly; having her primary care physician arrange an appointment at the abortion clinic minutes after the physician confirmed her pregnancy. In this sense, her choice is not authentic.

All three levels of analysis provide insight and have benefit. However, I believe that a correspondence between the consequences of a patient's choice and the markers of a patient's current identity are critical under most circumstances. By contrast, correspondence between the content of a patient's choice (i.e. exactly what the patient chooses, independent of its consequences to the patient's lifestyle) and the markers of a patient's current identity are only critical under certain circumstances. These include situations where one of the treatment choices challenges deeply held beliefs or where the treatment is continuous or repetitive (which makes the act of receiving treatment lifestyle altering). Similarly, a correspondence between the

procedure used to arrive at a decision and the markers of a patient's current identity is unimportant in most cases, independent of the choice's consequences to the patient. If we were dealing with a patient who typically made hasty, foolish, and bull-headed decisions, but on this occasion made a wise and considered choice, I think we should be more concerned with detecting the authenticity of the choice's consequences than the inauthenticity of the decision-making process. When important disputes arise between the content and consequences of a choice (as in Julie's case, or other cases involving controversial topics such as medical aid in dying, human enhancement, etc.), these conflicts could again be resolved through an appeal to higher-order evaluations by the patient. We could ask Julie "Which matters more to you: avoiding a medical choice that is inconsistent with your values and ideal self or avoiding a future lifestyle that is inconsistent with your plans and ideal self". Either choice may be justifiable, depending on how seriously a transgression of values the abortion would represent to Julie. Under most circumstances, the act itself and the decision-making process will have importance primarily based on their consequences for the patient. Considering this, the statements outlined below will centre on consistency of the action's anticipated consequences to the markers of the patient's identity.

Additionally, it is important to understand how I am using the phrase "consistent with markers of a patient's current identity". I see authenticity and inauthenticity as two extremes on a continuum, with the former being entirely consistent with a marker of the patient's current identity, and the latter being entirely inconsistent with this same marker. For an action to be "consistent" with a marker of current identity, in the sense that I am using the word, it must facilitate or reinforce the marker. Specifically, it would facilitate the patient's plans, it would exemplify the patient's values, it would bring the patient closer to approximating their ideal self

(in terms of personal traits, behaviours, lifestyle, etc.), and it would reinforce a pre-existing pattern of patient behaviour (for each marker of identity, respectively). For an action to be “inconsistent” with a marker of current identity, in the sense that I am using the word, it would undermine or disrupt the marker. Specifically, it would undermine the patient’s plans, exemplify the antithesis of the patient’s values, bring the patient further away from approximating their ideal self, and would represent a disruption of a previous pattern of behaviour (for each marker of identity, respectively). In advocating for the addition of authenticity to the standard model, I am aiming to shift patient decisions away from inauthenticity and toward authenticity, even if the choices available to the patient do not allow them to achieve a particular degree of authenticity. In the medical setting, patients may face decisions involving choices that are both somewhat authentic. In these cases, encouraging the patient to select the most authentic choice would be the aim. Conversely, patients may face decisions involving choices that are both somewhat inauthentic. In these cases, encouraging the patient to select the least inauthentic choice would be the aim. In other cases, the decision may present the patient with a mix of choices, some falling on the authentic end of the spectrum, and others falling on the inauthentic end of the spectrum<sup>4</sup>.

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<sup>4</sup> Some decisions might involve two or more choices that are at the midpoint of the continuum (being neither authentic nor inauthentic). For instance, imagine a patient who is deciding whether to have blood drawn as part of a standard physical examination. Both choices would neither obviously support nor undermine the patient’s plans or ideal self, thereby making them neutral with respect to these aspects of identity. Both choices would not exemplify patient values or their antitheses. It might also be the case that both choices would not

In these cases, encouraging the patient to select the choice displaying the highest degree of authenticity would be the aim<sup>5</sup>.

It is also worth mentioning that it may sometimes be more valuable to evaluate patterns of choices than individual choices. Some choices can be authentic, or at least not inauthentic, if made once, while becoming inauthentic if repeated frequently. This occurs when the choices have cumulative consequences to the patient. For instance, if an athlete chooses to have one cortisone injection to control neuromuscular pain, this may have few consequences for them, while weekly shots could cause enough joint and bone damage to undermine their ability to compete entirely.

Finally, it is also worth mentioning the model of the physician-patient relationship that is being assumed with my approach. As part of this, contrasting this model with several other models of the physician-patient relationship would give a sense of when a physician would, in my view, be acting outside of his or her acceptable role. In a highly cited article, Ezekiel and Linda Emanuel outline four prominent models of the physician-patient relationship (33). The first is the paternalistic model, where the physician “acts as the patient’s guardian, articulating and

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reinforce or hinder established patterns of behaviour. In these cases, the choice would not be influenced by consideration of each choice’s authenticity.

<sup>5 5</sup> Throughout this manuscript, I will refer to a patient “acting authentically” and “acting inauthentically”. This is shorthand for saying “performing an action that contains some degree of authenticity/inauthenticity” (respectively). This does not imply that I am turning the continuum into a binary classification that equates all choices containing some degree of authenticity, or all choices containing some degree of inauthenticity. It is simply less cumbersome to talk about two options that are on opposite ends of the spectrum in this manner.

implementing what is best for the patient” from the perspective of “restor[ing] the patient’s health or ameliorat[ing] pain”, by “discern[ing] what is in the patient’s best interest with limited patient participation”. This model is incompatible with both the standard model of consent (which aspires toward autonomous authorization under conditions of adequate disclosure and voluntariness), and the authenticity-informed model, which shares this aspiration and further considers the authenticity of patient choices. The second model is the “informative model”, where the physician acts as a “purveyor of technical expertise” by “provid[ing] all available [medical] facts” and then once the patient selects their preferred intervention “execut[ing] these selected interventions”. In this model, “there is no room for the physician’s understanding of the patient’s values”, and the patient is essentially a consumer. This model is also not compatible with the authenticity-informed model, since it does not see the physician as having any place in discussions around patient values. I see this model as an over-correction to the problem of paternalism, where the physician is removing themselves from the consent process aside from acting as a patient information sheet and handmaiden. The third model is the “deliberative model”, where the physician is acting as a “teacher”, by “helping the patient choose the best health-related values that can be realized in the clinical situation”. This would involve “suggesting why certain health values are more worthy and should be aspired to”. This model underlies some forms of shared decision-making (34–36), such as Brock’s influential account, which states “the physician can have a responsibility to explore, together with the patient, the values by which alternatives should be evaluated’ (34). I believe that using this model of the physician-patient relationship to underpin a model of valid consent that included authenticity would be too intrusive and would pose too great a risk of the physician paternalistically interfering with the patient’s current identity. This model would allow the physician to advocate

for not only what *would* be authentic for the patient, but also what *should* be authentic for them. This would mean that the physician could challenge the value of the patient’s past actions, plans, stated values, and ideal self. Considering these concerns, I also reject this model of the physician-patient relationship. This leads us to the fourth model, which I have chosen to underpin the authenticity-informed model of valid consent. In this “interpretive” model, the physician acts as a “counsellor”, by “assisting the patient in elucidating and articulating his or her values and in determining what medical interventions best realize the specified values”. This model recognizes that “the patient’s values are not necessarily fixed and known to the patient”, and thus part of this counselling would involve the physician “working with the patient to reconstruct the patient’s goals and aspirations, commitments and character”. In the context of authenticity, this would involve the physician helping the patient to understand and articulate the markers of their current identity, helping the patient to sort through any inconsistencies in these markers, and helping the patient to identify the treatment that would be most authentic for them. With this in mind, the additions that I propose to the procedural practice of the CMPA in order to reflect a switch to the authenticity-informed model of valid consent include:

**Practice 1) Encouraging the patient to consider the authenticity of each possible option in selecting a treatment**

In the case where a patient was deciding between a choice containing some degree of authenticity, and a choice containing some degree of inauthenticity, practice 1 could be achieved by making statements such as:

“As you know, medical decisions can have important effects on your life. When I am approaching an important decision, I like to think about whether the choice I am making would

help me to have a life that is consistent with who I am- in terms of the plans I have, my values, the kind of person I want to be, and even my past behaviour and choices. I always encourage patients to ask themselves similar questions when facing a big medical decision, and I recommend that they consider these criteria in selecting a treatment option.”

**Practice 2) Engaging in a conversation with the patient in order to learn about their current identity, including the patient’s past actions, plans, stated values, and ideal self**

Practice 2 could be achieved by asking:

“Would you be willing to tell me a bit about your past behaviour/plans/values/ ideal self so that we can try to figure out which treatment would be more in line with who you are?” (Initiating the conversation)

“If you were to choose treatment *X*, you could no longer do/ would have a harder time doing activities with characteristic *Z*, such as *A*, *B*, and *C* activities. Would that keep you from participating in activities that you used to enjoy and might want to start up again? If so, how important would that be to you?” (Discussing coherence with past actions)

“If you were to choose Treatment *X*, you could no longer do/ would have a harder time doing activities with characteristic *Z*, such as *A*, *B*, and *C* activities. Would that keep you from participating in any activities that you plan on doing in the future, or have always wanted to do? If so, how important would that be to you?” (Discussing coherence with future plans and aspirations)

“People who value *A* are more likely to pick treatment *X* because of reason *Y*, while people who value *B* are more likely to pick treatment *H* because of reason *Z*. Which one of *A* or *B* do you

think is more important to you? Are there other more important values at stake with the decision?” (Discussing coherence with explicitly stated values)

“If you think about who you would be if you could achieve your highest aspiration, which of the two treatments would bring or keep you closer to that ideal in terms of your future lifestyle, behaviours, and character traits?” (Discussing coherence with ideal self)

**Practice 3) in cases where the patient is unsure of their identity markers: offering to help the patient elucidate the markers of their identity through discussion, additional tools (e.g. values assessment and goal planning worksheets), and by providing them with extra time to reflect on these issues**

Practice 3 could be achieved by making statements such as:

“If you are having problems summarizing how you have acted in the past, we can sit down and try to figure it out, I can give you some tools that may help, or I can give you more time to think about it”.

“If you aren’t sure about your plans/values/ ideal self, we can sit down and try to figure that out, I can give you some tools that may help, or I can give you more time to think about it”.

**Practice 4) In cases where the patient has identity markers that don’t agree: guiding the patient through a process of higher order evaluation**

Practice 4 could be achieved by making statements such as:

“It seems like treatment X would be more consistent with marker A, but treatment Y would be more consistent with marker B. Would you agree? Which do you identify more with: marker A or B?”



**Practice 5) Using the information elucidated through practices 1-4 to form a tentative assessment of which treatment would be most authentic for the patient and sharing the assessment with the patient in order to acquire feedback**

Practice 5 could be achieved by asking the patient questions such as:

“Based on our discussion, it seems to me as though treatment X would help you to fulfil your plans/ would be a way of acting out your values/ would bring you closer to being the person you aspire to be/ would be consistent with the way you have acted in the past, for reason Y. Do you agree?”

**Practice 6) In cases where the patient is seriously considering the option that the physician perceives to be the less authentic option: Inquiring further about the motivation for a patient’s choice**

Practice 6 could be achieved by asking the patient questions such as:

“Based on what you’ve told me, the treatment that you picked seems like it might be less consistent with your past actions/future plans/ values/ ideal self. I would like to help you make the best decision, if you are open to that. Do you disagree with my assessment, or are there other more important factors to consider? What is your strategy in picking the option you did??”

**Practice 7) Encouraging patients (through means of persuasion) to choose medical treatments that the physician considers to be more authentic for them**

Practice 7 could be achieved by making statement such as:

“It sounds like you are leaning toward treatment A. While I see the advantages of that treatment, it seems to me as though treatment B would be a better way to help you fulfil your plans/ would be a way of acting out your values/ would bring you closer to being the person you aspire to be/ would be consistent with the way you have acted in the past, for reason Y. Do you agree? Do you think that there more important factors to consider?”

Notice that the tone of each of these example questions and statements is tentative and invites correction and further discussion. It would be preferable if physicians used a communication style that recognizes the fact that the patient typically has a much greater knowledge of himself or herself than the physician. The goal is to be deferential to the autonomous decision-making of patients and cognizant of the fact that the patient will likely have a deeper understanding of who they are than the physician. Since authenticity is an additive condition, the physician could not reject the patient’s choice on the grounds that it was not authentic.

***5. Deficiencies of the standard model related to the practical goals of acquiring valid consent***

There are distinct limitations to the procedural practices recommended by the CMPA. For this paper, I will focus on problems that trace back to the exclusion of authenticity from the standard model of valid consent.<sup>6</sup>

Recall that the broad goals of the consent process are to establish the decisional capacity of the patient and to ensure that the patient is making an autonomous choice. I suggest that the authenticity-informed model would do a better job of achieving both aims than would the standard model. A hypothetical example of a consent scenario will help to illustrate why this is the case. This scenario will have several variations, with each demonstrating a different limitation of the standard model. Following the description of each limitation, I will outline how the procedural practices stemming from the authenticity-informed model could help to overcome the limitation.

A patient is referred to an orthopaedic surgeon. He is a 25-year-old male who recently sustained an upper arm injury while catching a child who was falling from a tree. An MRI shows that the patient has completely torn his bicep tendon off its distal insertion. The other arm flexor muscles

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<sup>6</sup>I should also point out that it is an open empirical question as to whether any, some, or most clinicians exceed the procedural practice recommendations of the CMPA in a way that allows the assessment and encouragement of authentic choices by patients. However, the procedural practice recommendations act as a minimum standard to which the CMPA advises physicians to adhere. In the best-case scenario, my criticisms of these practices are pointing to significant issues in the minimum recommended procedural practice that should be remediated. In the worst-case scenario, they are pointing to substantial problems occurring in the consenting practices of a large number of Canadian physicians.

remain intact. The surgeon gives the patient the option of having the insertion surgically reattached or leaving the bicep unattached.

If he has the surgery, he will likely regain the full strength and functioning in his right arm. However, this recovery process will be longer, with pain and physical restrictions, and a risk of surgical complications. If the patient chooses not to have the surgery, his recovery will likely be quicker than if he had the surgery. He would also not be exposed to any of the risks of surgery. However, when fully recovered his arm flexion strength will be approximately 10-20% weaker, his supination strength will be approximately 50% weaker, and his grip strength will be approximately 15% weaker in his right arm compared to his left. He will also have a decreased endurance when performing these motions. The slight loss of functioning does not affect the day-to-day activities of most people.

The surgeon follows the procedural practices for informed consent outlined by the CMPA. The surgeon personally attends the consenting session and engages in a dialogue with the patient. He gives the patient any information that a reasonable person would want to know. This includes the nature, anticipated effects, and risks of both medical treatments. He includes descriptions of common but low severity risks and rare but severe risks and emphasizes the uncertainty of the outcomes. He checks the patient's level of understanding by having the patient restate the information he provides. He looks out for third parties who might be undermining the voluntariness of the decision and looks for any markers that the patient has compulsions or mental conditions that could be controlling him. None of these is readily apparent. Finally, in order to ensure that he is tailoring the information to the needs of the patient, the surgeon asks the patient some general questions about his current family situation, his occupation, and his participation in any physical activities that require special use of his arm. The patient gives brief

answers. He was recently married, works at a desk job as a government employee in the day and as a parking lot attendant a few nights a week for extra income. He states that he is not currently involved in any hobbies or physical activities. He offers the patient the opportunity to ask questions, but the patient has none.

The patient chooses to avoid the surgery. Based on procedural practices meeting but not exceeding those recommended by the CMPA, the surgeon judges that the patient has sufficient decisional capacity to make the decision at hand and that the choice he has made is autonomous. In several situations, at least one of these judgments would be incorrect and a switch to the authenticity-informed model would have avoided the misclassification. The common problem in these situations is that the procedural practices stemming from the standard model do not give the physician sufficient information about the patient. This leads to uncertainty about the authenticity of the patient's choice.

Using the procedural practices stemming from the authenticity-informed model, we find out that the patient spent years as an amateur mechanic, who would torque wrenches often using both hands (i.e. his past actions). In the past, he has also competed in bicep curling competitions. He wants to resume these activities in the future, by pursuing these activities vigorously for the next few years, and then gradually tapering as he ages (i.e. his plans). He values hard manual labour, physical strength, and do-it-yourself self-sufficiency (i.e. his stated values). At his highest aspiration, he would be a champion strength athlete, a competent and efficient mechanic, and someone who is not reliant on the manual labour of others for the maintenance of his home and property (i.e. his ideal self). Based on this information, his choice to forego surgery is inconsistent with his past actions, plans, stated values, and ideal self. The decreased strength and

endurance he would experience by foregoing surgery would undermine his performance of both preferred physical activities, would undermine his future plans (to some extent), would not support his values, and would distance him from his ideal self. Thus, the choice would be inauthentic. By making inquiries about the authenticity of the patient's choice, the surgeon would have gained this information and been able to determine that the patient's choice was apparently not authentic. This information provides an impetus to a physician to investigate the cause of the apparent inauthenticity.

In some instances, the presence of an inauthentic choice can indicate that the patient lacks the decisional capacity to make the decision at hand<sup>7</sup>. The first variation of this clinical scenario provides an illustrative example. Suppose that the child caught by the patient was large. In addition, the patient was "back-peddaling" (moving backward on his toes) to put himself in a position to catch the child. Because of these factors, he was off balance and fell backward, hitting his head on the ground. This resulted in a yet undetected mild traumatic brain injury. He is experiencing difficulties concentrating at work and has problems keeping multiple pieces of information in his mind concurrently (i.e. he has a temporary working memory impairment). While these are post-concussive symptoms, he falsely attributes them to being distracted by the pain in his arm and being preoccupied with avoiding movement to prevent re-injury.<sup>8</sup>

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<sup>7</sup> While I provide the example of an inauthentic choice, a patient choice that was authentic, but still less authentic than an alternative could also act as an indicator of insufficient decisional capacity.

<sup>8</sup>This is not as outlandish as it might sound- mild traumatic brain injury can be missed initially, and up to 15% of those who are injured experience ongoing symptoms for up to 1 year after the original injurious event. <https://www.traumaticbraininjury.com/mild-tbi-symptoms/>

If the authenticity of the patient's choice were investigated, there would have been a greater probability of detecting the patient's concentration and memory deficits, independent of the authenticity of the patient's choice. More information would have been solicited from the patient, with a proactive inquiry into the patient's reasoning for his choice, and an inquiry into the linkage (or lack thereof) that the patient perceives between his choice and his current identity. If the patient could not put the facts of their medical situation together and apply them to their own life, or provide reasons for their decision, this could be grounds for other actions by the surgeon. If the surgical decision was of little risk or practical consequence, the surgeon might speak to the patient's family or advise the patient to give the decision further consideration. If the choice were risky or very consequential, a more formal and extensive assessment of decisional capacity could be conducted (e.g. the MacArthur competence measure, a psychiatric consult, etc.). In cases where the patient wanted to make an inauthentic choice, there would be an even greater probability of detecting the lack of decisional capacity. The inauthenticity itself would serve as an impetus for further dialogue, and if the patient could not provide a sensible rationale for the apparently inauthentic choice, this would be possible grounds for further assessment of decisional capacity.

I suspect that the assessment of authenticity would be more effective at detecting misclassifications of patients with inadequate decisional capacity than misclassifications of patients with adequate capacity. The first reason for this belief is that misclassifications of patients lacking adequate decisional capacity seem more likely. Misclassifying patients with adequate decisional capacity as patients who lack this capacity is typically seen as a grave violation of the patient's right to autonomy. The performance of an unwanted medical procedure on a competent patient is both an act of paternalism, and from a legal perspective, an act of

battery. Given the importance of avoiding such a misclassification, the burden of proof lies on the physician to provide certain types of documented evidence to support their claim that the patient does not have adequate decisional capacity. The requirement of this evidence acts as a safeguard to prevent such misclassifications. In cases where the patient's choice is life or death, or where a particular option may result in severe harm to the patient, the physician must support his or her claim with documented formal tests of decisional capacity, psychiatric consults, court orders, etc. Such a stringent evidentiary standard does not exist to prevent the misclassification of patients lacking in decisional capacity as having adequate capacity, since it is assumed that the patient can make their own choices unless there is convincing evidence to the contrary. The second reason for this belief is that the assessment of authenticity is more likely to yield information beyond that produced by the standard model in cases where there was originally no impetus for formal assessment of the patient's decisional capacity.

Misclassifying patients with inadequate decisional capacity could lead to a poorer fulfilment of the physician's duty to act beneficently, based on Faden and Beauchamp's conceptualization of beneficence<sup>9</sup>. They (and most others) assert that physicians have a duty to act beneficently

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<sup>9</sup>For the purposes of this paper, I have adopted the perspective of a rule consequentialist, who "elects rules solely in terms of the goodness of their consequences and then claims that these rules determine which kinds of acts are morally wrong" (23).

In particular, I am adopting the perspective of a utilitarian, who considers the "aggregate well-being or welfare" (23) that would be created through the widespread adoption of the rule. Therefore, I do not believe that it is intrinsically good to fulfil the duties to respect autonomy and to act beneficently. Instead, I see the moral principles of respect for autonomy and beneficence as useful rules of thumb for bringing about good consequences to patients (in terms of supporting their interests). The



toward patients, since: “Beneficent acts are demanded by the roles involved in fiduciary relationships between health care professionals and patients” (1) p.12. This duty stems from the principle of beneficence (one of the three key principles of bioethics they identify), which “... requires us to abstain from intentionally injuring others and to further the important and legitimate interests of others, largely by preventing or removing possible harms” (1) p.11. The harms to be “prevented, removed, or minimized are the pain, suffering, and disability of injury and disease” (1) p.12, with the overall goal of “seek [ing] the alleviation of disease and injury, if there is a reasonable hope of a cure” (1) p.12. Rarely is there a single choice that is better in all regards than its alternatives, leaving the physician “to weigh and balance benefits against harms, benefits against alternative benefits, and harms against alternative harms” (1) p.13. In instances where the patient lacks adequate decisional capacity, patients cannot properly weigh the pros and cons of a choice or appreciate the impact that the choice will have on their life. These incompetent decisions represent possible harms to the patient’s own interests, since the selected medical treatment (or refusal of treatment) may exacerbate the medical condition, or at least be less effective in reducing pain, suffering, and/or disability than alternative courses of action. It might therefore be a physician’s duty to prevent such harm by not accepting the patient’s choice and having an appropriate surrogate decision-maker act on behalf of the patient.

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utilitarian justification for the principle of respect for autonomy tends to rest on the idea that agents are in the best position to make decisions that support their welfare (55). In contrast, the utilitarian justification for acting beneficently presumably rests on the fairly uncontroversial idea that if third parties aim to act beneficently toward patients who cannot make choices for themselves, this will better support the welfare of these patients than if such a rule were not adopted.

The second and third scenario variations represent instances where the judgment about the decision-making capacity of the patient is correct, but the judgment about the autonomy of the patient's choice is incorrect.

I suspect that the assessment of authenticity would be more effective at detecting misclassifications of non-autonomous choices compared to autonomous choices. The first reason is that the unintentional misclassification of autonomous choices as non-autonomous seems less likely to occur, given current practices. While the CMPA does not specify what physicians should do if they suspect that a patient's choice is not autonomous, physicians are encouraged to "take reasonable steps so as to be relatively satisfied that the patient does understand the information being provided", suggesting that some sort of follow-up actions would be required. If the physician suspected that the patient's choice was not adequately voluntary, he or she would likely gather additional information to identify the controlling influence, and then try to lessen or remove it. If the physician suspected that the patient's choice was not adequately informed, he or she would likely attempt to correct misunderstandings, reduce knowledge gaps, and increase appreciation. Follow-up actions to facilitate these goals could include providing the patient with more information or finding better ways to disseminate the information that was already disclosed. Thus, any initial classification of autonomous choices as non-autonomous would likely be corrected by follow-up procedures. In contrast, there would be less impetus to collect additional information if the physician perceived the patient's choice as being autonomous, even if the physician were basing this judgment on limited information. The second reason is that over-ruling the autonomous choice of a competent patient is seen as a grave violation of respect for autonomy, meriting legal repercussions. The CMPA warns, "...a physician may be liable in assault and battery when no consent [from the patient] was given at all [for the treatment initiated

by the physician]”. The third reason is that given concerns about paternalism, it is typically understood that “the burden of moral justification rests on those who would restrict or prevent [the] exercise of autonomy” (1) p.8, with a patient’s choice assumed to be autonomous in the absence of strong evidence to the contrary. The final reason is that my claim is supported by statements from the CMPA themselves, who are keenly aware of legal actions in Canada, since they provide legal defence to all Canadian physicians: “Most legal actions involving physicians are based on claims of negligence and often raise allegations about the adequacy of the consent discussion with the patient”(10). In accepting the choice of a patient who was not adequately informed, this would represent the misclassification of a non-autonomous choice as autonomous. In the second scenario variation, the patient chooses to avoid surgery because he is terrified of the prospect of experiencing intraoperative awareness with postoperative recall. The fear is irrational based on the remote possibility of the complication, and the patient’s fear-driven compulsion to refuse any surgery- even a lifesaving one- in order to avoid the risk. This irrational fear is an internal constraint that is undermining the voluntariness of the patient’s choice.

If the authenticity of the patient’s choice had been investigated, the inauthenticity of the choice would have been readily apparent, and the investigation of the cause of the inauthentic choice would have likely revealed the irrational fear. This could allow the physician to reduce or remove the controlling element. For instance, the physician could help to allay the patient’s fears by further discussing the precautions to prevent awareness or by reinforcing how remote the risk is (e.g. that around 999 people out of 1000 will not experience awareness). The physician could also take stronger action and arrange for the patient to attend several sessions with a counsellor or therapist.

Misclassifying choices that lack adequate voluntariness could lead to a less satisfactory fulfilment of the duty to respect patient autonomy, based on Faden and Beauchamp's conceptualization of respect for autonomy. Generally speaking, they hold that "to respect an autonomous agent is to recognize with due appreciation that person's capacities and perspective, including his or her right to hold certain views, to make certain choices, and to take certain actions based on personal values and beliefs" (1) p.8. A critical aspect of the principle of respect for autonomy is that patients "...should be free to choose and act without controlling constraints imposed by others" (1) p.8. This principle places a duty on physicians in all instances "not [to] interfere with the autonomous choices and actions" of patients, and in special instances "to enable [patients] to make autonomous choices" (1) p.7. Since these misclassifications stem from a failure by physicians to remove an important barrier preventing autonomous decision-making, they represent a failure to show adequate respect for patient autonomy. Simultaneously, since the controlling influence represents a possible harm to the patient's own interests, not attempting to remove this influence could fail to protect the patient from possible harm. This could lead to a less satisfactory fulfilment of the duty to act beneficently toward patients.

In the third scenario variation, the patient has chosen to avoid surgery because he is not adequately informed. The disclosure by the physician was adequate and the patient has an adequate abstract understanding of the risks and possible benefits of the two courses of action. However, he does not appreciate the impact that this choice will have on his life. He does not realize that after 20 min or so of using a wrench, his arm will be very fatigued, thereby requiring him to take frequent breaks. He also does not realize that his arm will be more taxed by a single session of using the wrench, which will necessitate a longer recovery between sessions, thereby limiting the number of times he will be able to work on cars per week. Additionally, the patient

does not appreciate the effect that the decreased strength will have on his bicep curling. Before the injury, he could curl nearly 200 pounds with both arms (roughly 100 pounds per arm). He does not realize that once fully recovered, if he can curl 100 pounds with his left arm, he will only be able to curl 70 with his right arm. This dramatically decreases his chances of winning any competition.

Had the surgeon assessed the authenticity of this choice, he would have identified its inauthenticity, and had he inquired about the motivation behind the inauthentic choice, the surgeon would have been more likely to detect this lack of appreciation. This could give the physician the opportunity to apply the abstract information more concretely to the patient's past and future activities. Misclassifying non-autonomous choices as autonomous could lead to a less satisfactory fulfilment of the duty to respect patient autonomy. The patient's lack of understanding or appreciation represents a barrier to autonomous choice, which physicians should ideally minimize or remove.

As a historical note, adding authenticity to the informed consent process to help assess the autonomy of a patient's choice is an older idea currently enjoying resurgence<sup>10</sup>. One of the earliest references to the idea was from physician and ethicist Tristram Engelhard, Jr., who stated, "An uncharacteristic choice should in such circumstances bring the patient's understanding of the communication or even the patient's competence into question". This suggests the potential for inauthentic choices (in the sense of being inconsistent with past actions) to be indicators that the patient either lacks decisional capacity or is not adequately informed.

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<sup>10</sup>The idea was first proposed to me by my co-advisor Professor Arthur Schafer, who anticipated these recent philosophical advances in 2014.

Very recently, Lucie White proposed an authenticity-based view of autonomy: “Authentic values form an essential underlying basis upon which the conditions of autonomy in medical settings can be evaluated” (37). She elaborates:

I have advocated that authenticity be seen as playing a certain role in medical autonomy or competence assessments; rather than an additional criterion which decisions must meet, it should be seen as an underlying framework which better allows us to assess the existing criteria of autonomy and competence. This gives us a means of distinguishing between contestable beliefs that patients shape their life around and that determine a patient’s goals, and beliefs that may present an obstruction to achieving these goals. (37)

Similarly, while philosopher Jesper Ahlin recently asserted that “authenticity should not be part of informed consent”, he simultaneously conceded that “a well-founded suspicion that a desire is inauthentic [in a hierarchical sense] may call for other measures than the invalidation of consent (or refusal), such as a moral obligation to double-check that the patient is competent to make healthcare decisions” (38). Thus, there has recently been a convergence on the idea that the concept of authenticity may be helpful in achieving the practical goals of the consent process.

#### ***6. Limitations of the standard model related to supporting the psychological and physical well-being of patients***

The standard model has a third important limitation. The recommended procedural practices derived from the authenticity-informed model are more likely to support the psychological and physical well-being of patients when compared to the practices stemming from the standard model, especially under certain circumstances that will be described.

Owing to the variety of mechanisms by which this benefit may come about, I will provide a broad overview of the argument before making conceptual distinctions and providing an explanation of each mechanism.

The broad structure of my argument is as follows. The authenticity-informed model of valid consent involves procedural practices that are more likely to promote trait authenticity, which is associated with psychological benefits (mechanism 1). Second, the goal of the authenticity-informed model is to encourage patients to make choices that are both authentic and autonomous. Under certain circumstances, compared to choices that are solely autonomous, choices that are both authentic and autonomous can: 1) Maintain the size of the set of authentic actions available to the patient; 2) Allow the patient to take part in the activities that would be most authentic for them. This could help patients to maintain or increase trait authenticity (mechanism 2) and may maintain or increase their probability of experiencing state authenticity (mechanism 3). Both state and trait authenticity are associated with psychological benefits. In addition, the promotion of choices that are both authentic and autonomous may prevent decisional regret and promote decisional satisfaction (mechanism 4); and may prevent non-compliance with postoperative instructions (mechanism 5). The former is associated with psychological benefits, while the latter is associated with physical benefits.

Given the complexity of the argument, I will outline it in sections. First, I will define state authenticity and describe how the recommended procedural practices may increase this characteristic (mechanism 1). Second, I will describe the exact circumstances where the other four mechanisms are most likely to come into play. Third, I will briefly describe each of the four remaining mechanisms in subsections.

### **Mechanism 1: The procedural practices may cultivate trait authenticity**

So far, I have only discussed “authenticity” as a characteristic of a choice, with some choices having more of it, and some choices having less. Indeed, I am proposing that a consideration of

the authenticity of choices is what should be added to the standard model of consent, with physicians attempting to promote choices that have high degrees of both autonomy and authenticity. However, the term can also be used to describe a psychological trait of a person. A psychological trait is “an individual’s base-rate proclivity toward (or away from) a set of emotions, cognitions, or actions” (39). Someone who has high levels of “trait authenticity” tends to feel, think, and act in a way that psychologists label as being authentic. This includes a tendency to “act [] in ways congruent with one’s values, preferences, and needs” (40). Thus, people who make many authentic choices and regularly act authentically have higher trait authenticity. However, this trait also has other components, which reflect other senses in which the word “authentic” is used. If we accept the commonly used and assiduously developed model of Kernis and Goldman (40), trait authenticity has four components, including the “behaviour” component already described. The “awareness” component consists of “awareness and knowledge of, and trust in, one’s motives, feelings, desires, and self-relevant cognitions”, including “awareness of one’s strengths and weaknesses, dominant–recessive aspects of personality, powerful emotions, and their roles in behaviour” (40). Consequently, the more a person knows him or herself, the more authentic they are seen to be<sup>11</sup>. The “unbiased processing” component consists of minimizing “denial, distortion, exaggeration, or ignoring of private knowledge, internal experiences, and externally based self-evaluative information”, including objectively accepting one’s weaknesses and strengths (40). Thus, the more aware people are of

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<sup>11</sup>It is currently an open empirical question as to whether awareness beyond a certain threshold provides additional benefit in terms of the outcomes discussed in this section. Hyperawareness may have detrimental effects to psychological wellbeing. Nevertheless, this model assumes that there is a positive relationship between awareness and authenticity.



their own biases about themselves and others, the more authentic they are seen to be. The “relational orientation” component involves “make [ing] efforts to achieve openness and truthfulness in close relationships” by being “genuine and not “fake” in one’s relationships with others”, so that these individuals can have a deep understanding of who you are (40).

Consequently, the more transparently and truthfully a person communicates with others, the more authentic they are seen to be. The sum of these four components is seen by psychologists as being the total amount of trait authenticity that a person has. Since each of these components can change over time, individuals can become more or less authentic with different experiences.

Higher trait authenticity is associated with many positive psychological outcomes (40–43), including measures of psychological health, coping skills, self-concept, healthy role functioning, goal pursuits and relational functioning.

The psychological well-being of patients may be supported by the procedural practices associated with the authenticity-informed model of valid consent, whether the consent process leads the patient to make an authentic choice. Using the seven procedural practices outlined may increase up to three of the components of trait authenticity, thereby making the patient a more authentic agent. As per the model of Kernis and Goldman (40), trait authenticity is seen as having four components: awareness, unbiased processing, behaviour, and relational orientation. Due to the inquiries about the patient’s identity, the consent discussion stands a fair chance of increasing, or at least coalescing the patient’s self-knowledge (the “awareness” component). In working through the patient’s descriptions of their past actions, future plans, values, and ideal self, as well as in working through the patient’s reasoning, the physician has an opportunity to challenge some biases and distortions that are present in the patient’s thinking (the “unbiased processing” component). Finally, by participating in an open discussion with the physician (and

perhaps others) regarding their values, past behaviour, goals, and ideal self, the patient may also begin to develop an increased awareness of and appreciation for being transparent and truthful in their discussions with others (the “relational orientation” component). However, these benefits would be contingent on the patient’s willingness to engage in the procedures by disclosing the information required for a productive dialogue and by being open to receiving input from the physician and others.

### **Circumstances where the additional mechanisms are most likely to be at play**

The underlying goal of the authenticity-informed model is to promote choices that are both authentic and autonomous over those that are solely autonomous. The value of this goal comes from the fact that under certain circumstances, choices that are both authentic and autonomous can lead to better consequences. This manuscript focuses on the possibility that under certain circumstances, authentic and autonomous choices may better support the psychological and physical wellbeing of patients.

To best describe these circumstances, some additional distinctions and definitions are necessary. First, let’s distinguish between a cognitive ability and a physical ability. A cognitive ability is “any form of information processing capability that can be assessed objectively...” including skills as diverse as attention, concept formation, invention, and the use of language, amongst many others (44). There are several related senses of the term “physical ability” that apply to this discussion. From a lay perspective, a physical ability is “the ability to perform some physical act” (45). The ability to perform an action would similarly involve being able to do the activity safely and competently. By “safely”, I am referring to the human factors definition that the person does not have a “higher probability of injury for themselves or others if performing [a

given] task than others would” (46). Building on this distinction, we can differentiate between the cognitive ability and physical ability to act authentically. The cognitive ability for authentic action would be the patient’s capacity to safely and competently perform mental activities that would be consistent with their identity (e.g. the capacity for an artist to create, a mathematician to calculate, an emotional person to feel things deeply, etc.). The physical ability for authentic action would be the patient’s capacity to safely perform physical actions that would be consistent with their identity (e.g. the capacity for an athlete to play and compete in their sport, a musician to play their instrument, a caregiver to physically assist the individual they are caring for, etc.).

Next, it also merits distinguishing between what I would call the “non-specific” ability to act authentically and “action-specific” abilities to act authentically. By the “non-specific” ability to act authentically, I mean that the person has the ability to perform at least one authentic action. To have this ability, you don’t need to be able to do any particular authentic action, or to have a range of authentic actions from which to choose. There just must be *something* authentic that you are able to do. By an “action-specific” ability to act authentically, I mean that the person has the ability to do a *particular* authentic action (e.g. the ability to ride a bike, assuming this particular action is authentic for the person in question). If a person had multiple actions that would be authentic for them (as would normally be the case), there would be an action-specific ability associated with each, thereby leading to multiple action-specific abilities. When I refer to a choice preventing a patient from participating in one or more activities, I am saying that certain action-specific abilities are decreasing, as opposed to saying that their non-specific ability to act authentically is decreasing.

Finally, I should also introduce the idea that each person has a set of actions that would be authentic for them (to some degree) and that they have the action-specific ability to do. The size

of this set of actions would depend on several key factors. The first would be the restrictiveness of the patient's current identity. For instance, a person with narrow interests, very specific goals, uncompromising values, and an ideal self that is inflexible will likely have a smaller set of authentic actions from which to choose. The second factor would be the physical and mental abilities possessed by the agent. Every action requires a certain level of physical and mental ability to be performed safely and competently, with some requiring higher levels of ability than others.

Medical decisions involve choosing between two or more possible courses of action (e.g. treatment vs. no treatment, treatment 1 vs. treatment 2, etc.). Under certain circumstances, one choice would decrease the patient's action cognitive and/or physical abilities, while the other choice would irreversibly decrease these abilities to some extent. In a further subset of scenarios, this decrease in functioning could reduce the size of the set of authentic actions available to the patient. In other words, it would limit the authentic activities in which the patient could partake. This is especially relevant when the person's most authentic actions require a high level of physical or cognitive ability. In such cases, the decrease in the size of the set of authentic actions is also likely to prevent the patient from partaking in activities that would be most authentic for them. A patient may experience decreases to their psychological and physical well-being as a result of facing these circumstances.

It is not unusual for a choice that is both authentic and autonomous to better preserve the size of the set of authentic actions and the ability to take part in one's most authentic activities than a choice that is solely autonomous. When the patient considers how they will want to act in the future, they may be more likely to err on the side of preserving the action-specific abilities to partake in their most authentic activities. Our illustrative example is one such case. The patient is

choosing between bicep reattachment surgery and non-surgical recovery. If the patient chooses to have the bicep reattachment surgery, this would prevent him from taking part in his most authentic activities (i.e. fixing cars and competing in arm curling competitions) and would limit the authentic actions available to him. Under these circumstances, the authenticity-informed model's goal of promoting patient choices that are both highly authentic and autonomous could help to support the well-being of patients.

Before describing each of the mechanisms by which this benefit could occur, several counterpoints are worth addressing. I must first recognize that decreases in the size of the set of available authentic actions, and an inability to participate in one's most authentic activities do not necessarily mean that the patient will act authentically (to some degree) less often or that the patient will lose the non-specific ability to act authentically (i.e. will be left with no authentic activities in which they can partake). Furthermore, it may not necessarily affect how authentic a patient acts over the course of their life, depending on the metric of total authenticity being used. If we were to plot the authenticity of every action that the patient took after their choice as a function of time, the area under the authenticity curve would be one way of evaluating how authentic the patient acted over the course of their life following the choice. The total area under the curve could, in fact, be identical for a patient whether they selected the treatment that was both authentic and autonomous or the treatment that was solely autonomous. To maintain the area under the curve, the patient might simply find equally authentic or nearly as authentic alternatives and perform them as often as they would have performed their most authentic actions. Alternatively, they could find somewhat authentic actions and perform them more frequently than they would have performed their most authentic actions. For instance, while our amateur mechanic may not be able to work on cars or compete in bicep curling competitions,

perhaps he could find an activity that was slightly authentic (say, reading auto repair magazines), and just partake in that activity very frequently. For the patient to be able to maintain the area under the authenticity curve, however, certain conditions would need to be met. First, since their most authentic actions would be excluded (thereby decreasing the peak amounts of authenticity contained in their set of actions over time) the patient would have to maintain or increase the frequency with which they act authentically. Our amateur mechanic would have to read about cars far more than he ever worked on them. However, there may also be a demoralizing effect on the patient if they are unable to partake in their most authentic activities, which causes them not to seek out and take part in alternative authentic activities. The amateur mechanic may be depressed at the prospect of not being able to work on cars, and spend his days sulking instead of looking for alternative actions that are authentic to some degree. He might also find that reading car repair magazines is a poor substitute for repairing cars and this may dissuade him from reading these magazines often. Second, there must be alternative authentic actions in which the patient could partake as replacements for the patient's most authentic activities. This is not a given. The reduction in the available authentic actions could be so severe that there may be no other activities that are authentic, or at least nearly as authentic as the previous activities. For instance, imagine that the clinical situation of the amateur mechanic was different, and he had to choose between amputating his arm or some other treatment. If he chose the amputation, this would likely eliminate a much broader range of authentic activities than the situation originally described, where he chose not to repair his bicep. It may be far more difficult for the patient to find suitably authentic alternative physical activities in the former situation compared to the latter.

Even if it were the case that numerous patients were able to maintain the area under the authenticity curve by partaking less authentic activities more often, it does not follow that their psychological wellbeing will be equivalent. It is possible, if not probable, that the number of actions or the area under the curve that is above a certain threshold of authenticity may be more predictive of maintaining psychological health than simply the area under the curve. In other words, a life containing a constant stream of ever so slightly authentic activities may not be as satisfying or enjoyable as a life containing sporadic participation in highly authentic activities. The approach I am favouring is to maintain the size of the set of available authentic actions and maintain the ability to partake in one's most authentic activities by avoiding irreversible decreases in cognitive and physical functioning. However, I must also acknowledge that a patient who has chosen a solely autonomous action resulting in decreases in cognitive and physical ability would be able to avoid an impact on the size of the set of authentic actions and an elimination of their most authentic actions. Given his or her new physical or cognitive restrictions, the patient could make an immediate project of substantially modifying his or her current identity to suit these limitations. We all do this over the course of a lifetime. As we age, it is predictable that our cognitive and physical abilities will decrease (if ever so slightly and gradually), which may would limit the authentic activities in which the patient can partake and prevent participation in their most authentic activities if we do not modify our plans, values, and ideal self in response. When he is 80 years old, the patient in our example will likely no longer aspire to be a champion strength athlete in an all-ages category. He may instead simply aspire to continue competing or may reframe his plans and ideals around a less physically demanding activity. However, the age-related decrease in ability typically occurs gradually and over a long epoch, thereby only requiring gradual changes in identity to maintain the size of the set of

authentic actions and the ability to partake in one's most authentic activities.<sup>12</sup> The selection of medical treatments that precipitously and irreversibly alter cognitive and physical functioning in a manner that decreases the set of possible authentic actions and precludes participation in one's most authentic actions is risky. It often requires the patient to change their identity quickly in order to avoid an epoch where they lacked alternative activities that would be as authentic as the precluded activities. Regardless of the pace at which the decreases in ability occur, the process of modifying one's plans, values, and ideal self is typically slow, since it requires reflection, planning, and in some cases the agreement and support of others. Cultivating new behavioural patterns takes even longer. During this transition stage when the patient is likely to have lower peaks in the authenticity of their actions, the patient may experience a significant decrease in trait and state authenticity (i.e. not feel or act like themselves). This leads to the third and fourth mechanisms by which authentic and autonomous choices could support psychological wellbeing.

**Mechanism 2: Promoting authentic and autonomous choices could maintain or increase trait authenticity**

By preserving or increasing the size of the set of authentic actions available to the patient and maintaining their ability to partake in their most authentic actions, an authentic and autonomous decision in this situation could have several other benefits. It could allow patients to develop the fourth aspect of trait authenticity (the propensity to act in a manner that is consistent with one's

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<sup>12</sup> It is true that some unfortunate circumstances result in severe and rapid decreases in cognitive and/or physical functioning, which often cause a sharp decrease in the ability to act authentically (e.g. in the case of a significant stroke or sudden disability). However, in these situations the need for dramatic change to our identities is forced upon us.



values and preferences), thereby contributing to overall trait authenticity. If this capacity is developed, the patient will likely see additional psychological benefit<sup>13</sup>.

### **Mechanism 3: Increasing the probability of experiencing state authenticity**

The term “authenticity” can also be applied to a temporary state of mind. A psychological state is “a set of emotions, as well as cognitions and actions, in a particular situation”, which is “phenomenologically experienced” by the person in that state (39). State authenticity is “the sense that one is currently in alignment with one’s true or real self” (39). The experience of “state authenticity” is very positive, with nearly all people reporting feeling contentment, satisfaction, and enjoyment (47), and most reporting feeling as though certain needs were met, including those related to self-esteem, relatedness, and autonomy (47). Its opposite is state inauthenticity, which refers to “the sense or feeling that one is currently in alignment with an untrue or false self... that one is being a fake self” (39). The inauthentic state is associated with opposite feelings and is a negative experience. When reflecting on past experiences of state authenticity, people have greater feelings of moral self-regard (48), positive mood (47), subjective feelings of power (49), and nostalgia (47), as well as lesser feelings of impurity (48)

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<sup>13</sup> It is an open empirical question as to how often individuals have an amount of these components that would generate the maximum possible benefit for a given psychological outcome, with no further room for improvement. Given the enormous number of psychological outcomes influenced by trait authenticity, such a research program could take decades to complete. Until such information is available, I will err on the side of assuming that most people will have at least some room to improve these outcomes even if they already possess great self-knowledge, processing abilities, and transparency and truthfulness.

compared to when they reflect on inauthentic actions. Acting in a way that is authentic (in the sense that the action is consistent with the ideal self) increases the probability of experiencing state authenticity (50,51). This is not surprising, as people tend to see their ideal self as their “true” self (52). While acting authentically is no guarantee of the experience, there is a modest correlation between state and trait authenticity. Considering this, making authentic choices and then acting upon them does seem to be a reasonable way to increase the probability of experiencing state authenticity. While these states are transient, an average person experiences state authenticity one to two times each week and state inauthenticity nearly every two months (47). Thus, increasing the frequency of the former and decreasing the frequency of the latter could improve patient affect for an appreciable amount of time. The positive psychological effect of reminiscing about instances of state authenticity increases the duration of benefit, with the mathematical sum being especially large if the patient is prone to reflecting on the past. It is also likely to be recognized by the patient as being significant, since people on average are strongly motivated to seek authentic states, and avoid inauthentic ones (47), regardless of the person’s current level of trait authenticity (47).

Making a choice that is both authentic and autonomous in the situation described could also increase the number of instances where the patient experiences state authenticity, while decreasing the number of instances where the patient experiences state inauthenticity. This point requires some qualification. Recall that state authenticity is a phenomenological experience where the person has “the sense that one is currently in alignment with one’s true or real self” (39). I suspect it is very unlikely that an authentic medical choice will put the patient in an authentic state (i.e. make them feel authentic) at the time of the choice. Authentic states are typically triggered by familiar settings, “hanging out” with other people, or experiencing a

significant personal achievement (47). They also tend to be experienced when people are acting in accordance with their ideal selves (50,51). For most people, the medical setting is not especially familiar, and attending a medical consult is not typically seen as an achievement. In fact, I suspect that medical choices are much more likely to result in an acute inauthentic state for the patient, since these are normally triggered by feeling judged, sensing that you must meet the expectations of others, and by facing a difficult situation (47). These factors are all common when selecting a medical treatment and are especially common when selecting a treatment with important implications for the patient's life. Inauthentic states are also triggered by being unable to behave consistently across situations (53). In some instances, adopting the role of a patient encourages a person to act differently in that context compared to how one typically acts.

I also suspect that it is unlikely that an authentic and autonomous choice could produce a greater frequency of authentic states and a lower frequency of inauthentic states over the short-term. In many cases, all of the candidate treatments will involve a recovery period where the patient's cognitive and/or physical ability will be temporarily decreased. This stands a good chance of preventing them from taking part in numerous authentic activities. In addition, factors such as pain and suffering are likely to stack the deck in favour of more negative affect and a higher risk of inauthentic states. The exception to this would be circumstances where the authentic choice shortens the recovery process. In most cases, I suspect that the benefit of the authentic and autonomous choice would be most pronounced and commonplace over the medium to long term, once the patient can resume their normal activities. During this period, a patient who had made the authentic choice would be resuming their most authentic activities, while in the counterfactual they would face a reduced set of authentic actions to choose between and a need to find equally authentic alternatives. The period of benefit from the autonomous and authentic

choice would extend from recovery until age-related changes precluded participation in the patient's most authentic activities.

**Mechanism 4: Authentic and autonomous choices may decrease decisional regret and increase decisional satisfaction**

I hypothesized that patients would experience less decisional regret and more decisional satisfaction over the long term after making a choice that was both authentic and autonomous compared to one that was solely autonomous (under the circumstances previously described). Indeed, my own empirical research supports this assertion. I had a group of respondents react to a vignette describing a protagonist who made an autonomous but inauthentic medical choice that would irreversibly decrease his physical ability (and would limit the authentic activities in which the patient can partake and prevent participation in their most authentic activities), and another vignette describing a protagonist who made an autonomous and authentic medical choice that preserved his physical ability. Putting themselves in the place of the protagonist, respondents anticipated that a year after the surgery, they would feel a significantly larger amount of decisional regret and a significantly smaller amount of decisional satisfaction after making the inauthentic but autonomous choice compared to the choice that was both authentic and autonomous.

**Mechanism 5: Authentic and autonomous choices may promote compliance with medical instructions**

I also suspected that even if the patient were ultimately successful in changing their current identity to maintain the size of the set of authentic actions and find suitable replacements for

their most authentic activities, the slow transition to this state poses an additional risk to patients. Old patterns of behaviour can be hard to break and urges toward existing goals can be difficult to resist. In cases where an authentic action is contraindicated instead of physically impossible, a patient may revert to these actions out of habit or frustration, thereby placing him or herself at risk of additional injury. In our example, the risk of re-injury or additional injury might be so high that the physician advises the patient to give up his hobby of auto-repair. The patient might abstain from this activity for a while, but ultimately succumb to the urge to “get under the hood again”. Indeed, this is also supported by my empirical research, which I introduced earlier. When reacting to the vignette describing a protagonist who made a solely autonomous medical choice, respondents anticipated that they would be less likely to comply with postoperative physical activity restrictions than when reacting to an autonomous and authentic medical choice. In fact, there were more than eight times as many respondents in the “solely autonomous” condition who anticipated some level of non-compliance compared to the “authentic and autonomous” condition. In such cases, a single relapse may be sufficient to cause additional injury, thereby decreasing the patient’s physical and psychological wellbeing. In the example provided to the respondents, a single instance of high impact physical activity following the inauthentic choice could cause dislodging of the implant (surgical failure), thereby requiring further surgery, as well as increasing the risk of further injury. The risk of non-compliance provides yet another reason why identity shifting in order to maintain the size of the set of authentic actions and to find highly authentic alternative activities would be a less prudent than simply making choices that avoid or minimize such requirements.

In summary, by encouraging patients to make choices that are both authentic and autonomous we may do a better job of supporting their psychological and physical wellbeing. If successful in

achieving these outcomes, the physician could further fulfil their duty to act beneficently toward the patient.

### ***7. Limiting the risk of physician paternalism***

The primary reasons why Faden and Beauchamp, as well as many other philosophers, have rejected the inclusion of authenticity as a component of valid consent, despite it being “the leading candidate for a position as an additional condition” for autonomous choice (1), is over concerns that this inclusion would result in physicians acting paternalistically toward patients more often (19,21,54). Due to the centrality of Faden and Beauchamp’s work to this paper, I will focus on their rejection of authenticity as a criterion of valid consent. I will attempt to show that these criticisms do not apply to the model and procedural practices that I propose. My conclusion is that the authenticity-informed model of consent would limit the risk of paternalism.

Faden and Beauchamp define “paternalism” in the context of the physician-patient relationship as a “parental-like decision by a professional [which] overrides an autonomous decision of a patient” (1) p.13, “in order to benefit them or prevent harm to them” (1) p.13. The main view of authenticity that they consider (and reject based on concerns over paternalism), is:

An authenticity condition would require actions to be consistent with a person's reflectively accepted values and behaviour in order to be autonomous. Authenticity in this usage requires that actions faithfully represent the values, attitudes, motivations, and life plans that the individual personally accepts upon due consideration of the way he or she wishes to live (1) p.263.

There are several key terms in the above passage. The first is “reflectively accepted”, which indicates that they are offering a hierarchical version of authenticity according to which first order actions must be consistent with second order values, behaviours, attitudes, motivations, and life plans (which in turn have been subject to a form of higher order endorsement) in order to be

authentic. With a hierarchical definition such as this one, the recommended procedural practices would need to be more involved. Every patient would not only have to reflect on whether the choice was consistent with markers of their identity but would also need to engage in a higher level of reflection about their feelings toward each of these markers before they were accepted as benchmarks for the assessment of the authenticity of choices. My view only requires this sort of reflection in cases of disagreements between the markers of the patient's current identity or the levels of authenticity analysis. This two-tiered endorsement would be more difficult to achieve in practice and would more easily allow the physician to assert that the choice was not authentic, due to unendorsed markers of the patient's identity. The largely non-hierarchical view I propose would reduce the probability that a physician would attempt to over-rule a patient's decision based on an assertion that the markers of the patient's identity had not been adequately endorsed. The second key term in the above passage is "would require", which indicates that they are evaluating the addition of authenticity as a necessary condition. Faden and Beauchamp state this fact, and its anticipated consequences, even more clearly: "If authenticity were made a necessary condition of autonomous actions, many familiar acts of consenting and refusing would fail to qualify as autonomous, and thus would not qualify for protection from interference by the principle of respect for autonomy" (1) p.265. They worry that this would give physicians illegitimate justification to "validly over-rule" patient preferences on the grounds that "there is no autonomy in them to be respected" (1) p.265. Critically, I am not proposing that authenticity be made a necessary condition for valid consent. The proposal here defended is that authenticity be included as an "additive condition" for valid consent; meaning that it enhances the validity of consent to the extent that it is present (or at least to the extent that inauthenticity is absent), but there is no minimum degree of authenticity either necessary or sufficient for the consent to be

adequately valid. Thus, physicians are asked to promote decisions that are both autonomous and authentic but would not be allowed to classify a consent as invalid solely because it is inauthentic. This helps to safeguard against the contingency that autonomous patient choices would be over-ruled by the physician. Only in situations where this lack of authenticity could be traced to a lack of decisional capacity could the patient's choice be over-ruled. In those instances, a surrogate decision-maker would make the decision for the patient. In situations where the lack of authenticity was, or could be, traced to a lack of voluntariness or understanding, the physician's default action would be to reduce or remove the controlling influence, or to better inform the patient, respectively. These actions are consistent with respect for autonomy.

As a third measure to reduce the likelihood of paternalism, the authenticity-informed model permits physicians to encourage patients to consider authenticity in their decision-making but rules out any manipulation or coercion. According to the framework laid out by Faden and Beauchamp, coercion occurs when "one party intentionally and successfully influences another by presenting a credible threat of unwanted and unavoidable harm so severe that the person is unable to resist acting to avoid it" p.339. Turning this claim into a procedural practice, I would suggest for prudential reasons that the physician should simply be barred from using any physical force or threats of any kind, whether or not he or she believes that the threat will be effective or resistible. While there is likely a threat that is so mild and resistible that it would be unlikely to coerce anyone, threats should not in principle be used to promote authentic decision-making. Even jokes involving threats should be avoided, as the patient may misconstrue the intention behind the physician's words. Faden and Beauchamp define "manipulation" as "any intentional and successful influence of a person by non-coercively altering the actual choices



available to the person or by non-persuasively altering the person's perception of those choices" (1) p.261. Following their analysis, I would restrict physicians from using a number of manipulative tactics. These include offering rewards or punishments to incentivize the selection of a particular treatment, deceiving the patient, intentionally confusing the patient by withholding information or bombarding them with information, using exaggeration, tweaking the consent process in any way to exploit cognitive biases, using subliminal suggestions, flattery, or using appeals to loyalty, guilt, or fear (1). Faden and Beauchamp define persuasion as "influence by appeals to reason". Thus, physicians would be both permitted and encouraged to present patients with reasons for selecting what the physician perceives to be the authentic choice, in verbal, written, or even graphical/visual formats. This could include a description of the possible psychological benefits of making authentic choices. The physician could either state these reasons outright or bring them to the patient's mind using a guided discovery/Socratic approach. These suggestions all come from the desire to promote choices that are both authentic and autonomous, as opposed to promoting those that are authentic at the expense of being autonomous (i.e. solely authentic).

Finally, paternalism is likely to be contained if physicians adopt my recommended practices, the model of the physician-patient relationship that underlies these practices, and the conversational style that I recommend. Critically, it would be preferable if physicians used a communication style that recognizes the fact that the patient typically has a much greater knowledge of himself or herself than the physician. For this reason, patients should be the key players in the decision-making process. This would involve the physician using tentative wording when making statements about the current identity of the patient and asking for further information and clarifications when the patient's choice appears to be inauthentic. It would also involve assessing

charitably the authenticity of the patient's decision. A complete coherence between patient choices and the markers of a patient's current identity may be difficult (if not impossible) to achieve given the patient's existing duties and responsibilities to others and the available treatment options. Part of accepting that the patient is the key player in the decision would be deferring to the patient in deciding when a sufficient conversation about the inauthenticity of their choice has occurred. The consent conversation should be over once the physician has established the decisional capacity of the patient, established the autonomy of the patient's choice, and has attempted to go through the seven additional recommended procedural practices, as applicable. A competent patient might decline to be persuaded by the physician's view of what an authentic decision would be for someone in the patient's circumstances. Alternatively, a patient might even refuse to hear the arguments in favour of authentic decision-making. Under both circumstances, the physician should not belabour the point unless the autonomy of the choice or the decisional capacity of the patient is also in question.

### **8. Conclusion**

In summary, I propose that the authenticity of a patient's choice (its consistency with markers of a patient's current identity) should be included as an additive condition to the standard model of valid consent, forming what might be called the "authenticity-informed model of valid consent". To reflect this change, seven procedural practices would need to be added to those recommended by the CMPA. 1) Encourage the patient to consider the authenticity of each possible option in selecting a treatment. 2) Engage in a conversation with the patient in order to learn about their current identity. 3) Offer to help elucidate the markers of the patient's identity if they are uncertain about these markers. 4) Guide the patient through a process of higher order evaluations if they have identity markers that don't agree. 5) Form a tentative assessment of which treatment

would be most authentic and seek feedback from the patient. 6) Inquire further about the motivation for a patient's choice, if it appeared to be the less authentic option. 7) Encourage patients (through means of persuasion) to choose medical treatments that the physician considers to be more authentic for them.

The use of this model and its recommended procedural practices could have important benefits. Specifically, it could help to overcome three limitations of the standard model of consent. This could help physicians to fulfil their moral duties to act beneficently toward patients and to respect the autonomy of patients.

In light of this, I conclude that the authenticity-informed model of valid consent and the seven procedural practices that I recommend should be considered for inclusion in the CMPA guidelines. However, prior to implementation, future philosophical research should first address other possible criticisms regarding the authenticity-informed model of consent and its associated procedural practices, such as concerns over the minimum amount of self-knowledge that patients would require to make authentic choices, and the feasibility of the recommended procedural practices, given that they will likely lengthen the consent process. Conversely, philosophical research should also examine possible benefits of the authenticity-informed model that were beyond the scope of this paper, such as the model's potential to improve the physician-patient relationship and foster trust in the healthcare system. Empirical research should also be conducted to verify the presence, magnitude, and frequency of the benefits that I claim would result from the added procedural practices.

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### **C. Prologue to Chapter 3**

The philosophical manuscript in Chapter 2 provides a broad introduction to the topic of informed consent. It also presents a defense of the thesis that the standard model of valid consent may be improved by including the “authenticity” of a patient’s choice as an additive condition, thereby forming what I call the “authenticity-informed model of valid consent”. As part of this defense, it introduces the arguments in favour of the inclusion of authenticity that are supported by the empirical manuscript. With this context established, the empirical work can be better understood and appreciated.

The methodological manuscript in Chapter 3 describes pretesting methods for enhancing the rigor of vignettes used in empirical bioethics research. The focus on pretesting stems from the fact that it is arguably the most flexible, effective, and inexpensive means to improve vignettes. This manuscript also introduces the vignettes used in the empirical manuscript and illustrates how data from a respondent debriefing procedure was used to evaluate vignette construct validity.

In addition to the measures described in the methodological manuscript, other pretesting steps were taken to evaluate and promote the rigor of the vignettes and clinical scenario. To supplement the methodological manuscript, the following text reviews the entire vignette development procedure and presents the results of additional analysis.

One clinical scenario and four vignettes were developed. The clinical scenario introduced a patient with early onset arthritis of the knee who was deciding between having a partial knee replacement or an osteotomy. The four vignettes described different sequences of events that could occur to the scenario protagonist. The vignettes differed regarding the treatment chosen by the protagonist (i.e. an authentic vs. inauthentic choice) and whether this choice was made

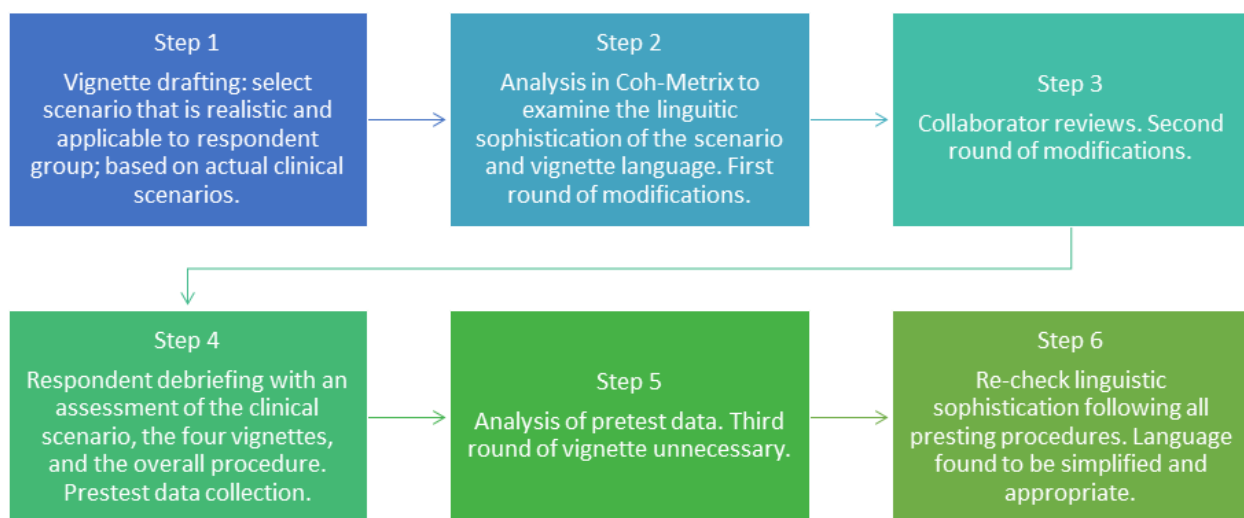
voluntarily (i.e. an autonomous vs. non-autonomous choice). Thus, the vignettes manipulated the presence of authenticity and autonomy in the patient's choice.

### ***Vignette development procedure***

The six-step vignette development procedure is shown in Figure 1. This included drafting of the vignettes, computational linguistic analysis [1], collaborator reviews, respondent debriefing with data collection and analysis [2,3], and a second computational linguistic analysis to confirm acceptability of the language following the previous steps. These procedures resulted in three iterations of the clinical scenario and vignettes. Additional iterations were unnecessary based on an analysis of the pretesting data and the linguistic analysis.

The first step involved drafting the clinical scenario and vignettes based on a clinical decision that could be faced by individuals with different forms of knee arthritis. This scenario was chosen for several reasons. It represented a choice between two treatments that have different postoperative physical restrictions (one that prevented the vignette protagonist from participating in his most authentic activities, and the other that did not). It represented a scenario where a single instance of non-compliance with these activity restrictions could result in surgical failure. Finally, it featured a condition that can afflict individuals around the expected age of the participants (i.e. the 3<sup>rd</sup> decade of life). This step is not described in the methodological manuscript, as an existing review already does a good job of discussing the generation of ideas for (and initial drafting of) vignettes [4].





*Figure 1- Summary of the vignette development procedures*

The second step involved using Coh-Metrix computational linguistic software [1] (v.3.0, University of Memphis, USA) to evaluate the sophistication of the language used in the clinical scenario and four vignettes. To my knowledge, this is a novel application of the software. While past studies have evaluated the quantitative readability of vignettes, more comprehensive computational linguistic analysis is typically not done. In this study, two readability metrics were examined. The Flesch-Kincaid readability formula is a long-standing metric that considers a combination of word length and sentence length, with increases in either (or both) being associated with increases in text difficulty [1]. In contrast, the Coh-Metrix readability metric considers measures of text cohesion (i.e., content word overlap, sentence syntactic similarity), as well as a measure of word difficulty (i.e., word frequency) [1], with increases in cohesion and decreases in word difficulty associated with increases in text difficulty. However, we also examined composites of variables falling into two categories: syntactic complexity variables (six variables) and word information variables (ten variables). The composites were calculated by taking the median value of the variables in each category (after converting the linguistic

measures into grade level equivalents). Syntactic complexity variables consider features of *sentences* that make them easier to understand (see Table 1 for definitions of each variable and its relationship to text difficulty) [1]. Word information variables include those that consider features of *words* that make them easier to understand (similarly described in Table 1) [1]. By examining these additional groups of variables, a much more comprehensive assessment of the language used in the scenario and vignettes is possible [5,6].

The linguistic variables are measured on different scales and are not easily interpreted without reference to norms. A way of enabling comparisons between variables and making the results more understandable is to turn the raw scores of the linguistic variables into their grade level equivalents. This, however, requires some calculation. Coh-Metrix provides linguistic norms for different types of text, including science writing. These norms are further divided into different grade level groupings from kindergarten to grade twelve. Coh-Metrix derived the norms for each grade level grouping from 300 excerpts of science texts that were written specifically for this grade level grouping. I used these science text norms to develop regression equations that allowed me to convert the raw scores of the linguistic variables into their grade level equivalents (Table 1). In searching for the best regression equation to describe each of the relationships, numerous candidate regression equations were considered, including linear fits, polynomial fits of the 2<sup>nd</sup> to 4<sup>th</sup> degree, logarithmic fits, and exponential fits. The simplest equation that resulted in a good fit (define as an  $r^2 > 0.85$ ) was selected in order to avoid radically changing or non-monotonic results with extrapolation (the latter often seen with exponential formulae, and both often seen with higher degree polynomials). Grade levels were allowed to range from zero to positive infinity.

Table 1- Formulae to predict grade levels for computational linguistic variables

Category and variable name	Definition	Relationship to text difficulty	Formula to predict grade level	R <sup>2</sup> of derived formula	Initial grade level	Final grade level
<b>Quantitative readability</b>						
1. <b>Flesch-Kincaid Grade level</b>	Readability score based on average word length and average sentence length, converted into a grade level.	The shorter the sentences and the shorter the words are, the easier the text is to understand	not needed	n/a	11.32	10.55
2. <b>Coh-Metrix L2 Readability</b>	Readability scores based on a mix of average content word overlap, sentence syntactic similarity, and word frequency.	The more the content words overlap, the more syntactically similar the sentences are, and the more frequently the words are used in the English language, the easier the text is to understand	$y = -0.6478x + 21.103$	0.988	11.32	10.31
<b>Syntactic Complexity</b>						
1. <b>Left embeddedness, words before main verb, mean</b>	How many words, on average, are put before the verbs of the sentences	Greater left embeddedness makes sentences more difficult to read	$y = 3.4994x - 6.185$	0.995	10.33	8.72
2. <b>Number of modifiers per noun phrase, mean</b>	How many words that are meant to modify or qualify a noun appear, on average, in each sentence (e.g. "bus station" has one modifier- "bus", which identified the station as a particular type)	More noun modifiers make sentences more difficult to read (e.g. "Bus station" is easier to understand than "Winnipeg transit handicap-accessible express bus station")	$y = 32.908x - 21.485$	0.969	9.65	9.35
3. <b>Minimal Edit Distance, part of speech</b>	The number of changes you need to make to a sentence in order to make it have the same syntax (i.e. grammar) of another e.g. The sentence: "During WWII, the USA was allied with Canada" has the same grammar, but not meaning as "During WWII, the UK was allied with Canada"	The more consistent and similar the sentences are syntactically (i.e. based on the grammar of the sentence) and semantically (i.e. based on the meaning of the sentence), the easier they will be to connect and understand. These are all markers of structural cohesion.	$y = -453.6x + 289.64$	0.955	8.41	0
4. <b>Minimal Edit Distance, lemmas</b>	The number of changes you need to make to a sentence for it to have the same meaning as another, based on its lemmas (i.e. word stems that are also actual words, as "run" is the lemma for "running")		$y = 337.33x - 273.06$	0.966	13.00	13.00

5. <b>Sentence syntax similarity, adjacent sentences, mean</b>	A metric of the average grammatical similarity between adjacent sentences or between sentences across paragraphs. These metrics are complicated. They are derived using “parse trees”-ways of graphically breaking down the structure of sentences based on the ordering and types of words used within them. Once “trees” are created for two sentences, the ratio between the number of similarities and the number of dissimilarities between them is calculated)	The more grammatically similar nearby sentences are, the easier it will be to connect them and understand the content of each  (E.g. the sentences “Dogs are bigger than cats. But cats are bigger than mice” is easier to connect and understand than “Dogs are bigger than cats. But mice are not as big as cats”	$y = -122.23x + 26.044$	0.964	11.13	11.74
6. <b>Sentence syntax similarity, all combinations, across paragraphs, mean</b>		The more similar and uniform the grammar across paragraphs, the easier it will be to connect and understand them.	$y = -204.19x + 34.572$	0.955	11.09	12.11
<b>Word Information</b>						
1. <b>CELEX word frequency for content words, mean</b>	From the Center for lexical information database (CELEX)	The more commonly the words in the text are used in large canons of English text, the easier they will be to understand.	$y = -27.565x + 68.132$	0.982	10.22	7.65
2. <b>CELEX Log frequency for all words, mean</b>	From the Center for lexical information database (CELEX)		$y = -69.599x + 214.91$	0.979	12.52	9.523
3. <b>CELEX Log minimum frequency for content words, mean</b>	From the Center for lexical information database (CELEX)		$y = -14.852x + 24.692$	0.974	12.63	11.76
4. <b>Age of acquisition for content words, mean</b>	The average age at which people believe that they learned a content word (i.e. a word that refers to an object or its qualities), also averaged across words within the text.	The older the age that people gain a mastery of the words used, the more difficult they will be to understand  (e.g. “mom” is more easily understood than “dogma”)	$y = 0.1158x - 30.6$	0.989	9.98	10.13
5. <b>Familiarity for content words, mean</b>	Rating of how familiar, easy to visualize (imageability), and easy it is to link a word to other words (meaningfulness), based on ratings provided by human assessors. These ratings are catalogued in the Medical Research Council’s Psycholinguistic database.	Words that are more familiar to most people are easier to understand	$y = -0.5718x + 333.94$	0.975	5.55	4.75
6. <b>Imageability for content words, mean</b>		Words that are more easily visualized by most people are easier to understand	$y = -0.016x^2 + 13.251x - 2733.5$	0.867	0	0
7. <b>Meaningfulness, Colorado norms, content words, mean</b>		Words that are more easily related to other words are easier to understand	$y = -0.6705x + 296.76$	0.967	18.20	17.97
8. <b>Polysemy for content words, mean</b>	Mean rating of how many different but related meanings teach content word has  (e.g. “man” can mean “male human” vs. woman, “adult male human” vs. male child, or “member of the human species” vs. animal)	Words that have more related meanings are more difficult to understand based on their larger number of possible interpretations	$y = -9.9974x + 50.987$	0.987	10.06	7.74
9. <b>Hypernymy for verbs, mean</b>	The number of hypernyms (overarching categories) a noun or verb has.  (e.g. “poodle” has many hypernyms in going from more to less specific: “dog”, “mammal”, “animal”,	The more hypernyms that a word has, the more easily it will typically be understood.  (e.g. “poodle” is easier to understand than “entity”)	$y = 2847.3x^2 - 9039.1x + 7175.2$	0.932	51.40	51.40
10. <b>Hypernymy for nouns and verbs, mean</b>			$y = 2E-10e12.83x$	0.980	8.67	8.89

	"entity")					
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A target was set to have the readability measures and composite linguistic measures at or below the grade 12 level, since prior demographic surveys of Mechanical Turk respondents have found that most respondents have some post-secondary education [7,8]. While the grade level target was met in the first draft (Figure 2) the text was simplified further based on the proximity of the Coh-Metrix readability values to the grade 12 level. This resulted in the first round of revisions to the scenario and vignettes. This step is not described in the methodological manuscript, since it is a relatively novel approach to assessing vignette clarity, while the manuscript focused on more well-established and commonly used approaches.

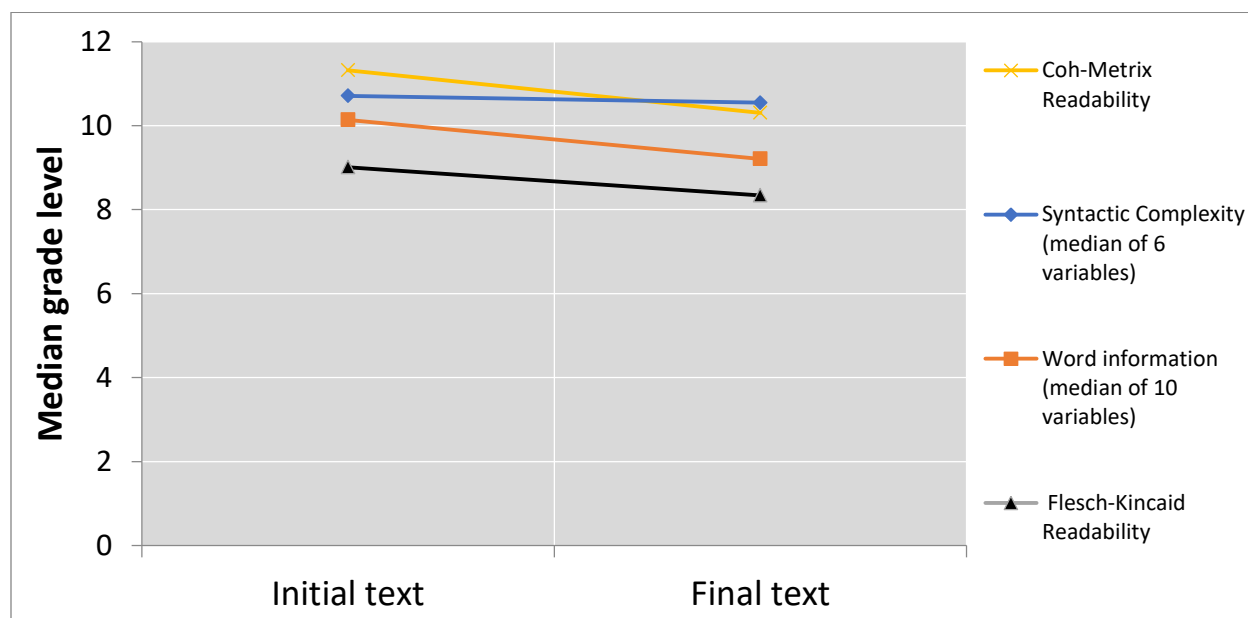


Figure 2- Computational linguistic measures of the combined scenario and four vignettes, both before and after all pretesting procedures

Third, the vignettes were distributed to the collaborators, who provided qualitative feedback via email and a group teleconference. The scenarios were modified substantially based on concerns related to realism and construct validity (2<sup>nd</sup> round of revisions). A summary of the concerns that were raised, and the actions taken to address each of these concerns can be found in a summary email that was sent to the collaborators following the teleconference (Appendix 1). Due to the less formal arrangement of this feedback acquisition and its qualitative nature, this step is not outlined in the methodological manuscript.

In the fourth step, 13 respondents were recruited from the same population as the main respondents (i.e. the Mechanical Turk platform) to take part in a respondent debriefing procedure. A full description of the respondents can be found in the methodological paper. Each respondent completed the survey in its entirety and then completed a series of questions designed to evaluate whether the study procedures were too long or complex, and whether the clinical scenario was adequately clear and realistic. Responses to each question were provided on a five-point ordinal scale (ranging from “not at all” to “entirely”). Using open-ended questions, respondents were asked to elaborate on any issues they perceived and to suggest remediating strategies. The respondents also evaluated the amount of autonomy and authenticity that they perceived in the patient choice depicted in each of the four vignettes.

The fifth step involved evaluating the respondent debriefing data by comparing it to pre-established cut-offs and using it to test *a priori* hypotheses. These latter results are explained in detail in the methodological manuscript (Chapter 3). A revision of the clinical scenario and vignettes based on this analysis was unnecessary, since all cut-offs were met, and all hypotheses were supported.

Finally, in the sixth step, the scenario and vignette text were again evaluated using Coh-Metrix to ensure that the sum of the procedures did not increase the difficulty of the wording substantially (Figure 2). The three revisions in fact simplified the language, with the grade level ranging from eight to ten for all four-composite metrics. This reduction in difficulty was taken to be beneficial, since it could better accommodate respondents with lower literacy skills and would allow all respondents to understand the vignettes more easily [9]. A final revision intended to reduce the complexity of the language to below the grade 12 level was unnecessary given these results. In summary, the additional procedures outlined in this section demonstrate that the language used in the scenario and vignettes was appropriate for the target audience. The methodological manuscript will demonstrate that the study procedure was of an appropriate length and complexity, that the clinical scenario was clear and realistic, and that the vignettes have construct validity.

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*Appendix 1- Excerpts from a summary email to collaborators that outlines the second round of revisions based on collaborator feedback*

“Hi all,

Malcolm and I just wanted to give everyone a quick update about the vignettes in paper 3. I have reviewed both the written comments from the committee and my notes about the comments made during the teleconference. I would like to summarize my interpretation of the problems that were pointed out, and thereafter point to the efforts that we have made in order to address these problems. The broad approach taken was to modify the existing clinical scenario and vignettes instead of creating an entirely different scenario.

The two main themes that I derived from the comments were as follows:

- 1) Some aspects of the scenario and vignettes lacked realism.
- 2) The scenario and vignettes needed to be altered to present a more compelling motivation for the protagonist to select the action that we deemed "authentic", and to convincingly show that the other option was in fact not authentic.

There was concern that these issues would interfere with the respondent's ability to understand and identify with the scenario, and therefore undermine their ability to properly answer the questions that we are asking.

Problem 1 (i.e. lack of realism) stemmed from several issues, including the age of the protagonist, the call for a psychological assessment of the protagonist, the assumed knowledge that the surgeon would have about the desires and aspirations of the protagonist, and the simplified description that we gave about the trade-offs between the two surgeries.

-After careful consideration, I have taken the following actions to address this first concern:

1) The early age at which the protagonist developed arthritis is now justified in the scenario. In the first draft of the scenario, we explained that the arthritis was "early-onset", and it explained how this onset began. Sometimes when a young person breaks their leg it does not heal properly, and this results in a mis-alignment between the upper and lower legs. This misalignment results in the knee getting worn down at an accelerated rate. These details were removed in the draft that you saw out of concern that the scenario may have been too long. However, due to the concerns expressed, an abbreviated explanation has been re-introduced to the scenario.

2) We feel that while it may not be common, a psychiatric consult for a younger surgical patient is not unheard of. This is especially true if the decision-making skills of the patient are being questioned by the surgeon. In my experience I have seen surgeons call for a psychiatric consult when they believe that the decision-making capacity of the patient is in question. This is probably done in part to avoid the trouble of having to do the assessment themselves, and in part to avoid legal liability.

3) We concede that the primary care physician would likely know the patient better than the surgeon and would be in a better place to judge authenticity. However, surgery decisions typically only involve the patient and the surgeon, with perhaps some involvement from the loved ones of the patient. The primary care physician does not often contribute to this particular decision. Therefore, we have kept the interaction between the patient and the surgeon.

4) We accept that our descriptions of the likely scenarios were somewhat simplified. However, while developing a scenario that involved uncertainties, ambiguities, etc., would be more realistic, it would also decrease the internal validity of the scenarios and vignettes.

The vignettes are meant to be simplified representations of real-life scenarios. Making the scenario and vignettes more complex would increase the probability of information overload, respondents discounting important considerations, and a confounding effect originating from differences in how respondents react to uncertainty. We are willing to accept increased internal validity at the expense of generalizability and realism.

The second theme went deeper, questioning the clinical scenario itself and the description of the protagonist. Suggestions were given about alternative scenarios that might be better.

Originally, we wanted the trade-off between the two scenarios to be functioning vs. pain control. If the patient chose the knee replacement, he would be prioritizing pain control over functioning and vice versa if he picked the osteotomy. Since he was a runner, the authentic choice would be the osteotomy, which would allow him to continue running, compete in a marathon, and live up to his ideal self.

Arthur pointed out several issues with the scenarios, namely:

-If the protagonist acted authentically and chose the osteotomy, he may quickly destroy his body and spend the rest of his life facing much greater physical activity restrictions than if he had the knee replacement and stopped running. This frames the trade-off as being long term functioning at a lower level with good pain control vs. high functioning for a short period followed by possibly abysmal functioning and definitely poorer pain control.

-Members of the committee didn't think that it was reasonable for the protagonist to make this trade off, especially since the "pay off" for the increased short-term functioning wasn't very high. Suggestions were made that if the protagonist were a professional athlete who stood to make millions of dollars because of that increased short term functioning, the trade-off could be plausible- But not for a recreational athlete.

-There was also concern that the protagonist was being too rigid about his ideal self. When there is a discrepancy between one's action and one's ideal self, there are several ways to decrease this incongruity: change one's action to match the ideal self, change one's ideal self to match the action, or change one's action while being more flexible with the ideal self. Arthur suggested that the protagonist might be equally as authentic if he just took up another, less demanding, sport.

After careful consideration, I have taken the following actions to address this second concern:

-We needed to adjust the circumstances so that the trade-off was more truly pain vs. functioning, and so that the protagonist had more at stake in not acting authentically.

-To eliminate the long term & short-term trade off, we:

- 1) Eliminate the protagonist's goal of running a marathon, which was too potentially damaging
- 2) Change the goal to being as physically active as possible (within reason) for the longest period of time, thereby decreasing the possibility of long-term deterioration. It is implied that he recognizes that the intensity of his involvement with the activities will need to be tempered as he ages.

-To "up the stakes", we:

- 1) Made the protagonist a personal trainer and a karate coach, thereby making his livelihood at stake if he were to get the knee replacement surgery instead of the osteotomy
- 2) Made him a multi-sport athlete in his spare time
- 3) Emphasized that the knee replacement would challenge all of these things simultaneously. If he got the knee replacement, his life as he knows it would be over since both his jobs and hobbies would not be feasible.

In this scenario, it would be much more difficult for the protagonist to adjust his ideal self to fit the knee replacement, and it would be much easier to simply choose to have the other surgery."

### **D. Chapter 3: Using pretesting to improve the quality of vignette studies**

Alexander Villafranca, Malcolm Doupe, Corey Mackenzie

#### ***Abstract***

Recently bioethics has been said to take an “empirical turn”, with ethicists conducting empirical research to discover morally relevant facts. However, some authors have raised concerns that the standards of rigor in these empirical studies are lacking in comparison to other scientific disciplines. Vignettes are short descriptions of one or more scenarios, which are presented to respondents to elicit reactions that serve as study outcomes. The use of vignettes in empirical ethics research is one area where methodological rigor is thought to be particularly lacking. Pretesting, a range of techniques used to evaluate survey tools study prior to their distribution, is one of the most useful, flexible, and cost-effective means of enhancing vignette development. While manuscripts describing ways to enhance vignette rigor in empirical ethics are needed, few exist. The objective of this paper is to discuss the use of pretesting to evaluate and enhance the rigor of vignettes used in empirical ethics research. Common questions related to pretesting are first discussed, which address the purpose of pretesting, approaches to pretesting, the design of pretesting procedures, and the analysis of pretesting data. This manuscript includes an illustrative example of how data collected through respondent debriefing can be used to evaluate desirable vignette characteristics. Special focus is placed on vignette construct validity, which was empirically assessed by testing twelve hypotheses. This example represents one of the most comprehensive assessments of a vignette criterion reported in the empirical literature. As a new field, empirical ethics has an opportunity to not only match the rigor of the fields from which it

draws its methods, but also to strengthen existing standards. If rigorous and innovative pretesting measures were common practice, it would help the field to draw more valid inferences, avoid further criticism, and ultimately achieve the respect and recognition that it deserves.

## ***Introduction***

Throughout history, philosophers have drawn upon facts to inform their normative reasoning [1]. However, recently bioethics has been said to take an “empirical turn” [2–4], with ethicists beginning to conduct their own empirical research to discover morally relevant facts. However, some authors have raised concerns that the standards of rigor in these empirical studies are lacking in comparison to other scientific disciplines [1,5–7]. These concerns originate from two sources. First, a recent survey found that 22% of European bioethicists who conduct empirical research had no formal training in either quantitative or qualitative methods [7], leading the author of this study to question whether these bioethicists “have the necessary skills to conduct their empirical research” [7]. Second, other researchers have criticized the quality of the research itself [1,8]. For instance, Dr. Saima Hurst, professor at the University of Geneva, asserts that “Bioethics has imported methodological tools from empirical disciplines, but too often it has not imported the standards to which researchers in these disciplines are held” [1].

The use of vignettes in empirical ethics research is one area where methodological rigor is thought to be particularly lacking [8]. Vignettes are short descriptions of one or more scenarios [9], most often taking the form of written narratives. These vignettes are presented to respondents to elicit reactions that serve as study outcomes. Respondent reactions can be grouped into categories, including: evaluative (e.g. judgments, attitudes), affective (e.g. feelings, distress), cognitive (e.g. recall, knowledge), and behavioural (e.g. choices, behaviours) [9–19]. Vignette studies are typically conducted to determine whether these various outcomes are affected by respondent characteristics or independent variables that are represented in vignette narratives [13]. A vignette set is required to experimentally manipulate the represented independent variables. Measuring how respondents’ reactions differ across vignettes allows



researchers to quantify the influence that independent variables have on study outcomes. The most vocal critic of vignette studies in empirical ethics has been psychologist Peter Mudrack. He has emphasized the need for empirical ethicists to more rigorously design vignettes and commented that in much of the research to date “material appearing in the brief vignettes or scenarios... has seemed an afterthought in most investigations.... vignette diversity has seemingly led to an inchoate and rather fragmented body of questionable work” [8]. While manuscripts describing ways to enhance vignette rigor in empirical ethics are needed, with notable exceptions [8,13,20,21], few such articles exist. Furthermore, these articles have not focused on what is arguably the most useful, flexible, and cost-effective tool to enhance vignette development - the pretest.

Pretesting in social sciences refers to a range of techniques used to evaluate one or more aspects of a survey study (e.g. a questionnaire, interview script, or vignette) before data collection is initiated on the full study sample [22,23]. Pretesting has long been seen as a flexible and effective means of evaluating and improving the quality of survey items and data collection protocols [24], and the US Census Bureau has formally recommended the use of pretesting in numerous working papers [22,23,25]. Various authors have also asserted that pretesting is a powerful tool to evaluate and promote numerous desirable vignette characteristics including construct validity, realism, and others [21,26–29]. Pretesting has also been recognized as one of the least expensive ways to reduce both bias [30] and random measurement error [31] in survey studies.

The objective of this paper is to discuss how pretesting can be used to improve the rigor of vignette development in empirical ethics research. Common questions related to pretesting are

first discussed, followed by an illustrative example designed to demonstrate how pretest data can be used to evaluate vignette construct validity.

***What is the purpose of pretesting?***

Pretesting can be used to evaluate essential vignette characteristics including clarity (i.e., the absence of vagueness and ambiguity) [27,28], simplicity (i.e., ease of understanding) [27], cultural neutrality (i.e., omitting culturally specific references and vernacular) [29], and construct validity (i.e. whether the vignette accurately represents the construct as intended by the researcher) [27,29]. Pretesting can also help to evaluate whether respondents notice the experimental manipulation (e.g., differences between vignettes) without prompting, and whether respondents report that their reactions to each vignette were informed by the variable being manipulated (a characteristic sometimes referred to as “internal experimental realism” [32]). The vignette criteria that could be assessed in the pretest usually must be triaged based on the anticipated probabilities that the vignette could be lacking the different characteristics [33] and the number of vignettes requiring assessment. Selecting too many criteria may place excessive demands on the pretest respondents’ time [23]. A central vignette characteristic is construct validity, since a failure to accurately represent the independent variables within the vignettes undermines the ability to make valid inferences. Since construct validity is a necessary but not sufficient condition for accurate responses, assessing other vignette characteristics can be selectively done based on the investigator’s level of concern regarding each, and based on restraints related to time and cost.

***What approaches to pretesting are commonly used?***

Different approaches to pretesting can be used to achieve the same purpose (such as evaluating an essential vignette criterion). Common approaches include cognitive interviewing, respondent debriefing, and expert panels. Cognitive interviewing involves having a broad range of participants “think aloud” as they complete the survey (i.e. concurrent cognitive interviews) or while they review the survey after having completed it independently (i.e. retrospective cognitive interviews) [13,16,22,23,34]. Cognitive interviews typically occur in private and may or may not involve prompting or follow up questions [22]. Interviews are recorded so that they can be reviewed and potentially coded afterward. This helps to ensure that the richness of the data is used to its fullest advantage. Cognitive interviewing approach is typically used to understand how participants interpret and go about answering survey questions [22,31]. Similarly, this approach can be used to understand the extent to which respondents interpret vignettes as intended [13]. They can provide important information about response processes and reveal specific areas of confusion or misunderstanding. They also offer the unique advantage of allowing the interviewer to follow up on unexpected or ambiguous responses in real time without requiring an additional contact with the respondent. This can clarify feedback and can facilitate a causal understanding of any revealed problems. Lastly, by evaluating perceptions and response processes in depth, cognitive interviewing offers the unique advantage over other pretesting techniques of revealing hidden biases in the responses [30].

In respondent debriefing, a small group of individuals either review or complete the survey, and then answer additional questions to describe their study experience, including their interpretation of the survey questions or the vignettes employed [22,23,35]. The goal of the latter questions is to determine how well the study vignettes, both individually and as a set, “work” under

conditions that simulate the data collection procedure [13,35]. As with cognitive interviews, a major purpose of respondent debriefing is to determine whether the survey or vignette is interpreted as intended [23]. It also represents an opportunity to have respondents evaluate numerous desirable vignette characteristics quantitatively. This form of pretesting can identify whether vignettes are lacking in simplicity (thereby suggesting that vignette language needs to be simplified or defined), or clarity (suggesting the need to disambiguate details) [13]. Compared to cognitive interviews, debriefing is more standardized and quantitative, which makes it more useful for identifying and documenting the magnitude/prevalence of vignette problems [23]. In addition, because it is less time-consuming than cognitive interviewing, debriefing can include a greater number of respondents [36], which in turn generates a larger dataset that is more amenable to statistical analysis. Typically, the debriefing questions are posed in the same format as the survey (e.g. a questionnaire would be followed by a debriefing that also used a questionnaire, instead of a different format such as an interview) [35]. Generally speaking, it is preferable to ensure that debriefing respondents match the sampling frame as closely as possible to ensure that the result applies to the sample population [24,31].

Expert reviews involve gathering a purposefully selected group of experts to discuss relevant aspects of the study such as the design of the vignettes [30]. Ideally, this group should include content experts who are familiar with the topic being studied, and methodological experts who have experience with vignette development and evaluation [30]. Expert reviews have certain advantages over the other pretesting methods. By involving people with expertise, researchers can acquire sophisticated and articulate feedback about the vignette design. If a vignette is meant to depict a protagonist who meets diagnostic criteria for a physical or psychological condition, the face and construct validity of this vignette can be supported by showing that a panel of

clinicians would consistently suspect the desired diagnosis based on the information presented within the vignette [19]. Similarly, expert reviews can help to detect issues with construct conceptualization, especially if the conceptualization was meant to be consistent with the way experts define the construct.

Numerous researchers recommend using a combination of pretesting approaches in a multi-step procedure [22,23,28,30,31]. This has the advantage of combining the unique benefits of each method and cross-validating that the vignettes are ready for use [22,23,28,30,31]. Researchers using this multi-step approach will often commence with cognitive interviews or an expert review, followed by respondent debriefing [22,31,36].

### ***How many people should be included in the pretest?***

Not surprisingly, the number of people required to include in pretesting depends on the pretest approach and the overall study purpose, and the difficulty in recruiting individuals from the sampling frame. There are no hard and fast rules regarding the number of required participants. Generally, cognitive interviews include 5 to 15 participants [31,34,37], with anything greater than 20 being unusual [22]. Depending on the factors previously mentioned and the planned size of the overall study, respondent debriefing samples can range from ten to hundreds [30], with sample sizes even sometime reaching thousands [36]. Conversely, expert review panels tend to be small ( $n < 15$ ) due to the rarity of content and methodological experts, which can increase the difficulty in finding and recruiting them to help [38].

With expert panels and respondent debriefing, a larger sample size would be required if inferential testing is planned [23]. The exact sample size would depend on how much deviation from the ideal criteria researchers are willing to tolerate, and how much variability in ratings they are expecting both between vignettes and respondents. An *a priori* power analysis can be used to

determine the number of participants necessary to achieve a confidence interval of a desired width for any criterion ratings [39]. If it is suspected that the study might be underpowered to run inferential statistics on the pretesting data, a sensitivity power analysis can be useful to identify the smallest effect that you would be able to detect [39,40]. This result should be compared to the smallest difference considered practically important in order to determine whether the study can detect a meaningful range of effect sizes. If no quantitative analysis is planned, alternatively the criterion of “saturation” that is employed in qualitative research could be used, which involves stopping recruitment once no new problems or insights are gained by subsequent interviews [30]. However, relying on the criterion of “saturation” is likely most valid when the pretest sample is purposefully selected for variability across the sampling frame instead of being randomly selected. This would help to ensure that the most diverse feedback is acquired. If the participants are too similar, the saturation achieved may not reflect the full range of comments that would be provided by a more diverse sample.

***What types of questions should you ask the pretest sample?***

In most cases, the presence of a desired vignette characteristic can be assessed by asking respondents or experts how much of the characteristic they perceive as present in each vignette. Questions that assess respondent understanding of the facts presented in the vignettes can be useful for evaluating vignette clarity and simplicity, as inaccurate responses to factual questions can indicate difficult language, too many superfluous or distracting details, or ambiguous descriptions. Similarly, manipulation checks (e.g. asking participants if they noticed that the independent variable differed across vignettes) [32,41]) can help to evaluate vignette clarity and simplicity [28]. These checks also directly measure internal experimental realism (i.e. the

criterion that respondents notice and consider the manipulated variable when reacting to the different vignettes). In other instances, cultural neutrality can be assessed by asking respondents to explain references that may be culturally specific, and by identifying whether there are systematic misunderstandings or alternate interpretations that relate to the ethnicity, first language, or country of birth of the respondents.

Construct validity can be assessed through direct questions about the amount of the construct present in each vignette or by asking participants to rank the vignettes based on the criterion being evaluated. Questions directly assessing perceived relatability can be supplemented by measuring and quantifying the difference between respondents and the vignette protagonist in terms of demographics, social and socioeconomic circumstances, and self-reported values (thereby measuring so-called “disjunctures” between respondents and the protagonist [14,42]). Likert-type or sliding scale (e.g. 0-100) questions provide more precision and flexibility for analysis in assessing the perceived characteristics than yes/no questions and should therefore be preferred. When Likert-type scales are used, it is typically best to use 5- or 7-point rating scales, as these have better reliability, validity, and discriminating power than scales with less than 5 options, with further categories beyond seven showing diminishing returns [43,44]. These structured questions can be followed by more open-ended requests for commentary, as these can provide additional detail, point to any overlooked issues, and inform follow up questions.

### ***How should you analyze the pretest data?***

Once quantitative pretesting data has been collected, it must be interpreted using pre-defined criteria to judge whether the desirable characteristics are adequately present. To achieve this, at the very least any perceptions of the criteria should be tabulated [33] or described using

measures of central tendency and spread and compared to the pre-defined criteria. Hypotheses can also be made based on the results that would be expected if the criteria were present. For instance, if a vignette is meant to contain large amounts of one construct and no amount of the other, then this should be reflected in comparisons of the construct ratings. If the sample size is sufficiently large, inferential statistics should be used to test these hypotheses.

### *An illustrative example*

This section illustrates how pretesting data can be combined with descriptive and inferential tests to rigorously assess desirable vignette characteristics using data generated from a respondent debriefing. The example shows an extensive way to assess a criterion, as illustrated by construct validity. However, it also shows a less involved way of assessing multiple criteria. Results are taken from a recently completed vignette study that assessed whether patient choices that were both authentic and autonomous had additional instrumental value over choices that were solely autonomous. A range of pretests were conducted in the original study, including collaborator reviews of the survey, a respondent debriefing procedure regarding the study procedure, vignettes, and clinical scenario, and several computational linguistic analyses. However, in the present manuscript we focus on the respondent debriefing questions, since this part of the procedure generated quantitative data related to pretest participant perceptions<sup>14</sup>.

The clinical scenario in the original study involves a patient with early onset arthritis of the knee who is deciding between having a partial knee replacement or an osteotomy. Four vignettes were created, each describing a different sequence of events that could occur to the scenario

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<sup>14</sup> The results from the remainder of the pretesting procedures are available from the corresponding author upon request.



protagonist. The vignettes differ regarding the treatment chosen by the protagonist (i.e. an authentic vs. inauthentic choice) and whether this choice is made voluntarily (i.e. an autonomous vs. non-autonomous choice). Thus, vignette conditions were acting as manipulations of authenticity and autonomy. The definition of autonomy comes from an influential model of informed consent [45] and the definition of authenticity was informed by previous literature in ethics [45–48]. Markers of instrumental value in the original study included anticipated decisional regret, decisional satisfaction, and intentions to comply with medical instructions. As part of the pretesting procedure, thirteen respondents were recruited from the Mechanical Turk platform for a respondent debriefing procedure. This number was informed by both previous literature [30] and an a priori power analysis conducted using GPower software (v.3.1.9.4). A total sample size of 6 respondents would be required, assuming that a two-tailed, paired t-test was being conducted, with an alpha of 0.05, a beta of 0.05, a mean within-person difference of 75 rating points, and a standard deviation of 35 rating points (effect size  $d=2.14$ ). This smaller sample size was possible since the differences in the intended construct amounts both within and between vignettes were maximized by the chosen study design, where the construct was either meant to be completely present or completely absent.

To establish a common baseline, all pretest respondents were first presented with a reference vignette (i.e. the vignette describing a choice designed to be neither autonomous nor authentic) and were then presented with the three additional vignettes in random order. Following each vignette, respondents were asked to give ratings of their anticipated decisional regret, decisional satisfaction, and compliance with postoperative activity restrictions (as would the respondents from the full trial). After this, pretest respondents answered the debriefing questions.

The first questions evaluated whether the study procedures were too long or complex, and whether the clinical scenario was adequately clear and realistic. Responses to each question were provided on a five-point ordinal scale (ranging from “not at all” to “entirely”). Using open-ended questions, respondents were asked to elaborate on any issues they perceived and to suggest remediating strategies. If more than 20% of respondents were to identify a similar problem (defined as a response of “somewhat”, “very much”, or “entirely” for the questions assessing excessive procedure length and complexity, and responses of “somewhat”, “marginally” or “not at all” for the questions assessing adequate scenario clarity and realism), the plan was to revise the identified component and present it to the entire respondent debriefing sample for re-assessment. Next, respondents were presented with definitions of both autonomy and authenticity and were asked to give ratings of how authentic and autonomous the protagonist’s choice was in each vignette. Thus, each respondent contributed 4 autonomy and 4 authenticity ratings in total. Each rating was continuous (0-100), with anchors placed at the ends and midpoint of the response scale, with 0 meaning that the choice was “not at all” consistent with the construct, 50 meaning that it was “somewhat” consistent, and 100 meaning that it was “entirely” consistent.

Ratings from the respondents were used to test 12 hypotheses that, if supported, would each provide evidence of construct validity. These hypotheses were grouped into three categories based on the types of comparisons made (e.g., within or between people). Table 2 shows all hypotheses and provides the inferential tests used in each instance. Hypotheses categories are defined as follows:

- 1) Category 1 (Within-Vignette, Within-Person, Between-Construct): Two hypotheses were developed to predict, in each vignette, the difference in authenticity and autonomy ratings for each respondent. For example, we predicted that each respondent would rate the “authentic only”

vignette as having significantly higher levels of authenticity versus autonomy. These hypotheses were tested using paired t- tests.

- 2) Category 2 (Across-Vignette, Within-Person, Within-Construct): Six hypotheses (three for each construct) were developed to predict how respondent ratings would vary across vignettes. Two of these hypotheses predicted that on average, each respondent would rate the presence of the construct significantly higher in vignettes where this construct was intended to be present versus absent. The other four hypotheses predicted that on average, each respondent would not rate the presence of the construct differently between the two vignettes where it was intended to be present, as between the two vignettes where it was intended to be absent. These hypotheses were evaluated using Friedman tests with two types of follow-up tests: Asymptotic Wilcoxon-Pratt Signed-Rank tests [49] to evaluate expected differences, and two-sample equivalence tests [50] to evaluate expected equivalences (within an equivalence limit of +/-10 units).
- 3) Category 3 (One-sample, within-vignette, within-construct): Four hypotheses were developed to predict the average rating of each construct in a given vignette in comparison to expected construct amounts. In vignettes where the construct was intended to be present, the proximity of the average pre-test rating (allowing an equivalence margin between 75-100 units) to the expected value (100 units) was evaluated using one-sample non-inferiority test [50]. In vignettes where the construct was intended to be absent, the proximity of the average pretest rating (allowing an equivalence margin between 0-25 units) to the expected rating (0 units) was evaluated using a one-sample non-superiority test [50].

### ***Results of the respondent debriefing data analysis***

#### **Sample**

The respondent debriefing procedure only included respondents from the US who had a task approval rating of greater than 80% (i.e. had 80% or more of their previous tasks rated as being good by task requestors). Broad socio-demographic characteristics of the sample were collected, including respondent age, biological sex, and level of educational achievement (Appendix 1) The sample consisted primarily of non-religious individuals around the age of 36 (standard deviation=12) with some post-secondary education.

Abbreviated assessment of the clinical scenario and study procedure

On average, the respondents indicated that the study procedures were “not at all” too long or too complex (Figure 3, as shown by the red dots, which represent the interpolated median response to each question). Only 1/13 and 0/13 respondents gave ratings of “somewhat” or above for these criteria. Respondents on average also rated the clinical scenarios as being “entirely” clear and realistic (Figure 3). Only 1/13 and 0/13 respondents gave ratings of “somewhat” or below for these criteria. Thus, modifications to the scenario and procedure based on the respondent debriefing were not necessary.

### **Descriptive results**

The entire dataset of the vignette construct ratings is shown in Figure 4. For each of the four vignettes, this plot consists of the raw data displayed as a dot plot, a description of the overall distribution using a bean plot, and the mean and 95% confidence interval shown in a bar plot.

### **Within-person, within-vignette, between-construct hypotheses**

As hypothesized, respondents perceived significantly higher amounts of authenticity than autonomy in the solely authentic vignette (mean difference= -57 units,  $t = -7.9615$ ,  $p-$

value $<0.001$ ). Similarly, respondents perceived significantly higher amounts of autonomy than authenticity in the solely autonomous vignette (mean difference= 44 units,  $t = 4.6547$ ,  $p\text{-value}<0.001$ ). Thus, hypotheses 1-2 (Table 2) were supported.

### **Within-person, within-construct, between vignette hypotheses**

A Friedman test demonstrated that on average, vignette condition significantly impacted each respondent's autonomy rating (Table 3). Examining the contrasts, all the expected differences in authenticity ratings were statistically significant, while the expected equivalences were significant within an equivalence margin of ten units (Table 3). For instance, respondents gave significantly higher ratings of autonomy in the vignettes where autonomy was intended to be present than in those where it was intended to be absent (Table 3). This supports hypotheses 3-5 (Table 2). Similarly, a second Friedman test demonstrated that vignette condition had a significant effect on the average respondent's rating of autonomy (Table 4). Examining the contrasts, all the expected differences in authenticity ratings were statistically significant, while the expected equivalences were significant within an equivalence margin of ten units (Table 4). This supports hypotheses 6-8 (Table 2).

### **Proximity to intended ratings (One-sample, within-vignette, within construct)**

The one-sample non-superiority tests demonstrated that in all vignettes where either authenticity or autonomy was meant to be absent, the mean rating of the given construct was not significantly greater than 25/100 (Table 5). In addition, the one-sample non-inferiority tests demonstrated that in all vignettes where either authenticity or autonomy was meant to be present, the mean rating of the given construct was not significantly smaller than 75/100 (Table 5). Collectively, this supports hypotheses 9-12 (Table 2).

### **Overall conclusion regarding vignette construct validity**

In total, all 12 hypotheses were supported by the descriptive and inferential statistics employed, thereby providing strong evidence supporting the construct validity of all four vignettes. Thus, no further changes to the vignettes were required, and we proceeded to running the full study.

### ***Discussion***

This manuscript provides an introduction to using pretesting to increase the rigor of vignettes used in empirical ethics research. While criticisms of the empirical ethics literature have motivated beneficial actions, such as the recent consensus initiative to improve the quality of empirical ethics research [51], more specific guidance regarding different data collection methods must be disseminated. The content of this manuscript will prove useful to researchers who are designing vignette studies or are evaluating the development of vignettes used in other studies.

However, a review of past articles that discuss vignette use in empirical bioethics would also prove useful to beginning empirical ethics researchers. Hyman et al. [20] provide a useful comparison of two vignette study designs: the constant variable value vignette design (where all respondents are presented with identical vignettes, such as in our illustrative example) and the factorial design (where respondents are randomly assigned variations of the same vignette, with the variations reflecting differences in the presence or amount of independent variables). They also provide recommendations regarding the circumstances when each design may be preferable. While the focus is on business ethics, empirical ethics researchers in other areas will also benefit from the ideas in Hyman et al.'s paper.

Researchers would also benefit from reading, in full, Mudrack et al.'s criticism of vignette studies in empirical ethics. In addition to sharp critique, they provide an analysis of common themes in the content of ethics related vignettes (e.g. the runaway trolley problem, the whistleblower, etc.) and point out common problems with vignettes classified under each theme. Finally, they also present recommendations to develop a standardized set of vignettes, which if commonly used would facilitate comparisons between the results of different studies.

Østby and Bjørkly [21] present a procedure to write a set of candidate vignettes and narrow them down based on considerations such as vignette construct validity, familiarity, and relevance. The example provided focuses on ethical dilemmas faced by staff in interacting with individuals who have intellectual disabilities. However, the ideas within the paper are transferrable to other areas of empirical research. While the Østby and Bjørkly paper does not present the broad overview of pretesting found in the current manuscript, their proposed procedure provides another example of how pretesting could be implemented. More critically, Østby and Bjørkly dedicate considerable time to explaining the process of generating and refining vignette ideas, which complements the current manuscript well.

Finally, we recommend a chapter by Ulrich et al. [13], which focuses on the use of vignettes in empirical bioethics research. They discuss vignette studies broadly, including study design, vignette development, sampling, and data analysis. They also describe how vignettes have been used in past bioethics studies, and they outline the strengths and weaknesses of vignette studies more generally. As part of this, they discuss several approaches to pretesting that were not discussed in this paper (i.e. focus groups, pilot trials). However, they do not discuss sample size selection for a pretest procedure, designing pretest questions, nor the analysis of pretesting data. They also do not discuss as broad a range of desirable characteristics for vignettes as does this

manuscript. Thus, the content of this manuscript again complements the previous work.

Collectively, these four papers and the current manuscript represent a comprehensive foundation for conducting vignette studies in empirical ethics.

One unique contribution of the current manuscript is the comprehensive illustrative example of how to assess the construct validity of vignettes. It is rare that multiple hypotheses supporting the presence of desirable vignette criteria would be formally stated and then rigorously tested using inferential statistics. In testing 12 hypotheses (falling into three separate categories) for a single vignette characteristic, we present one of the most comprehensive assessments of a vignette criterion reported in the empirical literature. While researchers should not be expected to evaluate each criterion with such depth, a more truncated evaluation of key criteria (perhaps testing several hypotheses) would be valuable if made standard practice. As a new and innovative field of empirical investigation, empirical ethics research has an opportunity to not only match the rigor of the fields that it draws its methods from, but also to strengthen and expand upon existing standards. This would help the field to draw more valid inferences, avoid further criticism, and ultimately achieve the respect and recognition that it deserves.



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## Figures

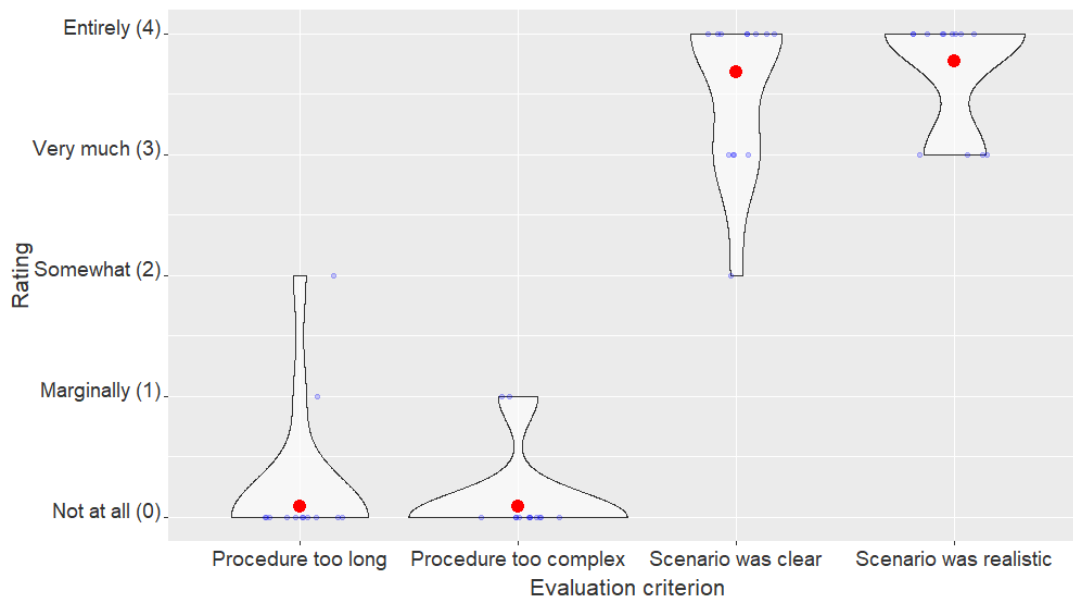


Figure 3- This combined dot and violin plot shows the pretesting questions related to the study procedure and clinical scenario. The small dots represent the individual data points. The violins (shapes) represent the probability density of each response category. The red dots represent the interpolated median responses for each question.



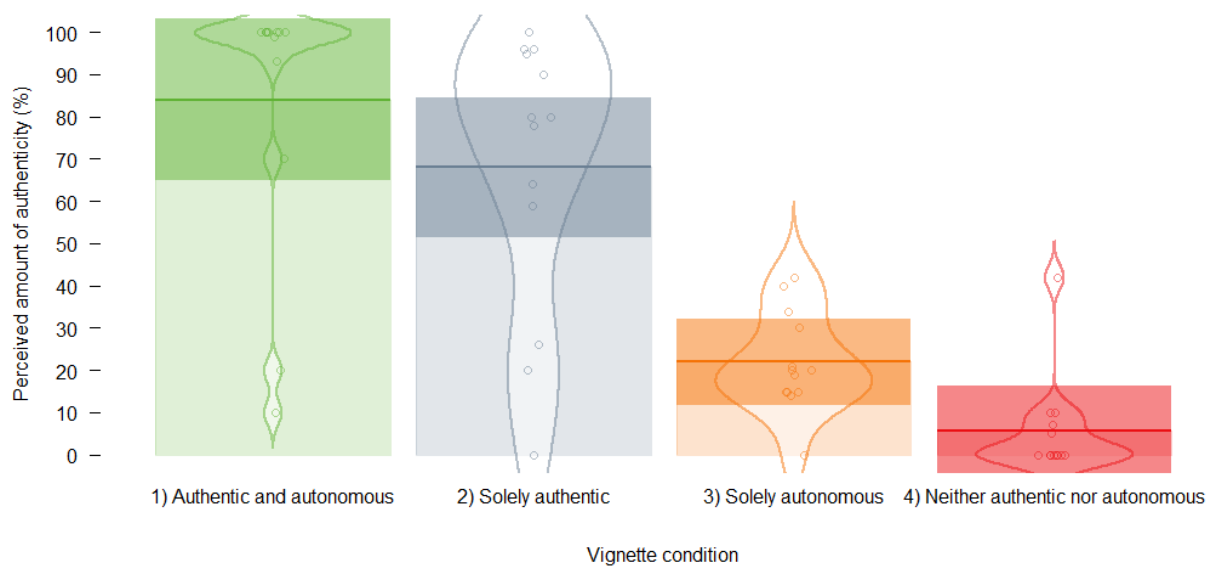
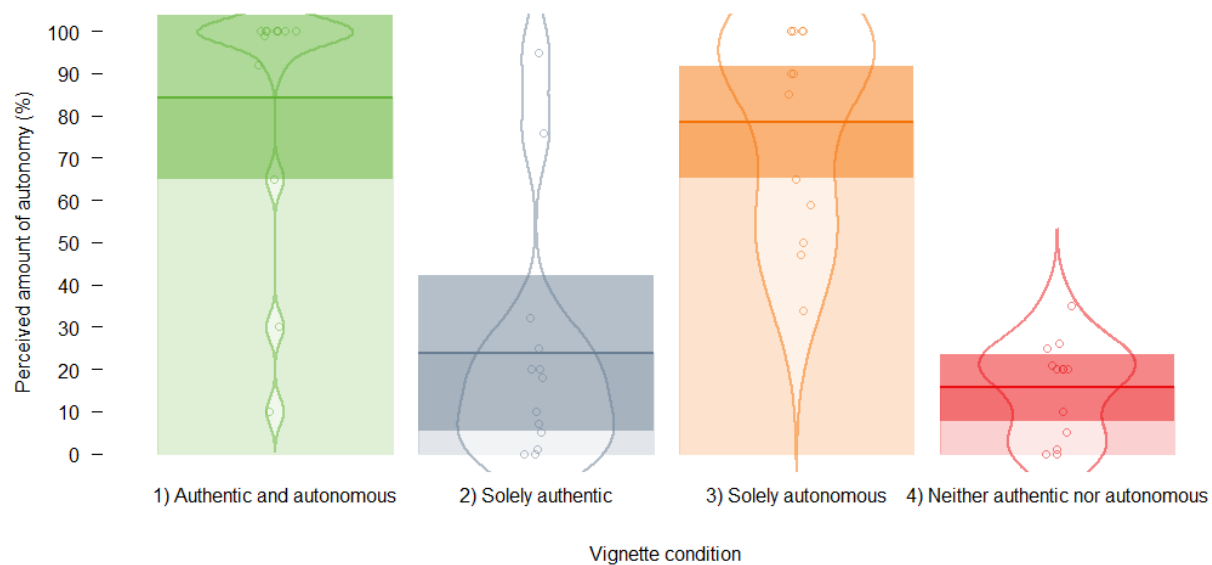


Figure 4-Pirate plots showing the raw data (dot plots), probability of each rating value (bean plot) and the median and 95% CI of the ratings (bar plot) regarding autonomy (top) and authenticity (bottom).

## Tables

Table 2- Hypotheses tested to provide support for vignette construct validity

Hypothesis category	Alternative hypotheses, which if true, would each provide evidence of construct validity:	Method of assessment
<b>Within-person, within-vignette, between-construct</b>	1. Ratings of authenticity are higher than the ratings of autonomy in the vignette presenting a choice that is authentic but not autonomous.	Paired t-tests
	2. Ratings of autonomy are higher than the ratings of authenticity in the vignette presenting a choice that is autonomous but not authentic.	
<b>Within-person, between-vignette, within-construct,</b>	3. There is more autonomy in the vignettes where autonomy is intended to be present than in those where it is intended to be absent.	Wilcoxon-Pratt Signed-Rank Tests (both vs. solely authentic; solely autonomous vs. neither)
	4. There is not a substantial difference in autonomy between the vignettes where autonomy is intended to be present.	Two-sample equivalence tests (equivalence margin +/- 10 units)
	5. There is not a substantial difference in autonomy between the vignettes where autonomy is intended to be absent.	
	6. There is more authenticity in the vignettes where authenticity is intended to be present than in those where it is intended to be absent.	Wilcoxon-Pratt Signed-Rank Tests (both vs. solely autonomous; solely authentic vs. neither)

	7. There is not a substantial difference in authenticity between the vignettes where authenticity is intended to be present.	Two-sample equivalence tests (equivalence margin +/- 10 units)
	8. There is not a substantial difference in authenticity between the vignettes where authenticity is intended to be absent.	
<b>Proximity to intended ratings (One-sample, within-vignette, within construct)</b>	9. The average amount of authenticity is $\geq 75/100$ in the two vignettes where authenticity is intended to be present.	One sample, non-inferiority tests (vs. 100, margin 75-100)
	10. The average amount of autonomy is $\geq 75/100$ in the two vignettes where autonomy is intended to be present.	
	11. The amount of authenticity is $< 25/100$ in the two vignettes where authenticity is intended to be absent.	One sample, non-superiority tests (vs. 0, margin 0-25)
	12. The amount of autonomy is $< 25/100$ in the two vignettes where autonomy is intended to be absent.	

Table 3-Friedman tests and contrasts to evaluate within-person, within-construct, between-vignette hypotheses regarding autonomy

<b>Friedman rank sum test</b>	<b>Chi-squared value</b>	<b>Degrees of freedom</b>	<b>P-value</b>
<b>Autonomy rating and vignette condition</b>	25.264	3	1.359e-05

**Contrasts - Asymptotic Wilcoxon-Pratt Signed-Rank Tests**

<b>Vignettes compared</b>	<b>Median within- person difference in autonomy rating (first listed minus second listed)</b>	<b>Z</b>	<b>p-value</b>	<b>Hypothesis being tested</b>	<b>Consisten t with hypothesi s?</b>
<b>Authentic and autonomous vs. Solely authentic</b>	82	2.83	0.004	H3	Yes
<b>Solely autonomous vs. Neither authentic nor autonomous</b>	65	3.18	0.001	H3	Yes

**Contrasts- two sample equivalence tests (equivalence within +/-10 units)**

<b>Vignettes compared</b>	<b>Median within- person</b>	<b>t</b>	<b>d</b>	<b>p-value</b>	<b>Hypothesis being tested</b>	<b>Consisten t with hypothesi</b>
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	<b>difference in autonomy rating (first listed minus second listed)</b>					<b>s?</b>
<b>Authentic and autonomous vs. Solely autonomous</b>	0	4.76	1.87	<0.001	H4	<b>Yes</b>
<b>Solely authentic vs. Neither authentic nor autonomous</b>	0	0.93	0.37	<0.001	H5	<b>Yes</b>

Table 4-Friedman tests and contrasts to evaluate within-person, within-construct, and between-vignette hypotheses regarding authenticity.

<b>Friedman rank sum test</b>	<b>Chi-squared value</b>	<b>Degrees of freedom</b>	<b>P-value</b>
<b>Authenticity rating and vignette condition</b>	27.798	3	<0.001

**Contrasts (Asymptotic Wilcoxon-Pratt Signed-Rank Tests)**

<b>Vignettes compared</b>	<b>Median</b>	<b>Z</b>	<b>p-value</b>	<b>Hypothesis</b>	<b>Consistent with hypothesis?</b>
	<b>within-person difference in authenticity rating (first listed minus second listed)</b>			<b>being tested</b>	<b>t with hypothesis?</b>
<b>Authentic and autonomous vs. Solely autonomous</b>	80	2.97	0.003	H6	Yes
<b>Solely authentic vs. Neither authentic nor autonomous</b>	70	3.15	0.002	H6	Yes

**Contrasts- two sample equivalence tests (equivalence within +/-10 units)**

<b>Vignettes compared</b>	<b>Median</b>	<b>t</b>	<b>d</b>	<b>p-value</b>	<b>Hypothesis</b>	<b>Consistent with hypothesis?</b>
	<b>within-person difference in autonomy</b>				<b>s being tested</b>	<b>t with hypothesis?</b>

	<b>rating</b> (first listed minus second listed)					
<b>Authentic and autonomous vs. Solely authentic</b>	10	1.26	0.494	<0.001	H7	<b>Yes</b>
<b>Solely autonomous vs. Neither authentic nor autonomous</b>	15	3.55	1.39	<0.001	H8	<b>Yes</b>

Table 5-Non-superiority and non-inferiority tests evaluating the proximity of the observed ratings to the intended ratings.

Vignette Condition	Authenticity		t	d	p-value	Hypothesis being tested	Consistent with hypothesis?
	Ideal rating (equivalence limits)	Mean rating					
<b>Both present</b>	Non-inf. (100, 75- 100)	84.0	- 1.82	-0.50	<0.001	<b>H9</b>	<b>Yes</b>
<b>Autonomy alone</b>	Non-sup. 0, 0-25)	21.9	- 3.51	-0.97	<0.001	<b>H11</b>	<b>Yes</b>
<b>Authenticit y alone</b>	Non-inf. (100, 75- 100)	68.0	6.75	1.87	<0.001	<b>H9</b>	<b>Yes</b>
<b>Neither</b>	Non-sup. (0, 0-25)	5.6	1.77	0.49	<0.001	<b>H11</b>	<b>Yes</b>
Vignette Condition	Autonomy		t	d	p-value	Hypothesis being tested	Consistent with hypothesis?
	Ideal rating (equivalence limits)	Mean rating					
<b>Both present</b>	Non-inf. (100, 75-	84.3	- 1.86	-0.52	<0.001	<b>H10</b>	<b>Yes</b>



	100)						
<b>Autonomy alone</b>	Non-inf. 100, 75-100)	78.5	- 3.22	-0.89	<0.001	<b>H10</b>	<b>Yes</b>
<b>Authenticity alone</b>	Non-sup. (0, 0-25)	23.8	2.91	0.81	<0.001	<b>H12</b>	<b>Yes</b>
<b>Neither</b>	Non-sup. (0, 0-25)	15.6	5.00	1.39	<0.001	<b>H12</b>	<b>Yes</b>

**Appendix 1- Pilot study demographics and characteristics**

Table 6- Pilot study demographics and characteristics

**Pretest (n=13)**

<b>Variable</b>	<b>Level</b>	<b>Frequency (%)</b>
<b>Sex</b>	Male	5 (38%)
	Female	8 (62%)
<b>Religion</b> (only populated categories shown)	Christianity	3 (23%)
	Spiritual but not religious	1 (8%)
	Nonreligious (E.g. Secular/ Agnostic/ Atheist)	9 (69%)
<b>Highest level of Education completed</b>	Elementary school	0 (0%)
	High school	2 (15%)
	Associates degree	5 (38%)
	Undergraduate degree	5 (38%)
	Graduate degree (e.g. MA, PhD, etc.)	1 (7%)
<b>Variable</b>		<b>Median (IQR)</b>
<b>Age</b>		38 (27-44)

## **E. Prologue to chapter 4**

The philosophical manuscript proposes seven procedural practices to reflect the addition of authenticity to the standard model of valid consent. While the empirical paper does not directly assess the impact of the proposed procedural practices, it does test whether the goal that underlies the authenticity-informed model of valid consent (i.e., promoting choices that are both authentic and autonomous) has instrumental value in a consequential clinical scenario. This relates to the third postulated benefit of the recommended procedural practices (i.e., that the procedural practices would result in an increase in the number of authentic and autonomous choices, which in turn would better support the psychological and physical wellbeing of patients). Manuscript three (Chapter 4) applies the vignettes established in Chapter 3, and empirically assesses if the addition of authenticity to an autonomous decision impacts decisional regret, decisional satisfaction, and compliance with postoperative instructions.

**F. Chapter 4: Should we promote patient choices that are both  
autonomous and authentic? A vignette study of layperson  
reactions to authentic and inauthentic choices**

Alexander Villafranca\*, Corey Mackenzie\*\*, Arthur Schafer\*\*\*, Stephen  
Moses\*, Malcolm Doupe\*

*\*Department of Community Health Sciences, University of Manitoba, Winnipeg,  
Canada*

*\*\*Department of Psychology, University of Manitoba, Winnipeg, Canada*

*\*\*\*Department of Philosophy, University of Manitoba, Winnipeg, Canada*

Please address correspondence to Alexander Villafranca, CR31-42, 369 Tache Ave,  
Winnipeg, Manitoba, Canada, [umvilla5@myumanitoba.ca](mailto:umvilla5@myumanitoba.ca)

## *Abstract*

**Background:** A valid consent is an autonomous choice. Some ethicists suggest that consent should also be authentic (i.e. consistent with the self). However, the value of shifting from a choice that is solely autonomous to one that is both authentic and autonomous is unknown. We hypothesized that such a shift (in the medical context) would increase patient decisional satisfaction, decrease decisional regret, and promote compliance with postoperative instructions.

**Methods:** We developed four vignettes outlining different patient choices related to knee surgery (i.e. a choice that was solely autonomous, solely authentic, both, or neither). The clinical scenario was chosen in part because a single instance of non-compliance with postoperative activity restrictions could result in surgical failure. A randomized block design was used; 91 Mechanical Turk respondents reacted to each vignette by stating their anticipated decisional regret and satisfaction, and by endorsing a question examining compliance with postoperative activity restrictions. For each outcome, we calculated the within-person percent point (pp) difference scores between the “authentic and autonomous” and the “solely autonomous” vignette conditions. Wilcoxon signed-rank test with continuity correction (regret, satisfaction) and an asymptotic Wilcoxon-Pratt Signed-rank test (compliance) determined whether the median difference between vignette conditions differed from zero. The consistency of the results between demographic subgroups was examined using stratified analysis.

**Results:** Median within-person differences for all outcomes differed significantly from zero (regret= -40pp, satisfaction= 29pp, compliance=25pp, all  $p < 0.01$ ), with authenticity on average increasing satisfaction to 100% capacity and decreasing regret to 5% capacity. There were over 8 times as many respondents who

anticipated non-compliance in the autonomy only condition (17/91) compared to the authentic and autonomous condition (2/91).

**Conclusions:** Shifting to an authentic and autonomous choice increased anticipated satisfaction and compliance, while decreasing anticipated decisional regret. Clinicians may consider encouraging patients to make choices that are both authentic and autonomous. Future research should replicate these findings using other scenarios.

Key Words: authenticity, vignette, consent, autonomy, ideal self

### ***Introduction***

In order for healthcare providers to perform a medical procedure on a competent patient in an ethical manner, the patient must first provide valid consent. Consent is valid when it represents an autonomous choice on the part of the patient <sup>1</sup>. An “autonomous choice”<sup>xv</sup> is typically defined as one that is made by a person who is acting voluntarily, with an adequate understanding, and who has the decisional capacity to make the choice at hand <sup>1,2</sup>. Autonomous choices are seen as valuable due either to their intrinsic value (i.e. in and of themselves) or instrumental value (i.e. in promoting other good things, such as beneficial consequences)<sup>3</sup>.

In the past sixty years, “authenticity” has also become an important value in Western society <sup>4-7</sup>. In one sense, an “authentic choice” is one that is consistent with some aspect of the self <sup>8</sup>. Some philosophers suspect that authentic choices may also be intrinsically or instrumentally valuable. This has led them to consider the view that authenticity

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<sup>xv</sup> For the purposes of this paper, I will be placing terms in quotes to distinguish references to a word from uses of a word, as is common practice in analytic philosophy.

should be a separate necessary condition of autonomous choices<sup>1,9-12</sup>, a necessary condition for a component of autonomous choice (i.e. voluntariness)<sup>2</sup>, or a component of the capacity to consent<sup>13</sup>. Critics of this view have argued that including “authenticity” in a model of valid consent may not provide adequate instrumental value to merit the additional effort<sup>14-17</sup>. There is a lack of empirical evidence in support of the claim that shifting from a decision that is solely autonomous to one that is both autonomous and authentic would provide additional instrumental value in the context of clinical informed consent.

The purpose of this vignette study is to evaluate the instrumental value of shifting from a choice that is solely autonomous to a choice that is both authentic and autonomous in a single but consequential clinical scenario. Study outcomes included several recognized patient-centred affective outcomes (i.e., decisional satisfaction and decisional regret related to their choice of operational procedure)<sup>18</sup> and a relevant patient behavioural intention (i.e., to follow postoperative instructions). Respondents were instructed to assume that the given surgery went as planned, with the anticipated benefits and limitations of each treatment. Given the ethical concerns associated with manipulating the autonomy and authenticity of patient choices in an experimental setting, a vignette study design was used. We hypothesized that shifting from a choice that is a solely autonomous choice to one that is both authentic and autonomous would provide additional instrumental value to the patient in the form of altered patient-centred outcomes and behavioural intentions.

## *Methods*

### **Vignette development and stipulated definitions**

A clinical scenario and four vignettes were developed using a multi-step procedure, informed by previous work by our group<sup>19</sup>. Numerous strategies were used to increase the rigor of the vignettes. These included having investigators review the vignettes and provide feedback and using computational linguistic analysis to help simplify the language used<sup>20</sup>. The vignettes were also pretested on 13 Mechanical Turk<sup>xvi</sup> respondents using respondent debriefing<sup>21,22</sup>. Using this data, a series of analyses were conducted to ensure that common problems with variable representation in vignettes were being prevented or remediated. Analytical techniques used for these steps included equivalence, non-superiority, and non-inferiority testing<sup>25</sup>, and traditional inferential testing.

The vignettes describe a patient making a choice that was either solely autonomous, solely authentic, both, or neither. Consistent with an influential model<sup>1</sup>, we defined an autonomous choice as one that is made by a person who is acting intentionally, with an adequate understanding and appreciation of the decision at hand, and without the influence of controlling interests. Since there is no universally accepted definition of an “authentic choice”, we concurrently represented several prominent and

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<sup>xvi</sup> Mechanical Turk is a crowdsourcing marketplace where respondents are paid by requestors to do human intelligence tasks such as completing surveys. It is commonly used for psychological research.



influential candidates in our vignette<sup>1,26-28</sup>. These included coherence of the choice with one's ideal self, one's long-term plans, one's expressed values, and one's past actions.

The specific clinical scenario presented describes a patient (protagonist) with early onset arthritis of the knee who is deciding to undergo either a partial knee replacement or an osteotomy (i.e., a surgery to modify the shape of the tibia or femur to relieve pressure on the knee). The partial knee replacement would allow the protagonist to recover faster with better pain control during and after recovery but would limit the physical activities he could perform in the longer-term. The osteotomy would restore the protagonist to full functioning in the long-term but would cause him to recover more slowly with poorer pain control. We described the protagonist as having a past life centred on high-impact physical activity, plans to continue this lifestyle in the future, an ideal self that embodied physically active living, and an implied value system prioritizing function over pain control. Thus, in this scenario the partial knee replacement would be inauthentic, given its inconsistency with these aspects of him, while the osteotomy would be authentic, given its consistency with these aspects. The vignettes differ regarding the treatment chosen by the protagonist, with the choices being neither authentic nor autonomous, solely autonomous, solely authentic, or both authentic and autonomous. This scenario is consequential because the inauthentic choices would permanently prevent the protagonist from participating in his preferred authentic activities and would decrease the range of authentic activities in which he could partake. Additionally, in this circumstance single instance of non-compliance with these activity recommendations could result in surgical failure.

This study focuses on the benefits of shifting from a solely autonomous choice to one that is both authentic and autonomous, and hence only considers the “solely

autonomous” and “authentic and autonomous” conditions. In the “solely autonomous” condition, the patient autonomously chose to undergo the partial knee replacement. His rationale for selecting this inauthentic choice was to favour a short-term consideration over the potential long-term benefits of the authentic choice (thereby acting as a form of hyperbolic discounting<sup>29</sup>). In the “authentic and autonomous” condition, the patient autonomously chose the osteotomy, which is consistent with all the represented aspects of himself. The final version of the clinical scenario and vignettes is found in **Appendix 1**.

## **Design**

Vignettes were presented using a randomized block design. To establish a common baseline, we first presented each respondent with a reference vignette scenario (i.e. a lack of autonomy and authenticity). Each respondent then received, in random order, the three other vignettes.

## **Power calculation and sampling**

Power calculations were conducted using g-power (V.3.1)<sup>30</sup> and were based on the pre-test data. The outcome with the lowest difference to standard deviation ratio of the three outcomes was used for the test (decisional regret). Assuming an alpha of 0.05, a beta of 0.05, a mean difference of 12 and a standard deviation of 22 (corresponding to an effect size of 0.55) and the use of a two-tailed Wilcoxon signed-rank test, a minimum of 48 respondents would be required.

The sample was a crowd-sourced, non-probability, convenience sample recruited from the Mechanical Turk platform<sup>31,32</sup>. This study only included respondents

from the US who had a task approval rating of greater than 80% (i.e. had 80% or more of their previous tasks rated as being good by task requestors). Broad socio-demographic characteristics of the sample were collected, including respondent age, biological sex, and level of educational achievement.

### **Quality assurance**

To ensure data quality, two attention checks and two bot checks were embedded within the survey. The former was included to eliminate respondents paying inadequate attention to the study tasks, and the latter to eliminate respondents using bots to automate survey completion. Attention checks included the Likert-style items “I am not paying attention to the answers that I am giving for this survey” and “I am checking boxes in this survey completely randomly”, with response options ranging from “strongly disagree” to “strongly agree”. Responses indicating ambivalence or agreement were considered failed attention checks. Bot checks involved displaying simple photos and asking the respondents to identify the subject of the photo. In one instance, a photo of a baby was shown, and the respondents were asked to identify whether the subject of the photo was a child, teenager, or adult. In the other instance, a blurry photo of an illuminated Eiffel tower was shown, and the respondents were asked to select the displayed landmark from a list of options. All other options were transparently not plausible given the rough shape and lighting of the object (i.e. “Great wall of China”, “Hollywood sign in Los Angeles”, “Mount Everest”). Any subject who failed one or more of the attention checks or bot checks was omitted from the study and replaced with an additional respondent.

Responses were also screened based on the time it took to complete the survey. Surveys

completed in less than five minutes were rejected due to a higher probability of being a bot or a respondent who was providing thoughtless responses. In addition, surveys completed in more than one hour were rejected due to a higher probability of being a stalled bot, a multi-tasking respondent, or a respondent completing the survey in a discontinuous manner. To target high-quality survey respondents on the Mechanical Turk platform who set alerts regarding higher paying tasks, we paid participants seven US dollars to complete the survey.

### **Outcome selection, measurement and psychometric verification**

We selected three outcomes that served as indicators of instrumental value. Respondent affect was measured using anticipated feelings of satisfaction with the decision-making process and anticipated medium to long-term regret regarding the decision itself (assuming that the procedure went as planned, with the expected benefits and limitations).

Anticipated respondent regret was measured using the “Decisional regret scale”<sup>33</sup>. This five-item Likert-style scale asks respondents to endorse questions on a five-point response scale ranging from “strongly agree” to “strongly disagree. Higher scores indicate greater regret. It is recommended by the creators of the scale to express the score on a scale from 0-100 to enable comparisons with other scales and outcomes<sup>34</sup>. Previous studies have demonstrated evidence of reliability (Cronbach’s alpha=0.81-0.92), and evidence of validity based on factor structure and consistency with theory<sup>34</sup>.

Anticipated respondent satisfaction was measured using the “Satisfaction with decision-making” scale<sup>35,36</sup>. This six-item, Likert-style scale asks respondents to endorse

questions on a five-point response scale ranging from “strongly disagree” to “strongly agree”. Higher scores indicated greater satisfaction. Previous studies have demonstrated evidence of reliability (Cronbach’s alpha= 0.85-0.86)<sup>35,36</sup> and evidence of validity based on factor structure and consistency with theory.

The previously established one-factor structure of both scales was evaluated on our dataset using two separate multi-level confirmatory factor analyses in R statistical software (V.3.5.1)<sup>37</sup>. In addition, the internal consistency of the dataset, both overall and stratified by condition/trial, was established using Cronbach’s alpha and Cronbach’s alpha with deletion<sup>38</sup>. These steps ensured that both tools generated valid and reliable scores in this new context.

Respondent’s willingness to comply with postoperative activity restrictions was measured using a single question that was extracted from the “Satisfaction with decision-making” scale<sup>35,36</sup>. The final question posed was, “I expect to carry out (or continue to carry out) the decision I made (“e.g. avoid activities that are not recommended after my surgery”). The bracketed example was added to give respondents additional information about what “continuing to carry out” the decision would mean in the context of surgery (i.e. compliance with postoperative activity restrictions). This outcome was selected as a lack of compliance with treatments and post-treatment lifestyle modifications is an important problem in healthcare, with non-compliance ranging from 4-50%, depending on the clinical population and specific instruction in question.<sup>39-43</sup> This places patients at risk of experiencing the side-effects and possible harms of treatment without the ensuing benefits<sup>39</sup>. In the context of the clinical scenario used, postoperative instructions would include physical activity restrictions (varying based on the surgery). A single instance of non-compliance (e.g. by

John doing Karate once, or training someone once) could result in reinjury, further injury, or surgical failure.

Raw scores for each of the three outcomes were converted to a percentage of the highest achievable score (i.e., percent capacity). This strategy retains the relative rankings of the scores and facilitates descriptive comparisons between study outcomes both within and across vignette conditions. It has also been suggested for at least one of the tools<sup>34</sup>.

Within-person differences in the study outcomes between the two vignette conditions were defined as percentage points (p.p.). For instance, a respondent with a satisfaction score of 20 percent capacity in the “solely autonomous” vignette condition and 30 percent capacity in the “authentic and autonomous” vignette condition would have a 10p.p. improvement).

### **Statistical analysis**

The statistical analysis was conducted in R statistical software (V.3.5.1). Our study design enables us to measure “within-person” changes in study outcomes between the ‘autonomous only’ and ‘autonomous plus authenticity’ vignette conditions. Paired t-tests were first attempted, however q-q plots and Shapiro Wilk’s tests demonstrated non-normal residuals for all outcomes (all  $p < 0.01$ , data not shown). A series of outcome transformations to correct for over-dispersion (including log 10, square root, negative reciprocal, minus median & then cubed, folded log, folded root, and arc-sin) could not correct the issue. A Wilcoxon signed-rank test with continuity correction was therefore used to test whether the median difference between vignette conditions regarding decisional regret and decisional satisfaction was significantly different from zero. The continuity correction was applied due to the pseudo-continuous or discrete nature of the

data. Due to the larger number of zero differences (41/91) in the compliance outcome, an asymptotic Wilcoxon-Pratt Signed-rank was used to test this outcome<sup>44</sup>. Lastly, in order to determine the consistency of the study results, we stratified the dataset into demographic subsamples based on biological sex, age (i.e.  $\geq$ / $\leq$  the median sample age of 32 years), and educational attainment (i.e. bachelor's or postgraduate degree versus less education). For each of the subgroups, the asymptotic Wilcoxon-Pratt signed-rank test was used to determine whether the median outcome differences between vignette conditions were significantly different from zero (due to the proportion of zero values sometimes increasing with stratification). We used Holm's sequential Bonferroni procedure of adjusting for multiple comparisons for this stratified analysis<sup>45</sup>. Missing data was identified as responses were received and incomplete responses were treated using list-wise deletion, with data collection continuing until we had 91 complete responses.

### **Ethics approval**

Ethics approval for the study was obtained from <institutional name deleted for peer review>.

## ***Results***

### **Data quality assurance and sample description**

In total, 13 responses were excluded from the analysis (six failed attention checks, two failed bot checks, four incomplete responses and one duplicate response). Each was replaced with a new respondent at the time of data collection. The median time of the included respondents was 16 minutes and 8 seconds, with an IQR of 12 minutes and ten seconds to 20 minutes and 34 seconds. Only one respondent had a completion time

outside of the allowed range (2 minutes and 21 seconds). However, this respondent was already excluded based on a failed attention check. The factor structure and internal consistency of the dataset related to decisional satisfaction and regret were found to be good based on repeated measures confirmatory factor analysis (data not shown) and Cronbach's alpha with and without deletion. This justified the use of the scales with this sample. Across all vignette conditions, alpha was 0.96 for decisional regret, and 0.92 for decisional satisfaction.

Demographic characteristics are shown in Table 7, with included and excluded respondents shown separately. For reference, these are placed alongside demographic percentages from the 2017 US census<sup>46,47</sup>. There were several notable differences between the sample and the US population. Specifically, our sample contained a larger proportion of men (61% vs. 49%), people with undergraduate degrees (44% vs. 20%), and fewer people who had not completed high school (0% vs. 11%). Our sample was also slightly younger (median age 32 vs. 38). Included and excluded respondents were similar, aside from the excluded responses containing a much larger proportion of individuals with graduate degrees. These more educated individuals may be more likely to have the programming skills to create and use bots that complete surveys.

### **Descriptive Study Results**

The distribution of outcome scores for each of the two vignette conditions is shown in Figure 5. The median satisfaction score was 54% and 100% of capacity, within the “solely autonomous” and “authentic and autonomous” vignette conditions, respectively. Similarly, the median regret score was 65% and 5% of capacity for the “solely autonomous” vignette condition and “authentic and autonomous” vignette condition, respectively.



The median anticipated rating of compliance with postoperative activity restrictions was 75% and 100% capacity for the “solely autonomous” and “authentic and autonomous” condition, respectively (Figure 5). The shift also affected the tails of the distribution. First, the number of respondents who strongly agreed with the statement of compliance was three times as many in the “authentic and autonomous condition” (54/91, 59%) compared to the “solely autonomous” condition (18/91, 20%). Second, the number of respondents who either disagreed or strongly disagreed with the statement (thereby indicating an intention not to comply) was 9 times greater in the solely autonomous” condition (17/91, 18%) compared to the “authentic and autonomous condition” (2/91, 2%).

### **Inferential Study Results**

The inferential tests (Table 8) and the plots of the within-person percentage point improvements support the descriptive findings. Across vignette conditions, anticipated patient satisfaction increased a median of 29 p.p. ( $p < 0.01$ ), decisional regret decreased a median of 40 p.p. ( $p < 0.01$ ), and anticipated compliance with post-operative activity restrictions increased a median of 25 p.p. ( $p < 0.01$ ). These results did not vary statistically across participant age, sex or educational attainment (Appendix 2).

### ***Discussion***

This study demonstrates that shifting from an elective surgical choice that is solely autonomous to one that is both authentic and autonomous was seen by most respondents as likely to decrease their decisional regret, increase their decisional satisfaction, and increase their endorsement of a question evaluating the anticipated compliance with postoperative activity restrictions.

As an outcome, regret matters. It negatively affects the well-being of the agent who is experiencing the emotion. In the postoperative context, greater decisional regret scores are correlated with higher patient anxiety scores<sup>48</sup>, lower quality of life scores<sup>49,50</sup>, and greater symptoms of depression<sup>51</sup>. The median within person decrease of 40pp for decisional regret associated with authentic choices therefore represents a large effect, both statistically and practically. For reference, a recent review examined post-decision regret scores in the context of a variety of healthcare decisions (oncology, genetics, family practice, rheumatology, etc.). It also only included studies measuring regret with the same decisional regret scale that we used. This review found that the average regret score across 59 studies was 17/100 (range 3-49)<sup>52</sup>. The amount of anticipated decisional regret being reported in our “solely autonomous” vignette condition is nearly five times this amount, being 65/100. Admittedly, the difference in effect sizes may be due in part to the review’s focus on retrospective regret, compared to our focus on anticipated regret<sup>53,54</sup>. Nevertheless, the decrease to a median of 5 percentage points in the “authentic and autonomous” condition put respondents in a situation where they have almost no regret, representing a substantial percent decrease even from the average regret score reported in the review.

The shift in decisional satisfaction shown in the present study is also substantial, with a median increase of 27pp, leading to a median score of 100% (as high as possible). This provides evidence that authentic and autonomous choices (in the absence of complications) are a plausible way to help promote full decisional satisfaction. Patient satisfaction (regarding process and outcomes in medical care) is an important outcome, since it is a useful indicator of the quality of patient care<sup>18</sup>. Since the respondents were all from the USA, it is also worth pointing out that in their privatized

healthcare system, patient satisfaction metrics can influence institutional market share and are used to secure approval, funding, and bonuses from certifying bodies and health systems<sup>55,56</sup>.

The median anticipated compliance response in the “solely autonomous” vignette condition was 75/100, representing the Likert option “agree”, while the median response in the “authentic and autonomous” vignette condition was “strongly agree”. These results are somewhat intuitive, since the protagonist in the “solely autonomous” condition would have had to alter his lifestyle dramatically and permanently in such a way that would exclude his preferred authentic actions and the surgery would reduce the range of authentic actions in which he could partake (unless he alters his identity). This could lead to the temptation to participate in contraindicated activities. Conversely, the authentic choice would require little long-term lifestyle modification. Any decrease from the highest level of certainty regarding compliance is important, as a single instance of high impact physical activity following the inauthentic choice could cause dislodging of the implant (surgical failure), thereby requiring further surgery. The effect of the shift on the tails of the distribution underscores this point, with the number of respondents endorsing the highest level of agreement being tripled, and the number of respondents explicitly indicating some level of anticipated non-compliance being over 8 times higher in the autonomy only condition.

Our findings that authenticity is associated with improved patient-centred outcomes involving affect are supported to some extent by the psychological and medical literature. The psychological literature has established associations between trait “authenticity” and numerous benefits including improved measures of psychological health, coping skills, self-concept, healthy role functioning, goal pursuits

and relational functioning<sup>57-63</sup>. While this literature focuses on the benefits of either being a person who has a self-reported propensity to act in an authentic manner (i.e. having a high “trait authenticity”), or feeling as though one is an authentic person in a particular circumstance (i.e. having a high “state authenticity”)<sup>64</sup>, in the present study we have focused on the benefits of making a single choice that could undermine the patient’s ability to act authentically in the future. The psychological studies also do not separate the benefits of authenticity from those of autonomy. For instance, the two most influential psychological scales used to assess trait authenticity include questions that address “procedural independence”, which parallels the necessary condition for autonomous choice that is “voluntariness”. Specifically, one of these authenticity scales includes “accepting external influence” as a latent factor that undermines an agent’s authenticity<sup>65</sup>, while the other<sup>63</sup> contains specific individual questions that address procedural independence. The present study demonstrates that the presence of authenticity in patient choices adds value that is additional to the value brought by the presence of autonomy.

Substantial medical literature focuses on the broader idea of patient-centred *care*, whose conceptualization typically includes an increased consideration of the coherence between patient choices and patient preferences, beliefs, and/or values<sup>66,67</sup>. While the word “authenticity” is not used, this approach includes several non-hierarchical and non-substantive definitions of authenticity into a model of care. The use of patient-centred care is associated with decreased healthcare utilization and less frequent hospitalization<sup>68</sup>, improved adherence to prescribed medications<sup>69</sup>, and reduced patient stress<sup>70</sup>. However, this approach to medical decision-making includes numerous other elements aside from the presence of “authenticity” as coherence with

patient values. Many of these are procedural, focusing on the manner in which clinicians should go about providing care, and/or relational, focusing on improving the clinician-patient relationship<sup>66,71,72</sup>. While some of these elements may be valuable because they help patients make choices that are authentic, they may also provide value on their own. Thus, the extent to which the benefits of patient-centred care originate from authentic decision-making is unclear. Nevertheless, our study is broadly consistent with examinations of patient-centred care, which have demonstrated psychological and behavioural benefits for patients.

This study has several potential limitations. First, these data were derived from a crowd-sourced convenience sample that is not representative of the general population in terms of demographics, health status and health behaviours<sup>32,73</sup>. However, it is more representative and diverse than other convenience samples often used in social science research, such as first year psychology students<sup>32</sup>. In comparison with a cohort of first year students from a single institution, our sample has greater diversity in terms of respondent age, education, and geographical location. In addition, many experimental interventions used on Mechanical Turk sampling frames result in similar sized effects as those seen in convenience or national probability samples<sup>74,75</sup>. Furthermore, when differences occur, Mechanical Turk samples more often result in underestimations of effect size than over-estimations<sup>32</sup>. Any underestimations of effect size would only underscore the importance of our results. Most importantly, data from mechanical Turk has been found to be comparable in quality to other convenience samples, as indicated by similar levels of passed attention checks, time spent completing the survey, open-ended descriptions of the survey, and self-reported instances of multi-tasking<sup>76</sup>.

As a second limitation, our vignettes used a scenario representing a composite of several definitions of “authentic choice”. These definitions are similar, in the sense that they are all non-hierarchical<sup>77</sup> (i.e. they do not normally require a reflective endorsement of the agent’s actions, plans, values, or ideals, contrary to other influential accounts of “authentic choice”<sup>12,78</sup>). They also allow each person to have their own personal criterion against which the authenticity of an action can be judged (i.e. their own values, ideal self, past actions, etc.). This is in contrast to “substantive accounts” of authenticity<sup>79,80</sup>, which require that authentic choices meet a criterion that is not specific to the agent in question. Candidates for such a criterion include moral adequacy, transparency, sincerity, or consistency with a particular aesthetic (such as non-conformity, spirituality, etc.)<sup>16,17,81</sup>. We have at least established that there is instrumental value in promoting choices that are broadly “authentic” in non-substantive and largely non-hierarchical senses, with the exact value of each included sense requiring further investigation.

As a third potential limitation, it is possible that respondents reacted differently to vignettes than they would have in real life. However, given our study design, which included manipulations of autonomy, our experiment would not be ethical in real life medical settings. On a related note, we did not attempt to cross-validate the results with data that was collected using a methodology other than survey-based research. This may leave the study open to mono-method bias<sup>82</sup>. Combining survey data with observational data from patients was not feasible for this project but may be considered in the future once appropriate tools to measure the autonomy and authenticity of a choice are developed.

This study also has notable strengths. It relies on a well-accepted definition of “autonomous choice” and a definition of “authentic choice” that differentiates it from “autonomous choice”. This study also used vignettes that were developed using a comprehensive multi-step procedure<sup>83</sup>. It examined instrumental value using three separate indicators, and assessed latent outcomes using developed and widely used survey scales, where available. It also used a rigorous complete block design, which involved randomization after the presentation of a reference vignette.

Future research is required to confirm and extend the present study findings. Since the influence of the presence of authenticity may vary depending on the clinical decision in question, future vignette studies should examine alternative clinical scenarios. For instance, decisional regret tends to be lower when patients make decisions related to health screening or prevention, as opposed to treatment decisions<sup>52</sup>. Since respondents may react differently to vignettes compared to real life, observational studies could be employed to track the autonomy and authenticity of patient choices in a clinical setting and measure the relationship between these variables and actual decisional regret, satisfaction, and compliance with activity restrictions at one year postoperatively. In addition, the impact of authenticity on behavioural intentions in situations where the patient experiences surgical failure or complications should also be examined. Finally, other behavioural intentions or patient-centred outcomes (e.g. Compliance with other medical instructions, coping strategies) should be studied to examine more fully the instrumental value of shifting to a decision that is both authentic and autonomous.

In conclusion, this study demonstrates that authenticity, broadly conceived, offers benefits above those of autonomy concerning decisional regret, satisfaction, and

anticipated compliance with postoperative instructions in at least one medical context. If future research confirms these benefits in a broader range of circumstances, across other samples, and using other methods of assessment, this would provide good evidence that clinicians should strive to *ensure* that patients make autonomous choices, while also *encouraging* them to make authentic choices, in order to yield the benefits seen in this study. Such a procedure would treat autonomy as a necessary condition for effective consent, and authenticity as an additive condition (i.e. the more authenticity there is in a patient's choice, the better, but with no minimum amount required). Regardless of the benefits of authenticity, clinicians should certainly not over-rule a patient's autonomous choice with an authentic choice, due to the potential for this to result in paternalism<sup>1,77</sup>. The results of this study may ultimately help to support an alternative model of valid consent that could improve psychological and medical outcomes for patients and strengthen the clinician-patient relationship.



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**Tables**

Table 7- Demographic profile of included and excluded respondents, with comparison to US census population data.

<b>Variable</b>	<b>Level</b>	<b>Included Respondents N=91<sup>§</sup></b>	<b>Excluded Respondents N=13<sup>*, §</sup></b>	<b>US population (civilian, non- institutionalized)<sup>†, §</sup></b>
<b>Sex</b>	Male	61.5	63.6	49.2
	Female	38.5	36.4	50.8
<b>Age</b>		32 (28-38)	29 (26-31)	38.0
<b>Highest level of Education completed</b>	Did not complete high school	0.0	0.0	11
	High school diploma	30.8	27.3	28.9
	Technical/vocational education	4.4	9.1	18.9 (“some college”)
	Associates degree	14.3	9.1	9.8

Undergraduate degree	44.0	9.1	20.0
Graduate degree (e.g. MA, PhD, etc.)	6.5	45.5	11.4

\* 2 of these respondents did not provide demographic data.

† Data obtained from the 2017 US census <sup>46,47</sup>

§ All data are shown as a percent, except for age, which is shown as a median (25<sup>th</sup>-75<sup>th</sup> percentile)

(Median value for US population data only)

Table 8- Wilcoxon signed-rank test with continuity correction testing whether the median difference between vignette conditions regarding decisional regret and decisional satisfaction was significantly different from zero.

**Wilcoxon signed-rank test with continuity correction**

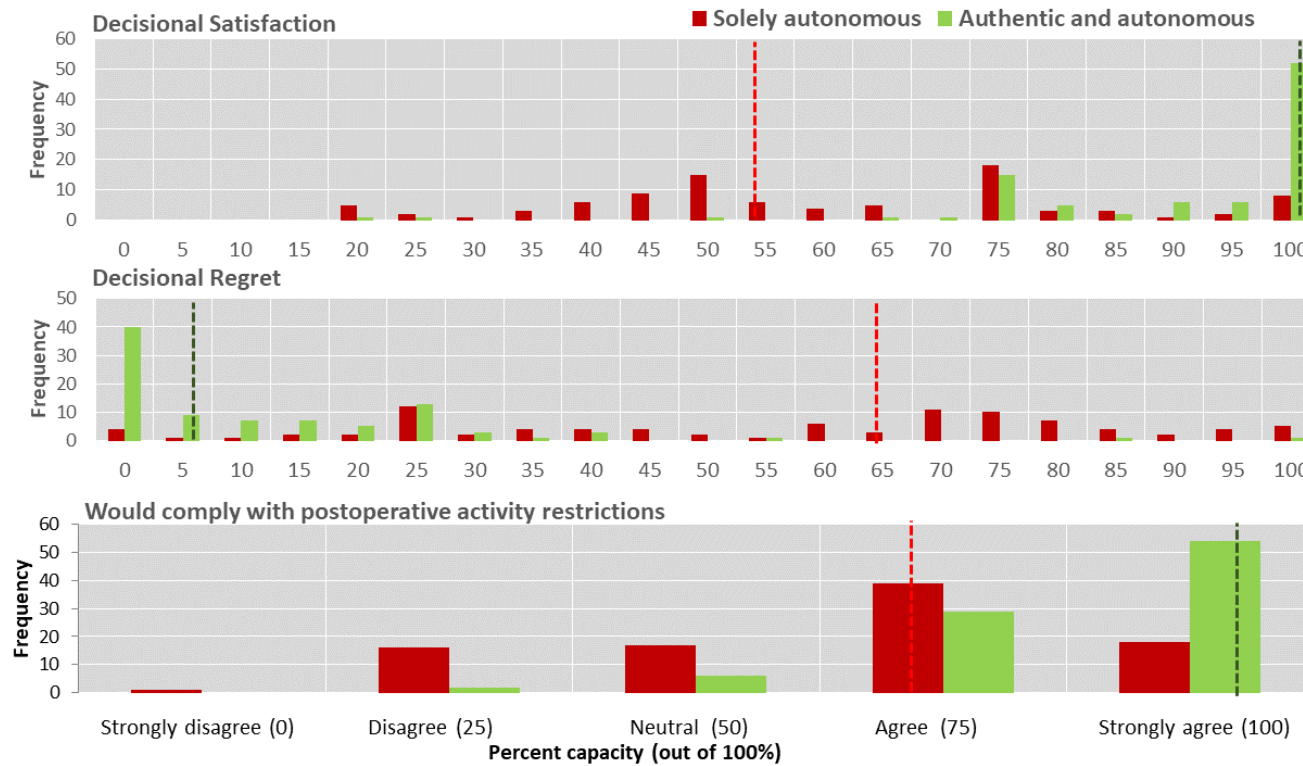
<b>Outcome</b>	<b>Median Difference (authentic and autonomous condition- autonomy only condition)</b>	<b>V- statistic</b>	<b>p-value</b>	<b>Interpretation</b>
<b>Decisional regret</b>	-40	133	1.72e-13	Median difference is not equal to zero
<b>Decisional satisfaction</b>	29.1	2899	1.27e-12	Median difference is not equal to zero

**Asymptotic Wilcoxon-Pratt Signed-Rank Test**

	Median difference	Z	p-value	Interpretation
<b>Compliance with postoperative instructions</b>	25 (1 Likert category)	6.0999	1.061e-09	Median difference is not equal to zero

Due to the larger number of zero differences (41/91) in the compliance outcome, an asymptotic Wilcoxon-Pratt Signed-rank was used. Identical conclusions were reached if the Asymptotic Wilcoxon test or Sign test were used (data not shown).

*Figures*



\* The vertical lines show the median value for each outcome within each condition, with the red lines representing the median for the “solely autonomous condition”, and the green line representing the median for the “authentic and autonomous group”.

Figure 5- The influence of vignette condition on each of the outcomes, as shown by a panel of histograms.

## *Appendix 1- The final version of the clinical scenario and the four vignettes*

*Table 9-The final version of the clinical scenario and the four vignettes.*

### **Final Scenario**

John is a 35-year man who works in the fitness industry as a personal trainer and Karate instructor. As a teenager, he broke his leg and it did not heal properly, leaving his upper and lower legs not aligned properly. This poor alignment led to early onset arthritis in his twenties, making his knee stiff and painful. Despite this health problem, he has taken part in multiple sports his whole life. In the future, he wants physical activity and sport to remain an important part of his life. To him, this means participating in the widest range of sports and activities for the longest period of time, and by continuing to work as a personal trainer and Karate instructor. Until now, John has treated his arthritis with every option except for surgery. Recently, these treatments have stopped working and the pain and stiffness has gotten much worse. He can no longer demonstrate lower body exercises or kicking movements properly, as is required by his jobs. Frustrated, he consults an orthopaedic surgeon (a doctor who specializes in fixing muscles and bones that are injured or deformed).

After examining John, the surgeon says:

“As you know, part of your knee has worn down. While the symptoms of arthritis can come and go, the problem generally gets worse. Since

the other treatments have not worked, without surgery, your pain and stiffness will get worse and you will be more and more limited in the activities you can do. I would strongly recommend that you choose between two surgeries. The first option is a partial knee replacement. With this surgery, we scrape away the remaining cartilage on the side of the knee that is worn down, and we cover the surface of that side with metal. This keeps the leg bones from being irritated. The second option is a knee osteotomy. With this surgery, we cut and reshape one of the lower leg bones so that your upper and lower legs are better aligned. This shifts weight off of the damaged side of the knee and relieves pressure and pain. Both surgeries will reduce your pain and improve your ability to function to some extent. But, which surgery is best for you will depend on a lot of personal factors.

If you go for the partial knee replacement, your recovery is usually easier and quicker. You will be off crutches within days and most likely, you will be doing your everyday activities in less than a month. You will need physical therapy after the surgery, but you should be completely recovered within 6 months. Afterward, your knee pain will likely be nearly or completely gone. However, the activities that you can do will still be limited. Lower impact activities like walking, swimming, golf, and biking are OK. However, high-impact activities like jogging, heavy lower-body weightlifting, and contact sports like Karate should be avoided because this can damage or loosen the metal implant.



If you go for the osteotomy, the first year will be harder. You will have to use crutches while your bone is healing, and it will take you up to a full year to completely recover. This surgery also isn't as dependable at reducing knee pain. But once you are recovered you can do any physical activities that you want, including high impact activities like heavy weightlifting and contact sports.

If you value quick recovery and pain control over higher long- term functioning, I would recommend the partial knee replacement. If you value higher long-term functioning over quick recovery and pain control, I would recommend the osteotomy.”

<b>Condition</b>	<b>Final Vignettes</b>
<b>Choice that is neither autonomous nor authentic</b>	<p>John tells the surgeon that he is willing to put up with some longer-lasting discomfort and a longer time to recover if it allows him to be more like the person he wants to be- someone who sets a great example of physically active living, by participating in a wide range of sports, and by working as a personal trainer and martial arts coach. Based on these concerns, he values function over quick recovery and pain control. Therefore, he would prefer to have the osteotomy.</p> <p>The surgeon is not happy with John's choice. He thinks that John's goals are immature and that he should be more worried about pain control. He tries to convince John to have the partial knee replacement. When that doesn't work, the surgeon criticizes and insults John, and threatens to delay doing the surgery. To avoid any more hassle, John gives in and chooses to</p>

	have the partial knee replacement instead. A week later, the surgeon does the knee replacement.
<b>Choice that is autonomous but not authentic</b>	<p>John tells the surgeon that he is willing to put up with some longer-lasting discomfort and a longer time to recover if it allows him to be more like the person he wants to be- someone who sets a great example of physically active living, by participating in a wide range of sports, and by working as a personal trainer and martial arts coach. Based on these concerns, he values function over quick recovery and pain control. Therefore, he would prefer to have the osteotomy.</p> <p>The surgeon agrees with the choice because he respects John’s ability to choose what is best for him. He also sees that the choice is consistent with the type of person that John wants to be in the future. A week later, the surgeon does the osteotomy, as John asked.</p>
<b>Choice that is authentic but not autonomous</b>	<p>While John wants to be the type of person who sets a good example of physically active living, this conflicts with a short-term desire. His high school reunion is happening in three months. When he attends he wants to be off his crutches so that he "will seem normal" and "won't stand out". If he gets the partial knee replacement, he would be off crutches by that time.</p> <p>This is not true if he got the osteotomy. Based on this concern, he tells the surgeon that he wants to get the partial knee replacement.</p>

	<p>The surgeon points out that the knee replacement won't let John to be the person that he wants to be, and will make it so that he has to get a new job. John agrees, but says "the reunion is more important to me right now". Out of concern, the surgeon asks a psychiatrist to assess Jon. The psychiatrist finds that John has the mental ability to make the choice. No one seems to be pressuring him into preferring the partial knee replacement or attending the reunion, either. A week later, the surgeon does the partial knee replacement, as Jon requested. The surgeon justifies doing the surgery by saying that a patient has a right to make his or her own choice, even if it seems short-sighted or wrong-headed.</p>
<p><b>Choice that is both autonomous and authentic</b></p>	<p>While John wants to be the type of person who sets a good example of physically active living, this conflicts with a short-term desire. His high school reunion is happening in three months. When he attends he wants to be off his crutches so that he "will seem normal" and "won't stand out". If he gets the partial knee replacement, he would be off crutches by that time. This is not true if he got the osteotomy. Based on this concern, he tells the surgeon that he wants to get the partial knee replacement.</p> <p>The surgeon points out that the knee replacement won't allow John to be the person that he wants to be, and will make it so that he has to get a new job. John agrees, but says "the reunion is more important to me right now". Out of concern, the</p>

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surgeon asks a psychiatrist to assess Jon. The psychiatrist finds that John has the mental ability to make the choice. No one seems to be pressuring him into preferring the partial knee replacement or attending the reunion, either. The surgeon is unhappy with John's choice, since he sees it as being short-sighted. He tries to persuade John to have the osteotomy. When that doesn't work, the surgeon criticizes and insults John, and threatens to delay doing the surgery. To avoid any more hassle, John gives in and chooses to have the osteotomy instead. A week later, the surgeon does the osteotomy.

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*Appendix 2- Analysis of the difference in outcomes between the two vignette conditions within demographic subgroups*

Table 10- Analysis of the difference in decisional regret between the two vignette conditions within demographic subgroups of the sample, using Asymptotic Wilcoxon-Pratt Signed-Rank Tests. Alpha was adjusted using the Holm-Bonferroni correction (across all tables in appendix 2, based on 18 comparisons).

Outcome	Solely autonomous	Authentic and Autonomous	Asymptotic Wilcoxon-Pratt Signed-Rank Tests		
	Median score (% capacity)	Median score (% capacity)	<b>Z</b>	<b>P-value</b>	<b>Holm-Bonferroni Adjusted p-value</b>
Male	67.5	5	5.9585	2.545e-09	0.002941
Female	60	10	-4.7196	2.363e-06	0.01
Age<=32	47.5	5	4.8413	1.29e-06	0.00625
Age>32	70	5	5.8292	5.569e-09	0.003125
Less than undergrad	70	0	-5.3195	1.04e-07	0.004167
Undergrad or post grad degree	60	12.5	-5.3914	6.99e-08	0.003846

Table 11- Analysis of the difference in decisional satisfaction between the two vignette conditions within demographic subgroups of the sample, using Asymptotic Wilcoxon-Pratt Signed-Rank Tests. Alpha was adjusted using the Holm-Bonferroni correction (across all tables in appendix 2, based on 18 comparisons).

Outcome	Solely autonomous	Authentic and Autonomous	Asymptotic Wilcoxon-Pratt Signed-Rank Tests		
	Median score (% capacity)	Median score (% capacity)	<b>Z</b>	<b>P-value</b>	<b>Holm-Bonferroni Adjusted p-value</b>
Male	56.3	100	6.1273	8.94e-10	0.002778
Female	54.2	95.3	4.3798	1.188e-05	0.0125
Age≤32	62.5	100	4.7535	1.999e-06	0.007143
Age>32	50	95.8	5.7943	6.859e-09	0.003333
Less than undergrad	54.2	100	5.4849	4.138e-08	0.003571
Undergrad or post grad degree	60.4	91.2	5.1804	2.215e-07	0.004545

Table 12- Analysis of the difference in the endorsement of the compliance question between the two vignette conditions within demographic subgroups of the sample, using Asymptotic Wilcoxon-Pratt Signed-Rank Tests. Alpha was adjusted using the Holm-Bonferroni correction (across all tables in appendix 2, based on 18 comparisons).

Outcome	Solely autonomous	Authentic and Autonomous	Asymptotic Wilcoxon-Pratt Signed-Rank Tests		
	Median score (% capacity)	Median score (% capacity)	<b>Z</b>	<b>P-value</b>	<b>Holm-Bonferroni Adjusted p-value</b>
Male	75	100	5.0779	3.817e-07	0.005
Female	75	100	3.3912	0.000696	0.05
Age<=32	75	100	3.7743	0.0001605	0.025
Age>32	75	100	4.8651	1.144e-06	0.005556
Less than undergrad	75	100	3.9546	7.667e-05	0.016667
Undergrad or post grad degree	75	100	4.7254	2.297e-06	0.008333

## **G. Chapter 5: Conclusions**

This dissertation has achieved the previously stated research objectives as summarized in the following text.

**Manuscript 1 (philosophical manuscript):** This manuscript defends the thesis that the standard model of valid consent may be improved by including the “authenticity” of a patient’s choice as an additive condition, thereby forming what I call the “authenticity-informed model of valid consent”. I propose seven procedural practices reflecting this addition. As compared to the standard model of consent, I assert that the procedural practices of the authenticity-informed model would do a better job of assessing the decisional capacity of patients and the autonomy of their choices, while under some circumstances, better supporting their psychological and physical wellbeing. The risk of clinician paternalism can be contained by including authenticity as an additive condition instead of a necessary condition, by restricting physicians from using coercion or manipulation, and encouraging physicians to communicate with patients in a manner recognizing that patients are likely to have a deeper understanding of their identity than clinicians.

**Manuscript 2 (methodological manuscript):** This manuscript provides an introduction to the use of pretesting to help evaluate and improve the quality of vignettes used in empirical ethics research. It also illustrates how pretesting was used in the present study to ensure that the vignettes used had construct validity, the clinical scenario was clear and realistic, and the procedure was not overly complex or long. Twelve hypotheses were tested that, if rejected, would indicate the need for vignette refinement to improve construct validity. This manuscript provides empirical ethics researchers with strategies for improving their own vignettes and for



evaluating the vignette literature. It also represents a further step toward increasing the rigor of empirical ethics research.

**Manuscript 3 (empirical manuscript):** Using the vignettes developed and pretested in the methodological manuscript, manuscript 3 evaluates the instrumental value of shifting from a choice that is solely autonomous to one that is both authentic and autonomous in a single, but consequential, clinical situation. Results from this manuscript demonstrate that this shift can provide additional instrumental value by reducing anticipated decisional regret and increasing both anticipated decisional satisfaction and compliance with postoperative activity restrictions. This conclusion was stable by respondent age, sex, and education level.

### *Strengths and significance*

This dissertation contributes significantly to the empirical and philosophical literature. The methodological manuscript describes concerns regarding the lack of rigor used to create vignettes in the empirical ethics literature and discusses the value of pretesting as a cost-effective means of improving this rigor. It addresses pragmatic questions for researchers to consider when designing pretesting strategies and provides an illustrative example that demonstrates how data acquired through a debriefing procedure can be used to assess vignettes and the study procedure. Collectively, this knowledge will help guide researchers who are conducting vignette research in empirical ethics and contributes to the broader efforts aimed at increasing rigor in empirical ethics research.

The empirical manuscript examines a clinical scenario where a patient is choosing between two treatments. One represents a treatment choice that is both authentic and autonomous, that allows the vignette protagonist to partake in his most authentic activities in the future and does not reduce the range of authentic activities available to him. The other treatment choice represents a

choice that is solely autonomous, that prevents the protagonist from taking part in his most authentic activities and reduces the range of authentic activities available to him. In comparing these treatment options, respondents anticipated that they would experience less decisional regret, more decisional satisfaction, and would be more willing to comply with postoperative instructions following the authentic and autonomous choice. To my knowledge, this is the first empirical evaluation of the instrumental value gained by the addition of authenticity. It establishes that the goal of promoting choices that are both authentic and autonomous has instrumental value in a consequential clinical scenario.

I have also proposed and defended a novel model of valid consent in the philosophical manuscript, which may better achieve the goals of the standard model of valid consent and better support the psychological and physical wellbeing of patients. This represents a substantial challenge to both the standard model of valid consent and the procedural practices of the CMPA. If future empirical research demonstrates that the theoretical benefits of the authenticity-informed model of valid consent apply frequently and with a magnitude of improvement that is both clinically significant and cost-effective, this would provide substantial evidence that the procedural practices of the CMPA should be modified to reflect the practices I am proposing.

### *Limitations, delimitations and future research directions*

Future research directions stem from the limitations (related to internal validity) and delimitations (related to generalizability) of this project and its individual manuscripts

### **Manuscript 1 (philosophical manuscript)**

Building on the philosophical manuscript, further philosophical and empirical research would be valuable. Future *philosophical* work should examine a broader range of arguments both for and against my proposal of adding authenticity to the standard model of consent. In the present manuscript I have not entertained the plausible claim that the seven procedural practices I recommend would strengthen the physician-patient relationship, and the more tenuous claim that this could ultimately increase patients' trust in the healthcare system. These would be important benefits to consider. Conversely, I have not addressed other possible counter-arguments against the inclusion of authenticity in a model of valid consent. First, that it would not be feasible since it would increase the time necessary to consent each patient, or it could be too difficult in practice to differentiate between authentic and inauthentic choices, since a "method to reliably determine the authenticity (or inauthenticity) of a desire cannot be developed" [1]. Second, that it would require the patient to have an abnormal or excessive amount of self-knowledge, making authentic choices an ideal that is rarely seen in practice. Kernis and Goldman see self-knowledge as a component of authentic agents [2] and some philosophically inclined academics assert that "characteristics necessary for authenticity include capacities for unbiased self-examination and accurate self-knowledge" [3]. Third, there have been concerns related to the relationship between authenticity and patient privacy. Gunderson, for example, points out that the authenticity-based Dworkinian sense of autonomy separates the concepts of autonomy and privacy, which creates problems because "there are cases where requiring informed consent seems appropriate even though privacy rather than autonomy in Dworkin's sense is being violated" [4]. It is also possible that some patients may find the seven procedures that I proposed to be privacy violating. I do not believe that any of these are devastating criticisms against my stance, given my proposal to include authenticity as an additive condition instead of a necessary or sufficient condition, and

my stipulation that patients will dictate the nature and extent of authenticity discussions (unless there is also suspicion of a lack of decisional capacity or a lack of autonomy in their choice). Feasibility arguments may be overcome by using less costly healthcare team members to conduct the procedural practices. Alternatively, the time spent on the procedural practices could be scaled based on whether the treatments under consideration pose large risks to the patient and have the potential to threaten their identity. However, these criticisms (and possible reformulations of them) must be examined more carefully in future philosophical work and a thorough defence against them should be presented. I have also not systematically reviewed the various philosophical and conceptual criticisms against the idea of authentic choice, discussing which would apply to my chosen definition of authenticity, and providing reasons why my definition could overcome the abstract criticisms that apply to it. This includes concerns regarding the reasons why second order endorsements would be given more authority than first order desires (known as the “Ab initio problem” or the “problem of authority”) [5–7]. While I adopt more of a coherentist view than a traditional hierarchical view of authenticity, I do make appeal to higher order preferences as a tool to help resolve conflicts between levels of authenticity assessment and conflicts between markers of a patient’s current identity. I have also not outlined a full theory regarding the distinctions between first and second order endorsements, nor placed stipulations regarding how second order endorsements should be evaluated, aside from suggesting that investigations of the authenticity of the agents may be of use in such circumstances. An important next step would be to identify how the authenticity-informed model of informed consent would identify and deal with second order endorsements that came about through mechanisms that *are* counter to autonomy, such as brainwashing (i.e. coercive manipulation), or *may be* counter to autonomy, such as social conditioning. (known as the “Problem of

Manipulation”) [6]. I have begun to do this by including a historical component to my account of authenticity (by examining the consistency between a patient’s choice and their past behaviour), but a more complete account would be preferable. Related to this, my model should ultimately discuss in detail how radical personal transformations and less dramatic forms of personal growth should be dealt with [5]. By including future-oriented markers of personal identity such as goals and the ideal self, my account does allow for growth that transcends past behaviour patterns. By not outlining a full account of the differences between first and second order desires, some philosophers would assert that my model is in one sense incomplete (known as the “Incompleteness problem”) [6].

Formally addressing these criticisms would be a useful task. For the purposes of this dissertation, however, I was more concerned with addressing the most important and commonly leveled practical criticism against the inclusion of authenticity into a model of informed consent (i.e. the problem of paternalism) than engaging in prolonged conceptual analysis.

There are also broader concerns about authenticity as an ideal, such as the worry that its adoption would cause a “focus on one’s own inner feelings and attitudes [that] may breed a self-centred preoccupation with oneself that is anti-social and destructive of altruism and compassion toward others” [8]. In other words, a fixation on acting authentically could breed narcissistic tendencies. There is also the concern that using authenticity as a guide to action would result in a tendency toward immoral behaviour [8]. These are empirical claims that would require long-term studies to properly evaluate on a societal scale, leaving them beyond the scope of this study. The perceived *a priori* plausibility of these arguments would depend on one’s view of human nature (or, if one does not believe in a universal and context independent human nature, it would at least depend on one’s beliefs about the internal tendencies of people embedded in a specific culture,

situated in a specific geographical region, during a specific time). If humans are naturally selfish and immoral, facilitating the autonomy and authenticity of patient choices could lead to detrimental consequences to broader society. Conversely, if humans are naturally moral, facilitating either of these constructs would likely lead to good consequences to broader society. In the philosophical manuscript, I have also proposed several empirical possibilities, which, if true, would provide strong evidence that the authenticity-informed model could resolve important issues with the standard model. While I have asserted the logical possibility of these claims and have in some cases postulated the mechanism by which these benefits could occur, these claims should be investigated empirically. First, I claim that the authenticity-informed model could result in a decreased misclassification of patients who have a lack of decisional capacity, and a decreased misclassification of non-autonomous patient choices. It would be useful to do either simulation or clinical studies to quantify how often the procedures that I recommend would avoid these misclassifications. Second, I claim that the seven proposed procedural practices may result in an increased state authenticity due to increased self-knowledge, unbiased processing, propensity toward authentic action, and/or transparency. A study comparing the proposed procedural practices to the practices of the CMPA would be required to confirm or refute these claims, and to establish their frequency and magnitude. I also claim that preserving a patient's ability to do their preferred authentic activities and their range of possible authentic activities could cause patients to have greater state and trait authenticity than patients who did not have these abilities preserved. The effect of this preservation could be examined in a follow up vignette study comparing anticipated state and trait authenticity in response to solely autonomous choices vs. authentic and autonomous choices.

## **Manuscript 2 (methodological manuscript)**

Much could be done to build on the methodological manuscript. A variety of meta-scientific (e.g., bibliometric, epistometric) investigations could be conducted to establish the range of issues with the empirical bioethics literature, and the frequency with which they occur. In particular, it would be valuable to describe in depth, using quantitative methods, the transparency of existing empirical ethics studies regarding vignette development. This could include identifying the proportion of vignette studies with a complete lack of transparency, the proportion with a partial lack of transparency, and identifying the items of information that are most commonly omitted and/or ambiguously described (e.g. the vignettes themselves, measures taken to prevent problems with vignettes vs. measures taken to detect or remediate them, etc.). Cluster analysis could be used to identify patterns of non-disclosure using factors such as the journal of publication and the country of article origin. Similar investigations could be conducted based on the pretesting measures that were described, thereby identifying clusters of studies using different vignette development procedures. Results from these analyses would help to target and tailor subsequent remediating efforts.

Since the methodological manuscript only provides a brief introduction to vignette pretesting in general, future reviews may focus on giving more in depth guidance regarding the use of specific pretesting approaches. The current manuscript focused primarily on the design and evaluation of individual vignettes. An introduction to important decisions in vignette study design (e.g., the design and integration of a set of vignettes within a study) would also be an extremely useful contribution to the related literature in empirical bioethics. This could address decisions such as using a factorial survey design vs. purposefully selected vignettes, using a within-person vs. between-group vs. mixed design, and the use and temporal placement of a reference vignette.

### **Manuscript 3 (empirical manuscript)**

The empirical manuscript demonstrates that authentic and autonomous choices can result in decreased anticipated decisional regret, while increasing anticipated decisional satisfaction and intentions to comply with postoperative activity restrictions. Building on the empirical vignette study, future research should ideally extend in several directions.

The most conservative direction (from a knowledge generation perspective) would be to cross validate the results of this study using complimentary methodologies. To confirm that respondents would react similarly in real life compared to in response to a vignette, observational studies could track the autonomy and authenticity of patient choices in a clinical setting and measure actual decisional regret, satisfaction, and compliance with activity restrictions at one year postoperatively. This could help to evaluate whether overestimations of detrimental outcomes are occurring, and if so, to what extent [9]. This is a concern, as research has demonstrated that the most common bias in affective forecasting is the “impact bias”, where respondents have a “tendency to overestimate the enduring impact that future events will have on [their] emotional reactions” [10]. This bias applies both prospectively (i.e. the impact an event *will* have) and retrospectively (the impact an even *did* have), as opposed to assessments of the impact at the time of the event [10]. Consequently, affective assessments that are conducted as part of a study should be conducted during the epoch of interest to avoid this bias. However, it is worth mentioning that the effect sizes seen in the empirical study were large enough (i.e. 40pp shift in decisional regret and a 27pp shift in satisfaction), that even if an impact bias accounted for half of the size of the effect, the results would remain of practical significance even after correcting for the bias. Nevertheless, more accurately quantifying the contribution (if any) of impact bias to the result would prove useful.



The second direction would examine other measures of the instrumental value in the same clinical scenario. For instance, the regret and dissatisfaction experienced by patients in the face of an inauthentic choice may cause them to behave in ways that are detrimental to themselves and others, aside from failing to comply with postoperative instructions. For example, they may adopt poor coping strategies or engage in self-destructive behaviour.

The third direction would examine other clinical scenarios. Recreating the research in the context of health screening decisions and preventative health decisions are necessary, since these types of decisions are typically associated with less regret and higher satisfaction than surgical decisions. The present empirical study compared a solely autonomous choice that preclude a patient's most authentic activities and that reduce the range of authentic activities in which the patient could partake, and authentic and autonomous choice without these consequences. When patients face a solely autonomous choice with these anticipated consequences, they anticipate experiencing greater decisional regret, lower decisional satisfaction, and poorer compliance with postoperative activity restrictions. In some situations, neither the solely autonomous choice nor the authentic and autonomous choice would prevent the patient from participating in their most authentic activities. The benefits to satisfaction, regret, and compliance may not apply to these other scenarios. However, we have at least established that there is an anticipated benefit of authentic and autonomous choices compared to solely autonomous choices in the type of situation where such a benefit would be more likely to occur. Had we found no benefit to these outcomes in the selected situation, this would have cast doubt over whether there was any scenario where authentic and autonomous choices would have such advantages over solely autonomous choices. It should also be established whether the differences in outcomes remain significant in instances where patients are deciding between treatments that differ less

dramatically in terms of their authenticity. For example, a comparison could be made between choices that were both somewhat authentic, but to different extents. This would help to establish how large a difference in authenticity must be present in order to result in significant differences in the studied outcomes. Finally, the effects observed in this study may originate in part from superficial situational factors such as vignette protagonist sex, age, etc. The effect of varying each of these factors could be explored in future research.

A fourth direction would break down the broad composite definition of authenticity used in this dissertation in order to examine the potentially unique effects of its components. For instance, it may be the case that inauthenticity, in the sense of incongruence with the ideal self, drives patient regret while inauthenticity, in the sense of incongruence with past action, has little effect on regret.

### ***Knowledge Translation (past and future efforts)***

To ensure that researchers in related fields are aware of this work, the manuscripts are being prepared for submission to peer-reviewed academic journals. The findings of the methodological manuscript were presented at a national bioethics conference as a concurrent session (the 2019 Canadian Bioethics Society conference in Banff, Canada), and as a poster discussion at an international psychology conference (the 2017 Asian Psychological Association conference in Surabaya, Indonesia). An earlier version of the philosophical manuscript (including several results from the empirical manuscript) was presented at the 2018 United Nations Educational, Scientific, and Cultural Organization (UNESCO) Bioethics chair conference (Jerusalem, Israel). Planned future knowledge dissemination activities include methodological workshops at experimental philosophy and bioethics conferences (for the methodological manuscript), presentation of the empirical data in dedicated scientific posters at international conferences

related to moral psychology and empirical ethics, and drafting articles discussing how patients could incorporate authenticity into their medical decision-making for publication in popular magazines (e.g. Prevention, Viva, Alive, etc.).

### *Policy and care implications*

Given the speculative nature of many of my philosophical arguments and the limited data on the benefits of individual choices that are both authentic and autonomous, I will be conservative in suggesting policy and care implications. As a consequentialist, I believe that further philosophical and empirical research is needed to evaluate the consequences of my recommended additions to the consent process. Based on the existing cannon of psychological research, it is fairly clear that making patients more authentic agents would be a reasonable way of increasing their wellbeing. It is also reasonable to suggest that making patients feel more authentic could also benefit them. However, the effectiveness of the procedures that I propose in facilitating state and trait authenticity, in preventing misclassifications of patients with respect to decisional capacity, in preventing misclassifications of choices with respect to autonomy, and in promoting the physical and psychological wellbeing of patients are all uncertain. If the theoretical benefits of the authenticity-informed model of valid consent can be shown to apply with a frequency and magnitude that is both clinically significant and cost effective, this would provide substantial evidence that the procedural practices of the CMPA should be modified to include the procedural practices I recommend. For now, I only recommend that the CMPA *consider* my recommended procedural practices. This would consist in discussing the proposed practices internally, critiquing and proposing refinements to them, perhaps piloting them in simulations or limited settings, and taking any other evaluative actions they believe to be

appropriate. The practices should only be implemented on a wide scale once the CMPA and others (including myself) have amassed sufficient evidence of net benefit and have established that the practices I recommend are feasible.

### *Conclusions*

This dissertation has achieved three main objectives. It has presented an introduction to the use of vignette pretesting for empirical bioethics research. It has demonstrated that in certain situations, choices that are both authentic and autonomous have instrumental value that is additional to the value seen with choices that are solely autonomous. This value comes from decreased anticipated decisional regret and increased anticipated decisional satisfaction and compliance with postoperative physical activity restrictions. Finally, it has proposed a model of valid consent that includes authenticity as an additive condition. This model is supported by theoretical arguments asserting that including authenticity would result in physicians doing a better job of evaluating the decisional capacity of patients and the autonomy of patient decisions, while also better supporting the physical and psychological well-being of patients. Further benefits and drawbacks of this model should be explored, and future empirical research should evaluate how frequently the benefits hypothesized in this dissertation occur. Consideration should be given to including the seven recommended procedural practices into those of the CMPA.

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## H. Appendix 1- Consent scripts



### Survey consent script (respondent debriefing)

We invite you to participate in this research study. We are examining informed consent in the medical context, where a patient is choosing to have one surgery or another. We will present you with a description of a medical scenario being experienced by a specific person. Then, we will describe four different sequences of events (vignettes) that could happen. You will be asked to imagine yourself in the place of a patient and indicate how you would react to each of the circumstances. This will tell us about the relative importance of different values involved in informed consent. Since you are part of the pretesting group, we will also ask you to rate the scenario and the four descriptions based on a number of criteria. This will help us to improve the scenario and descriptions for a bigger study that we are about to start. If the pretest identifies parts of the survey that need improvement, we will make changes and send the altered element to you to confirm that it has been improved. This could happen up to 2 times. This research will help us understand whether existing models of informed consent are adequate. The University of Manitoba Psychology/Sociology Research Ethics Board has approved this study.

Your participation in this research study is voluntary. You may choose not to participate, and you can stop participating at any time. It will take approximately one hour to complete both the survey and the follow up questions. There is minimal risk in taking part in this survey study. Your responses will be confidential, and any identifying information about you (including your worker ID) will not be released. To keep the survey anonymous, you will complete the study tasks on Survey monkey. Upon completing the survey, we will give you a completion code to enter into Mechanical Turk in order to get your payment. All digital data will be stored on a password protected computer, and any hard copies will be stored in a locked filing cabinet in a locked room. When we publish or present the study, we will talk about the responses of the study participants in general and won't present the responses of individual people. To help protect your confidentiality, please do not write (or type) your name or other identifying information on the survey forms. Participating in this survey study will be of no direct benefit to you, aside from a compensation of \$5 USD. However, the information you provide will be useful in developing models of informed consent that have greater validity and usefulness. We will publish the data from this study in composite form in a peer-reviewed journal. By agreeing to participate you are allowing us to contact you again. If you participate in these re-contacts, you will be paid an additional \$1 USD per contact to evaluate whether changes we have made to the survey represent an improvement. These contacts should take no more than 10 minutes. Thank you for your time and effort.

I agree to participate: Yes  No

I agree to being re-contacted up to two times for the purposes of verifying improvements to the survey (with additional payment for each recontact): Yes  No



### Survey consent script (full study)

We invite you to participate in this research study. We are examining informed consent in the medical context, where a patient is choosing to have one surgery or another. We will present you with a description of a medical scenario being experienced by a specific person. Then, we will describe four different sequences of events (vignettes) that could happen. You will be asked to imagine yourself in the place of a patient and indicate how you would react to each of the circumstances. This will tell us about the relative importance of different values involved in informed consent. This research will help us understand whether existing models of informed consent are adequate. The University of Manitoba Psychology/Sociology Research Ethics Board has approved this study.

Your participation in this research study is voluntary. You may choose not to participate, or you can stop participating at any time. The survey will take approximately half an hour to complete. There is minimal risk in taking part in this survey study. Your responses will be confidential, and any identifying information about you (including your worker ID) will not be released. To keep the survey anonymous, you will complete the study tasks on Survey monkey. Upon completing the survey, we will give you a completion code to enter into Mechanical Turk in order to get your payment. All digital data will be stored on a password protected computer, and any hard copies will be stored in a locked filing cabinet in a locked room. When we publish or present the study, we will talk about the responses of the study participants in general and won't present the responses of individual people. To help protect your confidentiality, please do not type your name or other identifying information into the survey forms. Participating in this survey study will be of no direct benefit to you aside from a compensation of \$7 USD. However, the information you provide will be useful in developing models of informed consent that have greater validity and usefulness. We will publish the data from this study in composite form in a peer-reviewed journal. Please only complete this survey once, as duplicate responses will not be awarded additional remuneration.

Thank you for your time and effort.

I agree to participate: Yes  No