

## The Principlist Paradigm and the Problem of the False Negative: Why the Clinical Ethics We Teach Fails Patients

### **Introduction**

The predominant paradigm used to teach clinical ethics in both undergraduate and graduate medical education is "principlist" in approach, based on the theory of principlism set out by Tom Beauchamp and James Childress.<sup>1</sup> But unlike the original theory, the "Principlist Paradigm" that is taught to medical students, and then used by clinicians to resolve clinical ethics dilemmas at the bedside, functions in a way that undermines a nuanced assessment of clinical ethics cases. The Principlist Paradigm operates like a short, over-simplified diagnostic check-list that scans for a handful of ethical considerations in clinical encounters and then makes its normative assessment based entirely on that reductive set of ethical concerns.

If the check-list were exhaustive of all of the moral considerations that arise in a clinical situation, then this mode of moral diagnosis would not be cause for concern. But the Principlist Paradigm detects only a limited range of moral considerations, and the frequent result is a "false negative," in which the clinical situation appears to have no outstanding moral issues--and no moral obligations that would correspond to them--when in fact others remain. The effect of the Principlist Paradigm is a narrowing of the moral lens through which clinical ethics cases are viewed at the cost of missing important moral issues and the moral obligations they generate. The Principlist Paradigm under-trains clinicians for the difficult ethical dilemmas they face in practice.

To illustrate this problem, I examine a clinical ethics case through the lens of the Principlist Paradigm. While I acknowledge that the Principlist Paradigm is valuable for the moral issues and obligations it does detect, I argue that it should not be used as the sole template for case analysis given what it misses; clinical ethics consultations that singularly employ the Principlist Paradigm may be doing more harm than good. How widespread the use of the Principlist Paradigm is in clinical ethics is an empirical question, but anecdotal evidence suggests that it is common enough that biomedical ethics needs to rethink the tools it offers medical students and clinicians to guide their ethical analysis and begin to provide an array of ethical heuristics that can expand the moral lens through which tough clinical ethics cases are viewed.

### **The Principlist Paradigm Examined**

What I am calling the “Principlist Paradigm” is an out-growth of the moral theory of principlism laid out in Beauchamp and Childress’s *Principles of Biomedical Ethics*. Like the theory, the Principlist Paradigm begins with four principles--autonomy, beneficence, nonmaleficence, and justice--but its way of using them differs markedly from the way the theoretical system is designed to work. From these four principles, the Principlist Paradigm used in clinical ethics distills a fixed set of moral considerations which are used to analyze the salient features of a particular ethics case, determine the obligations that arise in it, and make the decisions with regard to it. The principle of autonomy, for example, is cashed out as (and limited in scope to): a respect for the medical decisions competent patients make, the requirement of securing informed consent for treatment or waiver of treatment, a recognition of the patient’s need for bodily and informational privacy, and the patient’s right to disclosure in medical

diagnosis and prognosis. In a similarly reductionistic way, the principle of beneficence is translated into a concern for public health or the safety or health of others connected with the case, an interest in securing legitimate substituted judgment in the case of patient incompetence, and a resistance to paternalism. The principle of nonmaleficence becomes a concern about participating in active euthanasia or PAS, a caution with regard to prescribing treatment modalities that hasten death, a concern for physician impairment or misconduct, and worries about medical error. And the principle of justice becomes a concern about micro-allocation of scarce resources, such as fair and equitable local transplant listings or continuation of futile treatment. Equipped with this list of ethically salient issues, the case is analyzed and decided.

None of this is bad as far as it goes. It isn't that the Principlist Paradigm fails to pick up legitimate moral concerns—the issues it detects are of critical importance in medicine and arguably brought to common moral consciousness through this very paradigm. What's wrong with the Principlist Paradigm is what gets left out and why, and it is what differentiates the Principlist Paradigm from the theory of principlism. The Principlist Paradigm is an approach to clinical ethics that recognizes a limited and fixed set of salient moral considerations that are grounded by the four principles, and then searches for these specific elements (and no others) in any particular clinical ethics case. Principlism, as a theory rather than a method, is not structurally limited in this way: it begins with the four general principles, but its argument is that any moral consideration that might be relevant in a concrete case can be subsumed under one of these four principles that anchor its objectivity; it sets out categories, but doesn't predetermine what will fill those categories.<sup>2</sup> An analogy oversimplifies a bit, but the Principlist Paradigm functions like a metal detector, whereas principlism is more like a kind of moral

archaeology. In an “archaeological” approach to ethics, there are broad categories of things one might find, but the search is open-ended and the objects to be found limited only by where one is looking. But a metal detector can only find a specific class of objects—no matter how many other objects exist and no matter how well or in what location it's used. The argument here is that the normative lens used most often in clinical ethics settings functions like a metal detector: the Principlist Paradigm is a tool that can only flag certain types of issues and considerations as morally salient in a case, and it leaves many others undetected.

This comparison explains why a defense of principlism is unlikely to constitute a defense of the Principlist Paradigm. Against the charge that the Principlist Paradigm narrows the moral lens of clinical ethics, missing important obligations and moral considerations, a proponent of principlism might reply that any and all moral obligations that exist will fall under the rubric of one of the four principles; there is no normative consideration that will fall outside of one of these four broad categories. But if the Principlist Paradigm functions the way I claim it does, then this defense will miss the mark because it looks at the problem from the wrong direction. It may be the case that any moral consideration one could detect in a clinical ethics case could be legitimately understood as falling under one of the four principles, but this is a very different claim from arguing that, armed with a limited list of what to look for, all of the moral considerations that exist in the case will be detected. This defense of principlism is a claim about the theory's ability to incorporate new understandings of moral obligation into the original schema; it is not an argument that the current schema cashed out as the Principlist Paradigm will enable us to uncover or perceive all of the moral obligations or considerations that exist.<sup>3</sup>

A more fruitful avenue for undercutting this critique of the Principlist Paradigm is to deny that it is in widespread use in clinical ethics. Many professional clinical ethicists will justifiably claim that their approach to ethics consultation is much more expansive and nuanced than I will describe. But in reflecting on the question of how often the Principlist Paradigm is actually employed, we need to remember that, by far, most of the ethical problems that arise in clinical medicine are resolved by the treating clinicians involved in a patient's medical care, and these individuals are not by and large "clinical ethicists." Only a small subset of the ethical dilemmas that occur in hospital-based medicine are brought to the attention of the clinical ethicist or ethics consult service of the institution. So one way of getting at this question is to think about how clinical ethics is or has been taught to the medical students and residents who will be making most of the ethics judgments and decisions at the bedside. Surely there are alternatives to the Principlist Paradigm, but we don't see "theory" converted into "mantra" when just a handful of people use it. And it shouldn't be surprising that it has had a high level of appeal: it is systematic and formulaic, so--parallel to other clinical diagnostic tools--it makes ethical analysis efficient and, on the face of it, accurate.

Its accuracy is, of course, what is at issue in this argument, so to illustrate the problems that occur with use of the Principlist Paradigm, I turn to the analysis of a difficult clinical ethics case.

### **The Principlist Paradigm in Practice**

Consider the following case, which I will claim is representative of a class of cases that is ethically serious and complex, but unlikely to come before an ethics consult service:

A 30-year-old man was admitted from the ED to the MICU for upper GI bleeding. Stat endoscopy revealed a large posterior duodenal ulcer as the likely source. Although he wasn't actively bleeding at the time of the endoscopy, he started to rebleed during the night. The patient agreed to get blood transfusions and signed the hospital's consent form. He received two units of packed red cells, which raised his hemoglobin 2 gm/dL. He had only two peripheral catheters (22 and 20 gauge) for IV access. Despite multiple attempts, the MICU house staff couldn't place a larger IV angiocath peripherally. The resident explained to the patient the need for a central venous catheter, its risks and benefits. The patient was upset at the failed attempts to place the large peripheral IV and lacked confidence in the house staff to place the central line. He refused to give consent for the central venous catheter. Later that night, the patient's blood pressure suddenly dropped. He rapidly lost consciousness and then his rhythm. Despite the ICU resident placing a femoral catheter stat, he could not be resuscitated due to the ongoing large GI hemorrhage.

If we back up in time to the point at which this patient refused to consent to the central line, what would an ethical analysis of this situation look like using the template of the Principlist Paradigm? What would the clinical team "see" as, first, the relevant moral issues in this case and, second, the ensuing ethical obligations that follow from them?

Here is the way in which this case would be "diagnosed" by the clinical team at the bedside: two principles would be brought to bear on the analysis, the principle of autonomy and the principle of beneficence, and a handful of limited options would follow. Protecting the patient's autonomy would be cashed out as either securing the patient's consent or respecting the patient's refusal, and this would mean making sure that the patient clearly comprehended the seriousness of his condition and the risks he was assuming in not complying. It would also require consideration of the patient's ability to comprehend the situation and rationally assess the risks of foregoing the central line; in other words, the patient's competence to make this critical decision would need to be assessed. The team would first try to convince the patient of the necessity of placing the central line. They would likely employ different members of the team, using different strategies and tactics. When that failed, and the patient continued to refuse the central

line, the team would begin to question the patient's competence to make the decision. Then the team would focus on the principle of beneficence and try to have the patient officially deemed incompetent so that they could act paternalistically in the patient's best interests and secure the line. This second option would require a consultation with the on-call psychiatry team.

In the case we have been analyzing, the patient does not receive the central line, so the events likely unfold in the following way. The team, having had no success in securing the patient's consent, calls for a psych consult, since they believe it is clearly irrational for the patient to refuse the team's recommendations in the face of being at high risk for rebleeding. When the psychiatrist comes, she finds the patient lucid and rational, and he is deemed competent to make this decision. The treating team's only recourse at this point is -- returning to the principle of autonomy -- to try again to get consent. They try repeatedly to explain to the patient the absolute necessity of inserting a central line, but the patient is adamant in his refusal.

At this point, the clinical team would view their hands as tied. Operating inside the Principlist Paradigm, they would have recognized two relevant moral principles in the case and the handful of options that follow from them; and, after exhausting these limited options, they would have been frustrated and sad, but also confident that they had discharged all of the moral obligations binding on them in this case. When the patient dies due to his own bad choice, they would view this as a tragedy, but they would see no moral culpability on their part: having done all they could, they are clinically and morally blameless.

### **Expanding the Moral Lens: Four Obligations the Principlist Paradigm Does Not Detect**

To see why the Principlist Paradigm might have failed to detect all of the salient moral features in this case -- and the obligations that attach to them -- let's attempt to reconstruct the case from the patient's perspective. The status of this account will be speculative, of course, because it is not literally the patient's own narrative; on the other hand, we stand a better chance of capturing the psychological motivations that drove his refusal through a fictional account than the patient would have likely had were he to have tried to voice his own account that night. Laying hold of one's own psychological dispositions is no mean feat, especially when confronted with a serious, acute health crisis. The test we'll use of this being a credible projection into the patient's experience is that it both resonates with how we might feel in that situation and offers a plausible explanation of the course of action he chose. Let's assume the patient's story has these elements in it:

From the very beginning, his experience in this hospital has been horrible, from the long wait in the ER, to the barrage of invasive tests, to the admission to the ICU. He has been passed from doctor to doctor, and no one seems to know what they're doing or be in charge. He feels like he is being used as a "guinea pig" for the training of new doctors. He feels indignation and resentment at the failed attempts to insert the larger catheters – if they had given him a real doctor, and these amateurs, this wouldn't have happened. The repeated, failed attempts by the house staff have made him lose all confidence in the team and undermined his trust in the treating resident. He feels powerless and helpless; he feels out of control. This shouldn't be happening to someone 30 years old. He feels betrayed by his own young body. He is very scared.

Does any part of this story add additional moral considerations to the ones we have already detected through the Principlist Paradigm; and, if so, do these other salient considerations generate obligations to the patient beyond the two already discharged?



To make the case that the clinical staff viewed this situation through too narrow a lens, I want to take a step back and lay out theoretically several common circumstances under which we universally recognize moral obligations to others. I take these several circumstances to be part of commonsense morality. We have a moral obligation to others: 1) when the recognition of someone's suffering is needed to acknowledge her standing as a person; 2) when we have wronged someone in some way; and, 3) when we have promised someone something.

Let's look at the first circumstance in more detail because it requires some explanation to make more obvious. When another person has experienced some type of emotional or physical pain, and I have a relationship with that individual, then I am obligated to convey that I recognize that pain and am sorry it has occurred. If I fail to do this, I have – by act or omission – dismissed the suffering of another person. To dismiss the pain of another person is to negate that individual's value as a person; it is to deny that the person matters and “is to be valued.” This is the theoretical explanation for the commonsense desire to have our feelings validated. Take an everyday example. If someone I have a relationship with has experienced a death in her family, I have a moral obligation to express condolence. If I don't, I have in effect declared that what has happened to her is of no significance or import. By ignoring her emotional pain, I am saying: “It doesn't matter.” But to be valued as a person is to have our concerns valued and validated. It isn't etiquette or mere convention that prompts my response, and it isn't optional: I owe her my condolences, and I fail to acknowledge her value as a person if I don't give them.

If we return now to the case, assuming that our story from the patient's perspective is plausible, it is not difficult to see that all three of the conditions that

generate additional moral obligations exist in this case. Consider the first condition: (1) when the recognition of someone's suffering is needed to acknowledge her standing as a person. This patient is clearly suffering – not merely in the way that all patients suffer (i.e., through the physical condition that makes them “patients” in the first place), but additionally because he has had to endure multiple attempts at a procedure that has repeatedly failed and because his rapid physical deterioration, and the difficulty the house staff has had in treating him, has made him feel terrified, used, powerless, and out of control. If this pain, both physical and emotional, is not recognized and validated, the individual will feel dismissed, undervalued, insignificant, and demoralized. If someone can easily prevent those feelings of disvalue in another person, then he is under moral obligation to do so. The circumstance of someone “needing recognition of pain to have one's value affirmed” generates a critical – not optional – moral obligation: the *Obligation to Express Regret*. Even if we assume that the treating resident's skill set is unrelated to the failed attempts to place the larger catheter (e.g., the man has small veins, no one could have done better), the resident still has an obligation to express regret in a form that conveys the sentiment: I recognize your suffering; It matters to me; You matter to me; I wish this hadn't happened to you. Because the patient has no other support people with him in this crisis (he has come to the ER, and now ICU, alone), the only individuals present with whom he has a relationship are the members of the treating team, and they must assume this role. The expressions of regret that have conventionally conveyed this significance or “mattering” of another person in a situation of suffering are very simple; they require almost no time and very little effort: one simply says (and really means), “I'm sorry that this has been so difficult. It's awful to be stuck so many times.”

The expression of regret that I have argued is obligatory seems so simple that it can appear to be trivial and unnecessary. To challenge the claim that it is morally optional, imagine how the patient feels whose gynecologist tells her she has had a miscarriage of a long-awaited pregnancy, but does not add a sincere: “I am so sorry.” Nor is the expression of regret related to clinical culpability or responsibility. The gynecologist did not *cause* the miscarriage; it is not because the physician played any role in the pregnancy’s outcome that the expression of regret is required. The physician says she is sorry to acknowledge the sadness, loss, and grief of her patient and to convey that this patient matters to her. The situation with our ICU case is no different morally. We have culturally come to recognize the emotional suffering caused by a miscarriage, and so “miscarriage” has been placed in the category of “suffering that must be recognized;” but surely the feelings of fear, indignation, resentment, and anxiety also place one’s experience in the category of “suffering that must be recognized.” If a physician is under moral obligation to express regret for a miscarriage, I argue she is also under moral obligation to express regret for the kind of situation this patient finds himself in. In summary, when the recognition of someone’s suffering is needed to acknowledge the patient’s standing as a person, there exists an obligation to express regret.

A second condition under which we have a moral obligation to another person is (2) when we have wronged someone. This is the most uncontroversial circumstance of the three, as are the two commonsense moral obligations that follow from this circumstance: the *Obligation to Apologize* and the *Obligation to Make Amends*. Returning to our case, let’s now assume that the resident’s skill level explains the failed attempts to place the larger catheter (e.g., with a more experienced clinician this wouldn’t have happened). If the successful placement of a larger catheter in this particular patient

would have been likely had the physician been more experienced, then an apology is required. The type of ‘wronging’ that exists in this case doesn’t rise to the level of medical error or negligence; nevertheless, if the skill set of the treating physician does not yet match the difficulty of the task, and this leads to the unnecessary suffering of the patient, this is a kind of wronging or harm. The Obligation to Apologize in this case comes from the unintentional harm done to the patient by a physician who is still completing her training. Medical culture has long resisted the practice of apologizing for a myriad of reasons, not all of which involve fear of malpractice litigation, but that resistance puts the field of medicine out of step with everyday morality and thwarts the moral expectations we hold for each other. Mirroring everyday moral life, the first obligation in response to causing harm is an apology: “I am sorry I couldn’t get this placed. I feel terrible about sticking you so many times.”

To the claim that a harm of this type demands an apology, one might argue that the harm is too small to warrant this obligation: the so-called “harm” here involves nothing more than a few extra needle sticks; the level of pain involved is a pinch. The first response to this objection is that the patient is unlikely to see it that way (in fact, it is the patient’s distress over these failed IV attempts that prompts him to refuse the central line); but a less case-specific response is that far lesser harms than unnecessary needle sticks trigger the obligation to apologize in this culture and the judgment about the level and degree of bodily invasion or pain that counts as “harm” is a cultural matter. If I am obligated to apologize when I accidentally, but lightly, step on a stranger’s foot, then I am surely obligated to apologize if I stick him with a needle more times than is necessary because of my inadequate level of skill.

But as a response to harming someone, an apology is usually not enough. A second obligation is required -- wherever possible -- in response to causing harm, namely the *Obligation to Make Amends*. The moral demand to “set things right” is again merely a part of everyday moral practice: if the harm can be reversed, or compensated, or avoided in the future, we are under obligation to take those steps. In this case, the action for making amends is obvious: find a clinician whose skill set is commensurate with the required task, and assure the patient that you will call in someone with more expertise to take over. In summary, when we have wronged someone, we have the dual obligation to apologize and make amends.

The final circumstance I want to consider that generates moral obligations to others is 3) when we have made someone a promise. The patient-physician relationship is a type of covenant or promise: the physician promises to treat the patient and commits to non-abandonment. The patient’s trust and confidence in the physician is the foundation of that relationship; therefore, one of the moral obligations that follows from the covenant made in establishing the doctor-patient relationship is the *Obligation to Secure the Patient’s Trust and Confidence*. When that trust has been undermined, for whatever reason, the physician needs to regain it or transfer care as part of the promise made in establishing that relationship. In the ideal case, the relationship can be repaired, and an attempt at repair is the obvious first step; but if that proves impossible, the clinician needs to facilitate the establishment of a new relationship. In the case we have been analyzing, the patient had clearly lost trust and confidence in the treating physician. At the point at which the patient expressed doubt and mistrust, the resident had a moral obligation to attempt to re-establish trust and confidence, one way or another. How would that conversation have looked, for example? The resident could have restated her

commitment to their common goal -- the patient's health, his getting well; she could have requested his help in reaching that goal by asking what he needed from her or the team to set things right; and she could have offered him someone else's expertise, if his confidence in hers couldn't be regained. She might have said something as simple as, "You and I both want you to get well. Let me help you or let me find someone else who can. I will find the best person here to put in this central line. Please allow us to help you. Don't let us fail you."

Too often in cases in which the patient resists or refuses the clinical team's recommendations, the treating clinicians assume the role of the Aesopian wind trying to blow off the man's coat: desperately trying to save this patient's life, the team tries to cajole, coax, and convince the patient to consent to the life-saving treatment plan. While the confrontational approach to secure consent is well-intentioned, it usually fails because it doesn't recognize what's driving the patient's resistance or refusal. In this case, the patient doesn't want to die; he consented to being admitted to the MICU because he wants to get well. So what is motivating his refusal to have the central line placed? He consented to all of the other procedures and tests over the course of the night, so why not this one? He is refusing now because he no longer believes he is being treated by a competent team of clinicians; the failure to place the peripheral lines has undermined his confidence. If I have lost my trust in what you say or my confidence in your abilities, I cannot be convinced that it is a prudent course of action. And in the absence of trust, the direct approach is likely to be perceived as coercive and suspect, adding to the patient's impression that he is not in good hands. Securing consent requires trust. Having established a doctor-patient relationship with this patient, the treating physician has an obligation to regain his trust and confidence or find him another clinician.

### **The Failure of the Principlist Paradigm: The Problem of the False Negative**

The Principlist Paradigm detects two moral obligations in our case, both of which the resident discharged by her actions: the obligation to respect autonomy, by either securing consent or respecting the refusal; and, the obligation to act beneficently, by ensuring that the patient is competent, and if not, by overriding the patient's decision to achieve the patient's own best interests. Looking through the lens of the Principlist Paradigm, there were no other moral obligations binding in this case. In contrast, I have argued that this case generates four additional moral obligations that must be discharged by the treating team: the obligation to express regret; the obligation to apologize; the obligation to make amends; and the obligation to secure the patient's trust and confidence. If any of these four obligations do apply in this tragic case, then the Principlist Paradigm failed to detect all of the moral obligations of the treating team.

Because the Principlist Paradigm offers us a limited moral lens through which to view clinical ethics cases, it cannot detect ethical obligations outside of the scope of the moral rules that have conventionally been attached to the four principles. The Principlist Paradigm is valuable as a method of moral analysis as far as it goes: it detects important moral obligations that have been critical in improving the delivery of healthcare. But the Principlist Paradigm also gives us a false reassurance that we have fulfilled all of the duties to patients when this limited set of obligations has been met, though, in fact, other obligations have not been met. At the conclusion of a case analysis, the Principlist Paradigm tells us we have no obligations where we actually do. The problem with the Principlist Paradigm is that it can generate an ethical "false negative" that actually compromises excellent patient care.

Ethics at the bedside has unequivocally embraces the Principlist Paradigm as the ideal mode of ethical decision-making, and it is the dominant mode of ethical analysis taught to student clinicians. While important for the moral obligations it does recognize, the Principlist Paradigm should not be used as the only moral template for case analysis. Medical ethics education needs to rethink the tools it offers students and clinicians to guide their ethical analysis so that we can expand the moral lens through which we assess the relevant obligations in tough clinical ethics cases.



<sup>1</sup>T. Beauchamp and J. Childress, The Principles of Biomedical Ethics. For a discussion of the difference between the theory of principlism and the Principlist Paradigm, see below.

<sup>2</sup> That is why the content of four principles is still an open debate. of course, principlism sets out a range of moral considerations that fit under any particular principles -- that's where the Principlist Paradigm got the list. The question is whether principlism has limited its own vision so that what's on that list is all that can be seen, or whether the list is tentative and the search on going for other important moral considerations that fall under the general principles. A full treatment of principlism is beyond the scope of this paper, and one question that remains is whether the Principlist Paradigm is a natural offshoot of principlism, in other words, whether principlism creates this paradigm. whether it succeeds or not is an open question.

<sup>3</sup> Of course this sounds like a criticism of principlism, not just a criticism of the Principlist Paradigm -- because I imply that the current schema -- here and all of them -- is an adequate to the task of detect in all of the moral considerations either. That would be a criticism of principlism if that were its intention, namely, to detect any and all moral considerations in obligations that exist. But that would be a strange goal for theory. My understanding of principlism is that its intention is to demonstrate and objectivity in the core principles that govern biomedical life, not to be able to generate an exhaustive list of everything that is subsumed under those principles. Why would generators of such a theory one that? Beauchamp Childress would be the last people to argue against moral development at our argue in favor of a static conception of ethics.