Acknowledgments

In the summer of 2011, I went to see my family physician about some abdominal pain. This was not the first time I had seen a doctor about this particular concern. After first experiencing the pain, a doctor had told me that it was probably menstrual cramps and that I shouldn’t worry. However, when the pain continued over several weeks I did worry, so I used a visit to my hometown as an opportunity to see a physician who had known me for a long time and whom I could trust. This time, my physician didn’t tell me not to worry. Instead, she made me an appointment for a CT scan. The CT scan led to a more invasive test, during which I was told that the technician “could not find my left ovary” – no further explanation was given. Soon after the test I received a call from my family doctor. Apparently, the technician had been unable to find my ovary not because it was missing, but because it was so big that it took up the entire screen. In her words, it was the size of a grapefruit. I was then sent to a gynecologist, who told me that I had a large cyst in my ovary and that I would need surgery to remove the whole ovary.

When I woke up from the surgery, I was told that my ovary did indeed seem to have a large cyst but that I should be fine. I spent a few weeks at home recovering and that would have been the end of the story…except that the story my parents and husband told me a few months later was very different.

What I remember as a somewhat rushed preparation to go to the hospital for the surgery and an analgesic-induced haze recovering at home afterward was for them an incredibly anxious, stressful time. It seems that while I was under the impression that I probably had a large, benign ovarian cyst based on the pre-op diagnosis, my family had been told after the surgery that it was now possible I had ovarian cancer. While I was still under anaesthesia, they had been taken into a conference room at the hospital by the gynecologist and told that she could no longer be sure whether or not it was a benign cyst or a malignant tumor, that a tissue sample would be sent to the lab, and that they would be notified of the result as soon as possible. When the gynecologist called a few days after the surgery to inform my husband and me that the cyst had not been cancerous, there was a palpable sense of relief in the house for what to me had been the formal confirmation of what was already the informal diagnosis. I was not really aware of any of the doubt and fear my family was living with after the surgery. Of course, I am sure I was told of the possibility of cancer at some point, but the seriousness of the situation was never really emphasized to me, whereas it had been to my parents and husband.

That I had not been fully brought up to speed after the surgery does not bother me. In fact, if someone had sat me down and walked me through the possibility of ovarian cancer, I would have been a nervous wreck. The fact that my physician and my family did not feel the need to make sure that I really, truly understood the situation was an act of compassion for which I am grateful.

The significance of this experience is not restricted to my personal life. I study medical ethics, and I have been intrigued by arguments about informed consent in Japan for some time. The parallels between what happened to me and the so-called “unethical” practices of informed consent in present-day Japan were immediately obvious. This made me wonder what it was about the behavior of my physician and my family that seemed justified, and why, despite my own intuitions, Japanese informed consent so clearly
bothers the majority of American researchers. The curiosity born of this experience has largely driven the present project, and I would therefore like to thank first and foremost my hometown physician, for listening to me and for taking my concerns seriously, and my gynecologist, for showing me what an ethically responsible medical practice looks like.

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I would never have pursued this project if I had not been given the chance to conduct research on the ethics of organ transplantation in Tokyo, Japan as an undergraduate at Williams College. Thank you to the college, as well as to my host in Japan, Tomoaki Tsuchida, and my adviser at Williams, Julie Pedroni, for sending me down this wonderful road.

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The chair of my dissertation committee, Ken Kipnis, has been incredibly supportive of what was at first a somewhat opaque project and has been invaluable in suggesting counter-points and alternative perspectives to my own outlook. He invited (and drove!) me to ethics committee meetings in Honolulu, incorporated me into his Ethics in Health Care course, and took me on as a research assistant for his project on correctional health care ethics. Were it not for him, I would not be on the career trajectory I am now and would certainly not have such a deep appreciation for making one’s research practically useful.

My research adviser in Japan, Carl Becker, warmly welcomed me to Japan despite the mountains of paperwork that such an endeavor entailed and was the first reader on drafts of several of these chapters. I am very thankful for the opportunities to attend his undergraduate bioethics lectures, participate in his graduate bioethics seminar, and join the Kyoto University community. As he was one of the first recipients of the Crown Prince Akihito Scholarship, I very much admire the trail he has blazed in Japan, without which much of my research would have been impossible.

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I am very lucky to have made friends while living in Japan, and they were instrumental in keeping me sane through the writing process and making sure that I didn’t miss out on opportunities to see beautiful sights, eat new foods, and participate in numerous matsuri. Thank you for balancing my research with invaluable life experiences, Yasuhiro, Yoshie, Taeko, Iyo, Zoe, Stevie, Miku, Anton, Cathie, and Itsuki.

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Finally, I thank my husband, Ian, for letting me bring him to Japan for 18 months to do research for this dissertation. He is a trooper, and while I know he loved living in Japan, I also know that living in a country where one doesn’t completely know the language can be hard. He stuck with me, however, and if he hadn’t been there to comfort my anxieties and to talk through my innumerable chapter reorganizations, this dissertation would have taken much longer to complete and would certainly be missing a certain element that brings the present work to life.
Abstract

Principlist ethical justification is the preferred mode of analysis in contemporary bioethical inquiry. Yet increasing bioethical discourse between different cultures has shown that this assumed methodology is problematic across cultures. In this dissertation, I establish a new methodology for cross-cultural bioethical inquiry based not on moral principlism, but on moral particularism. I show how relying on principles for ethical justification easily leads to cross-cultural disagreements, and I propose that ethical justification of practices across cultures is better pursued through a particularist approach that recognizes the practical contributions of institutional and social factors to ethical analysis. I then use this particularist approach to comparatively analyze practices of informed consent in the U.S. and Japan, demonstrating the explanatory power and ethical significance of this approach for one of the most central issues in contemporary global bioethics.

This particularist analysis shows that the discourse on informed consent is primarily concerned with how informed consent practices prevent physician paternalism and enable patient autonomy. This discourse privileges American practices and does not reflect global differences in how informed consent practices are conceptualized, institutionalized, and realized. By highlighting distinctive features of the Japanese practice of informed consent, I reveal a number of factors that are routinely omitted from the ethical discussion on informed consent, including psychosocial aspects of information provision and medical decision-making, systemic availability of secondary support staff, and responsibility for decisions and decision-making processes.
These factors are most apparent in the Japanese practice, but they are not unique to Japan. Rather, they are significant in the U.S. as well, where the conceptual focus on physician paternalism versus patient autonomy has narrowed the discussion and obstructed a wider perspective on ethical issues in informed consent. While in the U.S. the significance of psychosocial support for informed consent is unacknowledged but delegated, in Japan it is acknowledged yet undelegated. The comparative approach of this dissertation allows us to better address these under-recognized issues in the discourse on informed consent and to improve practices in both the U.S. and Japan.
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Introduction: Comparative Bioethics and Informed Consent

“There was a time when physicians didn’t convey the truth to the patients themselves. To think about it now seems like a lie, but when I first graduated, they didn’t say anything. Especially with stomach cancer. They wouldn’t speak to the patient at all, just with the family. They would call in the family, tell them the diagnosis, and ask if they should tell the patient. All Japanese people thought that the patient shouldn’t be told…Now not telling isn’t an option. To be told the truth, to react to it together, to think together, has a positive meaning, but there are also people who aren’t used to it, who are passive and can’t think strongly on their own, they are told in a jumble, they can’t understand. Initially most people thought that it is best to entrust things to the physician. If you’re told, then to actively choose, to have to decide, to take on responsibility, maybe comparatively people in the U.S. are more used to this.”

-- Interview with a Japanese physician, 2014

“I had a father and a son [from a Chinese family] on the same unit at the same time, both dying of cancer, and the family didn’t want either of them to know that they were in the hospital. They were in different rooms, and they would avoid the son’s room when going to see the father. They were afraid that dad would lose his fight if he knew that he had cancer. Never saw it as something positive.”

-- Interview with a medical social worker in Hawaii, 2013

Japanese physicians’ nondisclosures of cancer diagnoses to patients have been frequently discussed in both American and Japanese bioethics. The now familiar story is that, while in the 1970s American physicians universally changed their cancer diagnosis disclosure policies from nondisclosure to disclosure, Japanese physicians even now retain the rights not to disclose these diagnoses and to make disclosure decisions on a case-by-case basis. Reactions to this Japanese practice have been split, with some arguing that Japanese physicians’ nondisclosures are paternalistic, violate patients’ autonomy, and are thus problematic, and others suggesting that such nondisclosures make cultural sense in Japan and are therefore permissible. These two groups remain opposed. One side assumes the perspective of supposedly universal American bioethics and declares such nondisclosures unethical, while the other side takes the perspective of local Japanese
bioethics and declares such nondisclosures justifiable in Japan. In such circumstances, relativist and anti-relativist arguments are often invoked – if ethical values are relative, than Japan’s practice is justified, but if they are universal, then it is not. Problematically, neither side approaches the issue of Japanese informed consent from a cross-cultural perspective. No one has considered what Japanese physicians’ nondisclosures of these diagnoses may indicate about medical decision-making in other countries and contexts beyond Japan.

In this dissertation, I approach this issue from a new angle. Rather than rehearsing familiar arguments about paternalism, autonomy, and cultural relativism, I first ask whether the discussion of Japanese physicians’ practices got off on the wrong foot. Did the standard methodology of bioethical inquiry lead to this cross-cultural opposition? And if so, how might we resolve it? Motivating these questions are the facts that paternalistic physician behaviors are not as simple as their opponents assume and that so-called cultural practices are rarely as self-contained as their defenders suppose. For example, Hawaiian medical professionals routinely work with patients and families from diverse cultures. Narratives such as the one above from a social worker in Hawaii highlight the complex nature of medical decision-making and the difficulty of analyzing concrete decision-making practices in either abstract theoretical or essentialist cultural terms. Rather than pitting theory against culture, I ask whether there is a better way of approaching particular or local practices from a global bioethical perspective.

I begin in chapter 1 by examining comparative bioethical methodology. I identify problems with the dominant principlist methodology and suggest a better way to pursue ethical justification of particular practices across cultures. Chapter 2 takes the first step in
analyzing informed consent through the methodology identified in chapter 1 by examining the differences in institutional standards of informed consent in the U.S. and Japan. This identifies compelling structural differences in how the two countries’ informed consent standards distribute responsibility for decisions.

Rather than assessing informed consent in terms of institutional standards alone, in chapter 3 I ask medical professionals in Japan how they grapple with the Japanese institutional standard and I assess in what ways these Japanese professionals’ concrete practices are similar to or different from those of professionals in the U.S. These interviews reveal that, despite differences in institutional standards, the particular features and challenges of informed consent practices are actually quite similar in the United States and Japan. The two main differences are institutional divisions of responsibility and allowances of nondisclosure of some diagnoses, historically cancer, but now dementia as well.

To understand the features affecting American physicians’ decisions to disclose diagnoses and Japanese physicians’ decisions not to disclose, chapter 4 comparatively analyzes changes in physicians’ cancer diagnosis disclosure policies along with patient and family perceptions of cancer and attitudes towards disclosure in the U.S. and Japan. This analysis demonstrates that, while division of responsibility for medical decision-making is important for institutional standards of informed consent, the availability of psychosocial support may more significantly affect whether or not physicians convey diagnoses to patients and families.

1 As a comparative study, this research does involve some amount of functional simplification. A future study would need to examine local Japanese practices of informed consent along socioeconomic and geographic lines as well as in terms, age, gender, and other factors.
Chapter 5 examines dominant theories of informed consent, asking why support for decision-making has not been included in the theoretical discussion on informed consent. This examination reveals that dominant theories of informed consent utilize an individual-outcome model of responsibility that prioritizes liability for decisions, despite increasing academic and public concern with physicians’ and other medical professionals’ abilities to empathize with and understand their patients.

Chapter 6 then clarifies Japanese informed consent practices in light of a relation-process model of responsibility and asks whether these practices are ethically justified. Acknowledging that the relation-process model of responsibility is conceptually significant for Japanese professionals, I nevertheless suggest that Japanese informed consent practices should be revised to reflect the practical significance of this model and to better support patients, families, and medical professionals. Finally, I propose that these revisions are not unique to Japan, but are needed in the U.S. as well.
Chapter 1: Justifying Ethical Claims Across Cultures

“In one case, at a treatment center for lung cancer, my teacher had a lot of experience, and thought patients should not be told [their diagnoses]. But another physician, who had a lot of experience with hospitalized patients, thought it was strange not to disclose, and would disclose. Without consulting with the family, he would just recklessly tell the patient. Now this is normal, but at that time, to do full informed consent was weird, and other physicians couldn’t believe that the physician would do informed consent that way. It turned into an argument, but for me at that time, I thought that after all, it’s better to tell the patient.”

--Interview with a Japanese physician, 2014

“The discourse between physicians and patients is decisively influenced by the particular medical problem which brings them together. To promulgate an informed consent doctrine which articulates the extent of communication required for all medical encounters, as if differences between them and their impact on physicians and patients alike are inconsequential, is perhaps impossible. For analytic purposes it may be more profitable, at least to begin with, to give separate consideration, for example, to the diagnostic, prognostic, and therapeutic facets of medical practice, to acutely and chronically ill patients, to conditions that can be treated by a variety of means or none at all, and to interventions in which faith in the therapy makes a significant contribution to cure. Such an analysis may even reveal that at times compelling reasons exist for not communicating disturbing information to patients. To that extent physicians may have been right in their insistence on non-disclosure.”


Introduction

Bioethics is a complex field. It seeks to answer questions and resolve problems that change along with developments in medicine and biology. Ethical justification plays a crucial role in bioethics by clarifying the reasons that support complex judgments about particular actions and general policies. It helps us to determine what to allow, forbid, support, and minimize. When we disagree, it can also help us to understand competing positions. However, at times, particular issues become so complex that understanding

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3 In this chapter I use “moral” and “ethical” interchangeably. I also consider medical ethics to be one area of bioethics.
each other’s positions seems nearly impossible. In such circumstances, how might we respond?

In answering this question, this dissertation considers one such complex issue: the informed consent standards that guide medical decision-making in different countries. Since many medical procedures are transnational, it is thought that the informed consent standards for these procedures should be universal. However, global dialogue has revealed notable variation in local standards, resulting in questions about which informed consent practices are ethically justified. Recently, a number of conflicting positions have become entrenched, leading some to sense that the ethics of medical decision-making are not universal, but are instead culture or region specific. Thus the debate on informed consent, which began as a cross-cultural misunderstanding about the reasons behind local practices, has become a deep disagreement over the grounds of ethical justification.

In this chapter, I examine the arguments of several prominent figures in the medical ethical debate on practices of informed consent in East Asia. I suggest that the manner in which ethical justification has been attempted is responsible for the initial cross-cultural misunderstanding over these practices, and moreover, that reconceiving ethical justification will clarify the grounds of the misunderstanding and dissolve the deep disagreement over universal versus relative ethics in the cross-cultural bioethical debate.

This investigation proceeds as follows. First, I present the background to the discussion, which includes common tensions in cross-cultural bioethics and their tendency to reduce to a metaethical debate between universalism and relativism. Second, I provide an overview of the discussion on practices of informed consent in East Asia and
outline two opposing attempts (those of Akira Akabayashi and Ruiping Fan) to justify these practices ethically. Third, I analyze the metaethical positions and general commitments behind these attempted justifications to show that their assumptions about ethical justification render their arguments unsuccessful. Fourth, I critique Akabayashi and Fan’s shared moral generalism in terms of the problems it raises for cross-cultural ethical justification. Finally, I suggest a more useful method for explaining and justifying medical ethical practices across cultures.

1.1 Tensions in Cross-Cultural Bioethics

Bioethics was born out of the cultural and sociological conditions of the United States in the post-World War II era, and in the latter quarter of the 20th century many of its ideals and practices spread overseas. These ideals and practices were unproblematic in European countries that had been struggling with corresponding issues of medical research and experimentation in the context of similar legal and social systems, but the extension of so-called American bioethics to Asia and the Middle East has not been so easy. Cross-cultural bioethical discussions involving these cultures often manifest as collisions of disparate moral perspectives, with each side defending the intuitive correctness of their claims but neither side really understanding the other.

Scholars of bioethics and the medical humanities have been paying increasing attention to these cross-cultural discussions for two reasons. First, without resolution, disagreement about the justification of supposedly core bioethical practices like informed consent calls into question the ethical justification of all transnational practices over which there is disagreement. For instance, disagreement about how informed consent
ought to be justified in a particular context can challenge the justification of all informed consent practices, if justification is understood as universal and not relative (more on this below). To avoid continuing potentially problematic practices and to ensure that ethical justification is not just locally effective, it is thought that these disagreements must be resolved.

Second, these disagreements sometimes indicate not a failure of understanding, but a flaw in the field in which the disagreement takes place (just as moral disagreement is a major issue for ethics in general). Entrenched cross-cultural disagreements have implications for how bioethics as a field is defined and for how we “do” bioethics. If current methods of bioethical analysis are more likely to lead to misunderstanding than understanding between differing viewpoints and cultures, then we should reconsider the methodology of bioethics.

Of these two reasons for paying attention to bioethical disagreements across cultures, the latter reason is more pressing and thus is the focus of the present chapter. Without clarifying the theoretical background against which such disagreements take place, any attempts at resolution will be superficial. To seek a more effective solution, this chapter asks what cross-cultural bioethical disagreement indicates about bioethics as a field – both in terms of scope and methodology.

Several authors have already taken up this question. Their answers fall roughly into two categories. One group has argued that entrenched cross-cultural disagreements indicate that different cultures “disagree about moral premises and rules of evidence” of bioethics, so we can only “live together as moral strangers in the face of irresolvable

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moral diversity.”⁵ This suggests the absence of a unified global field of bioethics. In the words of one scholar, bioethics is a “cluster concept” that “comes in many not always mutually understandable dialects.”⁶

Another group, while sensitive to the threats of moral or cultural imperialism, has suggested that a common language of bioethics can be found if we “negotiate about the ‘reasonableness’ of arguments.”⁷ This common language will allow us to pursue a global bioethics by harmonizing and bridging regional “ethoses” to become “‘holistic’ as opposed to ‘individualistic.’”⁸ This suggests that there is something properly called “global bioethics,” which is more uniform than the amalgamation of viewpoints implied by the term “cluster concept.”

The former camp, skeptical about reaching consensus on specific issues and suspicious of universal bioethical declarations, leans towards moral relativism. By contrast, the latter camp argues that we can indeed speak a common moral language, while respecting local differences in how this common language is expressed. This implies a form of moral universalism. Unfortunately, neither side specifies what these positions entail; their arguments tend to be based on whether or not they think that agreement across cultures is a realistic goal.

These viewpoints about cross-cultural or global bioethics can be otherwise articulated in terms of two metaethical positions: cultural moral relativism and moral universalism. Both positions agree that moral claims are truth-apt, but they disagree on the grounds for moral claims’ truth-value. For moral universalists, true moral claims are

⁶ Holm, “Global Bioethics – Myth or Reality?” 10.
⁷ Campbell, “Presidential Address,” 189.
universally true. This means that if “lying is wrong” is true, it is true in all cases and for all people (although the grounds of its truth-value are contested, such that the truth of moral claims can depend on the structure of rationality, the word of God, or moral facts in the world that make them true). According to this position, if “lying is wrong” is true, then I should not lie, and nothing will be able to justify lying.

Cultural moral relativists reject that moral claims are universally truth-apt, and instead argue that their truth-value is relative to particular cultures. For example, if I am in a situation where I want to tell a lie and I need to know if lying is wrong, then I should appeal to my culture. If in my culture lying is wrong (i.e., if “lying is wrong” is true in my culture), then I should not lie and I will not be able to ethically justify lying.

Both cultural moral relativism and moral universalism hold that moral judgment and ethical justification depend on identifying the morally relevant properties of the situation. In the case of universalism, the property is defined as a moral principle or moral rule that demands obedience. In the case of cultural relativism, the moral property is my culture’s sanction or prohibition, also often phrased as a moral rule or principle. Moral universalism and cultural moral relativism as so defined (and as most often discussed in the bioethical literature) are forms of moral generalism, according to which morality is best described as a system of general moral principles. These moral principles can play two different types of roles: determinate or contributory. If the moral principles are determinate, then the fact that lying is wrong (either in my culture or

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9 Moral principles and moral rules are essentially identical, although moral principles tend to be general values or goods while moral rules are usually phrased as more specific imperatives.
10 In this paper I use moral generalism to indicate the metaethical position that ethics consists of moral principles, and principlism to indicate the related position that ethical justification must proceed in terms of principles.
universally) fully determines whether or not I ought to lie, and thus it also determines whether or not my lie is justified. No further aspects of the situation matter. If the moral principles are contributory, then the fact that lying is wrong is a significant component, but not the sole factor, in moral judgment and justification. Other aspects of the situation do matter, although these other aspects must also be morally relevant properties. For example, in the case of cultural relativism, my culture might prohibit lying while also sanctioning compassionate actions, and both these rules might hold in a single situation. Similarly, for the universalist, it might be true that “lying is wrong,” but also that “harming others is wrong.” Any process of moral judgment and justification will have to weigh and balance these contributory rules or principles. While few ethical theorists believe that moral principles are determinate, the presumption of determinate moral principlist methodology does tend to sneak into cross-cultural bioethical discussions along with other, more visible commitments, as I will show in section 3.

There is another possible metaethical position with regard to the question of “global bioethics” that is not currently represented in the debate – this is the view of moral particularism. Moral particularism is the rejection of moral generalism. For the moral particularist, while all situations have morally relevant features that contribute to

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11 Not all details are morally relevant. My relationship to the person I propose to lie to may be morally relevant (e.g. whether they are my mother or a stranger), while the weather that day probably is not.
12 Jonathan Dancy has been the foremost defender of moral particularism; his *Stanford Encyclopedia of Philosophy* entry is useful in defining this position. Also see Norris Lance, *Challenging Moral Particularism*, and Hooker and Little, *Moral Particularism*. Importantly, while Dancy makes moral particularism into an ontological claim, others (Garfield, “Particularity and Principle”) have argued that it is an epistemological one. My concern, however, is different from those of Dancy and Garfield. Rather than discussing what moral particularists think ethics is or how moral particularists think we have ethical knowledge, I focus on how moral particularists think ethical claims can be justified.
the judgment and the justification of what should be done in those situations, these
morally relevant features are not moral principles, and their truth-value is neither relative
to culture nor universal. Moral particularism thus often holds that moral claims are truth-
apt, but understands the relativity of their truth-value more radically. Determinate moral
principles are rejected, but so are moral principles understood as consistent across cases.
In other words, while “lying is wrong” may be “true” in one case, that is, may count in
favor of not lying, it is not necessarily “true” in another case. Its truth-value depends on
the interaction of innumerable features of the case. In assessing a situation that seems to
require lying, the moral particularist will ask what the reasons are for and against lying.
What is the situation? To whom will the lie be directed? What are the motivations for the
lie? Whether or not the action is “wrong” depends on this set of reasons holistically,
where participation in a culture or belief in a set of moral principles may matter, but are
by no means definitive.

I will have more to say about these positions later. For now, I suggest that one
reason for the entrenched nature of cross-cultural bioethical disagreements is that those
engaged in these debates assume that generalist moral universalism and moral relativism
are the only possible routes to ethical justification. This reveals a further assumption
about the methodology of bioethics.

Both general discussions and particular debates on cross-cultural bioethics assume
that bioethics deals with rules or principles that are either universally or relatively
applicable to particular cases. According to this dichotomy, bioethics must either have its
own set of universal principles, or be a classificatory term for culturally, nationally, or
socially defined principles. Very few scholars question whether bioethics must involve
ethical principles, or whether ethical justification in bioethics should apply principles to biomedical issues. The principled nature of bioethics – and thus the assumption of a moral generalist framework – is taken for granted. Yet to resolve these debates, these foundational assumptions about bioethical judgment and justification must be questioned. There is also a pragmatic reason for questioning moral generalism in the context of global bioethics. While most philosophical argumentation about generalism and particularism takes place metaethically, practical differences between the two positions are perhaps most clear in the sphere of applied or practical ethics, where these theories underlie potential solutions to real-world problems and may offer pragmatic, non-theoretical reasons to prefer one over the other.\textsuperscript{13}

This chapter will not prove which of the three positions is the proper metaethical foundation for bioethical justification. Indeed, the contemporary debate between these positions is lively in metaethics as well. However, commitments to the first two of these metaethical positions are hidden in contemporary debates on cross-cultural bioethical issues, and this is problematic. Metaethicists can separate themselves from practical considerations so as to focus on the logic of the arguments for and against these three positions. Cross-cultural bioethicists are more likely to commit to metaethical positions for reasons other than the strength of the arguments. For example, one may defend relativism to protect the distinctiveness of one’s culture from moral imperialism, or one may argue for universalism because one thinks that bioethics should not be culturally

\textsuperscript{13} I take the terms “applied ethics” and “practical ethics” to be interchangeable, although there is disagreement over whether the two really amount to the same thing. For example, applied ethics is often described as the application of abstract ethical theory to real world problems, whereas practical ethics is interpreted as the study or analysis of ethical issues in the particular contexts in which they arise.
insulated or “parochial.” Such hidden commitments lead to misunderstanding and contribute to the entrenched nature of these cross-cultural disagreements. Identifying the role of these metaethical assumptions in cross-cultural bioethical justification provides necessary clarification. The analysis that follows does not attempt a theoretical critique of these metaethical positions, but produces a practical argument for why some of them do not work in cross-cultural bioethics. Whether or not these practical issues suggest deeper theoretical difficulties remains a subject for future work.

1.2 Informed Consent Across Cultures

A well-known example of disagreement in cross-cultural bioethics comes from the debate on practices of informed consent in East Asian cultures. In the case of terminal illnesses such as cancer, physicians and families within these cultures are often more likely to withhold diagnoses of these illnesses from patients. For many scholars outside these cultures, these practices are morally problematic, either as blatant violations of patient autonomy, or because there seems to be no adequate justification for them.

Within these cultures, many find these practices to be intuitively morally acceptable, yet attempts to justify them ethically have led to disagreement about the foundation of their moral acceptability. The failure to resolve these disagreements has

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14 This disagreement has also occurred in the context of Islamic, Middle Eastern, Eastern European, and South American cultures. However, since it has been the most sustained in the East Asian case, I focus on this case here.
16 The responses by Robert Klitzman, Kenneth Kipnis, Yvette Pearson, and Anita Ho to Akabayashi and Slingsby’s article in the American Journal of Bioethics 6.1 (2006) are good examples of possible responses from outsider perspectives.
contributed to arguments based on the metaethical positions described in section 1. Some suggest that a local or generally Asian approach to bioethics is needed, others allege that Asian bioethics is just one version of a unified global bioethics, and yet a third group argues for “a collage of culturally informed perspectives built upon an ever-increasing aggregate of shared experiences.” To better understand these positions, this section focuses on the method of ethical justification used by two of the foremost East Asian representatives in the informed consent debate. One side leans towards universalism, while the other espouses relativism. It is crucial to understand why they support these positions and how they think their arguments get them to their desired conclusions.

1.2.1 First Viewpoint: Akira Akabayashi

One of the most vocal participants in this debate is Akira Akabayashi, a physician and medical ethicist at the University of Tokyo, who in 2006 advanced his idea of the “family-facilitated” approach to informed consent. Since 2006, Akabayashi has repeatedly defended this argument, most recently in the 2014 volume, The Future of Bioethics. Akabayashi alleges that the Japanese practice of informed consent, in which the family may be informed instead of the patient, is based on a form of autonomy that is compatible with relational autonomy. This “form of autonomy” better captures the autonomous nature of individuals with an “interdependent self-construal,” as compared

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17 Akabayashi et al., “Is Asian Bioethics Really the Solution?”
18 Castro, “Is There an Asian Bioethics?”
19 Akabayashi and Hayashi, “Informed Consent Revisited,” 745. “Relational Autonomy” has been proposed as an alternative to traditional Western autonomy, sometimes described as “rugged and individualist.” In contrast, relational autonomy emphasizes the importance of embodied experience, interpersonal relationships, and particular contexts for the development of autonomy (see Mackenzie and Stoljar, Relational Autonomy).
with individuals who have an independent self-construction, for whom the traditional understanding of autonomy as individual self-determination is more appropriate.

Akabayashi often uses case studies to clarify the family-facilitated approach. In his 2014 paper, he explains the family-facilitated approach through three case studies. In each case study, he presents the facts he takes to be relevant: the patient’s age, occupation, gender, mental state, relationship with family members, details of the diagnosis, prognosis, and proposed treatment. He describes the scenario in which the diagnosis is told, as well as the reactions of the patient, family, and physician. He then analyzes the roles of the family and physician. Akabayashi’s main concern throughout is whether the family-facilitated approach is consistent with patient autonomy.

Akabayashi conceives of this explanatory work as getting him almost all the way to ethical justification. Interpreting the family-facilitated approach in terms of autonomy allows him to use autonomy as a justification for family-based informed consent. While Akabayashi does not explain why this form of autonomy is valuable, he repeatedly stresses that it is commensurable with “the general ethical principle of respect for autonomy in the United States,” understood as “the minimization of physician paternalism and respect for patient preference.” Akabayashi’s concern to ground the Japanese practice in American/Western autonomy reveals his belief that this principle of autonomy is legitimate and universal, while his application of this principle to Japan

\[20\] The same cases he considers in articles from 1999 and 2006.
\[21\] Akabayashi and Slingsby, “Informed Consent Revisited,” 13. Akabayashi does not seem to intend any relation to the idea of incommensurability as it is used in contemporary analytic philosophy, where two values are incommensurable if there is no common unit of measurement in terms of which they can be measured (Hsieh 2008). Rather, his usage of commensurable suggests consistency or comparability.
\[22\] Akabayashi and Hayashi, “Informed Consent Revisited,” 745.
suggests that it is not an unchanging Platonic ideal, but one that can adjust to local considerations. He writes, “we attempt to pay due respect to local cultural values to the extent that they are compatible with the concept of autonomy that underlies the ideal practice of informed consent.”\(^{23}\) For him, autonomy is not only a common ethical standard, but further specifies an ideal practice of informed consent against which particular practices can be measured. He stakes his argument on whether or not he can show that the family-facilitated approach to informed consent is based on an alternative interpretation of the principle of autonomy that is still compatible with the ideal of informed consent.

Akabayashi’s justification reveals his motivations. He writes that the goal of his argument is “to reconcile apparently conflicting abstract ideals and local realities without giving either of them absolute status.”\(^{24}\) He is committed to respecting local values while pursuing justification based on abstract ideals to preserve the possibility of dialogue, critique, and revision. He summarizes these goals in what he calls the commensurability of values between cultures despite local specificity of practices, holding that particular practices must be defended in terms of universal principles in order to avoid being “cultural artifacts.”\(^{25}\) This implies that for Akabayashi, disagreements between local practices and universal principles are apparent, and local practices can be justified in terms of an abstract ideal or principle.

In short, Akabayashi values the possibility of dialogue about ethical valuations across cultures, so he does not allow that ethical judgments are predicated on unique

\(^{23}\) Ibid., 747.
\(^{24}\) Akabayashi and Hayashi, “Informed Consent Revisited,” 747.
\(^{25}\) Ibid., 737.
cultural values. Rather, ethical justification must have a universal foundation such that individuals in different cultures can engage in dialogue and critique. For Akabayashi, this foundation is a set of common abstract ideals used in moral judgment and justification. While judgment and justification occur in the context of local realities, their content (i.e., Beauchamp and Childress’s four principles: autonomy, beneficence, non-maleficence, and justice) and methodology (i.e., application of principles) are universal.

In a lengthy footnote to “Informed Consent Revisited: A Global Perspective” in The Future of Bioethics, Akabayashi recognizes the efforts of Ruiping Fan to ground family-oriented medical practice in Confucian culture as similar to his attempt to accommodate the importance of the family into medical decision-making. Yet he ultimately concludes that Fan’s justification, which relies on particular Chinese or East Asian cultural concepts “incommensurable with the Western principle of autonomy,” differs from his own, which seeks consistency or compatibility with Western autonomy. For Akabayashi, commensurability of ethical concepts across cultures is necessary for successful cross-cultural dialogue, so his defense of the Japanese practice of informed consent in terms of a form of autonomy compatible with Western autonomy achieves two goals: it accounts for the practice in non-culturally relative terms, and it justifies the practice according to non-culturally relative standards.

1.2.2 Second Viewpoint: Ruiping Fan

Fan’s argument is initially very similar to that of Akabayashi. Fan begins from the fact that the Western principle of autonomy, described as self-sovereignty and self-

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determination, is not realized in medical practice in East Asia. Akabayashi agrees that Western autonomy, strictly defined, does not account for many East Asian medical practices, and they both present the role of the family as an example of this difference. But while Akabayashi defends common abstract ideals across cultures, Fan advocates the relativity of cultural norms.

Fan describes the Western principle of autonomy as embodying “a general priority given to the value of patients’ self-determination in the clinical setting.” He argues that while this principle has been introduced into the East Asian context, it has not been widely accepted, as evidenced by East Asian disclosure practices. The main reason for this non-acceptance is that East Asia has its own principle of autonomy, which is incommensurable with that of the West. Fan terms Western autonomy “personal autonomy” and East Asian autonomy “moral autonomy,” and describes them as self-determination and family-determination, respectively.

In concrete terms, this plays out in the following ways. In the West: (1) final authority in decision-making belongs to the patient, (2) there is a subjective conception of the good such that a good decision is one that satisfies one’s own desires, preferences, and expectations, and (3) independence is “overwhelmingly important” to Western patients. Fan describes this as self-determination-oriented. By contrast, the East Asian principle of autonomy is family-determination-oriented. As Fan defines it: “Every agent

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28 Fan 2014 switches from the language of “incommensurability” to “incomparability,” but as with Akabayashi, he seems to mean inconsistency or incompatibility.
29 Fan’s choice of terminology here is not consistent with Western philosophy of autonomy, and so seems to be either a new usage or one unique to the Confucian tradition.
30 Ibid., 313-315.
should be able to make his or her decisions and actions harmoniously in cooperation with other relevant persons” and “no harmoniously made decisions and actions should be subjected to controlling constraints by others.” Based on this definition, in East Asia: (1) The family has the final authority to make decisions, (2) Eastern societies have an objective conception of the good such that a good decision satisfies family preferences and social expectations, and (3) “Harmonious dependence” is the value that is overwhelmingly important to East Asian patients. Fan suggests that these features are “common to all East Asian societies,” and while “similar to the behaviors of some Western groups,” “the difference between East Asia and the West is very clear.”

Setting aside worries about cultural essentialism, Fan’s argument mimics the model of conceptualization and ethical justification used in Western bioethics in order to ethically justify valued local practices to a Western audience. He argues that the East Asian principle of autonomy functions just like the Western principle of autonomy – it is the sole reason for, and justification of, “practices of truth-telling, informed consent and advanced directives.” In addition, the approaches to medical decision-making dictated by the two principles both reject physician paternalism. Thus the concrete motivations for the two principles are also the same.

Fan assumes that morality must consist of systems of principles, rules, and rights that are culturally and theoretically distinct. He uses the language of autonomy to describe the principle that applies in China, while holding that the content of ethical principles differs between Western bioethics and East Asian societies. He maintains that

31 Ibid., 316.
33 Ibid., 316.
34 Ibid., 319.
individual self-determination and family determination are incomparable principles.\(^{35}\) This means there is no universal common morality, because the principles that make up common morality are not universally shared (though they may have the same terminology, e.g., “autonomy”).

Fan thus accepts half of the picture of ethical justification used by Akabayashi – that ethical justification depends on principles, rules, and rights to define what is sanctioned and what is prohibited – but not the other half, which stipulates a common system of principles across all cultures and traditions. For Fan, a moral judgment’s objective truth depends on whether it accords with moral principles dictated by a certain culture or tradition. In the context of cross-cultural disagreement, he concludes that ethical principles are relative to the cultures in which they are found.

In conclusion, both Fan and Akabayashi assert that informed consent can be conducted with the family alone, and that it is sometimes ethically justifiable not to inform patients of their diagnoses. Akabayashi justifies family-facilitated informed consent by appealing to “a form of autonomy” commensurable with the absolute principle of autonomy, part of the universal set of moral principles. Fan justifies family-determined informed consent based on a principle of autonomy appropriate for the Chinese Confucian context and incommensurable with Western autonomy. Akabayashi and Fan reach the same general conclusion and understand ethical justification in the same way: it is the application of abstract ethical principles to concrete cases based on “the Western bioethical model.” They share this assumption – that bioethics deals with principles applied to particular cases – while disagreeing about the ground of these

\(^{35}\) See note 27 above.
principles due to their respective commitments to universal dialogue and cultural distinctiveness. In the following section, I clarify how these general commitments affect the normative force of their arguments.

1.3 Clarifying the Two Positions

The shared goal of Akabayashi’s and Fan’s arguments is to justify their cultures’ practices. Both assume that ethical justification must proceed through the use of principles and both rely on Tom Beauchamp and James Childress’s *Principles of Medical Ethics* for their methodology. Akabayashi and Fan refer to Beauchamp and Childress repeatedly and rarely cite positions that challenge the methodology of *Principles of Medical Ethics*. However, Beauchamp and Childress’s four-principles approach to bioethics should not be accepted as the standard in the field without critical reevaluation.

Akabayashi’s and Fan’s assumptions that principles play a determinate role in ethical justification may also follow from Beauchamp and Childress, whose defense of the informed consent standard according to the principle of respect for autonomy is used with nearly canonical frequency. This defense implies determinate principlism, despite Beauchamp and Childress’ outward claims that they do not support such a position. They allow that “respect for autonomy has only prima facie standing, and competing moral considerations sometimes override this principle,” but nevertheless write that “autonomy does provide the primary justification of rules, policies, and practices of informed consent.”

Accordingly, they tie informed consent directly to autonomy, such that a failure to provide informed consent is always a failure to respect autonomy (although it

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may be justified by another principle, such as beneficence). In other words, informed consent is never described in terms of a principle other than autonomy. If a competing principle suggests that informed consent ought to be practiced in a non-standard way, not only is this no longer a practice motivated by autonomy; it is also not a practice that can properly be called informed consent. While this emphasis on autonomy may be related to the particular history of informed consent as developed in the U.S., Beauchamp and Childress readily extend informed consent requirements beyond local boundaries. They suggest that the requirement to obtain informed consent is an ideal universal norm or rule, writing that some norms are

Intentionally formulated with the goal of including all legitimate exceptions. An example is, “Always obtain oral or written informed consent for medical interventions with competent patients, except in emergencies, in forensic examinations, in low-risk situations, or when patients have waived their right to adequate information.” This norm needs further interpretation, including an analysis of what constitutes an informed consent, an emergency, a waiver, a forensic examination, and a low risk. However, this rule would be absolute if it were correct that all legitimate exceptions had successfully been incorporated in its formulation.37

In addition, the scope of respect for autonomy is not circumscribed to informed consent, but covers multiple features of the physician-patient relationship, including confidentiality and respect for privacy.38

37 Beauchamp and Childress, Principles of Biomedical Ethics, 19. Emphasis added.
38 Ibid., 107.
Given this explanation of the relationship between informed consent and autonomy, Beauchamp and Childress’ relative confidence in their formulation of the norm of informed consent, and the wealth of books and articles focusing on the relationship between informed consent and autonomy (in the manner of Beauchamp and Childress), Akabayashi’s and Fan’s justifications of their local practices of informed consent solely in terms of autonomy are not surprising. Since they adopt a principlist methodology for bioethical inquiry and Beauchamp and Childress are the leading experts on this methodology, there are few other options open to them. However, this metaethical assumption leads to problems for their normative arguments.

In order to defend the East Asian practice of informed consent, Akabayashi and Fan must take on the Western autonomy-informed consent (AIC) complex directly. This means they must either accept the AIC complex or reject it and opt for a completely different East Asian version premised on a different set of bioethical principles. Both take the former route: Akabayashi by describing “a form of autonomy,” and Fan by defining a Confucian principle of autonomy.

This choice occasions another decision: within the AIC complex, Akabayashi and Fan must either accept the Western principle of autonomy or reject this principle and redefine autonomy according to East Asian cultures. Here their commitments to universal discourse and local practices resurface. Despite their shared methodology, Akabayashi and Fan rank global dialogue and traditional cultural practices differently. While each finds value in their local practices and in rational discourse across cultures, Akabayashi is committed to global discourse through universal principles and Fan defends local traditions through relative principles. Their primary commitments to either the global or
the local dictate whether they lean towards moral universalism or moral relativism. Their only two options are a universal principle of autonomy or a relative principle of autonomy; Akabayashi chooses the former, and Fan, the latter.

Accordingly, Akabayashi must explain how a practice, apparently different from Western informed consent, actually follows from the same universal principle of autonomy. Likewise, Fan must account for why a practice that is called informed consent and that deals with medical decision-making is based on a different principle than that of the West just because it takes place in China’s Confucian cultural context.

Akabayashi writes that his “method can provide a starting place for practical solutions that avoid the pitfalls of parochial ethnocentrism and arrogant universalism.” 39 To avoid these pitfalls, family-facilitated autonomy must be commensurable, compatible, or consistent with individual autonomy. This requires a theory of autonomy that can capture the East Asian practice of informed consent along with the Western practice. For this, Akabayashi turns to relational autonomy, a theory that recognizes the importance of human relationships in developing and maintaining autonomy. However, as Akabayashi recognizes, the theory of relational autonomy does not permit the family to be told the diagnosis first without the patient’s explicit consent (although it does more comprehensively address the relationship between patient autonomy and family concerns). 40 Accordingly, relational autonomy cannot stand in as Akabayashi’s theory of autonomy because it cannot account for East Asian practices. Akabayashi then appeals to Onora O’Neill’s conception of “principled autonomy,” where he takes the crucial point to

40 See Anita Ho’s response to Akabayashi: Ho, “Whose Interest is it Anyway?”
be the absence of coercion.\textsuperscript{41} However, it is hard to assess whether the appropriate safeguards for ruling out coercion are in place without further analysis of medical decision-making in Japan, as many of the respondents to his 2006 article argue. So principled autonomy cannot be Akabayashi’s theory of autonomy either, since it, too, only applies to Western contexts. In the end, Akabayashi has no universal theory of autonomy by which to justify his claims.

Fan’s argument encounters similar setbacks. His goal is to prove that Chinese/Confucian and Western moral principles are fundamentally different. He suggests that the concept employed in China is “moral autonomy,” which he describes as respect for the “moral will” rather than respect for an individual’s arbitrary will, where the moral will is grounded in the proper way of Heaven. The “normal way of Heaven” is “the proper, virtuous mutual care and interdependence of family members.”\textsuperscript{42} The moral will, in accordance with the normal way of Heaven, is akin to a familial or communal will in that the will exists at the family unit or community level. Granting decisional authority solely to the patient is deviation from this normal way. The goal is for all decision-making procedures to follow this way of Heaven, and such procedures are ethically justified if they fit this ideal.

However, while family harmony is a laudable ideal, it is hard to see why real-life situations that can only approximate this ideal should be judged according to this standard.\textsuperscript{43} Even if Confucian culture downplays an individual’s authority to make decisions that will affect the family and expects the family to function as a shared

\textsuperscript{41} Akabayashi and Hayashi, “Informed Consent Revisited,” 771.
\textsuperscript{42} Fan, “How Should We Defend a Family-Based Approach to Informed Consent?” 764.
\textsuperscript{43} This problem is not unique to the principle of family harmony, but is faced by all such “ideal” standards.
decision-making unit, not all families within Confucian cultures will function in this way. Some family members may prefer personal autonomy. To accommodate this variation, Fan suggests that patients who prefer personal autonomy should state this clearly in advance so they can receive the first-person approach to informed consent. All other situations will be assumed to follow moral autonomy. Yet, what happens if a patient prefers personal autonomy, but their family prefers moral autonomy? Is the patient’s preference a deviation from the normal way of heaven or an individual choice that must be respected? Here Fan’s deference to individual preference may collapse into individual autonomy, such that family-decision making depends on patient choice.

As with Akabayashi, Fan’s argument is too abstract to prove the existence of a unique principle of autonomy in Confucian culture. Without inquiring into how decision-making within the family is facilitated and how to resolve conflicts, Fan’s proposal falls short. In difficult cases, he must resort to personal autonomy, because at least it is clear how this principle applies in actual cases. His principle of moral autonomy fails to function as a guide to action; it is merely a descriptive ideal.

Neither Akabayashi nor Fan successfully justifies East Asian informed consent. This is not because the practices they describe violate respect for autonomy, as many critics have suggested. Nor is it because they have misinterpreted the theory of moral generalism or because the theory of moral generalism is necessarily flawed. Rather, the failure of these two arguments highlights a practical problem with how bioethical discourse is pursued across cultures. Akabayashi and Fan both assume that ethical justification must be attempted according to a moral generalist methodology – principlism. This assumption is not unique to Akabayashi and Fan. Many non-Western
bioethicists take the principlism of *Principles of Biomedical Ethics* to be the accepted method of bioethical justification. However, this assumption narrows attempted justifications: (1) it focuses the justification on the definition of ethical principles rather than a detailed description of the practices in question, and (2) it requires an explanation of the chosen principles in terms of either moral universalism or moral relativism.

In the case of Akabayashi and Fan, they both seek to make their countries’ practices of informed consent understood in terms of a principle of autonomy, which requires that they (1) explain the content of the principle and (2) justify their use of the principle by accounting for how their countries’ practices fall under the scope of the principle. For Akabayashi, the relevant principle is a form of the universal principle of autonomy, the content of which is the obligation to prevent paternalism and respect patient preferences. For Fan, the relevant principle is a relative form of autonomy called “moral autonomy,” the content of which is family-determination. They make their arguments in terms of these principles *alone*; they consider neither other principles that may be in play nor other relevant moral properties that would affect their ethical justification. They focus on principles but inadequately explain the details of East Asian informed consent in practice. As a result, outsiders to these cultures cannot determine whether these practices should be allowed or forbidden, and insiders become distracted by a seemingly irresolvable opposition between universal and relative principles.

One might counter that the failures of Akabayashi’s and Fan’s arguments should not be blamed on moral principlism because they incorrectly use principlist methodology. Indeed, applying principles correctly requires careful judgment, and principlists suggest

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44 Alternatively, they may think it is the only method that will make their practices understandable to a Western audience.
that if a given case seems out of step with preexisting principles, then those preexisting principles should be altered. According to this suggestion, it is possible that East Asian informed consent practices indicate that a change to the principle of autonomy is necessary.\textsuperscript{45} In fact, revision to the principle of autonomy is exactly the argumentative route taken by both Akabayashi and Fan – Akabayashi seeks out alternative conceptions of autonomy, and Fan defines a Confucian form of autonomy. Yet while revision to principles is theoretically possible, it seldom occurs in practice. More common is that non-Western practices are perceived as exceptions to general rules (e.g., as cases in which beneficence is more significant than autonomy), rather than as opportunities to rethink these general rules.\textsuperscript{46} Despite principlism’s theoretical allowance for some variant of reflective equilibrium, the fact that principles are rarely revised in the face of diverse and dynamic practices should give us pause.\textsuperscript{47} This does not necessarily indicate a problem inherent in the idea of ethical principles, but rather an issue that arises as a result of moral generalists’ use of principlist methodology.

I contend that the tendency to focus on defining principles to the exclusion of explaining concrete cases is not just a problem for Akabayashi and Fan. Principlism relies on a set of assumptions about the structure and significance of ethical thinking that are not reflectively acknowledged within the methodology itself. Principlists’ allowance of flexibility in the order, balance, and definition of principles – whether through reflective

\textsuperscript{45} I would like to thank an anonymous reviewer for \textit{The Kennedy Institute of Ethics Journal} for making this point.

\textsuperscript{46} As Beauchamp and Childress note, practices of informed consent are not always justified by the principle of autonomy alone. In some cases, beneficence is more relevant than autonomy (Beauchamp and Childress, \textit{Principles}, 108).

\textsuperscript{47} The fact that Beauchamp and Childress’ four principles have been liberally applied to divergent practices in diverse cultures but have not themselves changed substantially in the twenty-some years since they were first proposed supports this claim.
equilibrium, coherentism, or some alternative – does not correct for a fundamental imbalance in principlist methodology. This imbalance favors abstract, supposedly universal ethical theories to the detriment of contextual, unique ethical concepts and ideas. The main issue is not that principles are inflexible, but that principlism focuses the ethical discussion on theory rather than complex practices. This is especially problematic in ethical discourse across diverse cultures, where general principles cannot be the intuitive action-guides they function as in discourse between parties with similar cultural backgrounds. Principlism’s proclivity for theory drives scholars from cultures whose practices do not fit the assumed universal framework to expend considerable effort fitting their practice into this universal framework or risk the charge of immorality. In the process, much of the context that could have justified their practices is lost, and misunderstanding and disagreement ensue. The only practices exempt from misunderstanding are those within the dominant culture in which the principlist theory arose.

In short, the assumption that principlism is the established method of ethical justification in bioethics is a major underlying reason for bioethical disagreement across cultures. Entrenched disagreement about whether local practices are ethical indicates neither that ethics is reducible to culture nor that explanations of these practices in terms of universal principles have been insufficient. Rather, ethical justification requires more than principles in the first place. In the following sections, I expand on how principlism frustrates cross-cultural understanding and gives rise to the universalism versus relativism divide.
1.4 Problems with Principlism Across Cultures

Principlism is one method of ethical justification by which moral claims are defended in terms of moral principles. A decision or action is justified if it can be shown to fall under a given principle’s scope of application. This is a top-down method of ethical justification, in which justification occurs at the most abstract level of analysis. In Principles of Biomedical Ethics, Beauchamp and Childress write that an ethical judgment such as “You should not lie to Mr. Stanford” is justified according to this method because we are able to derive the rule, “You should not lie to patients” from the general principle “You should respect the autonomy of patients.”48 In other words, principlist ethical justification begins with a judgment, and, instead of asking why the judgment would be or was made in practical terms, accounts for it in terms of a general rule and an even more general principle.

This method of ethical justification focuses only on the aspects of the judgment that relate directly to the principle thought to cover the judgment. Other reasons that may account for the judgment are likely to be disregarded because they do not fall within the scope of the principle. As Beauchamp and Childress themselves note, these reasons include traditional practices, institutional rules, and case judgments, as well as factual beliefs about the world, cultural expectations, judgments of likely outcome, and precedents. This list might also include subjective factors, such as the emotional states and intimate relationships of those involved.

Excluding supposedly irrelevant practical factors in favor of those that fall under a principle not only impairs the argument for ethical justification, but also risks

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48 Beauchamp and Childress, Principles, 392.
misunderstanding by those for whom the principle is not so intuitive. Within a given
culture, many details of a case remain unspoken because they are part of the presumed
background to the discussion. In different cultures, what is salient and what is unspoken
may vary. For example, to an American citizen the connection between informed consent
and autonomy may be salient, while the patients’ rights movement and mistrust of
physician paternalism might be unspoken. To a Japanese citizen, on the other hand, there
could be salient connections between “informed consent,” transliterated as infōmudo
konsento, and American ethical standards, while concerns about burdening one’s family
and increasing rates of medical malpractice could be unspoken. Both the salient and the
unspoken affect the ethical analysis of a given practice.

Without clarifying the presumptions, conceptual schemes, and forms of
understanding that affect decisions and judgments in local contexts, agreement about
whether a given principle applies to a particular situation is unlikely. Just as the
understanding of informed consent in the U.S. depends on a range of legal, social,
historical, and cultural factors unique to American life, so the understanding of informed
consent in Japan depends on similarly complex factors. This does not mean that practices
outside of one’s own culture cannot be understood, but it does mean that understanding
requires ample consideration of these practical factors. Uncovering unspoken aspects of
practices is no small feat. Accounting for cases in terms of single principles may seem
simpler, but it is likely to exclude relevant considerations of how and why judgments are
made. This engenders cross-cultural disagreement about ethical justification and
misunderstanding about the motivations and reasons for the judgment, especially if the
form and content of the principle is not agreed upon. But this is not the only way that
determinate principlism is problematic.

Principlist justification also readily leads to the opposition between universalism
and relativism, because it requires not only that we justify actions in terms of principles,
but also that we account for the principles themselves in terms of a higher-order, logical
framework. Principlist ethical justification invokes ethical theory as a final justification –
otherwise the chosen principle will explain, but not justify, the judgment in question. It is
very easy to come up with a principle that explains one’s judgment, but it is difficult to
show that the principle itself is normative. In other words, demonstrating that one can
find a relevant principle is not the same as demonstrating the significance of that
principle for living a moral life or making an ethical decision. As Beauchamp and
Childress recognize, the top-down model of ethical justification creates a “never-ending
demand for final justification… proof that some principles occupy this [self-justifying]
status…is an arduous demand that current ethical theory cannot meet… it would appear,
on the assumptions of this [the principlist] approach, that there are no justified principles
or judgments.” 49

Without consensus in ethical theory, choice of ethical theory is based on intuitive
ethical motivations. In the cases of Akabayashi and Fan, Akabayashi justifies his form of
the principle of autonomy by tethering it to Western theories of autonomy, which he
presumes to be theoretically secure. Fan, on the other hand, justifies his principle of
moral autonomy within the Confucian worldview, arguing that moral autonomy is a
justified principle within Confucian ethical theory, but is incompatible with similar

49 Beauchamp and Childress, Principles, 393. Beauchamp and Childress themselves solve
this problem by tethering principles to the “common morality.”
principles in Western ethical theory. The requirement that the principles themselves be justified by moral theory forces Akabayashi and Fan to defend universalism and relativism, respectively. Importantly, the choice of an ethical theory here is arbitrary – no further justification of the choice of a theory is possible. Within principlist ethical justification, there is no final reason why universalism or relativism is justified; the two positions are left in a deadlock.

In order to ameliorate entrenched disagreement and escape the universalism versus relativism dichotomy, cross-cultural ethical justification should seek to avoid the pitfalls of principlism described in this section. These include: (1) accounting for cases and practices solely in terms of principles to the exclusion of other morally relevant factors and (2) relying on moral theory to provide the final justification for principles. I discuss this in more detail in the next section, where I address how ethical justification can avoid the universalism versus relativism divide and mitigate entrenched disagreement and persistent misunderstanding.

1.5 Cross-Cultural Bioethical Justification

Principlist justification is essential to neither ethics nor bioethics, although it pervades both in the Western discourse. Concerns about relying on principlist methodology across cultures are also not new. In a 1984 paper, Renee Fox critiques American bioethicists visiting hospitals in China who assume that the “best way of moral thought” is to begin with a general moral theory or moral concepts and proceeding via logical reasoning. She observes that “this way of thought… tends towards dichotomous

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50 Fox, “Medical Morality is not Bioethics,” 355.
distinctions and bipolar choices… Even the field’s own self-defining conception of what
is and is not a moral problem is formulated in a bipolar, either/or fashion.”51 Fox notes
that in bioethics, the application of theory to real situations often manifests as thought
experiments, rather than detailed, in situ, empirical investigation. She suggests that this is
because “ordered, cerebral armchair inquiry” generates formalistic data, which “more
closely fit the norms of bioethical logic and rationality than information gathered from
firsthand research.”52 She argues that bioethics must investigate these real-life situations,
because “these very suppositions of bioethical thought contribute to its inadvertent
propensity to reflect and systematically support conventional, relatively conservative
American concepts, values, and beliefs.”53 In other words, for bioethics to function across
cultures and contexts, we must question the assumptions of bioethics’ moral
epistemology. This means asking whether the content of bioethics is best expressed in
terms of principles, and whether the method of bioethics ought to be the application of
these principles to particular cases.

George Khushf has also argued that the global bioethics discourse assumes that
bioethics must: “involve some minimal but overarching principles or structure, which
provide a common basis for moral discourse… downplay deep metaphysical and
theoretical differences [and abstract from] the rich textures and forms of life that give
content to ethical systems.”54 Khushf identifies this set of assumptions with principlism,
and suggests that this type of “constructivist minimalism” leads to an irresolvable tension

51 Ibid., 355-356.
52 Ibid., 355-356.
53 Fox, “Medical Morality,” 355-356.
54 Khushf, “Methodological Considerations in the Development of a Global Bioethic,”
123.
between so-called Eastern and Western principles.\textsuperscript{55} I agree with Khushf that principlism is problematic for cross-cultural analysis, and I think we can do better in the following two ways.

First, ethical justification should begin by explaining the rich background of local practices and specific cases. The experiences, motivations, and emotions of those involved in local practices should be described before any higher-order, logical ethical justification is attempted. Even in principlism, it is impossible to identify relevant principles before knowing the details of the case. While no description of a case or a practice can determine its evaluation (an “is” cannot determine an “ought,” as David Hume suggested), any evaluation or normative assessment requires this factual background. Before understanding the situation in which a judgment is made, we cannot determine which factors are morally relevant. Leaving out this crucial step results in misunderstanding and poorly constructed arguments. As Daniel P. Sulmasy and Jeremy Sugarman emphasize, “Good ethics depends upon good facts. Failure to understand the facts of a situation thoroughly will clearly lead to perils in moral decision-making.”\textsuperscript{56} A successful ethical justification of a judgment or a practice requires that the facts be understood. Careful clarification of these facts will go a long way towards making particular practices understandable across cultures.

This is not to say that Akabayashi and Fan misunderstand the relationship between the patient and the family in medical decision-making in East Asia. Akabayashi, for example, notes the mental states and relationships of those involved in specific cases and describes aspects of the conceptual framework in Japan that might be unknown to a

\textsuperscript{55} Ibid., 124.
\textsuperscript{56} Sulmasy and Sugarman, \textit{Methods in Medical Ethics}, 11.
foreign audience, including the importance of interdependence, the idea of *omakase* (reliance on others for guidance or decisions), and the use of non-verbal communication. However, he interprets these aspects’ relevance to ethical justification almost completely in terms of autonomy, even though they suggest the significance of relationality and mutual support. Given the narrow perspective of principlist ethical analysis, it is possible that he omits other considerations as well.

In his response to Akabayashi, Carl Becker cautions that using an abstract principle to justify a practice can blind one to other significant factors, writing that “if Japanese-style decision-making leads to danger or damage, then it should be reexamined, not because it is weak on autonomy, but rather because of other harms it may cause.” Becker is concerned with factors that Akabayashi excludes, including how to tell if a non-verbal nod expresses consent, how a physician can know that a patient has a trusting relationship with their family members, and what to do if the family does not agree on a decision (all too frequent in unanticipated medical situations). A focus on only those reasons that relate to a principle can obscure other ethically relevant reasons for and against the practice.

Second, ethical justification should rely on more than just abstract principles as good reasons. Anita Ho writes that “what makes Akabayashi and Hayashi’s family-facilitated approach particularly convincing is that it recognizes the clinical realities and relational complexities that patients face in grim health-care situations.” She suggests that understanding the practice as “a form of autonomy” or as sufficiently close to the “ideal” of informed consent does not suffice for Akabayashi’s ethical justification; rather,

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58 Ho, “Whose Interest is it Anyway?” 760.
she proposes that if his ethical justification is successful, it is due to his examination of
the details and his assessment of what count as good reasons to those engaged in the
practice. What is valuable, then, is precisely what is absent from Western autonomy:
concrete particulars. Akabayashi’s appeal to the principle of autonomy is at best a
distraction and at worst damaging to the practice.

This is not to say that principles cannot be good reasons, but rather that their role
in ethical justification is not as central and their definition is not as certain as principlists
suppose. Practically, principles function better as guidelines, values, or goods than as
rules strictly dictating conduct. This is somewhat in line with Beauchamp and Childress’
understanding – they define principles as general guidelines that specify more detailed
rules and judgments. 59 Yet the question of the theoretical source of these principles
remains. Are they universal, or are they relative to cultures or even to individuals? Unless
we can agree on at least a cursory explanation, misunderstanding is sure to persist.

Beauchamp and Childress seem to understand principles as contributory, not
determinate, yet nevertheless belonging to a universal or general moral structure.
According to Principles of Biomedical Ethics, principles are part of the common
morality, which contains “moral norms that are abstract, universal, or content thin.” 60 The
common morality is a complex of universally valid norms that can also be described as
standards of action or rules of obligation. Some of these standards include: tell the truth,
do not steal, keep your promises, and obey just laws. The common morality includes
features besides these rules, such as character traits (virtues), human rights, and moral
ideals. While this common morality is not ahistorical or a priori but has been learned and

59 Beauchamp and Childress, Principles, 14.
60 Ibid., 4.
transmitted, Beauchamp and Childress suggest that it is also universal and authoritative in all communities.\textsuperscript{61} This is because it is developed from ordinary, shared moral beliefs that all people pre-theoretically hold.\textsuperscript{62}

I cannot make a full argument against common morality here, but I suggest a few reasons why we should be suspicious of its claims in the cross-cultural context and how we might counter it while not sacrificing a sense of “ethics in common.”\textsuperscript{63} Beauchamp and Childress offer no empirical evidence for their claim that the common morality is universally shared, although they do suggest a possible methodology for investigating it. Yet their proposed study assumes what it is trying to prove. It limits participants to those who understand morality as consisting of norms and already subscribe to one of the moral norms they describe in \textit{Principles of Biomedical Ethics}.\textsuperscript{64} Beauchamp and Childress themselves assume that a “moral point of view” must take the form of universal action-guiding norms or rules. It is not clear why this must be the case, especially if we become familiar with the ethical philosophies of different cultures, which do not universally espouse rule-based morality.\textsuperscript{65}

Rebecca Kukla makes this point in her recent article “Living with Pirates: Common Morality and Embodied Practice.”\textsuperscript{66} Displaying Wittgensteinian commitments,

\begin{flushleft}
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\textsuperscript{61} Ibid., 5.
\textsuperscript{62} Ibid., 411.
\textsuperscript{63} Two debates on common morality take place in the \textit{Journal of Medicine and Philosophy} 25.3 and the \textit{Cambridge Quarterly of Healthcare Ethics} 23.
\textsuperscript{64} Beauchamp and Childress, \textit{Principles}, 416-417. Some of the opponents to common morality (according to the Beauchamp and Childress definition) include Rebecca Kukla, Carson Strong, Bernard Gert, and Charles M. Culver.
\textsuperscript{65} These are not just particular moral codes, an explanation that dismisses their philosophical contributions. Even among rule-based moral systems, not all require universality.
\textsuperscript{66} Kukla, “Living with Pirates.”
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Kukla doubts that a common basis for morality can be discursively explained, given that different expressions will “vary in their clarity and connotations to different audiences.”

She also suggests that, given the right explanation,

Almost any behavior can be understood as consistent with commitment to almost any rule, given that we allow that people will acknowledge different exceptions to the rules, apply them differently, and resolve conflicts between them differently. We cannot, therefore, read whether someone accepts a rule off of whether her particular actions accord with it, nor off of whether she agrees with a particular formulation of it. Thus it is unclear how to distinguish, even in theory, between disagreements over whether a principle should be accepted and disagreements over how to interpret and apply that principle. So the hypothesis that there are universally accepted rules is not only hard to test but perhaps ill-defined.

According to Kukla, moral principles, expressed as rules, are not helpful as a universal basis for morality. We can tell neither from another person’s action, nor from their word, whether they understand themselves as acting according to that rule. For example, while two people may agree with the norm “tell the truth,” they may interpret what this norm requires differently and decide on different paths of action in a similar situation. For person A, telling the truth might mean telling someone all the known facts, while for person B, telling the truth might mean revealing one’s innermost feelings. Conversely, person B may perform an action that person A understands as “telling the truth,” without person B accepting this norm as the justification for the action.

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67 Ibid., 80.
This indicates that our understanding of moral principles, if there are any, must be context dependent. Margaret Olivia Little makes precisely this argument in the context of Wittgenstein’s discussion of rule-following.\(^6\) She suggests that moral properties can function holistically, such that moral considerations have bearing in certain contexts due to the whole range of natural considerations that make up that context.\(^7\) Different moral considerations will arise out of different contexts. Because these moral considerations function holistically, they are impossible to isolate from their contexts or codify into a set of moral rules. For instance, the moral generalist might say that “tell the truth” is a universal moral rule such that telling the truth is always good and always allowable. Yet we can think of cases in which the situation dictates that one ought not to tell the truth, such as if an abusive husband comes in search of his wife whom you are harboring. The moral particularist will argue that “tell the truth” is not unique in this way – all statements of what one ought to do, or ought to allow, prohibit, or sanction, are dependent on contextual considerations.

This is not to say that there is no foundation for moral judgment – we do not fall into relativism, but avoid the universalism versus relativism opposition altogether. This opposition arises only in the case of moral generalism. If morality is defined in terms of moral principles or rules, then there must be an underlying structure – a reliable constant – dictating the content of these principles. This content can be universally or relatively defined, but it is required for the principles to have any identifiable meaning.

In contrast, moral particularism allows that there is a common aspect to morality, but it is not morality’s content. What is common is the bare activity of moral judgment,

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\(^6\) See Wittgenstein’s *Philosophical Investigations* for this argument.
moral action, and moral justification. Morality entails trying to be a good person, a good family, or a good society, and reflectively assessing whether or not that goal was achieved. The content of what it means to be good, and what we think we need to do to become good, will always be up for debate. Indeed, culture plays a major role not only in the evolution of shared values but also in the evolution of how we think about and practice values. This evolution is constantly progressing – there is no view from nowhere.

Yet as Rebecca Kukla observes, even without agreeing on what it means to be good, even without a shared absolute theory, we are remarkably adept at interacting with other people in non-problematic ways – we can understand others’ emotions and motives, we can make promises and convey gratitude, and we can respect others’ differences.71 Even if we profess no interest in being good and no need to be moral, we do so against a background of other people for whom this is a concern, and who will attempt to convince us otherwise. Accordingly, the common part of morality more properly refers to a shared moral life, not a common moral language. This shared moral life consists of “an endlessly complex yet remarkably stable web of embodied normative responses, coping techniques, perceptual skills, communicative rituals, ways of making public our desires and needs, etc., rather than propositional content.”72

In short, the fact that we can and do have a dialogue with each other across cultures indicates that we are engaged in the same project. We are not relativistically isolated along cultural lines – just as individuals within a given culture can disagree, so can agreement across cultures be achieved. This is not to say that we must always agree, but that we can at least have a conversation about why we disagree. When cross-cultural

72 Ibid., 101.
dialogue breaks down, we can try to understand and assess each others’ processes of moral reasoning through the critical reasoning skills we share, including “local normative standards, conceptual analysis, reflective equilibrium, ideals of coherence and practicability, empirical evidence about the good and bad effects of particular practices, and so forth.” This is true in ethics and bioethics, just as it is in all cross-cultural conversations.

One might express concern that, without a moral principle or moral ideal transcending context, moral particularism inadequately explains how critique and moral change are possible. However, the critical reasoning skills identified by Kukla can serve precisely this function and actually make moral particularism better able to accommodate the significance of critique and moral change than theories based on moral principles or ideals. According to moral particularism, responding to concerns about whether a given practice is ethically justified entails providing a critical picture of the practice on multiple levels: institutional standards, relevant concepts, social expectations, empirical data, and so on. The practice is not measured against an ideal or principle, but is judged in terms of its specific purposes, meanings, and expectations. For example, in the case of East Asian informed consent, we might ask what practical reasons physicians in East Asia have for informing families before patients: are there adverse effects if patients are informed directly? Do patients expect and desire physicians to consult with their families before themselves? Do patients obtain information about their condition through alternative means/from other professionals than informed consent from physicians? If the answers to

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73 Ibid., 83.
74 I thank another anonymous reviewer for The Kennedy Institute of Ethics Journal for this point.
these questions are not in keeping with what East Asian informed consent purports to accomplish, then it is correct to critique and reevaluate the practice.

As long as we recognize that different considerations count as good reasons in different cases, we will be less likely to propose that an action is good because everyone should do it, or because everyone belonging to a certain group or culture already does it. Rather, we will ask why a given reason is believed to be a good reason in the circumstances. Reasons such as “the family ought to be valued” or “individual autonomy ought to be respected” will not be sufficient for a moral particularist justification, because neither reason critically engages with an actual practice in context. A set of reasons such as “Japanese physicians know their patients personally, know whether patients expect them to include the family in decision-making, have communication training with families, and Japanese patients have a higher likelihood of adverse psychosocial effects following disclosure of a terminal diagnosis” would better approximate a particularist justification of some Japanese physicians’ informed consent practices, although more detailed consideration would be necessary. However, this does provide a general sketch of what a moral particularist justification might look like and what types of questions should be asked in ethical justification across cultures.

Understanding ethical justification in terms of the moral particularism described in this section avoids opposition between universalism and relativism and clarifies the complex of reasons underlying particular decisions and practices. Had Akabayashi and Fan more thoroughly examined the different reasons for East Asian practices of informed consent, including those outside the scope of the principle of autonomy, they would have
increased cross-cultural understanding of these practices while avoiding the competing positions of universalism and relativism.

1.6 Conclusion

Misunderstanding of local practices and the debate between universalism and relativism within cross-cultural bioethics trace back to the reliance on principlist ethical justifications from a moral generalist perspective. While ethical justification cannot ignore principles (or better, “rules of thumb”), it should neither be assumed that ethical justification depends solely on principles, nor that they can be defined independent of contextual considerations. Making these assumptions in the cross-cultural context only perpetuates unhelpful dichotomies, increases misunderstanding, and frustrates resolution.

Gaining clarity on what works in ethical justification helps to avoid such disagreements in the future, so that cross-cultural ethical dialogue can be more productively pursued. In this chapter, I have suggested two ways that such cross-cultural bioethical justification can be improved: (1) by describing the particular, practical factors of concrete cases, including the attitudes and perceptions of those involved, and (2) by considering how these practical factors might be morally relevant. Such steps will clarify, if not overcome, cross-cultural disagreements, allowing us to attempt ethical justification of diverse practices. What is common in the cross-cultural bioethical discussion is not a set of moral principles or a moral language, but a concern with bioethical questions in the context of our shared moral life. Indeed, there is global interest in ensuring that we judge and act ethically in the midst of rapid advances in biomedical technology and the shifting nature of the physician-patient relationship.
The following chapters of this dissertation demonstrate the explanatory power and ethical significance of the particularist approach to ethical justification through a comparative analysis of Japanese and American informed consent practices. This particularist approach suggests that before we can consider the ethical justification of Japanese informed consent, we need to have a clear idea of what this practice is, of particular situations in which it is employed, and of what people feel when they are engaged in it. Accordingly, chapter 2 analyzes the institutional standards of informed consent in Japan through a comparison with legal and professional informed consent requirements in the United States.
**Principlist ethical justification** begins with the narrowest considerations, ethical principles, and uses them to determine social rules in the form of legal guidelines and institutional policies and to assess the ethical status of concrete practices.

**Particularist ethical justification**, by contrast, begins by considering how concrete practices take shape in constant tension with social rules, before assessing possible ethical justifications of practices and considering future possibilities.

*Figure 1. Principlist Ethical Justification and Particularist Ethical Justification*
Chapter 2: Institutional Standards of Informed Consent in the U.S. and Japan

“In the past 10 years it [informed consent] has changed a lot, there aren’t really any things that shouldn’t be said. There is the fear of being sued. Previously, it was natural not to disclose, and there were very few court cases. There was shared aesthetics between physician and patient, a trusting relationship, and lawsuits were few. But, now, if you don’t tell the correct things, if this affects the options, then you might be sued. So more than the patient’s feelings, despite the patient’s anxiety, you have to tell the correct information early so they can make a good decision. If you don’t tell when it’s discovered, you can be sued. So whether it’s good or bad, you have to tell.”

--Interview with a Japanese Physician, 2014

“This decision-making in medical treatment, the decision-making initiative, what is called the subjectivity, is not that of the patient, but is something the doctor possesses. So, even though the subject of decision-making and informed consent is the patient’s body, life, and humanity, in Japanese informed consent, the subject of decision-making is mostly the medical doctor.”

--Interview with a Japanese Clinical Psychologist, 2014

Introduction

In chapter 1, I argued that clarifying the role of principles in ethical justification avoids the universalism versus relativism dichotomy within cross-cultural ethical discourse. Principles are a resource that can be used in ethical justification, but the broader foundation for ethical justification is the set of possible reasons for a decision or a practice, including “local normative standards, conceptual analysis, reflective equilibrium, ideals of coherence and practicability, empirical evidence about the good and bad effects of particular practices, and so forth.”75 It is from this set of possible reasons that ethical justification proceeds by identifying which reasons are good reasons, and which are not.

I suggested that one particular discourse that could benefit from a reconsideration and reapplication of ethical justification is the cross-cultural discourse concerning practices of informed consent. Within this discourse, some scholars justify local practices in terms of a principle of autonomy taken to be universal, or by defining a local principle of autonomy. However, principles like autonomy are just one tool in the ethicist’s kit, and it may be that the principle of autonomy is not the sole good reason for practices of informed consent in East Asia. Furthermore, the omission of practical factors such as legal standards, professional guidelines, and public understanding in accounting for the difference between American and Japanese practices has not only increased cross-cultural misunderstanding, it has also allowed for the perpetuation of a false dichotomy between Eastern and Western values and an oversimplified cultural essentialism in the discourse on informed consent. In the next three chapters, I examine these practical factors, including institutional standards, concrete practices, and social environments.\(^{76}\) This enables a more comprehensive assessment of how informed consent is practiced in Japan and whether nondisclosure practices are justified.

2.1 Informed Consent in Contemporary Discourse

The phrase “informed consent” is often thought to have two uses in contemporary discourse. The first is the “social rules of consent” – informed consent as an institutional requirement on professional practice mandated through court decisions and medical profession guidelines and codes.\(^{77}\) The second is informed consent as an ideal theoretical

\(^{76}\) The fact that these practical factors themselves influence and are influenced by culture further underscores their importance for a cross-cultural analysis.

\(^{77}\) Beauchamp and Childress, *Principles*, 122.
concept not necessarily realized in practice.\footnote{See Faden and Beauchamp, \textit{A History and Theory of Informed Consent}.} According to this division, ethical justification of particular informed consent practices entails describing the features of the ideal theoretical concept of informed consent and assessing the extent to which institutional guidelines and codes bring the particular practices in line with the theoretical ideal. For a depiction of how ethical justification works under this conception, see the image of “principlist ethical justification” in figure 1.

In contrast to this common two-part division, I distinguish three uses of informed consent in this dissertation. One use is informed consent as an institutional guideline and legal standard governing physician and patient behavior in medical decision-making. A second use is informed consent as a range of particular practices undertaken by physicians and other medical professionals. While these two uses mutually inform each other – practices affect policies and vice versa – particular informed consent practices may or may not be in line with institutional guidelines and legal standards, and the range of actual practices will be broader than those allowed by institutional policies. Finally, a third use is informed consent as an ethically justifiable practice. This is not an ideal conception of informed consent, but rather is an achievable goal – a future possibility – that arises out of an ethical assessment of the interaction of institutional standards (social rules) and concrete practices. For a depiction of how ethical justification of informed consent works under this conception, see “particularist ethical justification” in figure 1.

Within this three-part conception of informed consent, this chapter focuses on the first use of informed consent: as a legal standard and institutional guideline. Because historically, informed consent was first used in this way, delineating the birth and
subsequent development of legal and institutional policies of “informed consent” reveals how rules of informed consent came to have their present shape and what alternatives were excluded along the way. Chapters 3 and 4 then describe practices of informed consent in the U.S. and Japan, analyzing how they interact with these policies.

This chapter first briefly covers what are thought to be the catalysts for modern informed consent: the Nuremberg Military Tribunals and the resulting Nuremberg Code, as well as the related Declaration of Helsinki. Second, it presents the development of informed consent through American and Japanese court decisions and medical professional guidelines. Finally, it analyzes these institutional foundations of informed consent in both countries, distilling the most salient structural factors that influence both the practice of informed consent and the ethical discourse surrounding it. By reconsidering informed consent in the U.S. and Japan from its institutional beginnings, this analysis avoids the fallacious assumptions that either the legal and medical institutions in Japan and the U.S. have the same general structure and should pursue similar solutions to common problems, or that Japan and the U.S. are so radically different as to not admit of comparison. I take seriously Ruth Faden and Thomas Beauchamp’s caution that

“Informed consent” is a creature of a broad range of social practices and institutions in the twentieth century. To remove the notion from the contemporary cultural and historical contexts in which it was nourished in order to test retrospectively for its presence in other cultures is a dangerous undertaking requiring special precautions.79

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79 Faden and Beauchamp, A History and Theory, 55-56.
In this chapter, I am not interested in determining whether Japan’s practice of informed consent can be said to be the same as that of the U.S., although an understanding of their similarities and differences will be one of the results of my analysis. Rather, the goal is to understand the structural factors that have given rise to the practices called “informed consent” in both countries.

2.2 The Catalysts for Modern Informed Consent

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<tr>
<th>Year</th>
<th>Document</th>
<th>Significance</th>
<th>Drawbacks</th>
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<tr>
<td>1948</td>
<td>Nuremberg Code</td>
<td>Stipulated guidelines for human subjects research, including voluntary consent by subjects who understand what they are consenting to.</td>
<td>Vague – did not distinguish between clinical research and clinical medicine, nor between specific types of research. Created by lawyers and judges and applied to the medical profession.</td>
</tr>
<tr>
<td>1964</td>
<td>Declaration of Helsinki (revised in 2013)</td>
<td>Specified what subjects must understand prior to consent and distinguished potentially problematic cases, including conflicts of interest and vulnerable subjects.</td>
<td>Not legally binding – a set of guidelines created by the medical profession for the medical profession.</td>
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Figure 2. International Informed Consent Guidelines

Modern practices of informed consent are most often traced (in both the English and Japanese literature) to two documents that were created in the wake of World War II (WWII): the Nuremberg Code and the Declaration of Helsinki. Revelation of experiments conducted during WWII demonstrated the need to protect individuals from

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unwanted medical intervention, and for the first time the importance of a patient’s or research subject’s consent came to be recognized on the global stage.\textsuperscript{81}

The Nuremberg Code responded to the medical atrocities committed, under the guise of both treatment and research, during WWII. Prior to WWII, there was little need for a code stipulating patients’ rights against physicians; it was assumed that physicians were acting in their patients’ best interests. The earliest version (5\textsuperscript{th} century BC) of the Hippocratic Oath states that physicians will act for the good of their patients. In addition, medical ethical codes drafted before WWII were not for the protection of patients, but for the protection of professional physicians against unlicensed and lay practitioners.\textsuperscript{82} The Nazi-committed atrocities altered this landscape, making clear that lines needed to be drawn between medical research and medical treatment and that, with regard to both areas, patients’ voluntary consent was necessary to ensure that patients/research subjects both understood what they were consenting to and were not being coerced into giving consent.

The Nuremberg Code was enacted in 1948 following the Nuremberg Military Tribunals’ trial of Nazi medical specialists for biomedical experimentation on prisoners of war and those held in concentration camps. During the trial, the defendants (twenty doctors and three administrators who participated in such experiments) were convicted of crimes against humanity. The judges at the trial crafted a code that would protect research subjects against future abuses, in part because the Nazi doctors had defended their

\textsuperscript{81} Faden and Beauchamp, \textit{A History and Theory}, 152.
\textsuperscript{82} See Robert Baker, \textit{The American Medical Ethics Revolution}. 
experiments as “legally correct, medically necessary, and morally right” and in line with the Hippocratic Oath. Paul Julian Weindling notes the importance of drawing this line around ethical medical practices, not just for the protection of patients, but also for the protection of the future of medical research. In order for human subjects research to continue, standards had to be established proving that this research could be ethical. The resulting Nuremberg Code was one of the first instances of a code created by legal professionals for the medical profession, although formation of the code was influenced by both the American and British Medical Associations. The first principle of the Code emphasizes the importance of voluntary consent in the context of human subject research, where voluntary consent entails that the subject has

free power of choice, without the intervention of any element of force…constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision.

While the Nuremberg Code influenced subsequent legal codes and guidelines, including the 1978 Belmont Report in the U.S. (which became the common law Federal Policy for the Protection of Human Subjects in 1991), it was never explicitly incorporated into law.

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85 Ibid., 257-268.
86 The Nuremberg Tribunal was presided over by an extraordinary panel of judges outside of any regularly established court system.
87 Ibid., 270-293.
88 The first sentence of the code states, “the voluntary consent of the human subject is absolutely essential.”
Nevertheless, it was a watershed moment in research ethics, the first official distinction between ethical and unethical research on human subjects. However, many saw it as imprecise, and there was pressure to develop more specific guidelines for particular fields of research and potentially problematic types of cases.89

This led the World Medical Association (hereafter WMA, itself founded during the Nuremberg Trials) to begin constructing its own set of guidelines for responsible medical research, known as the Declaration of Helsinki. First adopted in 1964 and revised nine times since, the most recent revision was made in October 2013 at the 64th General Assembly of the WMA. The 1964 Declaration’s ninth principle states that potential subjects of research

must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail…The physician should then obtain the subject's freely given informed consent.

Subsequent principles outline the need for caution in cases where the patient is in a dependent relationship with the physician conducting the research (such as with prisoners and mentally ill patients in the custody of the state), is incompetent to provide consent, or is a minor. The Declaration of Helsinki specifies what voluntary consent to research in these cases entails, including the type of information that potential subjects should have. Such informational requirements have also affected ideas of what patients should know before consenting to treatment.

Unlike the Nuremberg Code, the Declaration of Helsinki was created by medical professionals for their profession and thus resembles early codes of medical ethics, such as

89 Faden and Beauchamp, A History and Theory, 156.
as the Hippocratic Oath and Thomas Percival’s 1803 *Medical Ethics*. Like the Nuremberg Code, the Declaration of Helsinki is less a binding legal or professional code than a set of guidelines that have informed the creation of local codes. Both are understood as significant historical markers in the general development of the individual’s right not only to self-determination but also to freedom from pressure or coercion in the context of medical practice and research, and the particular embodiment of this right in the practice of informed consent.

Following WWII and the dissemination of the Nuremberg Code and the Declaration of Helsinki, clear lines were drawn between medical research and medical treatment, and medical ethics split between issues relating to research and issues arising in the clinic (this chapter concentrates on the latter area). In addition, case law, government regulations, and medical professional guidelines continue to shape the meaning of “voluntary consent,” in part due to continued revelations of problematic medical research, including the Tuskegee syphilis experiments and the Willowbrook hepatitis studies. However, given that these cases relate to research ethics, not to clinical ethics, they will not be considered further here. Rather, the next sections focus on informed consent in the context of clinical ethics, tracing the development of informed consent practices and discourses through the interaction of case law and medical professional guidelines policies in both the U.S. and Japan.

Before moving on, it is important to note that Japan has its own history of atrocities committed during WWII, but these are not usually discussed in the

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91 And continue to be reexamined, e.g. in the case of the therapeutic misconception, in which patients in clinical trials mistakenly assume that researchers, whose main goal is scientific advancement, will act in patients’ best interests.
contemporary bioethics literature in Japan. As Tsuneishi Keiichi writes in a volume on unethical medical experimentation, “Even in the twenty-first century, the Japanese medical community continues to ignore the barbarism committed between 1930 and 1945.”92 In the same volume, Frederick R. Dickinson agrees, writing, “Among the most dramatic examples of Japanese amnesia is the failure to come to terms with Japan’s history of wartime experimentation.”93 While omission of these events from the bioethical literature may be because Japan-committed atrocities had less impact on subsequent international and domestic policy than those committed by the Nazis, Tsuneishi suggests that “the Japanese medical community is neglecting its social responsibilities.”94 Dickinson, however, suggests that the “amnesia” regarding these events may be attributable to political battles about historical truth in present-day Japan.95 Regardless of the reason, it is important to keep in mind that as an institution, Japanese bioethics has focused more on the Western history of medical experimentation than on its own history.

2.3 Structural Foundations of Informed Consent in the U.S.

2.3.1 Early Manifestations

In the U.S., some of the earliest mentions of physicians’ obligations to patients come from the American Medical Association’s (AMA) Code of Medical Ethics, first

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92 Tsuneishi in Lafleur, 81.
93 Dickinson in Lafleur, 85.
94 Tsuneishi in Lafleur, 81.
95 Dickinson in Lafleur, 91-97.
published in 1847.\textsuperscript{96} This code retained its form and content through revisions in 1903, 1912, and 1947, with a major shift in 1957, when it was reformatted as ten short principles, rather than a lengthy set of precise guidelines. The earliest, 1847 version of the code attempts to provide guidance to members of the medical profession on difficult issues. It stipulates that

A physician should not be forward to make gloomy prognostications, because they savor of empiricism, by magnifying the importance of his services in the treatment or cure of the disease. But he should not fail, on proper occasions, to give to the friends of the patient timely notice of danger, when it really occurs; and even to the patient himself, if absolutely necessary. This office, however, is so peculiarly alarming when executed by him, that it ought to be declined whenever it can be assigned to any other person of sufficient judgment and delicacy.

The reason given for this caution is that

The physician should be the minister of hope and comfort to the sick; that, by such cordials to the drooping spirit, he may smooth the bed of death, revive expiring life, and counteract the depressing influence of those maladies which often disturb the tranquillity of the most resigned, in their last moments. The life of a sick person can be shortened not only by the acts, but also by the words or the manner of a physician. It is, therefore, a sacred duty to guard himself carefully in

\textsuperscript{96} For pre-AMA codification, see Robert Baker’s \textit{The Birth of Bioethics} as well as \textit{The American Medical Ethics Revolution}.
this respect, and to avoid all things which have a tendency to discourage the patient and to depress his spirits.\textsuperscript{97}

This version of the code gives substantial weight to therapeutic privilege, otherwise known as professional discretion, which allows physicians to act according to their medical judgment in providing information to the patients or even to friends or family. The goals of the physician should be to comfort and encourage the patient and to avoid causing alarm – in some cases, this will even mean using a third party who may be able to convey information to the patient in a more calming manner than the physician. Importantly, this code says nothing about the patient’s right to consent; the language is overwhelmingly that of professional conduct and duty.\textsuperscript{98} The focus of professional conduct is support for particular patients when they are vulnerable and easily depressed.\textsuperscript{99}

The 1903 version of the AMA’s code, “Principles of Medical Ethics,” retitles these two sections “Honesty and Wisdom in Prognosis” and “Encouragement of Patients,” respectively, although the wording of the two sections is not significantly altered. It was not until 2006 that the allowance for therapeutic privilege (relating to nondisclosure) was removed from the code.

I return to the medical profession’s standards later in this section, but first I analyze how significant U.S. court decisions have shaped the American informed consent standard. As Faden and Beauchamp suggest, “it was case law that introduced the concept

\textsuperscript{97} American Medical Association, \textit{Code of Medical Ethics}, 1847.
\textsuperscript{98} A shift from earlier codes, which stressed virtue and character rather than conduct (Baker, \textit{The American Medical Ethics Revolution}, 36).
of informed consent to medicine in the mid-twentieth century using the language of ‘self-determination.’” In the following section I examine how this introduction took place.

2.3.2 Court Decisions

<table>
<thead>
<tr>
<th>Year</th>
<th>Case</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1905</td>
<td><em>Pratt v. Davis</em> (Illinois)</td>
<td>Patients have the right to the integrity of their body – no bodily infringement without consent.</td>
</tr>
<tr>
<td>1906</td>
<td><em>Mohr v. Williams</em> (Minnesota)</td>
<td>Patients must understand the nature of the surgery in order to give consent.</td>
</tr>
<tr>
<td>1914</td>
<td><em>Schloendorff v. Society of New York Hospitals</em> (New York)</td>
<td>Patients have the “right to self-determination.”</td>
</tr>
<tr>
<td>1957</td>
<td><em>Salgo v. Leland Stanford Jr. University Board of Trustees</em> (California)</td>
<td>Consent is not voluntary if the patient is not fully informed – an “informed consent” is necessary.</td>
</tr>
<tr>
<td>1960</td>
<td><em>Natanson v. Kline</em> (Kansas)</td>
<td>Physicians who do not give an adequate disclosure are negligent according to professional standards.</td>
</tr>
<tr>
<td>1972</td>
<td><em>Cobbs v. Grant</em> (California)</td>
<td>The physician has a professional obligation to support the patient’s self-determination by providing information and allowing the patient to make her choice independently.</td>
</tr>
<tr>
<td>1993</td>
<td><em>Arato v. Avedon</em> (California)</td>
<td>Courts cannot compel physicians to disclose a certain type of information (statistics).</td>
</tr>
<tr>
<td>1996</td>
<td><em>Johnson v. Kokemoor</em> (Wisconsin)</td>
<td>Courts can compel physicians to disclose a certain type of information (physician experience).</td>
</tr>
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</table>

*Figure 3. Informed Consent Court Decisions in the U.S.*

Two of the earliest cases that dealt with patient consent to medical treatment were *Pratt v. Davis* and *Mohr v. Williams*, both in 1905 (although Pratt v. Davis was affirmed

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by the Illinois Supreme Court in 1906). These cases rejected the possibility of implied consent, as prior cases had held and as each physician’s attorney attempted to argue.

In the Pratt case, the physician alleged that he had described the nature of the surgery to the patient’s husband, but both the husband and the patient argued that neither had been informed. The physician claimed that he had not informed the patient of the type of surgery because “he wished her to come to the operating room without violence.” The Pratt court found that

Under a free government, at least, the free citizen's first and greatest right, which underlies all others - the right to the inviolability of his person; in other words the right to himself - is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent… to violate, without permission, the bodily integrity of his patient by a major or capital operation, placing him under an anaesthetic for that purpose, and operating upon him without his consent or knowledge.

The Pratt decision grounds the necessity of permission for surgery in the patient’s right to the integrity of his or her body. This was the initial recognition of a patient’s right to consent in the U.S. A patient’s explicit consent drew the lines within which the physician could act – patient consent limited physician authority.

The Mohr case also uses this justification, finding that the physician committed an unlawful civil action of assault and battery by not informing the patient of the nature of the surgery. The decision in Mohr states,

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101 Pratt v. Davis, 118 Ill.3d pp. 161, 166 (1905), aff'd, 244 Ill. 30, 79 N.E. 562 (1906).
103 Pratt v. Davis, 118 Ill.11A. pp. 161, 166 (1905).
104 Ibid.
If a physician advises a patient to submit to a particular operation, and the patient weighs the dangers and risks incident to its performance, and finally consents, the patient thereby, in effect, enters into a contract authorizing the physician to operate to the extent of the consent given, but no further.¹⁰⁵

Under the legal standard of the tort of battery as applied to medicine, an unlawful action occurs when “a physician…fails to obtain a patient’s consent to a medical procedure that involves a touching of the patient.”¹⁰⁶ Physicians are guilty of battery when they fail to obtain consent before treating patients, even if patients’ health is improved.¹⁰⁷ In making this decision, the court drew from a commentary on torts (which suggested that the purpose of consent is not only to authorize treatment but also to make an effective treatment decision) and an analogy with entering into a contract after informed deliberation.¹⁰⁸

**Pratt** and **Mohr** established that consent is a necessary condition of administering medical treatment on the basis of the right to one’s self. In the following case, this right is logically extended to self-determination.

In the 1914 case of **Schloendorff v. Society of New York Hospitals**, a woman gave permission for an examination under anesthesia but staunchly opposed an operation;
nevertheless an operation was performed. Justice Benjamin Cardozo wrote in the decision that

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.\textsuperscript{109}

Justice Cardozo’s decision has become one of the most referenced quotes in the informed consent literature, and the case itself is the most frequently cited in later cases, largely due to use of the language of self-determination in the justification for the consent requirement.\textsuperscript{110}

This is not to say that Pratt, Mohr, and Schloendorff intended for the consent requirement to support the patient’s right to self-determination. The main issue in each case was not the extent of the patient’s consent, but the circumscription of the physician’s authority. The courts’ decisions were made in the context of surgeries to which the patients had not consented, and in the case of Schloendorff, had expressly forbid. These cases deal more with trespass of patients’ bodily integrity than with any ideal of self-determination through independent decision-making.\textsuperscript{111}

According to Jay Katz, the use of anesthesia was also a major factor in these judicial decisions. Judges were concerned that “the increasing employment of anesthesia would lead to chloroformed consent, to giving physicians license to proceed without even

\textsuperscript{109} Schloendorff v. Society of New York Hospitals, 211 N.Y. 125, 105 N.E. 92 (1914).
\textsuperscript{111} Katz, The Silent World, 50-52.
telling the patient what they intended to do to them.” Patient consent is seen as a limit on physician authority, but not necessarily as an essential ethical feature of all medical practices. The goal of the judges’ rulings was to avoid giving the physician “free license respecting surgical operations,” while granting “reasonable latitude” in particular cases; therapeutic privilege was to a certain extent upheld, since it was thought to be necessary for the practice of medicine. According to the *Mohr* court, “we would not lay down any rule which would unreasonably interfere with the exercise of his [the physician’s] discretion.” In these cases there is still some allowance for the medical professional’s expert judgment.

The fourth case, *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), differed from the previous three in that the patient *had indeed* consented to the treatment. The patient (who suffered paralysis as a result of a medical operation for which he had not been warned of the risk of paralysis) contended that the physician had not warned him of the possible risks of the procedure. Because bare consent was already present, the decision in this case used the term *informed* consent, deciding in favor of the defendant, Martin Salgo, that

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient’s consent…each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial,

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112 Ibid., 62.
113 *Mohr v. Williams*, 104 N.W. 12 (Minn. 1905).
and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.\textsuperscript{114}

Not only was this case the first to use the term “informed consent,” but it also specified the physician’s duty to disclose all information needed for the patient to make an intelligent decision, while allowing for the physician’s discretion in determining what this means for each individual patient. The ruling relied on both an individual’s right to autonomous self-determination and a physician’s obligation to respect that right by disclosing all the information needed to make a decision.\textsuperscript{115}

This ruling has occasioned much legal and philosophical debate. On the one hand, the court upheld the individual’s right to self-determination through consent to treatment after “full disclosure.” On the other, it allowed for the physician’s professional discretion as to what information would be disclosed. The court guaranteed a patient’s right to “full disclosure,” but then allowed the physician to determine what a full disclosure meant.

This creates a difficulty in practice, since the amount of information provided depends on both the patient’s needs and the physician’s judgment. In other words, in cases where the patient’s informed consent to treatment is at issue, the court has to determine which is more compelling: the patient’s argument that she needed more information about the procedure or the physician’s claim that he appropriately discerned how much information the patient needed. The former reflects patient autonomy, while the latter can be described as physician paternalism.


\textsuperscript{115} Katz, Informed Consent, 138; Silent World, 65; Faden and Beauchamp, A History and Theory, 127.
In a sense, this decision reflects the relational nature of the ideal of autonomous self-determination in medicine. Informed consent depends on having informational resources that one cannot always obtain for oneself; the patient is reliant on the physician. Allowing the physician to determine what resources to provide implies that the physician can judge individual patients’ informational needs and has an interest in making sure these needs are met. This assumes that the physician can recognize the patient’s dependence will choose to act in the patient’s interests. Thus, while supporting patient autonomy, the court also allowed for a certain degree of physician discretion. However, this faith in physicians’ good intentions was not long-lived.

Three years later, Natanson v. Kline (1960) further developed the idea of informed consent in Salgo, grounding physician liability for informed consent in negligence as opposed to battery. Informed consent is required for any invasive treatment in battery cases, while in negligence cases, informed consent is required only to the extent that the disclosed risks would affect the patient’s treatment decisions.

<table>
<thead>
<tr>
<th>Battery (Pratt, Mohr, Schloendorff, Salgo)</th>
<th>Bodily infringement without consent</th>
</tr>
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<tbody>
<tr>
<td>Negligence (Natanson, Canterbury, Cobbs)</td>
<td>Failure to inform adequately of the possibility of harm, based on the physician’s professional duty of care</td>
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</tbody>
</table>

*Figure 4. Battery versus Negligence*

In Natanson, the patient’s consent had been obtained, but the physician had not disclosed all the risks of treatment. The court found that this was a breach of the physician’s duty of care (the duty to adhere to a standard of reasonable care when

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performing acts that could harm others), constituting negligence. Reflecting on the previous Salgo ruling, Justice Schroeder wrote in the court’s decision that the rule employed in Salgo,

> In effect compels disclosure by the physician in order to assure that an informed consent of the patient is obtained. The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgment. So long as the disclosure is sufficient to assure an informed consent, the physician's choice of plausible courses should not be called into question if it appears, all circumstances considered, that the physician was motivated only by the patient's best therapeutic interests and he proceeded as competent medical men would have done in a similar situation (emphases added).

The Natanson court upheld the faith that had been placed in the medical profession by Salgo, but clarified and somewhat tempered it. In addition to employing the reasonable physician standard, the court outlined the requirements of an appropriate disclosure, stating that the physician should “explain to the patient in language as simple as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body.”

Both Salgo and Natanson used the phrasing of “informed consent.” However, the former employed a battery standard, determined by whether the patient’s bodily integrity

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117 Applebaum, Informed Consent, 40.
was breached without consent, while the latter appealed to negligence, determined by whether the physician’s failure to disclose harmed the patient. It is up for dispute whether either really supports self-determination. While Faden and Beauchamp (1986) note that the justification in both cases was self-determination and that a foundational premise of this justification is respect for autonomy,\textsuperscript{119} Katz (1984) convincingly argues that the theoretical justification and the practical result of the decisions do not line up.\textsuperscript{120} I briefly explain this argument below.

In battery cases, the main issue is the patient’s consent. A battery case depends on whether or not the patient truly gave consent to the treatment, as required by the legal right to bodily integrity established by Justice Cardozo in \textit{Schloendorff v. Society of New York Hospitals}. This allows room for discussion as to what constitutes consent, as in \textit{Salgo’s} recognition of patients’ informational needs. In negligence cases, on the other hand, the question is one of risk: if the physician fails to warn the patient of a risk and as a result the patient is injured, then failure to disclose the risk could be a source of the injury, premised on the materiality of the risk to the patient’s decision-making and the physician’s duty of care to prevent harm to the patient.\textsuperscript{121} However, if it was likely that the patient would have consented to the medical procedure even if the risk had been disclosed, then the physician is not negligent, because the physician’s failure to disclose is no longer a proximate cause of the injury.\textsuperscript{122}

Especially when it is based in professional obligation, negligence is much harder for the patient to prove than battery. In battery cases, patients need only provide evidence

\textsuperscript{119} Faden and Beauchamp, \textit{A History and Theory}, 132.
\textsuperscript{120} Katz, \textit{The Silent World}, 62-65.
\textsuperscript{121} Applebaum, \textit{Informed Consent}, 115.
\textsuperscript{122} Faden and Beauchamp, \textit{A History and Theory}, 132; Katz, \textit{Informed Consent}, 152.
that they did not consent to the treatment provided. What matters is whether consent was
given, not whether the treatment was beneficial. In negligence cases, a proximate cause
between knowledge of risks and patients’ decision-making is required, so patients must
prove that they would have decided differently had they known of the risks and that not
knowing of the risks harmed them. This switch from the battery standard to the
negligence standard was a move from patients’ legal advantage to a situation where they
must prove not only that most physicians would disclose the risk in question, but also that
disclosure of the risk would have affected their decision-making. In addition, as a defense,
physicians need only provide evidence that they were acting on a professional standard of
care. ¹²³ According to Justice Schroeder, the justification for disclosure of risks is “the
premise of thoroughgoing self-determination,” but based on the argument above, it is
difficult to see the court’s appeal to self-determination as anything more than lip-service
to an ideal.

In the 1972 case of Canterbury v. Spence (applying municipal, not federal law)
the court supported patient decision-making by combining elements of both battery and
negligence to create a standard in which the determination of negligence is based not on a
medical professional standard but on an objective one: the “reasonable, prudent patient.”
This was a hybrid standard. On the one hand, the court referred to the patient’s right to
self-decision and the necessity of consent to medical treatment – the standard used in
battery. On the other hand, it premised the consent given by the patient on the
“opportunity to evaluate knowledgeably the options available and the risks attendant on
each.” This made the patient’s consent dependent on the physician’s exercise of “due

“care” in warning the patient of “any risks to his well-being which contemplated therapy may involve.” Not all risks had to be disclosed, however. This was not a standard of full disclosure. Rather, “[a] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.”

This appealed both to patients’ right to consent and physicians’ duty of care and once again intertwined patients’ decisions with physicians’ judgments. In basing the standard for informed consent on the court’s assessment of the informational needs of a reasonable person in the patient’s position, not on the professional physician’s judgment concerning the particular patient, the court removed much of the authority from the latter. The court did allow that the physician is, in the first instance, responsible for determining the scope of the disclosure, giving “suitable leeway for the physician’s situation.” Yet this is not based on the physician’s knowledge of the particular patient, because “he cannot know with complete exactitude what the patient would consider important to his decision, but on the basis of his medical training and experience he can sense how the average, reasonable patient expectably would react.” As the court notes, this standard is not subjective “as to either the physician or the patient.”

One reason the court shifted emphasis from physicians’ reasonable disclosures to patients’ reasonable needs was doubt of any “discernible custom reflecting a professional consensus on communication of option and risk information” as well as skepticism that there could be any stable custom when the needs of different patients are so variable.

125 Ibid.
Another reason was worry that reference to custom may maintain professional silence so as to allow individual opinions to pass as professional standards. Finally, making reference to medical malpractice standards, the court found that the duty to disclose is not based on medical professional standards, although medical practice has evidentiary value. Given that “the decision to unveil the patient's condition and the chances as to remediation, as we shall see, is oftentimes a non-medical judgment… professional custom hardly furnishes the legal criterion for measuring the physician's responsibility to reasonably inform his patient of the options and the hazards as to treatment.” Rather, the crux of the duty to disclose is based in the patient’s right to self-determination, and as such, need not be grounded in medical practice but in “the general standard exacting ordinary care.”\(^\text{126}\)

This resulted in the conclusion that “respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.” In other words, “the patient's right of self-decision shapes the boundaries of the duty to reveal” and “the scope of the physician's communications to the patient… must be measured by the patient's need.”\(^\text{127}\) Unlike \textit{Pratt} and \textit{Mohr}, patient consent was no longer a limit of physician authority but a source of it. The goal of the ruling was to make it easier for patients to claim that their informational needs had not been met, but in doing so the court also made it more difficult for physicians to defend their behavior on a professional ethical standard.


\(^{127}\) Ibid.
The court did allow, in principle, for situations in which therapeutic privilege allows for non-disclosure, such as when patients become “so ill or emotionally distraught on disclosure as to foreclose a rational decision.” In these cases “the critical inquiry is whether the physician responded to a sound medical judgment that communication of the risk information would present a threat to the patient's well-being,” adding that “even in a situation of that kind, disclosure to a close relative with a view to securing consent to the proposed treatment may be the only alternative open to the physician.” However, it also questioned whether therapeutic privilege could ever really work in practice, due primarily to the possibility that discretion could disguise paternalistic aims:

The physician’s privilege to withhold information for therapeutic reasons must be carefully circumscribed, however, for otherwise it might devour the disclosure rule itself. The privilege does not accept the paternalistic notion that the physician may remain silent simply because divulgence might prompt the patient to forgo therapy the physician feels the patient really needs.

The *Canterbury* court succeeded in removing almost all of the physician’s “privilege to withhold information” in the name of protecting the patient from physician paternalism. The concern about physician paternalism is the same as that expressed in *Salgo* – that physicians will use any means necessary to treat patients according to their professional judgment. The undermining of therapeutic privilege signifies the loss of trust in the physician. No allowances for therapeutic privilege appear in subsequent informed consent cases.


\[129\] Ibid.
Avoiding physician paternalism did not come without costs. In rejecting a subjective standard for informed consent the court did not merely rule out the possibility that the duty to disclose would be determined according to individual physician’s actions. The court also made it more difficult for patients to argue for their informational needs in subjective terms by finding an objective test preferable to a subjective test for whether disclosure of risks would have been material to a patient’s decision. This objective test was grounded on “what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance.” Yet respect for individual choice should respect each individual choice, however idiosyncratic, not only those choices generally deemed reasonable by either physicians or the courts. In using an objective rather than a subjective test to decide such cases, the court may have done more harm to self-determination than good. On the one hand, it made it even more difficult for patients to defend their negligence claims, ostensibly in the name of protecting physicians from patients’ “hindsight and bitterness.” On the other hand, basing physicians’ disclosure decisions on the abstract, reasonable individual in the patient’s position arguably opened the door for physicians to avoid interacting with their patients as particular, idiosyncratic individuals. As exemplified by the following case, this damaged the nuanced, relational nature of particular physician-patient relationships.

*Cobbs v. Grant* (1972) was decided the same year as *Canterbury v. Spence*. It follows *Canterbury* in emphasizing the dependence of the physician’s professional obligation on the patient’s right to self-determination. The decision of the court reads at times just like that of *Canterbury* (“The scope of the physician's communications to the

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A medical doctor, being the expert, appreciates the risks inherent in the procedure he is prescribing, the risks of a decision not to undergo the treatment, and the probability of a successful outcome of the treatment… The weighing of these risks against the individual subjective fears and hopes of the patient is not an expert skill. Such evaluation and decision is a nonmedical judgment reserved to the patient alone.\textsuperscript{132}

According to Frances Miller and George Annas, this transforms the patient’s treatment decision into a consumer’s marketplace choice. In choosing among various alternatives, the patient must have the appropriate information in order to become a “knowledgeable consumer of the medical product.”\textsuperscript{133} The court permitted withholding of information only if the patient “cannot evaluate the data, as for example, when there is an emergency or the patient is a child or incompetent.”\textsuperscript{134} There was no exception for withholding disclosure due to a possible threat to the patient’s well-being, and the decision expressly states that the physician cannot know what is needed for the patient’s well-being.

The 1990s saw some attempts to rescue professional discretion, as in the 1993 case of \textit{Arato v. Avedon}.\textsuperscript{135} The question in this case was whether physicians are obligated to disclose statistical predictions of life expectancy in terminal illness cases such as cancer. Citing both \textit{Cobbs} and \textit{Salgo} (above) the court found that

\textsuperscript{132} Katz, \textit{The Silent World}, 78-79.
\textsuperscript{133} Miller and Annas, \textit{The Empire of Death}, 364.
\textsuperscript{134} \textit{Cobbs v. Grant}, 502 P.2d 1, 10 (Cal. 1972).
\textsuperscript{135} \textit{Arato v. Avedon}, 5 Cal.4th 1172, 23 Cal.Rptr.2d 131; 858 P.2d 598 (1993).
The contexts and clinical settings in which physician and patient interact and exchange information material to therapeutic decisions are so multifarious, the informational needs and degree of dependency of individual patients so various, and the professional relationship itself such an intimate and irreducibly judgment-laden one, that we believe it is unwise to require as a matter of law that a particular species of information be disclosed.\textsuperscript{136}

The \textit{Arato} court declined to comment on what the content of the physician’s disclosure must be to facilitate the patient’s decision and instead focused on the instructions that should be given to the jury in deciding informed consent cases, adding that

We can conceive of no trier of fact more suitable than lay jurors to pronounce judgment on those uniquely human and necessarily situational ingredients that contribute to a specific doctor-patient exchange of information relevant to treatment decisions; certainly this is not territory in which appellate courts can usefully issue "bright line" guides.\textsuperscript{137}

Miller and Annas object to this decision on the grounds that patients need to know the probability that a treatment will be successful as well as the criteria for success.\textsuperscript{138} This may very well be the case. Nevertheless, it is reassuring to see the courts backing away from further specifying the ideal physician-patient relationship. As the \textit{Arato} court writes, “A physician…evaluates the patient's decisional needs against a background of professional understanding.”\textsuperscript{139}

This trend did not continue past the early 1990s. A 1996 Wisconsin case, \textit{Johnson}

\begin{thebibliography}{9}
\bibitem{136} Ibid.
\bibitem{137} Ibid.
\bibitem{138} Miller and Annas, \textit{Empire of Death}, 366.
\bibitem{139} \textit{Arato v. Avedon}, 5 Cal.4th 1172, 23 Cal.Rptr.2d 131; 858 P.2d 598 (1993).
\end{thebibliography}
v. Kokemoor, found that, based on the reasonable person standard, the physician’s experience in carrying out a given procedure is one of the risks that must be disclosed to the patient, because such information could affect a patient’s treatment decision.\footnote{Johnson v. Kokemoor, 545 N.W.2d 495 (Wis. 1996); Gatter, “Informed Consent and the Forgotten Duty of Physician Inquiry.”}

Likewise, the court in another Wisconsin case, Jandre v. Physicians Insurance Company (2012), decided that physicians must also disclose information about alternative diagnostic and testing options.\footnote{Jandre v. Physicians Ins. Co. 340 Wis.2d 31, 813 NW 2d 627 (2012).} The scope of information relevant to a patient’s consent no longer simply relates to treatment, but extends to physician expertise, experience, and medical judgment in diagnosis. The patient’s freedom of choice is the sole determinant of these decisions; respect for the medical professional’s judgment no longer appears.

This examination of American case law reveals that early in the development of the informed consent legal standard in the U.S., the conception of the patient’s consent as a limit on physician freedom developed into a concept of patient self-determination. While initially it was unclear whether patient autonomy or physician beneficence determined the scope of disclosure, concerns over physician paternalism led to abandonment of the professional standard. In its place, an abstract, universal understanding of patients’ informational needs was employed. Despite attempts to make allowances for the contextual nature of the patient-physician relationship, informed consent in the U.S. courts developed into a consumerist emphasis on patients’ freedom of choice in the medical marketplace. Whether this situation exists outside the United States, and what this means for the ethics of the physician-patient relationship, will be taken up in chapters 5 and 6.
2.3.3 Medical Professional Guidelines

As with the case law on informed consent, the AMA has attempted to regulate the physician-patient relationship in different ways.\textsuperscript{142} The AMA’s early codes of ethics were narratively detailed guidelines; later codes (those after 1957) were published as guiding principles. Of most interest to this study is how the AMA’s policy on informed consent has changed.

Within the AMA, the Council on Ethics and Judicial Affairs (CEJA) is responsible for issuing opinions on the application of the principles outlined in the AMA’s code of ethics. The opinion relevant to this study is Opinion 8.08 on informed consent, first published in 1981 and revised in 2006. The 1981 opinion allows information to be withheld from patients if disclosure “poses such an immediate and serious psychological threat of detriment to the patient as to be medically contraindicated,” while making the proviso that

Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy.

Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment.\textsuperscript{143}

This is almost a verbatim restatement of the \textit{Canterbury} decision. The 2006 revision to Opinion 8.08 is more original:

The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should

\textsuperscript{142} For excellent detailed examinations of this topic, see Baker, Warner, Stevens, Pellegrino, and Friedson in \textit{The American Medical Ethics Revolution} (1999).
\textsuperscript{143} CEJA Rep. 2-A-06.
make his or her own determination about treatment. The physician’s obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accordance with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information.

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all the information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

The reasons for making this shift given in the CEJA’s Report 2-A-06, “Withholding Information from Patients (Therapeutic Privilege)” (2006) include: patients want more information; information eases patient anxiety, improves medical outcomes, and gives patients satisfaction; and information decreases medical liability. In addition, since the CEJA holds that withholding information affects the trusting nature of the patient-physician relationship, the AMA no longer allows information to be withheld from patients. While timing and manner of disclosure is within the physician’s discretion, all
patients with decision-making capacity must be informed of the nature of their diagnosis and proposed treatment.\textsuperscript{144}

The principles in the AMA’s code of ethics that relate to this determination include:

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.\textsuperscript{145}

While the legal standard of informed consent has come to be increasingly based on patients’ needs as generic consumers, the AMA’s most recent, 2006 code subtly pushes back against this standard. Rather than focusing solely on the informational resources to which patients are guaranteed access as a matter of law, the AMA’s position is based in professional conduct and duty, echoing the 1847 code introduced at the beginning of this section. The current code of ethics makes responsibility to the patient “paramount” while

\textsuperscript{144} Decision-making capacity is an ethical/professional standard, and is not the same as legal competency.

emphasizing professionalism, and it disallows therapeutic privilege because sharing information is thought to have a positive effect both on the patient and on the patient-physician relationship. This practical orientation is the AMA’s professional response to society’s changing understanding of patients’ needs, and it to some extent tempers the legal standard’s prioritizing of individual self-determination to avoid physician paternalism. However, this is not to say that the AMA does not value self-determination: patients’ right to information is their right to self-decision, and the physician provides information so that patients can exercise this right.

Accordingly, on the other side of professional responsibility are patient’s rights and responsibilities exemplified by the American Hospital Association’s Patient Bill of Rights, adopted in 1973 and revised in 1992:

The patient has the right and is encouraged to obtain from physicians and other direct caregivers relevant, current, and understandable information about his or her diagnosis, treatment, and prognosis.

…is entitled to a chance to discuss and request information related to the specific procedures and/or treatments available, the risks involved, the possible length of recovery, and the medically reasonable alternatives to existing treatments along with their accompanying risks and benefits.

…has the right to make decisions about the plan of care before and during the course of treatment and to refuse a recommended treatment or plan of care if it is permitted by law and hospital policy. The patient also has the right to be informed of the medical consequences of this action. In case of such refusal, the patient is still entitled to appropriate care and services that the hospital provides or to be
transferred to another hospital. The hospital should notify patients of any policy at
the other hospital that might affect patient choice.

The concomitant responsibility on the part of the patient is to
take responsibility for requesting additional information or clarification about
their health status or treatment when they do not fully understand the current
information or instructions.\textsuperscript{146}

In 2003, this document was replaced with a brochure entitled, “The Patient Care
Partnership: Understanding Expectations, Rights, and Responsibilities.”\textsuperscript{147} In addition to
information about privacy, billing, and leaving the hospital, the brochure emphasizes that
patients should be involved in their own care and describes what each patient needs to
know in order to make an informed decision, including risks and benefits of treatment,
experimental aspects of treatment, and expectations of treatment and long-term effects on
quality of life. To aid in the decision-making process it also asks patients to help health
care providers understand their goals, values, and desires.

The AMA’s code of ethics stresses responsiveness to patients’ needs and the
AHA’s patient bill of rights recognizes patients’ role in making these needs apparent.
While informed consent in U.S. case law protects an abstract individual’s right to self-
determination, the AMA and AHA codes attempt to fill out what this right means, so that
physicians are responsive to individual patients’ particular needs and patients play an
active role in medical decision-making. Informed consent in the U.S. is a two-way street:
the physician has the duty to provide information necessary for the patient’s decision,

\textsuperscript{146} AHA, Patient Bill of Rights (1992).
\textsuperscript{147} AHA, “The Patient Care Partnership: Understanding Expectations, Rights, and
while the patient is responsible for obtaining this information and participating in the decision-making process.

Case law and medical professional guidelines are the two primary institutional determinants of the discourse and practice of informed consent in clinical medicine in the U.S. The following section analyzes this same set of institutional considerations in Japan, before summarizing their similarities and differences.

2.4 Structural Foundations of Informed Consent in Japan

2.4.1 Early Manifestations

In Japan, as in the United States, ethical regulations and guidelines on the relationship between physician and patient did not begin with WWII. From the ancient until the modern period, medical ethical standards were primarily based in Buddhist texts, which specified the appropriate roles of the physician, nurse, and patient – in short, all those involved in the medical setting. The ethical attitude of this period was participatory rather than authoritarian; each role contributed to the ethics of the situation. The most important factor for medical practitioners was having a “heart of compassion/benevolence” (jihi no kokoro, 慈悲の心). According to these texts, physicians’ roles were to care for their patients to the best of their abilities and to act in their patients’ best interests.

In 1855/Ansei 2, a Japanese surgeon, Hanaoka Seishū 华岡清州, obtained the first “letter of consent” (shōdakusho 承諾書) from a patient prior to surgery (as well as

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148 Japanese names in this section are written in the Japanese form, Last name First name. In the bibliography, these names appear Last name, First initial. Years are cited using both the Western and Japanese systems.
149 Japanese Bioethics Series, Seimeirinri no Kihon Kōzu, 75-76.
from five members of his family). In the letter, the patient and his family agree not to bear resentment (*urami* 恨み) towards the doctor regardless of the outcome of the surgery. According to the authors of *Medicine in the Edo Period* (*Edo Jidai no Igaku* 江戸時代の医学), “from this point the rational contract relationship that would lead to modern medicine can be seen [*Koko Kara wa Kindai Igaku ni Tsūzuru Gōritekina Keiyaku Kankei wo Miru Koto ga Dekiru* ここからは近代医学に通ずる合理的な契約関係をみることができる].” Whether or not this is an example of a “rational contract” is up for debate, given that the focus of the letter is abdication of responsibility of a social emotion, resentment, and not the usual exchange of action-based duties or obligations that attach to a contractual relationship. This will become important in chapter 5, which analyzes the role responsibility plays in informed consent theories. For now, the significance of the letter is the physician’s desire to alleviate himself of responsibility for the patient’s and the family’s emotional states after the surgery. This will be relevant to my analysis of Japanese court decisions in the next section.

Japanese physicians in the Edo Period (1603-1867) became increasingly aware of Western medical practices, but adhered to traditional Buddhist ethical systems, repeating the mantra of “Eastern ethics, Western techniques.” Following the Meiji restoration in 1868, more Japanese physicians intentionally patterned their medical and ethical practices after those of the West, especially Dutch, German, English, and American practices. Numerous physicians also published works on medical ethics, drawing from sources in the Japanese tradition. Hashida Kunihiko (橋田邦彦), who wrote in the Taisho

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150 Aoki, *Edo Jidai no Igaku*, 213; Tanida, “*Infōmudo Konsento Seiritsu no Haikei ni Tsuite*,” 91.
period (1912-1926), applied his study of Zen master Dōgen to the medical context, arguing that benevolent acts (*jinjutsu*, 仁術) are the first principle of medicine.\(^{152}\)

Discussion on the ethical nature of the physician-patient relationship has a long history in Japan. However, “bioethics” in Japan derives from the field of study as it developed in North America and Europe, and usually does not make reference to this history (recall the lack of discussion within Japan on its own history of medical experimentation). This is not unique to the field of bioethics, but occurs in law as well. Mark Levin describes Japanese legal history using the metaphor of soup: from a Japanese base, Chinese stock is created; once European ingredients are added the soup seems distinctly European. Although the underlying Chinese and Japanese elements remain, they are less noticeable, and so while most assume that the soup is European, finer tastes can recognize these Chinese and Japanese features.\(^{153}\)

In the next section, I bring out some of these more subtle Japanese features by examining how informed consent has taken shape in Japanese court decisions.

### 2.4.2 Court Decisions

The concept of *infōmudo konsento* is significant in Japanese bioethics, but is not necessarily significant in Japanese law. Prior to the introduction of the American term for informed consent, the German word for “duty to explain,” *Aufklärungspflicht*, was used, transliterated as *aufukurērungusu pufurihito*, more commonly translated as *setsumeigimu* (説明義務).\(^{154}\) Robert Leflar notes that a Japanese judge used the German concept of the

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\(^{152}\) Ibid., 91.

\(^{153}\) Levin, “Continuities of Legal Consciousness.”

\(^{154}\) Matsui, “An Investigation of the Relationship Between Patient and Health Care
“duty to explain” as early as 1934.\(^{155}\) This use of German legal concepts is not unusual. Japanese law bears numerous debts and similarities to German law,\(^{156}\) and Japanese scholars have endeavored to understand their legal system through studies of German statutory and case law.\(^{157}\) However, in contrast to Japanese legal scholars, Japanese bioethicists take the U.S. more expressly as a model.

In Japan, informed consent is a loan word taken from American culture, which includes U.S. case law and the medical profession. The concept of informed consent spread in the 1970s, translated as setsumei to dōi (説明と同意), which in English reads “explanation and consent” and relates to the setsumei ginu described above. The transliterated infōmudo konsento was introduced shortly thereafter, and the two terms both continue to be used, although in recent years infōmudo consento has been used more frequently than setsumei to dōi.\(^{158}\) The main term used in the bioethical literature in Japan today is infōmudo konsento, and this serves as a potential tension in the Japanese system;

\(^{155}\) Leflar, Informed Consent in Japan, 46.


\(^{158}\) The Jurist, the book of the 100 “Medical Law Case Precedents” used the title setsumei to dōi in its 2006 collection, but switched to infōmudo konsento for its 2014 edition.
while the American *infōmudo konsento* dominates the Japanese bioethical literature, *setsumeigimu* is more relevant to Japanese case law.

Before proceeding with a consideration of Japan’s significant court decisions, it is necessary to note the different legal traditions in the U.S. and Japan. While the U.S. has followed the common law tradition of England, Japan is part of the civil law tradition, which includes Europe, Latin America, and parts of Asia and Africa. John Merryman defines a legal tradition as

a set of deeply rooted, historically conditioned attitudes about the nature of law, about the role of law in the society and the polity, about the proper organization and operation of a legal system, and about the way law is or should be made, applied, studied, perfected, and taught. The legal tradition relates the legal system to the culture of which it is a part.159

The civil law tradition officially recognizes only statutes, regulations, and customs as sources of law, although judicial decisions are becoming increasingly significant.160 Common law, on the other hand, gives more weight to judges and judicial precedents.161 Japanese judges are civil servants, obligated to decide cases in accordance with the Japanese civil code and constitution, and while they may refer to previous cases, there is no doctrine of *stare decisis* as in the U.S.162 Cases in the U.S. are decided in terms of previous cases, whereas Japanese judges must make reference to the civil code when making their decisions. American and Japanese judges thus interpret the law in different

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161 Merryman, *Civil Law*, 34.
162 “The power and obligation of courts to base decisions on prior decisions” (Merryman, *Civil Law*, 23).
ways: American judges are not bound to a general civil code, but they are bound by precedent; Japanese judges need not refer to prior cases, but they must justify their ruling in terms of the civil code, and they may refer to previous cases to support this justification. Importantly, here I consider civil and not criminal cases, although there is a rich literature on criminal prosecution for medical malpractice in Japan as well.\textsuperscript{163}

The articles of the Japanese Civil Code relevant to the cases dealing with informed consent under consideration here are: 1) Article 415 (Damages due to Default, \textit{sekimu furikkō}, 債務不履行): “If an obligor fails to perform consistent with the purpose of its obligation, the obligee shall be entitled to demand damages arising from such failure. The same shall apply in cases where it has become impossible to perform due to reasons attributable to the obligor.” To make this case the patient must prove a breach of (the medical) contract by the physician, which is often difficult because the court tends to conclude that the physician is obligated to act according to standards of the medical profession, rather than to produce good results.\textsuperscript{164} 2) Article 709 (Damages in Torts, \textit{fuhō kōi} 不法行為) “A person who has intentionally or negligently infringed any right of others, or legally protected interest of others, shall be liable to compensate any damages resulting in consequence.” In this case the patient must prove that negligence led to damage, which rarely succeeds due to the patient’s limited knowledge and access to information.\textsuperscript{165} In addition, rather than referring to the civil code some cases use the Medical Practitioner’s Law, enacted in 1948, which states that, “The physician must, at

\textsuperscript{163} See Leflar and Iwata, “Medical Error as Reportable Event,” Leflar, “The Regulation of Medical Malpractice in Japan,” and Leflar, “Unnatural Deaths, Criminal Sanctions, and Medical Quality Improvement in Japan.”

\textsuperscript{164} Morikiwa, \textit{Patients Rights}, 340.

\textsuperscript{165} Ibid., 340.
the time of medical examination and treatment, guide the patient or guardian in the important matters of methods of treatment and health improvement.”

| Article 415 (Damages due to Default, *sekimu furikkō*, 債務不履行) | Breach of Contract (violating the terms of a contract) |
| Article 709 (Damages in Torts, *fuhō kōi* 不法行為) | Tort Liability (intentionally or negligently infringing on others’ rights) |

**Figure 5. Relevant Articles of the Japanese Civil Code**

Keeping these distinctions in mind I now turn to the significant Japanese court decisions. I note in the text which article was at issue in each case, although when the case is decided in favor of the defendant, no article will be noted (as no damages are awarded). This analysis concentrates on cases that deal with informed consent in the context of cancer disclosure, although some of the landmark cases in informed consent in general are mentioned. The reason for this focus is that cases of end-stage terminal cancer are the most common exceptions to the rule that physicians must disclose diagnoses and treatment options to their patients, and thus best highlight where and why the Japanese practice of informed consent is similar to and differs from the American practice.

<table>
<thead>
<tr>
<th>Year</th>
<th>Case</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1971/Showa 46</td>
<td>Tokyo District Court, May 19, 1971</td>
<td>Physicians must obtain consent for surgery (<em>Damages in Torts, fuhō kōi 不法行為</em>)</td>
</tr>
<tr>
<td>1973/Showa 48</td>
<td>Omagari Chapter, Akita District Court, March 27, 1973</td>
<td>Same as above.</td>
</tr>
<tr>
<td>1977/Showa 52</td>
<td>Hiroshima High Court, April 13, 1977</td>
<td>Without disclosure of the risks associated with a procedure a patient’s consent is not effective.</td>
</tr>
</tbody>
</table>

167 Except where noted all translations of case decisions are my own.
<table>
<thead>
<tr>
<th>Year/Heisei</th>
<th>Court/Date</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1981/Showa 56</td>
<td>Supreme Court, June 19, 1981</td>
<td>Physicians must explain the type of surgery and the associated risks, but in an emergency situation this explanation can be simplified.</td>
</tr>
<tr>
<td>1981/Showa 56</td>
<td>Tokyo District Court, December 21, 1981</td>
<td>Physicians can withhold information if it is in the patient’s best interests.</td>
</tr>
<tr>
<td>1989/Heisei 1 (1)</td>
<td>Nagoya District Court, May 29, 1989 (Makino v. Red Cross Hospital)</td>
<td>The physician has a general duty to inform the patient or the family of the details of the condition, but the content of this information is within professional discretion.</td>
</tr>
<tr>
<td>1990/Heisei 2 (2)</td>
<td>Nagoya High Court, October 31, 1990 (Appeal of above)</td>
<td>Whether or not the diagnosis is disclosed to the patient is within the physician’s professional discretion.</td>
</tr>
<tr>
<td>1995/Heisei 7 (3)</td>
<td>Supreme Court, April 25, 1995 (Final appeal of above)</td>
<td>Reaffirmed above, and patients must cooperate with physicians to get better.</td>
</tr>
<tr>
<td>1990/Heisei 2</td>
<td>Fukuoka District Court, December 19, 1990</td>
<td>The physician’s obligation to disclose (kokuchi gimu 告知義務) depends on the case.</td>
</tr>
<tr>
<td>1994/Heisei 6</td>
<td>Tokyo District Court, March 30, 1994</td>
<td>In deciding what is disclosed and how to treat the patient, the physician must consult the family if the patient is not informed.</td>
</tr>
<tr>
<td>1996/Heisei 8 (1)</td>
<td>Akita District Court, March 22, 1996</td>
<td>Since there is not an established standard among medical professionals for cancer disclosure, the decision to disclose is left to the physician.</td>
</tr>
<tr>
<td>1998/Heisei 10 (2)</td>
<td>Akita Branch, Sendai High Court, March 9, 1998 (Appeal of above)</td>
<td>The physician’s carelessness in gathering information about the state of the patient, or in examining the retrieved information about the patient, harmed the patient and family (Damages in Torts, fuhō kōi不法令行為) (Reversed).</td>
</tr>
<tr>
<td>2002/Heisei 14 (3)</td>
<td>Supreme Court, September 24, 2002 (Appeal of above)</td>
<td>The physician has the duty to explain the diagnosis at least to the family (Upheld 1998 ruling).</td>
</tr>
<tr>
<td>1996/Heisei 8 (1)</td>
<td>Osaka District Court, May 29, 1996</td>
<td>Physicians should tell patients if they are inexperienced with a procedure.</td>
</tr>
<tr>
<td>Year/Heisei</td>
<td>Court/Date</td>
<td>Decision</td>
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<tr>
<td>1997/Heisei 9 (2)</td>
<td>Osaka High Court, 1997 (Appeal of above)</td>
<td>Physicians do not need to tell patients this information (Reversed).</td>
</tr>
<tr>
<td>2001/Heisei 13 (3)</td>
<td>Supreme Court, November 27, 2001 (Appeal of above)</td>
<td>If the patient makes a positive appeal for information about alternative methods of treatment, the physician should respect the patient’s self-determination (Upheld 1996 decision).</td>
</tr>
<tr>
<td>1997/Heisei 9 (1)</td>
<td>Tokyo District Court, March 12, 1997</td>
<td>Physicians can dismiss the desire of patients because of the fundamental value of human life.</td>
</tr>
<tr>
<td>1998/Heisei 10 (2)</td>
<td>Tokyo High Court, February 9, 1998 (Appeal of above)</td>
<td>The physician should have told the patient he would not follow her wishes (Reversed).</td>
</tr>
<tr>
<td>2000/Heisei 12 (3)</td>
<td>Supreme Court, February 29, 2000 (Appeal of above)</td>
<td>The physician must disclose information that will be relevant to the particular patient’s decision (Upheld 1998 ruling).</td>
</tr>
<tr>
<td>2003/Heisei 15</td>
<td>Kawagoe Branch, Saitama District Court, October 30, 2003</td>
<td>If the patient makes a positive appeal to know their diagnosis, to the extent that it will not adversely affect treatment, the physician should inform the patient. After informing, the patient’s reaction should be monitored.</td>
</tr>
<tr>
<td>2007/Heisei 19</td>
<td>Nagoya District Court, June 14, 2007</td>
<td>Once a patient has made a decision, the physician should respect it. If the physician has sufficiently informed the patient they do not need to inform the family.</td>
</tr>
</tbody>
</table>

*Figure 6. Informed Consent Court Decisions in Japan*

In the forerunner of cases dealing with informed consent in Japan, in 1971/Showa 46, a physician discovered cancer in the left breast of a woman who was undergoing a mastectomy of her right breast, and decided to perform a double mastectomy. The woman sued the hospital for damages on the grounds that the mastectomy of her left breast was unnecessary. The court ruled in favor of the hospital, stating that the physician had acted within their professional discretion. However, this decision was overturned on appeal. Subsequent cases have emphasized the importance of patient autonomy and the duty of physicians to inform patients about their medical options and the potential outcomes of different treatments. These decisions reflect a shift towards recognizing patients’ rights to make informed decisions about their own health care, reflecting broader trends in patient-centered medicine.
breast was unnecessary. The Tokyo District Court ruled that, before performing a major operation, generally a physician must explain the patient’s condition and the reason for the procedure before obtaining the patient’s consent.\textsuperscript{169} Since the removal of the left breast was not an emergency, the physician was culpable.\textsuperscript{170} The article of the civil code at issue was 709, Damages in Torts (fuho k\=oi 不法行為). A similar case was decided in 1973/Showa 48, in which a patient with tongue cancer was not told his diagnosis, but was informed that his tongue needed to be removed.\textsuperscript{171} Not knowing he had cancer, he consented to the removal of lesions on his tongue but refused removal of the whole tongue. He filed for damages when a third of his tongue was removed. The court decided in his favor, finding that surgery cannot be undertaken without a patient’s consent.\textsuperscript{172} These cases proceeded along lines similar to early cases in the U.S., establishing the necessity of obtaining consent before surgery and describing consent as a limit on physician authority. It is not insignificant that these cases deal with surgical operations, as did \textit{Pratt} and \textit{Mohr}. They share the concern that anesthesia, which extends physicians’ medical abilities significantly and can empower them against patients if unchecked.

Further cases demonstrated that, for the patient’s consent to be effective, the physician must explain the procedure and the risks involved. In 1977/Showa 52, the Hiroshima High Court ruled that without disclosure of the risks associated with a procedure, the patient’s consent was not effective.\textsuperscript{173} This raised question about what kind of disclosure would guarantee the effectiveness of a patient’s consent. Yet the court

\textsuperscript{170} Japanese Bioethics Series, \textit{Seimeirinri no kihon k\=o\=zu}, 189; Jurist (no. 183), 117.
\textsuperscript{171} Omagari Chapter, Akita District Court, March 27, 1973. 718 Hanji 98, 297 Hanta 275.
\textsuperscript{172} Maruyama, “Japanese Law,” 40.
did not specify this content and instead placed physicians’ duty to explain, *setsumeigimu* (説明義務), within the scope of their discretionary power, or *sairyōken* (裁量権).

In 1981/Showa 56, the Supreme Court of Japan reviewed a case dealing with the duty to explain, *setsumeigimu*. The parents of a young boy who had died during an operation sued the physician, alleging that the risks of the operation had not been sufficiently explained. The court ruled that, while physicians have a clear duty to explain the type of surgery and the associated risks, in an emergency situation this explanation can be simplified as necessary. The same year, the Tokyo District Court ruled in favor of a form of therapeutic privilege, finding that not only is there an emergency exception for explanation, but that whether or not patients are told their diagnoses at all is within physicians’ discretion. Physicians can withhold information if they think it is best for their patients.

The scope of physicians’ discretionary power in fulfilling the duty to explain became was further clarified in 1989/Heisei 1 through the well-known case of *Makino v. Red Cross Hospital* (as it is cited in the English language literature), first tried by the Nagoya District Court. In 1992, Higuchi Norio translated the initial decision into English, problematizing conflicting policies of patient self-determination and physician paternalism in Japan.

In the case, a scan result showed that Makino, a nurse, likely had gall bladder cancer. The physician determined that Makino needed to be admitted to confirm the

176 Nagoya District Court, May 29, 1989/Heisei 1, 1325 Hanji 103, 699 Hanta 279.
177 Higuchi, “The Patient’s Right to Know of a Cancer Diagnosis.”
diagnosis and to decide on treatment measures. However, due to her disposition, family relationship, uncertainty about whether her family’s cooperation with the treatment plan could be expected, and fear that disclosing the suspicion of cancer would cause an emotional shock and have a poor effect on her treatment, the physician did not inform Makino of her diagnosis. The physician decided that he would explain the diagnosis to an appropriate family member after a detailed examination. However, Makino declined hospitalization. She was subsequently examined by four different doctors between January 31st and March 2nd, 1983 but at no time was she or her family informed of her diagnosis, although the last doctor told her that she needed an operation on her gall bladder immediately. Citing plans to travel, Makino made an appointment for over a month later, April 11th, but she cancelled this appointment before coming in. She entered a general hospital after breaking down at work on June 8th and died on December 22nd of that same year.

The family sued the physician. The issue was whether telling the patient a different diagnosis and not explaining the real diagnosis to the family violated the physician’s duty. The court ruled as follows:

The physician’s concrete explanation of the type of disease, treatment method, and expected treatment results to the patient or family is one part of the medical contract. However, within the bounds of not being a violation of the patient’s rights, this duty to provide a given explanation of the diagnosis to someone, at a certain time, with a certain content, and to a certain degree, is recognized as a matter of degree within the physician’s discretion, if it will have an effect on treatment. Regarding incurable or hard to cure diseases, if caution is called for to
avoid an emotional shock to the patient, it is not a violation of the duty to explain
if a different disease from the truth is disclosed to the patient.\textsuperscript{178}

This decision, a landmark one in Japan, was that the physician has a general duty to
inform the patient or the family of the details of the condition, but that the physician
maintains “the discretion as to whom, when, and in how much detail he should
inform.”\textsuperscript{179} It also permitted the physician to use a white lie when communicating with
the patient, so long as the family is told the true diagnosis.

This case was initially appealed (while Higuchi’s article was in press) in
1990/Heisei 2 to the Nagoya High Court.\textsuperscript{180} The appeal was rejected, however, and the
court reaffirmed that it is within a physician’s “rational discretion,” based on the patient’s
condition (which includes disease, will (ishiki 意思), ability to accept, trust in the physician,
and relationship with family) to determine whether or not the diagnosis is disclosed to the
patient. As long as the physician’s rational discretion makes sense to the majority of
physicians at that time and there are no special circumstances, the physician’s
nondisclosure to the patient is not illegal.\textsuperscript{181}

The final appeal to the Supreme Court in 1995/Heisei 7 was also rejected.\textsuperscript{182} The
court made the following statement about disclosing a true diagnosis:

The physician considered the harmful effect that an emotional shock would have
on treatment, gave the explanation of severe gallstones, and planned to do a

\textsuperscript{178} Quoted in Ishida, Kazoku, 173.
\textsuperscript{179} Higuchi, “Patient’s Right,” 460.
\textsuperscript{180} Nagoya High Court, October 31, 1990/Heisei 2, 43(3) Minshū 178, 1373 Hanji 68, 44 Hanta 182.
\textsuperscript{181} Ishida, Kazoku, 173.
\textsuperscript{182} Supreme Court, April 25, 1995/Heisei 7, 49(4) Minshū 1163, 1530 Hanji 53, 877 Hanta 171; Ishida, Kazoku, 174-175.
precise exam after hospitalization. While details like the patient’s character were indistinct at the first exam, since it is typical of current doctors to tell patients a diagnosis different from the truth, these measures were unavoidable for the physician, and cannot be said to be irrational.

The court made this addition to the decision:

Once a patient has had a discussion with the doctor, it is necessary to cooperate with the treatment and respect the opinion given by the doctor, who is a specialist, in order to receive sufficient treatment.183

Several important elements of Japanese informed consent emerge from this case. The first is that setumei gimu, as interpreted by the Japanese court, entails a duty to inform either the patient or a member of the family, but that the physician can choose whom to inform. The second is that this duty to inform is exempted in cases where there is an emergency, where the patient is not able to consent (perhaps in cases of incompetence or lack of decisional capacity, in addition to medical reasons for inability to consent such as lack of consciousness), or where the physician is trying to protect the patient or a third party. Third, the duty to inform is also waived where there is a high risk that arinomama setumei (ありのまま説明), the explanation just as it is (implying that it is bluntly given), will affect the patient’s health or rational judgment. Among the exceptions listed above, only the final one is considered to be therapeutic privilege (literally, “a special right based on treatment,” chiryōjō no tokken 治療上の特権).184

Finally, the Supreme Court’s addition to the decision indicates that the power in the physician-patient relationship is firmly in the hands of the physician; the

183 Ishida, Kazoku, 175.
184 Jurist (no. 183,) 123.
responsibility of the patient is to cooperate with the physician in order to receive proper
treatment. Indeed, a patient’s failure to cooperate with the physician is grounds for
rescinding the “medical treatment contract” and thus the physician’s obligations to the
patient.\textsuperscript{185}

Despite the broad leeway given to physicians under the name of discretionary
power in the Makino case, two cases\textsuperscript{186} decided between the second and third Nagoya
appeals show that Japanese courts were willing to place some restrictions on this power.

In a 1990/ Heisei 2 Fukuoka District Court case, Ishida writes that a physician
suspected a patient had colon cancer, but did not tell the patient and did not suggest a
further exam.\textsuperscript{187} Twenty-one months later, the patient saw blood in his stool and went to
the same hospital. He was diagnosed with colon cancer that had metastasized to his liver,
had surgery, and left the hospital. Subsequently, he relapsed and was once more operated
on, but the cancer had metastasized to his lungs, and he died. The question was whether
the doctor who had performed the initial examination had made a medical error and if a
more detailed exam at that time would have saved the patient’s life.

The court found that the obligation to disclose (kokuchi gimu 告知義務) depends
on the case, stating that while it is best to disclose in cases where an anomaly is
discovered and a treatment plan needs to be established, other cases of disclosure (to both
patients and their families) are left to physician discretion. In this case, the court ruled
that the physician had a duty of care (chūi gimu 注意義務) to provide guidance to the

\textsuperscript{185} Moriyama, \textit{Iryō Genba ni Okeru Hōtekitaiō}, 48-49.
\textsuperscript{186} The descriptions of these cases are for the most part rough translations of Ishida,\textit{Kazoku}.
\textsuperscript{187} Fukuoka District Court, December 19, 1990/Heisei 2, 1394 Hanji 137); Ishida,\textit{Kazoku}, 173.
patient or the family, and violated this duty by not recommending a more detailed exam to the patient or the family.¹⁸⁸

In a 1994/Heisei 6 Tokyo District Court case, a physician diagnosed a patient with progressive stomach cancer and judged that the possibility of recovery was low.¹⁸⁹ The physician told the patient that she had an ulcer and recommended surgery, as was common practice in Japan at the time. Ishida writes that the patient refused surgery; since her husband had a heart issue, the physician did not inform him of the diagnosis. The physician did tell the younger brother, who asked the doctor to tell the patient the correct diagnosis. Despite this, the physician thought it was best not to tell the patient, and asked the brother not to tell the patient or her husband the diagnosis. The patient went to the hospital several times and the physician continued to recommend surgery, but the patient would not consent to it, and finally stopped going to the hospital altogether. Soon thereafter the patient received an exam at another hospital and was informed of her stomach cancer. She was told that if she had had an operation the previous year, the cancer might have been treatable, but it had metastasized to her liver, so she died of thrombocytopenia. The question was whether the original physician had violated his/her duty in not disclosing the cancer.

The court wrote that the medical care agreement stipulates that the physician’s duty is to “explain the diagnosis to the patient so they can make an appropriate judgment,” or in “some circumstances where it is not appropriate to disclose the diagnosis to the patient, the physician should disclose the diagnosis to the family or close

¹⁸⁸ Ishida, Kazoku, 173 (It is unclear which article of the civil code was at issue in this case).
¹⁸⁹ Tokyo District Court, March 30, 1994/Heisei 6, 1522 Hanji 104; Ishida, Kazoku, 173.
relatives and based on their cooperation, take measures to make it possible to provide appropriate treatment to the patient.” In the case of a cancer for which the possibility of treatment is low, the physician should use rational discretion to consider “the seriousness of the illness, the patient’s wishes, their personality, their family environment, their relationship of trust with the physician, and the personnel and material resources of the hospital, and judge prudently.”\textsuperscript{190} The court added that since this judgment is fundamentally affected by how much time the patient has left, the decision should not be left to the doctor’s personal judgment alone but must make allowance for the opinions of the family. Since the family is the source of information about the patient and may be able to influence the patient’s treatment decisions, it is important to inform the family or close relatives to ask for cooperation so the patient receives appropriate treatment.

According to Ishida, the court decided that, while in some situations it would be permissible not to disclose the diagnosis to the family living with the patient, the physician must make positive contact with a close relative and cannot just wait for the patient to come to the hospital with their family. While not telling the patient or her husband was not inappropriate, knowing that they had a son but not telling this son was a failure to fulfill the physician’s responsibility. The physician only contacted the younger brother, but neither asked him to persuade the patient as to hospitalization or surgery, nor to tell the son. Rather, his request not to tell the patient or the husband violated the duty to disclose. The court concluded that when patients are not told their diagnoses, the secondary duty to disclose the diagnosis to the family results from the duty of care for the

\textsuperscript{190} Ishida, \textit{Kazoku}, 174.
patient; the duty to disclose to the family is not a duty to the family but is interpreted as a
duty to the patient.\footnote{191}

These two cases clearly employ the standard that “someone must be told” as
expressed in the first Makino case. They also set limits on physicians’ discretion in the
context of the duty to explain, so that physicians do not have absolute authority over
whether or not patients receive treatment.

Following the final Makino appeal, a series of cases in Akita prefecture further
complicated the matter of physician discretion and the duty to explain, beginning with an
Akita District Court in 1996/Heisei 8.\footnote{192} A patient received an x-ray that showed shadows
in both lungs. The physician judged that the patient had terminal lung cancer and only
one year left to live. However, despite stating on the patient’s chart that an explanation to
the family was necessary, the physician worried that disclosure would resign the patient
to death, and so did not disclose the diagnosis to the patient or the family. Rather, the
physician suggested that the patient return for another exam and bring his family. The
patient declined for personal reasons, and the physician did not attempt to contact the
family. In deteriorating health, the patient went to another hospital, where the diagnosis
of terminal lung cancer was disclosed to the oldest son. The patient died soon after. The
issue was whether, since the diagnosis was not disclosed initially, valuable treatment time
was lost and the duty to disclose was violated.

The court rejected the petition, writing that in many cases it is harmful for a
patient to receive a diagnosis of terminal cancer and that it is desirable for the patient to

\footnote{191}{Ibid.}
\footnote{192}{The descriptions of these cases are also rough translations of Ishida, \textit{Kazoku}. Akita
District Court, March 22, 1996/Heisei 8, 1595 Hanji 123.}
live without the expectation of death. They also wrote that since there is not an
established standard among medical professionals for cancer disclosure, the decision to
disclose must be entrusted to the physician in charge – yet another decision in favor of
the physician’s discretionary power. In addition, the court admitted that there was no
professional standard, but continued to use the physician as a measure of the duty to
explain, setsumeigimu.

This case was appealed in the Sendai High Court, Akita branch in 1998/Heisei 10.193 The judgment in this case was that the physician was indeed culpable, not due to
default on a debt (saimufurikō 債務不履行), but due to an illegal offense under tort law
(fuhōkōi 不法行為). The former is failure to adhere to a contract (in previous cases, the
physician-patient medical contract), while the latter is liability for harming another
person. The court ruled that the physician’s carelessness in gathering information about
the state of the patient or in examining the retrieved information about the patient,
harmed the patient and family, because the patient was not able to spend more time with
their family.194 The physician should have told the family.

This case was appealed to the Supreme Court in 2002/Heisei 14.195 The court
rejected the appeal, writing that the physician has the duty to explain the diagnosis at
least to the family, because the family, upon understanding the physician’s plan, supports
the patient in treatment both physically and mentally. This case is cited as the precedent

193 Akita Branch, Sendai High Court, March 9, 1998/Heisei 10, 1679 Hanji 40.
194 Ishida, Kazoku, 176.
195 Supreme Court, September 24, 2002/Heisei 14, 1803 Hanji 28, 1106 Hanta 87.
for the obligation to disclose a cancer diagnosis to the family, and highlights the court’s concern for terminal cancer patients.  

The cases considered thus far reveal that the Japanese courts interpret physicians’ duty to explain as within their discretionary power. While early decisions indicated that the physician’s duty to explain is a requirement for the effectiveness of a patient’s consent, subsequent decisions softened this requirement through an appeal to discretionary power. Since the explanation is understood as within physicians’ professional responsibility, the extent of the explanation is part of their expertise.

As shown in the first Akita appeal in 1998, this is not reliance on professional standards, but an allowance for the exercise of discretion by individual professionals based on their understanding and judgment of particular cases and particular patients. This fits with John Owen Haley’s observation that Japanese courts tend to defer to “communities” to resolve their own internal affairs, where the medical profession can be interpreted as a community.

In addition, the standard used in these cases resembles what Stephen Wear has called the “subjective standard” for determining information disclosure, which “allows room for the idiosyncratic views and character of the individual patient in determining disclosure.” Wear writes that this standard is not used in any American courts, but the possibility is at least philosophically entertained. According to Faden and Beauchamp, proponents of this standard argue that patients’ rights to self-determination are protected neither by the reasonable person nor the professional standard employed in the U.S., and

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196 Jurist (no. 183), 120.
197 Uchiyama, Ishi no Sairyō to Kanjya no Jikkokettei, 55-58.
199 Wear, Informed Consent, 19.
that the subjective standard holds the only possibility of protecting particular patient choices. However, opponents note that this places an unfair burden on physicians to assess the values and desires of their patients. It is outside the scope of this chapter to decide between these competing requirements, although they will be discussed in chapters 5 and 6. What is important here is Japanese case law’s use of the subjective standard.

This is not to say that Japanese courts give all the decision-making power to physicians. Two Supreme Court decisions from the early 2000s show that while physicians have discretion as to how, when, and to whom to disclose a terminal diagnosis, they must respect patients’ right to self-determination by enabling them to make their own medical decisions, when patients so choose.

In 1992/Heisei 4, a 63 year-old female patient, a Jehovah’s Witness, was diagnosed with a malignant tumor in her liver and sought a hospital that would be able to operate without a blood transfusion. With the help of the Hospital Liaison Committee (iryō kikan renraku iinkai, Medical Liaison Committee), she checked into the Tokyo University Medical Research Hospital. The hospital policy, which the patient was unaware of, was that they would respect Jehovah’s Witness patients’ refusals of blood transfusions, but if there were no other life-saving measures, they would perform a blood transfusion whether or not the patient or family consented. During the operation, the physicians indeed judged that a blood transfusion was necessary and transfused 2245ml of blood.

The patient sued on the basis of sekimu furikō (違約不履行), breach of contract. The Tokyo District Court decided in favor of the physicians on the basis that “a human

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life is of sublime value.” The patient appealed the decision but died during the appeals process; her children continued the case. The Tokyo High Court reversed the district court’s decision, concluding that the refusal of a transfusion is not an issue of “public order and morals” (kōjyoryōzoku 公序良俗), but that since the patient was an adult with decisional capacity (handan nōryōku 判斷能力), the physician should have confirmed her refusal of a blood transfusion and explained the hospital’s policy in advance of the operation. The physician’s neglect of this explanation meant that the patient could not turn down the operation or seek another physician, and this violated her rights.

In 2000/Heisei 12, the Supreme Court upheld this ruling. This case is thought to be significant for its use of the patient’s right to self-determination and the scope it gives to the physician’s duty to explain. As to the former, the patient’s right to self-determination is a conditional limit on physician authority. According to the Supreme Court, “in cases when the patient refuses medical treatment with blood transfusions, as a human right this must be respected.” As to the latter, the requirement that the physician disclose information relevant to the patient’s decision relies on a different standard than the reasonable, prudent physician. In this case, the patient’s informational needs as she had expressly stated them determined the scope of the disclosure. Departing from the priority given to the physician’s discretionary power in earlier cases, this case demonstrates that the patient’s self-determination can usurp the physician’s authority.

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202 Tokyo High Court, February 9, 1998/Heisei 10, 1629 Hanji 34; Jurist (no. 219) 80.
203 Supreme Court, February 29, 2000/Heisei 12, 54 (2) Minshū 582, 1710 Hanji 97, 1031 Hanta 158. This case is called “Takeda v. State” by Robert Leflar (Leflar, Informed Consent (2001), 17).
204 Jurist (no. 219), 81.
The Supreme Court decided similarly the following year (2001/Heisei 13).\textsuperscript{205} In this case, a 43 year-old female patient had been diagnosed with breast cancer in 1991/Heisei 3; her physician judged that she needed a full mastectomy preserving the pectoral muscle. He told the patient that she needed to be hospitalized for the operation, adding that the operation needed to be done quickly, that radiation would blacken her chest and another operation would be necessary, and that while there were surgical methods that would leave some breast tissue they were not well established. He emphasized that although it was a full mastectomy, some muscle would remain. The patient had read a newspaper article the day before about surgical methods that would conserve the breast. She gave a letter in which she indicated her interest in this method to the physician at her pre-surgery exam; at the time, the physician had only performed one breast-conserving surgery. As he had planned, the physician performed a full mastectomy.

The question was whether the physician should have informed the patient about alternative surgical options. Breast-conserving surgery is used with much success in the U.S. and Europe, but in Japan full mastectomies are more common.

The Osaka District Court’s initial decision in 1996/Heisei 8 was that since the physician knew that the patient desired breast-conserving surgery, he should have explained his inexperience with the procedure.\textsuperscript{206} However, the Osaka High court found the next year that since the implementation rate of breast-conserving surgery is low and its safety is unconfirmed, the doctor’s explanation was not insufficient but in keeping with current medical practice.

\textsuperscript{205} Supreme Court, November 27, 2001/Heisei 13, 55(6) Minshū 1154, 1769 Hanji 56, 1079 Hanta 198. I would like to thank Professor Kodama Satoshi at Kyoto University for bringing this case to my attention.

\textsuperscript{206} Osaka District Court, May 29, 1996/Heisei 8, 1594 Hanji 125; Jurist (no. 219), 68.
The Supreme Court reversed the high court’s decision, concluding that while unestablished medical treatment is outside current medical standards and so is not normally within the physician’s duty to explain, in cases where the patient makes a positive appeal for information about alternative methods of treatment, the physician should respect the patient’s self-determination. The court stated that this is especially true in mastectomies, where the possibility that female patients will experience emotional and psychological effects is high.\textsuperscript{207}

As with the previous case, this case also attempts to balance the patient’s selfdetermination with the physician’s professional discretion. Within Japan, it has been described as an “important precedent that aims for harmony” in the “concrete exchange” between the patient and physician.\textsuperscript{208} While retaining the subjective standard for information disclosure described above, these cases add the requirement that the physician fit the disclosure to the patient according to both professional discretion and patient self-determination. The goal of this addition is to ensure that physicians are indeed responsive to individual patients’ needs. Yet cases using this individual patient standard for informed consent are rare, while cases using the reasonable, prudent physician standard are common.\textsuperscript{209}

Two additional cases show courts confronting the issue of how much responsibility physicians should bear for the particularity of patient decision-making. These cases illustrate the development of patients’ self-determination as an exception to physicians’ professional authority.

\textsuperscript{207} Jurist (no. 219), 69. 
\textsuperscript{208} Jurist (no. 219), 69; Jurist (no. 183), 124-125. 
\textsuperscript{209} Maeda, “Informed Consent for Anaesthesia.”
In a 2003/Heisei 15 case decided by the Kawagoe Branch of the Saitama District Court, a patient committed suicide after being hospitalized for cancer.\(^\text{210}\) The family alleged that the physician had failed in the manner of disclosure (kokuchi hōhō 通知方法) – both the way it was done and the time it was done. The issue was whether or not the physician had prudently considered how the patient would handle the disclosure.

The court ruled that when the patient makes a positive appeal to know the diagnosis, to the extent that it will not adversely affect treatment, the physician should inform the patient. While the physician’s handling of the family was not completely satisfactory, the physician did not violate the patient’s right to self-determination nor the duty to explain. The court restated the Makino ruling that a serious illness like cancer requires prudent consideration of the patient’s disposition, mental and physical state, family environment, and the effect that informing might have on treatment. They added that after informing the patient, the effects of disclosure, including any change in illness or condition, should be carefully heeded.\(^\text{211}\) In the end, the physician was not found culpable, but the court’s restatement of the Makino ruling in the context of manner of disclosure indicated that physicians’ professional responsibilities extend beyond setsumeigimu and that the duty of care includes the patient’s mental and emotional state during treatment. As with the two cases above, this court also concluded that positive exercise of the right to self-determination is a limit on physician responsibility, although they reiterated that the physician should “prudently” communicate with the patient, no matter the patient’s degree of self-determination.

\(^{210}\) Kawagoe Branch, Saitama District Court, October 30, 2003/Heisei 15, 1185 Hanta 252. The description of this case is also a rough translation of Ishida, Kazoku.

\(^{211}\) Ishida, Kazoku, 177.
Finally, in 2007/Heisei 19 the Nagoya District Court considered a case in which a patient with prostate cancer stopped taking his medication because he did not want the side effect of not being able to have an erection. He went to several different hospitals looking for an alternative treatment; in the meantime the cancer metastasized to his bones. He returned to the first hospital and resumed the initial treatment, but died soon after. The issue was whether the physician violated the duty to explain the diagnosis and treatment to the patient and should have disclosed the illness to the family.

The court rehearsed earlier decisions, writing that unless there are exceptional circumstances, the physician should explain all aspects of treatment and take into account the physical and mental effects of disclosure on the patient. The court ruled that the explanation given in this case was not insufficient, writing that the decision of what treatment to seek is ultimately up to the patient. Once a patient has made a decision, the physician should respect it. Furthermore, if the physician has sufficiently informed the patient they do not need to inform the family. As I explain below, this case serves as a good summary of informed consent in Japan.

The Japanese informed consent standard gives physicians discretionary power over disclosure, including cases in which withholding the diagnosis from the patient is judged appropriate. However, someone must be told, so in these cases a family member should receive disclosure. When patients themselves are informed, if they positively participate in treatment decision-making, physicians should respect their decisions. This makes physicians’ interactions with patients dependent on both professional discretion and patients’ self-determination. To the extent that patients wish to make decisions on

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212 Nagoya District Court, June 14, 2007/Heisei 19, 1266 Hanta 271.
213 Ishida, Kazoku, 178.
their own, families need not be informed.214 While patients’ positive exercise of self-determination can be interpreted as a limit on physician responsibility, physicians should continue to exercise care towards their patients in these cases as well. If a patient does not positively exercise self-determination, then the physician continues to bear the burden of responsibility. In short, physicians must alter their style of disclosure to suit patients in cases where the patient makes a positive appeal for information as well as in cases where they do not. In this way, the Japanese courts attempt to respect both physicians’ professional integrity and patients’ right to self-determination.

Reviews of informed consent in Japanese law written in English have tended to characterize the Japanese standard as either overwhelmingly paternalistic or as beginning to move towards individual autonomy.215 However, neither characterization reflects the particular development of this standard. As in the U.S., Japanese courts have struggled with the dilemma of how best to protect patients’ voluntary consent. In the U.S., this initially caused some wavering between patients’ right to self-determination and physicians’ duty of care, with the weight coming to rest on the side of individual self-determination. To avoid physician paternalism, regulations of physicians’ disclosures were grounded in an objective picture of patients’ needs.

In Japan, by contrast, paternalism has never been such a motivating concern. Rather, courts have sought to respect both physicians’ professional authority and patients’ rights. Japanese courts continue to prioritize physicians’ responsibility for their patients’ well-being, granting them discretion in determining the meaning of this well-being except

214 There may be some interaction with privacy law here as well, such that if patients are informed families cannot be. However, this question needs further investigation.
when the patient’s wishes are unequivocally stated. When the patient’s right to self-determination is invoked, it is generally done in order to shift the weight of responsibility from the physician to the patient. If patients exercise their right to make their own choices, physicians are no longer responsible for using their discretion to estimate the emotional and medical outcomes of these choices, although they should still exhibit care. In the next section, I review the JMA’s understanding of its responsibilities.

2.4.3 Medical Profession Guidelines

The Japanese Medical Association, like the AMA, has a code of ethics for physicians (i no rinri kōryō 医の倫理綱領), first called “medical ethics” (i no rinri 医の倫理) in its earliest instantiation in 1951) consisting of six principles adopted on April 2, 2000/Heisei 12. Its ethical guidelines (ishi no shokugyō rinri shishin 医師の職業倫理指針) were created in 2004 and published in a revised version in 2008. Like the AMA, the JMA also issues opinions on medical ethical topics, including “IC [informed consent] and litigation (such as in the case of cancer disclosure)” and “the physician’s duty of explanation to a bereaved family.”

However, membership in the JMA is not required, so their statements do not necessarily represent the positions of all Japanese physicians.

The JMA’s bioethics group issued its most well known report on informed consent, “A Report on Setsumei and Dōi” (information and consent), in 1990. The introduction states that setsumei to dōi has become an issue in modern medicine due to the changing nature of medical practice, the physician-patient relationship, and patient understanding. It writes that setsumei to dōi is a concept that first arose in the U.S. (a

claim they do not support with evidence), which it notes has a diverse ethnic population and a strong tradition of individualism.\textsuperscript{217} It suggests that Japan’s traditional culture of human relationships is unique, and while stressing the need to learn from the Western standard, it argues for developing a practice of \textit{setsumeitōdōi} that reflects Japan’s particular medical issues.\textsuperscript{218} This reflects the common claim that \textit{setsumeitōdōi} and \textit{infūmudokonsento} are conscious adaptations of a Western practice employed in the Japanese context.\textsuperscript{219}

The JMA’s ethical guidelines have developed differently than those of the AMA. In the 1990 report, they write that

The patient respects the physician’s specialist knowledge and judgment, and the physician respects the patient’s human rights and self-determination. Together they trust each other and cooperate, and if they are able to advance medical treatment, this is wonderful.”\textsuperscript{220}

The report gives concrete guidelines for explaining diagnoses using simple language, non-verbal communication, and images. It also cautions that physicians should be mindful of the effect that disclosure will have on patients and endeavor to allow patients

\textsuperscript{217} The appendix includes copies of the Nuremberg Code, the Declaration of Helsinki, the AHA’s Patients’ Bill of Rights (1972), the Lisbon Declaration of Patients’ Rights (1981), and a summary of the American Presidential Commission on Bioethic’s report on Informed Consent (1985).

\textsuperscript{218} This need to develop an informed consent appropriate to Japan is also emphasized in the publication, \textit{Genki ga Deru Infōmudo Konsento}, by the Ministry of Health and Welfare in 1996.


\textsuperscript{220} JMA, \textit{setsumeitōdōi}, 10.
to maintain hope. In the section on patient consent, they write that physicians should clearly communicate their treatment recommendations to patients, but caution that if the patient does not accept the physician’s recommendation, then the patient must be allowed to either choose a more preferred treatment or seek another physician.

The 2008 JMA guidelines concerning the physician’s duty to the patient echo the 1990 report’s pragmatic approach, although the influence of case law is clear. The guidelines state:

On informing the patient of their disease and diagnosis: the foundation of the physician-patient relationship in medicine, directly excluding emergency conditions that require life-saving measures, is for the physician to sufficiently explain the diagnosis to the patient and the patient to adequately understand the disease so that they may cooperate in order to overcome the disease. Accordingly, in general the physician should disclose the content of the diagnosis, including the name of the disease, to the patient at the time of the medical examination, and has the duty to simply explain the subsequent changes, tests, and methods of treatment so that the patient can understand. However as an exception, if for example just to tell the disease name and diagnosis to the patient as it is would cause a great emotional shock to the patient, and when there is the valid reason that subsequent treatment would be impeded, then it is permissible not to disclose. In this case, the physician in charge should consult with someone such as another physician and judge prudently. Further, when the patient is not told, it is important

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221 Ibid., 13.
to tell the appropriate family member the correct disease name and diagnosis in advance.

The reasons given for this policy are that:

It is important in the ethics of medicine to honestly inform patients of their correct disease and condition. This is indispensible to achieving both the patient’s consent to the ensuing tests and treatment and their cooperation concerning medical treatment (informed consent).

However, in the case that informing the patient of malignant cancer or incurable disease would cause an extreme emotional shock, prudent consideration regarding disclosure is necessary for the physician. Also, if the patient does not desire to know the correct disease name or condition, and it is anticipated that it would be a hindrance to further treatment, it is permitted to refrain from disclosure. However, this judgment must be made prudently, and at times it is necessary to consult with another member of the medical staff. In principle, it is necessary to inform the appropriate family member involved in caring for the patient of the correct disease name and condition. It is desirable to have this content in writing.\textsuperscript{222}

In addition, as with the 1990 report, in the 2008 guidelines the JMA addresses the physician’s duty regarding disclosure and patient consent separately. As to consent, the JMA writes that,

When the physician performs a medical examination and/or treatment, consent based on the patient’s free will is indispensible. At this time, in order to obtain the patient’s consent, it is necessary for the physician to explain the content of the

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\textsuperscript{222} JMA, \textit{Ishi no Shokugyō Rinri Shishin} (2008), 2-3 (my translation, emphasis added).
examination and/or treatment. Before obtaining consent from the patient, the physician should sufficiently explain the tests, treatment, purpose of measures taken, substance, nature, risks of implementation or not, pros and cons, and existence of alternative measures, and upon the patient’s understanding this it is important to obtain their consent, that is, “informed consent.” Further, in the case of undertaking high risk tests or treatment, it is desirable to create a consent form referencing the content of the explanation. However, when obtaining a consent form, one should endeavor not to become formalistic.\(^\text{223}\)

Within these ethical guidelines, the JMA’s separation of the duty to inform from the duty to obtain consent reflects both linguistic and legal considerations. The translation of informed consent as *setsumeitō dōi*, explanation and consent, separates the two processes (as opposed to the word “informed” modifying “consent”). Similarly, Japanese case law distinguishes cases considering *setsumeigimu* (physicians’ responsibilities) from those dealing with patient consent (patients’ rights). Where the two are mixed, patients’ exercise of their rights limits physician responsibility (or physician discretion), or physician discretion may limit patient self-determination.\(^\text{224}\) Physician discretion and patient self-determination are two possible methods of meeting patients’ informational needs, but they rarely coexist.

This is different from the picture of patients and physicians working together to advance medical treatment in the 1990 report, and reveals the influence that Japanese

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court decisions have had on the JMA guidelines.225 The guidelines rehearse the rulings of significant cases in broad strokes, including the emergency exception, the cancer disclosure exception, the requirement of informing patient or family, and the need to ensure patient cooperation. In addition, while emphasizing physician responsibility for the well-being of patients, they give little guidance to physicians as to how to anticipate the needs of particular patients; it is unclear whether physicians can expect much help from patients. The 1984 Japanese Declaration of Patients’ Rights states in Article 3.3 that “Patients have the right to support and assistance from medical practitioners at any time necessary.” Unlike the Patients’ Bill of Rights in the U.S., the Japanese declaration does not contain a section on patient responsibilities.226

As a general medical association, the JMA appears to rely on national legal standards with particular ethical issues addressed by specialized associations. For instance, therapeutic privilege in Japan is for the most part exercised only in the case of cancer disclosure, so Japan’s National Cancer Research Center has a more nuanced approach to disclosure. In their “Cancer Disclosure Manual” (Gan Kokuchi Manyuaru がん告知マニュアル) published in 1997 and revised in 2004, they write,

In relation to cancer disclosure, currently, especially in cancer specialist hospitals, the phase of debate over “to tell or not to tell” has already ended, and the time for

225 While the JMA does have special reports on informed consent, only one of these is a reflection on the physician-patient relationship, while the other is a survey of lawsuits related to informed consent: JMA, detailed exposition no.2 “IC and lawsuits (e.g. cancer disclosure)” and no.4 “Infomudo Konsento.”

thinking about the quality of the disclosure in terms of “how to convey the truth, and after this how to support and aid the patient” has come.\textsuperscript{227}

Physicians who specialize in cancer treatment recognize that responding to the mental and emotional needs of individual patients is the core of their professional duty. Despite use of a subjective standard and the increased formalization of the JMA’s guidelines, patients’ needs may be met in Japan through these specialized channels. In the next section, I review the features of the U.S. and Japanese structural foundations of informed consent that are highlighted by the foregoing analysis.

\textit{2.5 Comparing Structural Foundations}

This survey of the institutional standards of informed consent in the U.S. and Japan reveals distinctive characteristics of the two practices. The U.S. practice is based on the simultaneous development, in case law and the medical profession, of the respect for patients’ rights to self-determination and physicians’ professional responsibilities. In American case law, concern that physician paternalism could threaten patients’ freedom of choice led to the repeated rejection of a professional standard for informed consent in favor of an abstract concept of patients’ informational needs in medical decision-making. The medical profession and patients’ rights movement have developed a more balanced picture of responsible professionals and an informed public, but conceptually, the individual’s right to self-determination is ubiquitous in the discourse, if not fully guaranteed in the practice.

Japan has also struggled to balance respect for patients’ self-determination with

\textsuperscript{227} National Cancer Center, Cancer Disclosure Manual, December 2004 (my translation).
physicians’ professional responsibilities. However, fear of physician paternalism has never become the driving force in Japan that it was in the U.S. in the 1970s; as I will suggest in chapter 6, this may be because the concept of paternalism does not adequately capture Japanese physicians’ attitudes towards their patients. The Japanese legal standard has strengthened physicians’ professional discretion in fulfilling their duty to explain, while requiring respect for positively exercised patient self-determination. In some cases, this means that the patient’s self-determination overrides the physician’s responsibility for the patient’s emotional and mental state. In most cases, however, responsibility for medical decision-making remains firmly in the hands of the physician. The discourse is overwhelmingly one of professional responsibility, which may become increasingly specialized as patients’ particular and contextual needs are prioritized.

Given that the Japanese standard’s allowance of nondisclosure is similar to the American standard in the 1960s and 70s, it may be tempting to conclude that the structural foundations for informed consent in Japan lag behind those of the American practice. Indeed, some authors argue that Japan needs to “catch up” with the U.S., which they describe as a “developed country.” However, on closer examination it seems that this is the wrong approach to take. Rather than seeing Japan as under-developed, it is possible to interpret the Japanese standard as simply rejecting the shift from the standard of the reasonable, prudent physician to that of the reasonable, prudent patient. The Japanese system tries to balance physician discretion with patient self-determination in the name of seeking harmony in the “concrete exchange” between physician and patient. Occasionally, this can mean that patients will not be told their diagnoses directly.

228 For example: Mizuno, i.
According to the logic of the Japanese system, the best way to support patient autonomy is not to continually uphold patients’ rights to self-determination in order avoid physicians’ paternalism, but to make physicians increasingly responsible for providing support that is suited to each particular patient, whether patients’ needs are explicitly stated or not. Admittedly, this places a weighty ethical and legal burden on physicians and necessitates a significant emphasis on communication skills within physician education. To determine whether this system is successful, increased attention needs to be paid to how physicians operate and why nondisclosures might be justified within it.

Therefore, chapter 3 considers how informed consent is currently practiced in the Japanese medical system through interviews with medical professionals who participate in the practice, including physicians, nurses, and support staff. Examining these professionals’ perspectives on Japanese informed consent reveals how the institutional standards presented in this chapter are realized in concrete practices, bringing us closer to an assessment of whether and why nondisclosure to a patient of a diagnosis like cancer might be justified in Japan.

229 According to some authors, communication training for physicians in Japan is insufficient (Moji et al., “Infōmudo Konsento,” 107). Others suggest that improving communication is possible (Shijiki, “Kanjya/Kazoku,” 20), even given short periods of time and potential limited understanding by patients, if physicians communicate with patients about their desires and concerns (Kōsaka, “Jikokettei to Jikosekinin,” 47).
Chapter 3: The Practice of Informed Consent in Japan

“At a small hospital, they’ll say something looks suspicious, they need to do a more detailed study. They explain little by little and don’t give a full diagnosis until they’re sure. All the exams can often take half a month. When they’re sure, they ask the patient to come with a family member to explain the diagnosis. This lets the patient prepare and get ready for receiving the diagnosis. When they come in, they explain the whole diagnosis. But there are also physicians who don’t say anything at all while doing the exams to determine if it is cancer, and these patients are really surprised. Young doctors learn how to do this gradual revealing of the diagnosis little by little through practice.”

--Interview with a Japanese Nurse, 2014

“Formerly families were informed first and then the patient, now it’s become more common to talk to the patient, and it’s less common to speak with the family. But doctors have no confidence in disclosure. Bad news isn’t just bad for the patient and family, but for the physician as well. More support is needed for physicians, and for cancer patients. This is beginning to take hold, but... There is no follow-up at university hospitals. The goal is just treatment. They say here is what you have, here is what we can do, so let’s treat you. For the patient, they receive a great shock, they’re not sure what to do. They’re told to make a decision as to treatment in a week. University hospitals do a lot and develop new treatments, but they don’t follow the patients’ kokoro [mental spiritual] care.”

--Interview with a Japanese Nurse, 2014

Introduction

The previous chapter demonstrated that Japan and the U.S. have divergent institutional standards for informed consent. In the U.S., patients are made responsible for medical decision-making in an effort to avoid physician paternalism. In Japan, by contrast, physicians bear primary responsibility for medical decision-making in what is often described as a paternalistic medical system. To better understand this system, we need to evaluate how Japanese physicians learn, describe, and discharge their responsibilities. In what terms do they describe their practices of informed consent? How do they conceive of its goals? What challenges do they face?

To answer this question, this chapter considers the concrete reality of Japanese informed consent practices as revealed by qualitative interviews with Japanese medical
professionals and scholars. Over the course of 17 months, I conducted 16 semi-structured, 45 minute to two hour interviews in Japanese with physicians, nurses, medical social workers, clinical psychologists, bioethicists, and chaplains who practiced or were involved with the practice of informed consent in Japan. My interviewees were six women and ten men, five physicians, five nurses, three bioethicists, one medical social worker, one clinical psychologist, and one chaplain.²³⁰ Their ages ranged from mid-20s to late-60s and they were from various regions around Kyoto, Tokyo, Osaka, and Kobe. They had experience at medical institutions such as local city hospitals and large university medical centers, and their specialties included oncology, cardiology, obstetrics and gynecology, geriatrics, nephrology, and neurology.

In these interviews, I asked my subjects about informed consent: e.g., how it is practiced, what its goals are, and whether they think it needs improvement. All interviewees were forthcoming about their experiences and had clearly given much thought to medical decision-making and professional-patient relationships. In this chapter, I will first outline the content of my interviews with physicians and nurses to highlight the particularities of Japan’s informed consent practices as seen from these two different professional perspectives.²³¹ I will then analyze the data from all of my interviews in terms of distinctive features of the practice and current challenges, indicating how these features and challenges are similar to and different from informed

²³⁰ In this chapter the perspectives of the bioethicists and chaplain are not distinguished. This is in part because the bioethicists tended to appeal to American bioethical theory without referencing Japanese practices, and the chaplain had only limited experience with informed consent.

²³¹ I used grounded theory to collect and analyze my data. Data do not test predetermined theoretical hypotheses, but rather track common themes and concepts to gain a sense of current informed consent practices in Japan.
consent in the U.S. I will also point out data that contradict or contrast with previous studies of informed consent practices in Japan. In describing contemporary informed consent practices in Japan, this chapter will also hint at why nondisclosures to patients might occur within the Japanese system.

3.1 Qualitative Interview Data from Physicians

While previous studies have found that a majority of Japanese physicians seldom tell patients their cancer diagnoses, a practice allowed by the Japanese institutional standards presented in chapter 2, my interviews with physicians suggest that most, if not all, physicians in Japan do tell patients when they have cancer. None of the physicians I interviewed reported a policy of withholding cancer diagnoses from patients, and none reported knowing another physician with such a policy. Several of the physicians said that if they were approached by a family member with a request to withhold a diagnosis from the patient, they would explain to the family the importance of disclosing the diagnosis to the patient himself or herself and would not honor the family’s request to withhold disclosure from the patient.

In addition to consistently reporting that all patients are now told when they have cancer, the physicians I interviewed seemed surprised that I would even ask whether this is a universal policy, saying that “of course” all patients are told when they have cancer.

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232 For example, Seo et al. found that 27 of 35 physicians surveyed favored disclosing diagnoses to patients, while Elwyn et al. found that of 14 male physicians surveyed, only two had a policy of disclosing cancer diagnoses to patients.

233 While the fact that I am American may have influenced some physicians’ descriptions of Japanese informed consent as more in line with American informed consent, I believe the presence of a Japanese collaborator at several interviews helps to control for this possibility.
However, the basis for this universality was unclear. It cannot be the institutional standard of informed consent itself, which allows for diagnoses to be withheld in exceptional cases, as we saw in chapter 2. Indeed, some responses suggested that diagnosis disclosure depends on the type of disease. In cancer cases, patients are now always told their diagnoses. However, in dementia cases, it appears to be common not to tell patient their diagnoses, even (or especially) if they are not yet exhibiting symptoms of dementia. One physician suggested that this is because cancer is treatable. With cancer, patients have to be informed so that they can make future plans. With dementia, there is no treatment, and the family, not the patient, will bear the burden of care and decision-making in the future. For these reasons, families and physicians may judge it unnecessary to worry patients with these diagnoses.

While it appears to no longer be a common practice, some senior physicians reported having experience in the Japanese medical system when it was common not to tell a patient his or her cancer diagnosis. According to these physicians, diagnoses were only withheld in cancer cases, and this practice ceased in the mid-2000s. These physicians said that when confronted with such cases, they felt discomfort when patients were not told their diagnoses. They also stated that while withholding disclosure of diagnoses was incredibly common, it was not universal. Some remembered conflicts between physicians who thought it best to withhold diagnoses from patients and physicians who would tell patients any and all available information. Given the diversity of physicians’ practices, whether or not a medical student learned informed consent by shadowing a physician with a policy to disclose or a policy to withhold was a matter of chance.
Turning to more standard informed consent practices, physicians consistently stated that the main criterion for informed consent is the invasiveness (侵犯, shinshuu) of the treatment or test. Informed consent is always performed when patients are hospitalized, and the process is longer and involves more nurses and support staff in the case of inpatients than outpatients. There was consensus that informed consent differs depending on the situation (e.g., acute vs. chronic cases) and that different types of cases require different types of informed consent. For example, in an emergency case, informed consent is not so much explanation for a decision as explanation of the treatment that has already taken place or is necessarily about to occur. In a chronic case, by contrast, informed consent takes place gradually as the treatment and the patient’s lifestyle are both adjusted to bring the two into greater harmony.

Beyond these standards, particular practices of informed consent vary: some physicians reported that they always explain different treatment options to the patient without bias, while others stated that they always make clear which option they think is best. In other words, some physicians avoid influencing patients’ treatment decisions, while others provide recommendations in the decision-making process. Interestingly, this was a polarizing issue: physicians thought ranking and assessing treatment options for patients either must or must not be done. One physician said that if all treatment choices were explained as if they were equally viable, then patients would not be able to choose, so he tells patients which option he thinks is best and presents the other options in order from best to worst. Another said that it is important to explain everything to patients as evenly as possible so that their decisions are not externally influenced. When describing their own methods of providing consent, all physicians said they practiced informed
consent in ways that suit them, but that other physicians have other methods. However, none of the physicians were able to speculate on what these other kinds of informed consent practices might be like, saying that they only had experience with their own method.

When asked about problematic or difficult aspects of informed consent, physicians gave relatively consistent responses. Most physicians stated that informed consent is difficult if patients become angry, so they try to explain things so that patients and their families will not become angry. However, no one suggested that physicians should provide less information in order to avoid angering patients or families. In all cases, patients’ or families’ anger or frustration was understood as resulting from a gap between their expectations and reality. This complicates explanation of risk, and the importance of making sure that patients and families understand risk was stressed. One physician always begins the decision-making process by describing the worst-case scenario to patients and families, so that they will not be disappointed later. He said that it is much worse for patients to have high expectations that are not met than to have low expectations that are surpassed.

Patients seem to have limited sources of medical information outside of physicians’ explanations. Most physicians reported that patients are neither well informed nor proactive about their treatment, although one physician in obstetrics and gynecology said that patients are remarkably well informed. This may reflect a characteristic of that specialty: people tend to plan for children, whereas they do not plan to get sick. Overall, however, physicians noted both limited resources for patient health education and a low rate of health literacy in Japan.
Despite patients’ apparent lack of health literacy and the importance of managing patient and family expectations in order to avoid conflict, no physician had a method for confirming that patients and families had understood their explanations. Many physicians said, “you can usually tell just by talking with them [patients].” In fact, as will be clear from my interviews with nurses, Japan does have a system for confirming patient and family understanding, but it is not conducted by physicians, and physicians are not always aware that it has taken place.

Physicians’ inability to describe a method for confirming patient understanding may be traced back to their lack of formal education in communication and informed consent. Recall that physicians’ particular informed consent practices vary and that the type of informed consent practice a physician learns is a matter of chance. All physicians reported that they learned how to conduct informed consent from observing which of their superiors’ behaviors caused problems with patients and families and which did not. Almost all physicians received this informal training after beginning clinical work, although one physician had some prior training with a mock patient. None had formal training in communication with families, although one did report being taught to do a “self-introduction” and to make eye contact with the patient as a way to ease both physician and patient stress. A particularly young physician (with less than six years clinical experience) said that he learned how to do informed consent through trial and error, but that patients and families sometimes complained that his explanations were too blunt. Of all the physician interviewees, he seemed the most uncertain about his informed consent practice.
Older physicians in administrative roles tended to be the most confident about their abilities to do informed consent well, although they were also the least reflective about informed consent practices and tended to give formulaic descriptions of informed consent and its goals (e.g., “you explain the diagnosis, the treatment options and the merits and demerits, and then the patient decides. This supports patients’ self-determination”). As above, several younger physicians mentioned anxiety over whether their informed consent would anger patients and families. Most physicians also noted that time constraints prevent optimal care. Japan’s shortage of physicians makes them often overworked and short on time.

Many physicians stated that informed consent does not accord well with Japanese culture, since it presupposes active and independent patients who make their own decisions, which they said is hardly the norm in Japan. What is known as the “omakase” system is still quite strong, especially for people over the age of 50. “Omakase” means to entrust decisions to someone else, as is often heard in restaurants in Japan, where to ask for an omakase set is to have the chef determine the contents of one’s meal. It is a form of deference to authority, less as a position of power than as expertise in a certain area. Patients who prefer an omakase medical system want to leave decisions to their physicians, since the physician has more knowledge and training in medicine than the patient. Of course, this can cause problems if the decision to be made hinges on values rather than medical factors. Complicating matters are the facts that it is not always clear how far the scope of the omakase relationship extends (i.e., what types of decisions the patient wishes to entrust to the physician) and that it can sometimes be difficult to determine which patients prefer omakase and which do not. Japanese society is changing,
such that patients who prefer an *omakase* system are usually over the age of 50, while younger patients want to make decisions on their own. However, this is not a hard rule, and there is a substantial gray area in between.

Finally, family presence and involvement in informed consent is highly significant in Japan. All physicians reported that they usually practice informed consent with the family and patient together, that they would be extremely hesitant about practicing informed consent with the patient alone, and that they would try to persuade the patient to include family members in the decision-making process if the patient came to a disclosure or informed consent appointment alone. This is critical when the particular disease or treatment heavily burdens the family, as in ALS (Amyotrophic Lateral Sclerosis) or dialysis cases, as I discuss later. When I mentioned that family presence is not routine policy for informed consent in the U.S., all physicians seemed genuinely surprised.

### 3.2 Qualitative Interview Data from Nurses

Compared to physicians, who are officially in charge of informed consent, nurses focused more on the periods before and after informed consent than on the actual informed consent itself. While physicians and patients may be perceived as the main players in informed consent, my interviews with nurses made clear that they have a much more substantial role than is commonly recognized.

In Japan, nurses (or sometimes medical social workers) are responsible for both setting the stage (*bamen settei*) before informed consent and following-up with the patient after informed consent. The former entails coordinating schedules and, if
possible, discussing the patient’s case with the medical team. The latter involves checking with the patient after informed consent to make sure that he or she has understood the explanation and to elicit questions. Through questioning, the nurse finds out what the patients and families have not understood. The nurse can then tell this to the physician and can suggest having a conference or a discussion about the particular case with the other nurses on the ward.

A number of nurses stressed that coordination prior to informed consent is very important, because it ensures that all medical staff are in accord. If the patient hears conflicting advice or information from different medical professionals, he or she might become confused or panicked. Unfortunately, most nurses reported that there are not enough opportunities to do this “bamen settei” and that coordination among different medical professionals is still very difficult in the Japanese medical system. This echoed physicians’ reports that Japanese team medicine needs improvement.

Perhaps due to the nurses’ roles in ongoing care, there are more opportunities for follow-up than for preliminary coordination, although insufficient nursing staff renders it suboptimal. Several nurses mentioned that staff shortages or inadequate team coordination prevent preparation and follow-up. This leads to more significant problems later on, including psychological problems for the patient and conflicts between the patient, family, and physician (substantiating physicians’ fear of angry patients and families). University hospitals’ concern to develop state-of-the-art treatment over support services exacerbates this situation. According to many nurses and physicians, university hospitals often have fewer nurses and social workers for more beds than local or regional hospitals.
Nurses reported that, in almost all cases, families are present for the informed consent meeting, reinforcing the centrality of the family in medical decision-making. Even if a patient comes in alone, the nursing staff does their best to locate a family member who can attend the informed consent meeting. One nurse described this system as self-determination within the family (kazoku no naka no ishikettei, 家族の中の意思決定) and said that it is still very important in Japan. Several observed that patients almost always make decisions together with their families, but that nurses will try to aid in patient decision-making by offering suggestions and advice if a family member is not present.

Overall, nurses were critical of physicians’ abilities to conduct informed consent (echoing physicians’ own uncertainties). They noted that, in many cases, physicians tell patients all of the information related to the decision (the diagnosis, possible treatment options, the merits and demerits of the different options), and then they ask patients to decide. However, nurses observed that patients rarely understand all of this information, due to physicians’ poor communication ability and patients’ low health literacy, so it is essential for nurses or medical social workers to follow up with patients and families later to ensure they understand. To remedy some of these failures, when nurses attend the informed consent meeting they often act as patient and family advocates, asking physicians to rephrase their explanations or to clarify their questions.

According to nurses, if physicians do not just abandon patients to decision-making, then physicians subtly guide decision-making themselves. Nurses noted that

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234 Hiroyuki Hattori has termed this same phenomenon “substitute consent” (Hattori et al., “The Patient’s Right to Information in Japan”) and Susan Orpett Long has described it as “family surrogacy” (Long, “Family Surrogacy and Cancer Disclosure”).
when giving patients options, physicians tend to impose their own preferences. Two nurses observed that physicians often explain the merits of a particular treatment but not the demerits and that they rarely explain effects on lifestyle and quality of life. If the options are presented in this uneven way, nurses have found that patients often follow physicians’ recommendations.\footnote{A previous study found that 60% of surveyed Japanese patients would be inclined to follow a physician’s recommendation even if it conflicted with their own wishes (Sekimoto et. al., “Patients’ Preferences for Involvement in Decision-Making in Japan”).} Contributing to this is the fact that physicians are perceived as authority figures. *Omakase*, noted above, is still strong in Japan, so many patients are not willing to dispute the recommendation of an expert.

Even patients who do not favor the *omakase* system may be at a disadvantage in the patient-doctor relationship, because they acquiesce when they have not understood. The nurse’s follow-up is thus essential for ensuring that the patient has understood the explanation and wants to go forward with the chosen treatment. In the words of one nurse, her role is to ensure that the patient is giving “a sincere response.” Another nurse noted that patients show different faces to different healthcare professionals, and that patients’ relationships with nurses tend to be quite close. Sometimes this means the nurse acts as the patient’s *daiben* (代弁), or proxy, and communicates the patient’s desires directly to the physician.

As with physicians, nurses learn about informed consent through observation and training, but more systematically than physicians’ piecemeal informed consent education. For the first 18-24 months, nurses observe their superiors’ informed consent; after this period they are allowed to attend informed consent meetings without an advising nurse present. According to one nurse, the observation period is long because nurses play such
a delicate role in managing the informed consent process. Nurses’ lengthy training undergirds their credibility with all of the players involved in medical decision-making.

Nurses echoed physicians’ statements that cancer diagnoses are no longer withheld, but cited dementia and ALS as particularly problematic. One nurse remembered a case from the 1990s in which an elderly man had dementia as well as cancer. The man was informed that he needed treatment, but he had trouble understanding his diagnosis and treatment proposals. The family authorized a needed operation for him without his being told, but after the operation, he did not understand that he needed to rest, so he had to be restrained in his bed. According to the nurse who related this story and who was disturbed by the situation, it is critical for nurses and physicians to address the unique challenges presented by different diseases, dementia in particular.

Nurses also noted differences between inpatient and outpatient informed consent. Lengthy inpatient informed consent almost always involves a nurse, while the brevity of outpatient informed consent makes it difficult to confirm that the communication process has gone well. One interesting aspect of my interviews with both nurses and physicians was the observation that the decreasing length of hospitalization in Japan has made informed consent even more critical. Medical care teams need to ensure that patients and families understand their roles in the treatment process once they return home. Otherwise, they will be unable to continue treatment on their own and re-hospitalization will be inevitable.

Finally, one nurse stated that suicide following disclosure (as will be discussed in chapter 4) is really only an issue if there is no follow-up by a nurse. In other words,
suicide results from lack of post-disclosure support, not from some unique feature of Japanese psychology.

In the following section, I analyze the Japanese practice of informed consent as revealed from all of my interviews, including the viewpoints of medical social workers, clinical psychologists, bioethicists, and chaplains in addition to those of physicians and nurses.

3.3 Analysis

3.3.1 Features of Japanese Informed Consent Practices

My interviews suggested three ways in which Japanese informed consent practices are developed beyond the institutional standard described in chapter 2: (1) Japanese informed consent is conditional, depending on the circumstances and the parties involved; (2) in addition to physicians, Japanese informed consent involves nurses, medical social workers, and other medical professionals with different — although not always clearly demarcated — roles; and (3) ideally, Japanese informed consent is a three-step process, including confirmation of patient understanding and follow-up after a decision has been made. I consider each of these distinctive features in turn before turning to the challenges they raise.

3.3.1.1 Japanese Informed Consent is Conditional

Almost all interviewees emphasized that different situations require different types of informed consent. This is the case for emergency versus routine medicine, inpatient versus outpatient care, acute versus chronic conditions, and so on. Informed
consent also differs depending on the type of patient, the type of family, and the culture of the hospital or general region. For example, informed consent in kansai (West Japan) has a different style from informed consent in kantō (East Japan). Likewise, informed consent is conducted differently at university hospitals as compared with local hospitals.

Most interviewees also emphasized the unique history of cancer diagnosis disclosures in Japanese medicine and suggested that these diagnoses were withheld from patients due to particular concerns with cancer. It was also clear that while cancer diagnoses are now usually disclosed, disclosure of a number of other diagnoses, including ALS and dementia, present new challenges and concerns. To add nuance to our understanding of informed consent practices, it will be helpful to examine ALS and dementia in some detail, as they pose the largest obstacles to the practice today. By studying informed consent in these settings, we will become better equipped to address informed consent more generally and with regard to less difficult situations.

ALS requires a mechanical ventilator to sustain the patient past a certain point, and Japan prohibits disconnecting a ventilator once it is connected (disconnection is legal in the U.S. and the Netherlands). Also, a ventilator burdens family caregivers considerably, and unless the patient lives alone, home care support is not available through the Japanese government. This renders the informed consent process for ALS critical for the next 20-30 years of patients and families’ lives.

One nurse described her least successful informed consent as one in which an ALS patient needed to decide whether or not to have a ventilator. The patient had few relatives, so her only option was to live with an older sister who had dementia. The patient did not think the sister would be able to reconnect the ventilator should it become...
disconnected or unplugged, but the physician insisted on discharging her. To help her make a decision about the ventilator, the nurse showed her a ventilator and described how it worked, but the patient still vacillated. The nurse said she could not remember what the patient decided, only that it was an incredibly difficult case because the patient could not decide. In such cases, circumstances may dictate the overall success of the informed consent process more than any one decision by the physician or the patient.

Nevertheless, in many ALS cases the manner of explanation significantly affects patient and family outcomes. According to one physician, most patients nationwide (70%) do not choose ventilators, although this number is reversed in university hospitals (80% do choose), in part due to differences in informed consent practices and how the choice of a ventilator is explained.

In addition to ALS, dementia is also a special case. The family needs to make plans, and disclosure is difficult if the patient is already symptomatic. Informed consent can be even more complex if the patient is not symptomatic. Biomarker tests for dementia are inconclusive; in some cases, informing a patient that a test has come back positive may be unnecessarily alarming. Many interviewees noted that dementia will become increasingly significant for Japanese society as the average age of the population increases. Given the difficulty of decision-making in cases of dementia, family members and support staff play crucial roles. I now turn to these secondary roles in the context of general informed consent practices.
3.3.1.2 Japanese Informed Consent is Cooperative

3.3.1.2.1 Families

Families play a significant role in Japanese patients’ decision-making. Emotional support from the family is particularly important during informed consent and throughout subsequent medical decision-making. Many interviewees said that patients rarely make treatment decisions on their own and almost always involve their families. Others noted that if patients feel emotionally secure and supported by their families, they are less likely to become anxious or angry and are more able to make decisions smoothly. Family support for patients is also social and economic; families are patients’ conduits to friends and social events, and they often take on much of the economic burden of treatment.

However, decreasing numbers of patients have family who live nearby and who can shoulder the emotional, social, and economic burden of medical care and medical decision-making. Many young people in Japan have left their hometowns for cities, so elderly grandparents are often separated from their children. If families are not available, nurses and other secondary professionals can provide substitute support, but almost all interviewees emphasized the insufficiency of support staff in Japan. A number of interviewees also disparaged inadequate insurance coverage for nursing and other home care in Japan, as this leaves few options available for patients with limited resources.

Families also need support. One nurse relayed the story of a woman diagnosed with malignant stomach cancer and informed of the merits and demerits of each treatment option. She was then asked to make a choice, which was incredibly difficult. She felt that if she later experienced one of the demerits of her chosen option, then it would be her fault – she was hesitant about taking on the responsibility of the decision. However, the
family was not confident in their roles as supporters. They felt very confused and
distraught and had trouble helping the patient make a decision. The nurse suggested that
there should be more support from the medical team in making these decisions. Another
nurse noted that even when a decision is made, families might regret their decision if the
patient worsens quickly. In such cases, families need support as much as patients, and
even shared responsibility between patients and families may be ineffective. As we will
see below, this makes support staff essential participants in the informed consent process.

3.3.1.2.2 Nurses

Many of my interviews focused on the changing role of nurses. Nurses fulfill
many roles on the hospital floor, from physician assistant to patient confidant to family
counselor. One nurse described her role as a conversation facilitator who considers how
the physician’s diagnosis and proposed treatment options, the family’s desires, and the
patient’s situation affect medical decision-making. Social workers also perform this role,
but more nurses are better integrated into the Japanese medical system, so they are often
responsible for these tasks.

The idea that nurses bring people together was a common thread in my
interviews. In the words of one nurse, nurses “conduct traffic control” (kōtsū seiri) by
connecting all the different scattered roles that go into patient treatment. Many
interviewees said that the nurse makes informed consent possible by preparing a time and
place for the parties involved (bamen settei), following up by answering the patient’s and
family’s questions, and occasionally serving as an intermediary or proxy (chūkai or
(daiben) when the family or patient does not want to ask questions or admit that they do not completely understand.

One nurse described a successful case in which the patient and the family wanted to know everything about the patient’s condition, but in deference to their physician, they did not ask any questions. The patient had end-stage cancer for which no treatment was available. To camouflage this, the physician’s explanation was incomprehensibly complex. This nurse explained the situation in simpler terms to the patient and family, and through conversation was able to determine that the patient preferred to die at home in the bath, rather than in a hospital. In her view, since the patient was allowed to return home and pass away as he desired, this case ended very well. She described her role in this case as providing follow-up or support for self-determination. Nurses seem to play this role often in Japan.

Yet the ease of this nurse-facilitated informed consent process is an ideal, and many nurses and physicians expressed a desire for better team decision-making so that responsibility and status would be more equally shared among medical professionals. Despite this lack of consistent integration, nurses seem to play a crucial, albeit under-recognized, role in informed consent by facilitating the decision-making process, supplementing physicians’ poor communication, and remedying patients’ failure to speak up when they do not understand.

Many interviewees distinguished between physicians’ and nurses’ roles in informed consent. One nurse said that “physicians are most concerned with organs, with blood flow, and with treatment options. Their consciousness is that if they conveyed the
truth, they’re done, informed consent is over. But care is about whether or not patients are getting better, whether or not they continue their lifestyle.”

Another nurse described the difference between physicians’ and nurses’ approaches to informed consent as the difference between a point and a line: for physicians, informed consent is a one-time event, while for nurses, it is a process that continues both before and after the official informed consent meeting. Almost all nurses saw their role as more focused on patients’ lifestyles than on clinical prognoses. While physicians may be more concerned with treating medical problems, nurses are more aware of how treatment will affect patients’ lifestyles. Both professionals play important but disparate roles in informed consent. I turn to physicians’ roles now.

3.3.1.2.3 Physicians

Physicians are generally seen as skilled medical technicians, but not necessarily good communicators. Nurses and other medical professionals emphasized that the physicians’ goal is to heal the patient, so they tend to focus on the medical problem to the exclusion of other considerations. One interviewee said that physicians’ fundamental ability to notice patients’ and families’ emotions is outweighed by their orientation to medical treatment and surgery, rather than to interpersonal relationships. Without training in communication or patient support, and with little time per patient, physicians are often unaware of the psychosocial problems encountered by patients unless these problems are starkly obvious, as in the case of severe depression.

Another issue is that doctors are busy, so they have to weigh giving patients sufficient information with time management. In informed consent, physicians’ priority is
explaining medical issues and possible treatments, and nurses and other support staff must provide necessary interpretation and follow-up. All of my interviewees, including physicians and non-nursing medical professionals, supported this description.

With limited hospital resources to deal with psychosocial issues, physicians also worry about how patients will react to bad news. So physicians need support too; bad news is also difficult for physicians. Previous studies have noted that “the experience of emotional distress after telling the truth to cancer patients is a critical problem.”\textsuperscript{236} In such cases, additional psychosocial support may help physicians as well as patients. This means that secondary support staff will also play an important role in informed consent.

3.3.1.2.4 Other Professionals: Clinical Psychologists and Medical Social Workers

Given a shortage of physicians and nurses’ busy days, other medical professionals such as psychologists and social workers often fill nurses’ roles. However, this depends on the location and the hospital; Japan has a low number of clinical psychologists and social workers overall (as will be noted in chapter 4). According to one of my interviewees, a hospital in Osaka has 6-7 social workers for over 600 patients. At Kyoto University Hospital, in contrast, there are only 1-2 social workers limited to discharge planning for 1,000 patients. In general, these secondary roles are not clearly distinguished from nurses’, and this can cause confusion about who is responsible for which aspect of patient care. As these professions grow in Japan, it will become increasingly necessary to demarcate different roles in informed consent.

\textsuperscript{236} Seo et. al., “Telling the diagnosis to cancer patients in Japan,” 109.
3.3.1.3 Informed Consent Has Three Stages

As suggested by nurses and other support staff, it is important to “set the stage” for informed consent by coordinating between various parties and aligning attitudes among the medical staff. Better set-up leads to fewer problems in the subsequent disclosure and decision-making process. Support staff are also responsible for following up on informed consent, which often entails confirming patients’ understanding while also paying attention to their psychosocial reactions. Informed consent thus has three stages: set-up, confirmation, and follow-up.

Many interviewees were concerned about limits to patients’ understanding within physicians’ diagnosis disclosures and presentations of treatment options. While diagnoses are no longer generally withheld, many patients do not understand the content of their disclosures. This is not always due to cognitive impairments, but may result from patients’ mental pain and distress, which can impair their ability to process new information.

Moreover, many informants suggested that patients become anxious or angry, not about their diseases or proposed treatments, but when they do not understand what their doctor said. Conversations about cancer or dementia are difficult, so it is understandable that some physicians and patients might want to hasten this conversation. Yet both physicians and patients must work to prevent misunderstanding and misinformation for informed consent to go well.

One clear source of patient misunderstanding is physicians’ explanations. There is a gap between physicians’ medical techniques or skills and what they transmit to patients. Several nurses noted that, because physicians assiduously develop their medical abilities,
they may not realize that their words and descriptions are inaccessible to the general public. For example, one nurse said that many patients will not understand a word like “malignant tumor” (akusei shuyō 悪性腫瘍), so it is very important to use the word “cancer” (gan 癌) specifically. Physicians’ medical terminology contributes to patient misunderstandings, exacerbating the uneven balance of power between physician and patient.

Patient misunderstanding also occurs when physicians camouflage futile treatment. One nurse described a case in which a terminal patient was hospitalized in order to receive what the physician referred to as “treatment.” The patient and the family were eager to find something that would heal the patient, so the physician, despite knowing that treatment was futile, proposed that the patient be given antibiotics and nutrition in order to improve the patient’s performance status and implied that this would make treatment possible. It was clear to the nurse that the patient’s situation was not improving, but the family and patient held on to the hope of treatment. Eventually a feeding tube had to be connected to supply nutrients to the patient; the family interpreted this as a step that would make treatment possible. However, the patient continued to decline, and it was not until after the patient’s consciousness was impaired that the physician finally admitted to the family that treatment was no longer possible. The nurse who described this case said that physicians should be more careful about how patients and families interpret the words they use.

Misunderstanding and misinformation cannot always be attributed to physicians’ explanations. Several interviewees said that the main impediment to a smooth informed consent practice in Japan is patients’ health literacy. They described Japanese patients as
knowing less about medicine, less about their own bodies, and less about how to maintain health than Americans. One physician suggested that the ideal practice of informed consent depends on proactive and independent patients but that the situation in Japan is unfortunately not ideal. Patients are neither well informed nor prepared to make decisions on their own. This is not just due to lack of patient initiative. One nurse was impressed by many places in the U.S. with pamphlets about medical care and people available for health consultations. She said that while Japan realizes the importance of making medical information available for the general public, nascent programs to support health literacy lack needed manpower.

It is also often difficult for patients and families to admit that they did not understand. One interviewee said that Japanese patients offer agreement without fully comprehending the proposed test or treatment (perhaps to please the physician), so it is important to confirm that patients really understand their situation and are doing what they want to do – that patients have given a sincere response. Many nurses and other medical professionals suggested that this is part of their job: to follow up and determine what the patient and the family members did not understand.

3.4 Current Challenges

This analysis indicates that Japanese medical professionals currently face a number of challenges in their informed consent practices. These include the need for 1) communication education for physicians, 2) coordination of different professional roles and improved teamwork, 3) increased psychosocial support staff for physicians, patients, and families, 4) recognition of the complex role of nurses, 5) health literacy education for
patients and families, and 6) study and research of the unique features of informed consent for different diagnoses, including cancer, ALS, and dementia.

While a limit to the present analysis is its restriction to Japanese medical professionals, there are strong indications that these challenges are not unique to Japan and are in fact shared by the United States. For example, it has been suggested that American physicians need improved communication and informed consent education, have problems with use of technical terminology, and may focus on technical skill at the expense of making a human connection with their patients. There is also evidence that American patients have difficulty questioning physicians’ expert judgments and struggle with managing the vast amount of medical information available to them. In addition, a number of authors have identified the need for teamwork and increased attention to psychosocial skills among medical professionals, the importance of families in the medical setting, the significance of support in decision-making, and the role that emotion plays in informed consent.

Such reports indicate that Japanese and American physicians and patients grapple with similar problems in their informed consent practices, despite significant differences

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239 Doukas and Doukas, “Case Study,” Branch, “The Ethics of an Ordinary Doctor,” Lerner, “When the Doctor Knows Best,” and Schiff, “Crossing Boundaries: Violation or Obligation?”
240 Hertz, “Why We Make Bad Decisions.”
241 Hoffman, “Awash in Information, Patients Face a Lonely, Uncertain Road.”
242 Shakespeare, “A Point of View: How Important is Compassion in Healthcare?”
244 Torke et al., “A Conceptual Model.”
245 Supady et al., How is Informed Consent Related to Emotions and Empathy?”
in their institutional standards. This suggests that there is substantial ground for cross-cultural dialogue about shared concerns, especially those highlighted above.

Finally, while this study has indicated a number of significant features of contemporary informed consent practices in Japan, it has not identified a reason for allowing nondisclosures of cancer for such a long period of time. While all medical professionals reported that such diagnoses are no longer withheld, they also suggested that there may be difficulties with disclosing other diagnoses such as dementia directly to patients. Concerns about dementia are also not unique to Japan: a 2013 article in the *New York Times* on early diagnoses of dementia discussed how such diagnoses “may cause stress, anxiety, depression and even suicide in patients, and can have implications for…one’s overall quality of life, sense of autonomy and self-image.” Furthermore, a 2013 review found that even though the majority of physicians in the U.S. and abroad support disclosures of dementia diagnoses in theory, they “do not implement it in their practices.” In response, there have been calls for increased attention and sensitivity from clinicians, but as highlighted by the current challenges in informed consent practices described above, clinicians may neither know what they should be paying attention to nor which dimensions of the situation require sensitivity. Indeed, some scholars have suggested that the current bioethical discourse in the U.S. may overlook the realities faced by patients diagnosed with dementia. Within Japan, a recent special broadcast on the Japanese national news network NHK highlighted patients’ feelings of

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246 Rabin, “Concerns about Dementia Screening,” 1.
247 Werner et al., “Current Knowledge and Future Directions about the Disclosure of Dementia,” e81.
248 Ibid., e82.
249 Berlinger, “Alzheimer’s, Biomarkers, and Suicide.”
uncertainty and hopelessness following diagnoses of dementia and the lack of support services for patients with these diagnoses, as well as the current inadequacy of physicians’ ability to convey diagnoses and prognoses well.  

While a diagnosis of dementia certainly brings with it distinct concerns about how to navigate present and future decision-making (not to mention the fact that many forms of dementia are not treatable), disclosure of this diagnosis has a number of features in common with disclosure of terminal cancer. As in the case of cancer, receiving a diagnosis of dementia is personally significant and potentially harmful; conveying this diagnosis is not easy. Yet the practical necessity of disclosure is even stronger with dementia, where early decision-making is one of the only ways to ensure that patients’ wishes are, as much as possible, respected. To better understand the issues involved in decisions not to disclose diagnoses, we need to inquire more deeply into cancer, which has historically been the paradigmatic case of diagnosis nondisclosure in both the U.S. and Japan.

3.5 Conclusion

This chapter has identified three features of informed consent practices in contemporary Japan beyond those of the institutional standards, as well as five challenges faced by these current practices. These features develop the picture of informed consent in Japan established in chapter 2 and underscore similarities and differences between Japanese and American practices. In addition, this chapter suggests that while cancer diagnoses are no longer withheld from patients in Japan, other diagnoses such as

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250 NHK (June 9th, 2014).
dementia might be. In order to better understand why clinicians in the U.S. or Japan might choose to withhold such diagnoses from patients, chapter 4 will consider cancer disclosure policy changes in the U.S. and Japan.
Chapter 4: Cancer Diagnosis Disclosures in the United States and Japan

“Cancer is the representative fatal illness in Japan. It’s a really big thing in Japan. Other diseases, for example, like diabetes or viral infections of the liver, diseases like these are really common among Japanese, so this informed consent is not difficult. Patients know what they’re diagnosed with, and these diagnoses aren’t seen as a big deal, unlike a fatal illness. They know it’s because they drank a lot of beer or something. So they won’t be shocked, they don’t take it seriously. But cancer, I suppose cancer really is special/unique (特殊 tokushu).”

--Interview with a Clinical Psychologist in Japan, 2014

“One patient, her and her husband from Japan, been here for 10-15 years, children were born here. They’re very acclimated, but when she was initially diagnosed, her husband had a real hard time. He would come and be here for chemo for a moment and wouldn’t stay with her. And that's because he couldn’t cope with it. And then, she’s kind of having to cope with it, because we just slapped her in the face, right, ‘cancer,’ so she can’t escape it either, so she is here, and because of some issues I got called in...And so you know we connected, and I would take care of her, and the husband took off, so here she is alone, so we had some conversations, and we would talk and after the treatment she came back and thanked me for my support... I still remember her saying, ‘I couldn’t believe when you said that you can make cancer into something positive.’”

-- Interview with a Medical Social Worker in Hawaii, 2013

Introduction

Disclosing a diagnosis to a patient is not easy, especially when the diagnosis alters the patient’s life as profoundly as with terminal cancer or dementia. In the early twentieth century, few patients were informed of these diagnoses; now almost all patients in the U.S. are told when they have cancer. However, dementia diagnoses are not disclosed as consistently, with recent studies indicating that physicians in the U.S. and Japan are hesitant to disclose these diagnoses to their patients. While there are certainly important differences between the two diagnoses, a reexamination of how cancer disclosure policies changed from non-disclosure to full disclosure can reveal new dimensions of physicians’ decisions not to disclose diagnoses.
This chapter reconsiders the debate over cancer diagnosis disclosure through a comparison of American and Japanese practices. By analyzing how professionals and the public in each country have tackled the common problem of cancer disclosure, this comparative analysis provides a more comprehensive picture of the ethical considerations in diagnosis disclosure generally. The result shows that the ethical discourses in both the U.S. and Japan have omitted patient support from the discussion of diagnosis disclosure. I conclude that in order to meet the needs of patients diagnosed with diseases like cancer and dementia, and to ensure that the decision-making process goes well, the availability of patient support must be included as an essential element in the ethics of informed consent. This conclusion will be used in chapter 6 to conduct a more complete and effective assessment of the ethical justification of Japanese informed consent practices.

4.1 The Case of Cancer Disclosure

Regardless of national boundaries, cancer has been described as “the defining plague of our generation."\(^{251}\) It is not surprising, then, that how, when, where, and to whom a physician discloses a diagnosis of cancer pose difficult issues. According to Donald Oken, “no problem is more vexing than the decision about what to tell the cancer patient.”\(^{252}\) This is reflected in the Japanese attitude towards cancer disclosure. As noted in chapter 2, disclosure of cancer (and other terminal illnesses) is the only area where the JMA specifically allows for exceptions in the practice of informed consent, and court cases relating to cancer diagnosis disclosure are among the most frequently cited precedents for informed consent in Japan. In the U.S., by contrast, cancer has not been

\(^{251}\) Mukherjee, *The Emperor of All Maladies*, xiv.

\(^{252}\) Oken, “What to Tell Cancer Patients,” 1120.
granted such “exceptional” status since 1979, when 98% of physicians generally informed cancer patients of their diagnoses. While the percentage of Japanese physicians who disclose cancer diagnoses has increased, the practice is not universal. Accordingly, cancer disclosure is a critical case for investigating Japanese exceptions to informed consent. This chapter will investigate the background of cancer disclosure in the U.S. and Japan, beginning with a survey of physician disclosure rates and attitudes, then turning to the social phenomena that influence disclosure, such as epidemiology, public perceptions, social attitudes, diagnosis disclosure preferences, and social support available to cancer patients. I summarize the overall picture of cancer disclosure in each country before comparing and analyzing these practical, social considerations. This analysis uncovers the factors facilitating disclosure decisions in the U.S. and frustrating disclosures in Japan.

4.2 Cancer Disclosure in the U.S.

4.2.1 Physician Attitudes and Policies

![American Physicians' Cancer Diagnosis Disclosure Rates (%)](image)

*Figure 7. American Physicians’ Cancer Diagnosis Disclosure Rates*
Prior to the 1960s, few studies were conducted on physicians’ policies for cancer disclosure. A 1953 study of 442 Philadelphia physicians found that 3% always told patients of cancer diagnoses, 28% usually told, 57% usually did not tell, and 12% never told. Reasons for doctors’ telling were patients’ refusals of necessary treatment and their need to make plans, while reasons not to tell were requests by families or expectations of poor reactions.253 A similar nationwide survey of 5,000 physicians in 1960 found that 22% never told and 16% always did, with the remainder occupying a gray area of sometimes telling. Factors affecting telling included patient stability, family or patient insistence on knowing, the need to make plans, and having no one else to tell (i.e., no available family member or caregiver).254

Following these studies, Donald Oken’s 1961 article, “What to Tell Cancer Patients: A Study of Medical Attitudes,” published in the *Journal of the American Medical Association (JAMA)*, ignited the discussion on cancer disclosure in the U.S. Oken realized that the manner of disclosure may affect patients’ emotional status and capacity for everyday function following disclosure, but also recognized that the issues involved in cancer disclosure are “complex factors which are difficult to assess, weigh, and place in proper perspective,” so that “in his attempt to work out some solution, the doctor needs all the help he can get.”255

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Oken set out to study the “underlying determinants of these [the physicians’] strategies” to better assess them.\(^{256}\) His survey of 219 staff members at a private non-profit teaching hospital in Chicago found that 90% were inclined to withhold cancer diagnoses. The most important factor in determining their approach was clinical experience, with hospital training and personal experience as distant seconds. Young doctors were just as likely as older doctors to list experience as a factor. Physicians who told some patients and not others tended to use rules of thumb to guide decisions, but these were not consistent. More physicians (72 of 122) wanted to be told than tended to tell their patients. This is not to say that the group was homogeneous; some physicians had unique techniques for disclosure.

Commonalities were the use of euphemisms and the convergence on a single goal: maintenance of hope. Differences were found in how physicians thought hope was best maintained. Many thought cancer connotes certain death and that expectation of death deprived the patient of hope, while others felt a realistic hope was best. Regardless, the main reason not to tell was the anticipation of “profoundly disturbing psychological effects.”\(^{257}\)

Oken suggests that these effects may be projected fears and that “experience” may really indicate personal conviction: “Instead of logic and rational decision based on clinical observation, what is found is opinion, belief, and conviction, heavily weighted with emotional justification.”\(^{258}\) He suggests that:

\(^{256}\) Oken, “What to Tell,” 1121.  
\(^{257}\) Ibid., 1122-24  
\(^{258}\) Ibid., 1125
Intuitive understanding of what the patient experiences is a time proven and essential guide for the physician. Our own dread and concern mirrors what patients feel….To ignore wisdom based on insight into ourselves and to go around blithely telling patients they have cancer, obviously would be senseless. Intuitively derived insights are important and legitimate scientific data about psychological processes. Instinctive judgments, however, can be terribly misleading. In matters of life and death, personal intuition is far too likely to be subject to personal unconscious distortions and thus prove a false guide which clouds experience and hides truth.259

Oken argues against relying solely on intuition to make decisions about what to tell patients and identifies the need for better scientific data about the sources and effects of physicians’ informal policies. However, recognizing the emotional nature of cancer diagnoses, he concludes that while the American Cancer Society works to educate the public about the danger signs of cancer, education “utilizing only a rational appeal is insufficient. New techniques must be developed which will modify emotional attitudes…” Perhaps the doctor, more than the patient, should be a target for emotional reeducation.”260 Finally, he writes,

We block our own efforts. Awareness of these attitudes is the first step. Knowing of our deep pessimism about cancer and of our avoidance of research and teaching regarding communications with the cancer patient, we can advance to

259 Oken, “What to Tell,” 1127
260 Ibid., 1128
develop new knowledge of more sensitive and skilled approaches. We will then know how to be truly kind to our patients.\textsuperscript{261}

Sixteen years later, Oken’s study was mirrored by a 1977 study (published in 1979) by Dennis Novack et al., also published in \textit{JAMA}. Novack’s reason for revisiting Oken’s study was a 1970 report showing that of 178 physicians surveyed, 66\% sometimes “inform,” 25\% always “tell,” and 9\% never tell.\textsuperscript{262} In order to assess whether the increased tendency to tell was a general trend, Novack surveyed 699 physicians, receiving 278 responses.\textsuperscript{263} Respondents had a slightly younger mean age than those surveyed by Oken (37 years for Novack versus 50 for Oken), and more women were included (9\% in Novack’s study versus 3\% for Oken). 98\% reported that their general policy was to tell the patient. Two thirds of this 98\% said they never or very rarely make exceptions to this rule.

Factors influencing physicians’ disclosures included the patient’s age, intelligence, emotional stability, and relatives’ wishes.\textsuperscript{264} Clinical experience was a major source of this policy for 70\% of physicians, as it had been for Oken, although more physicians than in the Oken study mentioned medical school teaching or personal experience as sources of their policies. For oncologists, personal factors were less important, suggesting “that they believed that there was some objective policy to be followed that was independent of personal considerations.”\textsuperscript{265} 100\% of all respondents wanted to be told, and 100\% thought the patient has the right to know.

\textsuperscript{261} Oken, “What to Tell,” 1128
\textsuperscript{262} Friedman, “Physician Management of Dying Patients: An Exploration” (1970).
\textsuperscript{263} A response rate that may lead one to question the reliability of the study.
\textsuperscript{264} Novack, “Changes in Physicians Attitudes,” 898.
\textsuperscript{265} Ibid., 898.
According to Novack, sources of this change in attitudes may include 1) improvement in therapy for many forms of cancer, such that a diagnosis of cancer is no longer a death sentence, 2) an increase in public awareness of cancer (due to the media and the American Cancer Society) and of issues of death and dying, 3) a need for patients to know, due to clinical research protocols, and 4) social changes, such as consumerism, patient’s rights, and public scrutiny of the medical profession. Novack concludes,

One hundred percent of respondents stated that patients have a right to know. Yet in asserting this in a blanket manner, are physicians sometimes abdicating a responsibility to make subtle judgments in individual cases? … the current policy of telling the patient is accompanied by increased sensitivity to patients’ emotional needs….Yet how rational is the process of deciding what to tell the patient with cancer? Even though the policies have reversed, many physicians are still basing their communication with cancer patients on emotion-laden personal convictions. They are relying on honesty, sensitivity, and patients’ rights rather than focusing on the following relevant scientific psychological question: Does telling the diagnosis of cancer help or harm (which) patients and how? Only further systematic research can answer these questions.\textsuperscript{266}

Novack suggests that assessments of patient compliance with treatment, quality of physician communication, ratings of adjustment to illness, and psychological tests focusing on depression and anxiety may be helpful.\textsuperscript{267}

Oken’s and Novack’s studies of physicians’ attitudes towards disclosure found them to be determined mainly by sensitivity and concern for their patients. Both

\textsuperscript{266} Novack, “Changes in Physicians Attitudes,”900.
\textsuperscript{267} Ibid., 900.
researchers approve of this sensitivity, but they advocate for a more scientific understanding of how the manner and meaning of disclosure affect patients, recognizing that not all patients respond to disclosure in the same way. Oken and Novack both want to preserve physicians’ “responsibility to make subtle judgments in individual cases,” but argue that more information is needed to understand this responsibility. Novack in particular wonders, “Do patients also have a right not to know? Is it possible to determine who should be told what, when, and how? What are the criteria by which we judge if telling is right?”

Many of Novack’s questions were answered in ensuing years by philosophers, judges, lawyers, and medical professionals; their conclusions can be readily seen in the institutional frameworks examined in the previous chapter, and their arguments will be examined in more detail in chapters 5 and 6. We also now know more about the psychosocial effects of receiving a cancer diagnosis, thanks to the growth of psycho-oncological research in the U.S. However, the relative certainty with which cancer diagnoses are now disclosed to patients in the U.S. does not necessarily mean that Oken’s and Novack’s concerns about making subtle judgments in individual cases have completely disappeared. Recent studies have begun to revive these concerns. While most justifications for diagnosis disclosure rely on the patient’s right to autonomy, scholars note that focusing exclusively on autonomy may obscure other issues, such as patient welfare and socialization.

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268 Novack, “Changes in Physicians Attitudes,” 900
In addition, even when physicians justify their decisions using the principle of respect for autonomy, as many as 50% do not comply with patient wishes. A 1991 Rhode Island study found that the primary justification used by the majority of physicians surveyed (256; 187 men and 69 women) was “the patient’s wishes about life-and-death issues should usually be complied with” (in response to a set of 5 scenarios). As many as 50% of the surveyed physicians used this justification (in the case of withholding intubation) even when they did not comply with patients’ wishes. The authors conclude that “physicians demonstrated an attachment to the principle of autonomy but an aversion to specific actions that may derive from this principle, and they were not fully able to acknowledge that the conflict exists.” Importantly, when physicians did not comply with patients’ wishes, they were more likely to cite their idea of the ethical role of the physician as a factor. These studies revive Oken’s and Novack’s concerns about how physicians make complicated ethical decisions and how best to support this decision-making.

These concerns will be dealt with in more detail in chapters 5 and 6. The crucial point to take away for now is this: between 1961 and 1979 physicians in the U.S. reversed their policy on cancer disclosure from one of non-disclosure to almost universal disclosure. The next section will examine the epidemiology, public perception, social attitudes, and support networks that serve as the background to physicians’ disclosures of cancer diagnoses. This will highlight the social factors influencing American physicians’ decisions to disclose cancer diagnoses to their patients between 1961 and 1977 and their development thereafter.

270 Fried et al., *Limits of Patient Autonomy*, 725.
271 Ibid., 726.
4.2.2 Epidemiology and Public Perception

Cancer has been the second most common cause of death in the U.S. (after heart disease) since 1926, causing one in four deaths, with a survival rate (as of 2003-2009) of 68%, up from 49% in 1975-1977.\textsuperscript{272} The three cancer types with the highest incident rates in the U.S. are (in order from highest incidence to lowest) breast cancer, prostate cancer, and lung cancer.\textsuperscript{273}

According to a 2013 study of public perception of cancer in six countries, the U.S. had an average satisfaction rate with progress against cancer in the past 20 years (44%) and an average public perception that the number of people dying each year of cancer has increased (37%).\textsuperscript{274} Demonstrating some measure of optimism, the U.S. had the second lowest rate of thinking that cancer always leads to death (21%), and the highest public perception that the life expectancy for someone diagnosed with cancer has increased (67%). Treatment decisions are often personal: 83% of respondents in the U.S. thought that patients and their families should make decisions as to treatment, while 32% thought physicians should (where multiple answers were allowed). Faith in particular treatments is somewhat low. 43% of respondents in the U.S. were only “somewhat confident” that they would receive the best possible treatment. Americans expressed the highest rates of dissatisfaction with financial information following a cancer diagnosis, whereas dissatisfaction with information on other expectations (emotional, personal) was low. Specifically, 67% of patients and 61% of caregivers thought that information on finances

\textsuperscript{272} Mukherjee, The Emperor of All Maladies, 87; American Cancer Society, Cancer Facts and Figures (2014).
\textsuperscript{273} U.S. National Cancer Institute, “Common Cancer Types.”
\textsuperscript{274} The U.S., Japan, the U.K., France, Germany, and Italy. GfK Roper Public Affairs and Corporate Communications and GfK Healthcare (2013).
was “not enough.” By comparison, the U.S. had the highest rate of patient satisfaction with support groups or counseling for the patient (only 25% thought it was “not enough”), although caregiver satisfaction was somewhat lower (37% thought that support for the patient was “not enough,” while 46% thought that support for the caregiver was “not enough”). This study reveals American perceptions of cancer treatment options; how do Americans prefer to make decisions about these options? The next section will answer this question by analyzing American attitudes and preferences towards cancer diagnosis disclosure.

4.2.3 Social Attitudes and Preferences

Figure 8. American Preferences for Cancer Diagnosis Disclosure

Studies of American preferences even before Oken’s 1961 study reveal a favorable attitude towards cancer diagnosis disclosure. A 1950 study found that 89 out

275 Oken cites concerns about public and physician questionnaires in which publicly stated attitudes may be purely “academic” and patients who have already been told they have cancer “cannot permit doubts about the wisdom of the policy of those whom they
of 100 cancer patients surveyed wanted to know their diagnoses, while 82 out of 100 regular clinic patients would want to know if they had cancer.\textsuperscript{276} In 1956, a similar study found that 48 of 54 regular patients wanted to know their diagnosis, while 39 of 48 patients had been told their diagnosis and 9 denied that they were sick.\textsuperscript{277} A larger study, conducted in 1957, found that of 560 cancer patients and their families, 87% thought a diagnosis should be disclosed to the patient. In addition, attitudes towards information provision were favorable.\textsuperscript{278}

In 1979, a study of 256 outpatients at a Pennsylvania hospital found that 60.5% “absolutely had to have” cancer diagnosis disclosure, while 37.1% responded that they “would like to have this information.”\textsuperscript{279} Smaller numbers preferred to know the details of their prognosis (57.4% “had to have” information on the specific effects of treatment, and 51.2% “had to have” information on gradual progress of the disease), but in all cases except information on treatment failure, more than 90% of patients wanted information. Younger patients were more likely to desire all possible information, and the amount of information desired correlated with hopefulness. The authors suggest that this correlation may be because people who are optimistic desire more information, rather than provision of information driving their hopefulness. They did not discuss the significance of patient need to trust so desperately” (Oken, “What to Tell,” 1121). The studies here survey both patients with cancer and without; the former may not escape Oken’s concerns, but I believe the latter do.

\textsuperscript{276} Kelly and Friesen, “Do Cancer Patients Want to be Told?” (1950); Oken, “What to Tell,” 1120.
\textsuperscript{277} Branch, “Psychiatric Aspects of Malignant Disease” (1956); Oken, “What to Tell,” 1120.
\textsuperscript{278} Samp and Curreri, “Questionnaire Survey on Public Cancer Education” (1957); Oken, “What to Tell,” 1120.
\textsuperscript{279} Cassileth, “Information and Participation Preferences,” 834.
age.\footnote{Cassileth, “Information and Participation Preferences,” 835.} After 1979, studies shifted their focus from desirability of disclosure to manner of disclosure.

In 1989, an observational study of 439 cancer patients and oncologists in New York showed an increase in the amount of information desired. 92% of patients wanted all information, good or bad, while 69% of patients wanted to participate in decisions.\footnote{Blanchard, “Information and Decision-Making Preferences,” 1141.} For those that preferred to leave the decision to the physician, the physician was more likely to discuss the family’s role in the patient’s care.\footnote{Ibid., 1142.}

Overall, preferences for disclosure seem to be met. A 1999 study of 16 head and neck cancer patients in Pennsylvania who received their diagnoses at the clinic found that more than 80% were satisfied with several dimensions of the disclosure. In addition, American patients prefer privacy when hearing bad news: 81% wanted to be alone when receiving their diagnosis, and only 64% mentioned having discussions with their family following diagnosis.\footnote{Kim, “Breaking the Bad News,” 1066-1067.}

American patients also seem to highly value physicians’ technical abilities. In 2001, a survey of 351 cancer patients in Texas found that the most important aspect of bad news delivery was the physician’s technical knowledge about the patient’s cancer. “Supportive aspects of the communication” (providing comfort, informing family members, offering hope) were rated as important or very important, but less so than the informational aspects.\footnote{Parker, “Breaking Bad News,” 2051-2052.}

\begin{thebibliography}{9}
\bibitem{Cassileth} Cassileth, “Information and Participation Preferences,” 835.
\bibitem{Blanchard} Blanchard, “Information and Decision-Making Preferences,” 1141.
\bibitem{Ibid} Ibid., 1142.
\bibitem{Kim} Kim, “Breaking the Bad News,” 1066-1067.
\bibitem{Parker} Parker, “Breaking Bad News,” 2051-2052.
\end{thebibliography}
These studies indicate preferences for receiving correct medical and technical information and being told in person, in a medical setting, with less emphasis on support and family participation. This does not necessarily mean that social support was not present, but that physicians were not considered to be the primary means of support. As shown in the following section, the U.S. does have a substantial network of support beyond physicians. This will be the last element in this review of cancer diagnosis disclosures in the U.S.

4.2.4 Other Players and Social Support

The primary support network for patients in the U.S. is through medical social workers. Ida Canon began the medical social work movement in the U.S. at the turn of the 20th century. Cannon defined a social worker as one who “sees the patient not as an isolated, unfortunate person occupying a hospital bed, but as a member belonging to a family or community group that is altered because of his ill health.”285 Between 1905 and 1915, more than 100 hospitals began to hire social workers, with the country’s leading and earliest hospitals, including Memorial Sloan-Kettering, Massachusetts General and Johns Hopkins, establishing social service departments. In the 1940s, having social work services on staff became important for a hospital’s accreditation, and in 1942, Memorial Sloan-Kettering established a professionally trained Social Work Department. The 1950s witnessed the first studies of patients’ psychosocial reactions to cancer at Memorial Sloan-Kettering and Massachusetts General.

In the 1950s and 60s, the primary means of patient support were patient-formed self-help groups, as well as a program begun in the 1950s by the American Cancer Society for postoperative mastectomy patients. However, cancer was not yet a “public” issue. In the early 1950s, when one woman tried to advertise a breast cancer support group in the *New York Times*, she was referred to the society editor, who told her that the newspaper could not “publish the word *breast* or the word *cancer* in its pages.”

In the early 1970s, the first hospitals to establish social service departments were designated national cancer centers, which required them to create medical social work departments. Jimmie Holland, recognized as the founder of psycho-oncology, writes that in the 1970s people felt more optimistic about cancer, due in part to cancer survivors speaking about successful outcomes, celebrities disclosing illnesses to the media, and social movements championing human rights. In her words, “cancer came out of the closet, and the door opened for exploration of the psychological dimension of cancer.”

According to Holland, optimism about cancer, increased public knowledge, and advocacy for patient’s rights all made a cancer diagnosis easier to discuss, as did Elizabeth Kubler-Ross’s efforts to break the taboo against talking about death. This affected the cancer disclosure debates in the 1960s and early 1970s, coinciding with increased legal discussion of informed consent (*Canterbury v. Spence* and *Cobbs v. Grant*, which as chapter 2 showed based informed consent requirements on the needs of a “reasonable,

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286 Holland, “History of Psycho-Oncology,” 207.
287 Mukherjee, *Emperor of all Maladies*, 92.
289 Holland, “History of Psycho-Oncology,” 213.
290 Ibid., 212.
prudent patient,” were both decided in 1972) and more attention paid to how informed consent might protect patient autonomy.291

In 1972, training centers were opened to focus on the emotional needs of cancer patients. In 1974, the NCI’s National Cancer Program Plan indicated federal interest in the psychosocial problems of cancer patients and encouraged hospitals to add positions for medical social workers in the fields of pediatric and adult oncology. In 1975, the first national research conference on psycho-oncology took place in San Antonio, Texas, and the National Association of Oncology Social Workers became an organization in 1983.292

As of 2004, there were 460,000 social workers in the US, 63% of them licensed. From 1999-2003, the ratio of active licensed social workers to 100,000 of the population was relatively constant at 162, or one social worker for every 617 people. The majority of active licensed social workers specialize in mental health, health, or child/family welfare.293 Holland writes that psycho-oncology units exist in “virtually all cancer centers and community hospitals” as multidisciplinary groups that offer services to patients and maintain staff awareness of psychosocial issues in patient care.294 However, she notes that psychosocial services must be seamlessly integrated into oncology services to overcome attitudinal barriers against mental health issues.295 Nonetheless, this brief history highlights the broad availability of support services in the U.S. and their early integration into oncology departments.

292 Fobair, “Historical Threads,” 5.
293 Center for Workforce Studies (2006).
295 Ibid., 213.
4.2.5 Summary

The picture that emerges from the above data is that physicians in the U.S. almost universally disclose cancer diagnoses to patients, although prognoses may not be fully or optimally disclosed. In determining whether or not to disclose, physicians’ main concerns have been patients’ well-being and maintenance of their hope, although Oken and Novack, among others, question how well this concern is expressed. Physicians value patient autonomy but may have overriding concerns, such as those relating to their professional role.

Patients in the U.S. expect to receive all information relating to cancer diagnoses and they value technical skill in their physician. They also value hope and optimism, but they do not necessarily think it is the primary role of the physician to provide it, as evidenced by the relatively low valuation they place on this skill in physicians as compared with their technical ability.

Finally, cancer is not the leading cause of death in the U.S., people are not likely to think that cancer necessarily leads to death, and the majority is generally satisfied with the information they receive about their diagnoses, and with the support available to patients and caregivers. The U.S. has an established system of support for cancer patients, including licensed social workers integrated into oncology departments, although attitudinal barriers to psychosocial support remain. The next section considers cancer disclosure in Japan before turning to a comparison of changes in American and Japanese diagnosis disclosure policies.
4.3 Cancer Disclosure in Japan

4.3.1 Disclosure Rates and Physician Attitudes

Reported cancer disclosure rates in Japan have risen since the 1980s at a slower pace than in the U.S. and have never reached the level of a universal policy. According to a 2006 survey of hospitals in Japan, the mean proportion of cancer patients who had been told their diagnosis was 59.3% in hospitals with less than 50 beds and 83.3% in hospitals with over 500 beds.\(^\text{296}\) This indicates not only the lack of a universal policy, but wide variation in physician practices. Indeed, Japanese physicians seem to approach disclosure on a personal and case-by-case basis.

According to a 1982 qualitative study, the circumstances in which physicians would tell the patient they had cancer were limited to cases where surgery was required. Many physicians cited concerns that their patients would be depressed if they were

\(^{296}\) Sato et al., “Telling the diagnosis to cancer patients in Japan,” 2.
told. Even if chemotherapy or radiation was needed post-surgery, patients were often told that the cancer had been removed and that further treatment was for inflammation. Japanese physicians reported feeling that it was their job to support life in terminally ill patients. However, at that time, physicians seem to have been ambivalent about how to fulfill that role. A study conducted between 1986 and 1987 in rural Yamaguchi prefecture on physician-patient decision-making in general found that more than 50% of physicians and medical students surveyed thought that “information for the patient enabling him or her to make an informed decision should always be provided,” but that only about 21% considered the level of explanation to be up to the doctor’s judgment, and a mere 15% thought the doctor should inform the patient of “all aspects of diagnosis and treatment.”

Following this general study, a 1991 study on cancer disclosure in particular found that only 13% of physicians surveyed made “telling” the diagnosis to the patient their usual policy, while 87% reported not telling (with little leeway for exceptions). Some physicians commented that while truth disclosure was desirable, it needed to be practiced with thoughtful consideration; many who reported a policy of non-disclosure also said that they thought truth disclosure would become more common in the future. According to 1994 statistics, surviving family members of cancer patients estimated that 43.8% were not informed but probably knew, while 28.8% were not informed and did not know. A public opinion poll also found that 93.8% of physicians had explained the

diagnosis to the families but only 20% had informed the patients directly,\textsuperscript{300} and a 1997 study had similar results: of 1981 bereaved families of cancer patients, 98.1% reported that the families had been informed, while only 22.5% said that the patients had been informed.\textsuperscript{301} Likewise, 55.5% of 392 physicians from 31 teaching hospitals reported that their policy was never to tell their patients, while 17.5% said they seldom tell, 13.3% said they sometimes tell, 3.5% told approximately half and 10.2% told more than half.\textsuperscript{302} Most physicians (69.7%) reported feeling troubled by patients’ psychiatric issues, but few (35%) reported giving psychiatric referrals and the majority said they avoided the word psychiatrist when speaking with patients.\textsuperscript{303}

An influential study conducted by Todd Elwyn and Michael Fettes in 1995 (published in 1998) assessed physicians’ attitudes to cancer disclosure using Oken’s and Novack’s methodology. Seventy-seven physicians were studied, displaying similar demographic characteristics to those in the Oken and Novack studies: a mean age of 41 and 99% male. Physicians were asked to report on their current and past practices. They estimated that in 1985, 22% of cancer patients were informed of their diagnosis. This doubled to 45% in 1993. 56% reported being more likely to tell a diagnosis than 10 years ago. When asked about their disclosure policies, 40% reported telling the patient, while 60% said they did not normally tell the patient, with more of the “not tell” group reporting that they made exceptions to their policy.\textsuperscript{304} Compared with the Oken and Novack studies, the Japanese physicians listed more factors that influenced their

\textsuperscript{300} Long, “Family Surrogacy,” 33.
\textsuperscript{301} Uchitomi and Yamawaki, “Cancer Care in Japan,” 293.
\textsuperscript{302} Ibid., 295.
\textsuperscript{303} Ibid., 296.
\textsuperscript{304} Elwyn et al., “Cancer Disclosure in Japan,” 1158.
decisions to disclose, including the patient’s age, prognosis, and social status. Most physicians reported conflicts with families who opposed disclosure.\(^{305}\)

Qualitative studies build on these data. Susan Orpett Long reported in 1999 that only two out of 41 physicians interviewed had a policy of disclosure without exception; most decided case-by-case. Many felt that they needed guidance in communication but did not know how to ask their superiors for help.\(^{306}\) In a decade-long follow-up study conducted in the 1990s, Long again concluded that uncertainty about disclosure of diagnoses like cancer was common in Japanese physicians, and she suggested that that this necessitated a cooperation and negotiation process among medical staff, the family, and the patient. This negotiation process differed depending on the situation and the people involved, but overall, physicians “believe it is part of their obligation to determine whether the patient needs to know, would want to know, and could deal with the information.”\(^{307}\) In addition, while physicians were concerned about their patients’ reactions, they were also concerned about their own reactions: “Many health professionals confided that they did not know how to provide support for patients who were emotionally distraught. They felt that they might be unable to cope with a patient’s reaction.”\(^{308}\) In many cases, this necessitated consultation with the family, who would know the patient best: “most physicians believe that the family is in a better position to judge what the patient’s reaction might be.”\(^{309}\)

\(^{305}\) Ibid., 1160.
\(^{306}\) Long, “Family Surrogacy,” 34.
\(^{307}\) Long, Final Days, 97.
\(^{308}\) Ibid., 98.
\(^{309}\) Ibid., 99.
In 2000, Elwyn and Fetters conducted another study, interviewing 14 male physicians about disclosure. Only two reported that they always told the patient the diagnosis. The “tellers” tended to deal with cancers that were noticeable and/or more likely to have a good prognosis. Tellers found that most patients choose disclosure if asked, and they instructed such patients to return in a week with a family member to receive their results. They recognized that time and space are important for the patient to absorb the possibility of cancer. While they thought telling was important, they said that if more patients were told, there would be an increasing demand for support services. They agreed that resources for supporting patients were poor – little financial support for care and a stigma attached to psychiatric care – but suggested that things were changing.\(^{310}\)

The non-tellers focused on problems following disclosure and inadequate support staff.\(^{311}\) They disputed public attitude polls, saying that the attitudes of healthy people regarding disclosure is very different from that of people who are weakened by illness.\(^ {312}\) Tellers and non-tellers agreed that not telling is more difficult for the physician. “Telling is more logical and easier for the doctor, but if we just mechanically tell, like we are lopping them off, our humanity suffers.”\(^{313}\) Elwyn and Fetters conclude that, “perceptions about responsibility within Japanese culture in large part determine decision making about cancer disclosure.”\(^ {314}\) This echoes Long’s finding that physicians felt they had an obligation to identify and respond to patients’ needs.

\(^{311}\) Ibid., 284.
\(^{312}\) Ibid., 286.
\(^{313}\) Ibid., 289.
\(^{314}\) Ibid., 290.
Two other studies conducted in 2000 found that of 27 physicians interviewed, 77% agreed to give diagnoses to patients who wish to be informed, while 14% would not. 60% found a positive effect from disclosure for patients who request it, while 6% reported a negative effect for patients. The primary justification for disclosure was respecting patients’ wishes, while the main reason for not telling was that the social environment in Japan is not ready for disclosure. Of 21 nurses surveyed, 5 reported patient distress after disclosure, while 10 felt patients were better able to confront their disease. The second study surveyed 400 physicians throughout Japan, finding that 80% felt that when a patient has an incurable advanced cancer, the family should be informed first before deciding whether to tell the patient. 17% thought the patient should be told first, and 8% thought that even if the family did not want the patient to be told, the patient should be told anyway. Physicians were also more comfortable with decision-making situations in which the patient, family, and physician were all in agreement as to treatment than with situations where one party unilaterally decided.

Yet the family may be the source of much uncertainty. A 2008 study found that, within a focus group of 9 physicians (7 psychiatrists), 26% of ethical dilemmas were experienced in dealing with the family, second only to those experienced in determining levels of treatment (42%). The physicians did not report dilemmas relating to disclosure, although this could reflect their specialty (psychiatrists are rarely responsible for disclosure). One Japanese physician stated,

The problem of informed consent is that it tends to be biased towards the medical professional’s preference. I try to explain and discuss the matters in as neutral a

315 Seo et al., “Telling the diagnosis to cancer patients in Japan,” 108.
manner as possible, but in reality, I am often giving the family a lot of my own views. No matter how hard I try to give the assessment in a neutral way, I am not able to eliminate the bias problem of informed consent.\textsuperscript{317} This underscores the uncertainty Japanese physicians feel about their use of the subjective standard.

Unlike the U.S., until very recently Japan did not see an overall shift from policies of non-disclosure towards disclosure. Rather, physicians’ concern about psychological effects on their patients drove them not to disclose cancer diagnoses or bad prognoses. Many cited conflict with the family and lack of support services as complicating factors and themselves felt unprepared and anxious about communication with patients. Despite an increase in disclosure, the interviews presented in chapter 3 suggest that these challenges still exist. This may be because physicians still shoulder most of the responsibility for whether or not medical decision-making goes well. I will deal with this more fully in the comparison and conclusion, but now turn to the social factors influencing physicians’ policies.

\textit{4.3.2 Epidemiology and Public Perception}

In Japan, cancer has been the leading cause of death since 1981, causing 1 in 3 deaths, with a five-year survival rate (as of 2003-2005) of 58.6\%.\textsuperscript{318} The three types of cancer with the highest incidence rates in Japan are (in order from highest incidence to lowest) lung, stomach, and colon/rectum (lung cancer surpassed stomach cancer in 1998).

\textsuperscript{317} Malloy et al., “Ethical Decision-Making about Older Adults and Moral Intensity,” 293.
\textsuperscript{318} As of 2012, the 2\textsuperscript{nd} and 3\textsuperscript{rd} leading causes were heart disease and pneumonia.
Based on 2008 data, 1 in 2 Japanese will be diagnosed with cancer in their lifetimes; 1 in 4 men and 1 in 6 women will die of cancer. The cancer incidence rate is increasing while the age-adjusted mortality rate is decreasing. This increase could be related to the increasing life expectancy in Japan, or to better screening techniques and awareness. Japan has a historically low screening rate for breast and cervical cancer, while the U.S. has one of the highest.\(^\text{319}\)

Overall public perceptions of cancer in Japan are worse than in the U.S. A 2013 study showed that of six countries, Japan was the only country with a lower than 50% (29%) satisfaction rate with progress against cancer in the past 20 years.\(^\text{320}\) Japan had the highest public perception that the increasing numbers of people are dying of cancer each year (45%). Japan was the second most likely to think that cancer always leads to death (35%). Japan also had the highest rate of thinking that patients and their families should make treatment decisions (92%), overlapping with 31% for physicians (multiple selections were allowed), and reflecting the emphasis on family and physician involvement in decision-making. More than 50% of Japanese were only “somewhat confident” that they would receive the best possible treatment. They also had the highest rates of dissatisfaction with information on what to expect physically, financially, and emotionally following a cancer diagnosis. Specifically, 62% of patients and 55% of caregivers thought that “support groups or counseling for caregivers” was “not enough,” while 55% of both patients and caregivers thought that “support groups or counseling for patients” was “not enough.”

\(^\text{320}\) Including (in addition to Japan) the U.S., Italy, France, the U.K., and Germany. GfK Roper Public Affairs and Corporate Communications and GfK Healthcare. 2013.
Japanese public perceptions are considerably less optimistic than those in the U.S. Perhaps as a result, as of the writing of this dissertation, advertisements for “cancer insurance” were ubiquitous on television and in public areas in Japan. In the next section, I analyze how these perceptions interact with Japanese attitudes towards cancer diagnosis disclosure.

### 4.3.3 Social Attitudes and Preferences

**Figure 10. Japanese Preferences for Cancer Diagnosis Disclosure (%)**

Before the 1980s there was little discussion of cancer disclosure in Japan.\(^{321}\) Studies in the early 1980s found few people wanting to be informed of cancer diagnoses, citing loss of hope and inability to handle the news on one’s own as major concerns.\(^{322}\)

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The family’s role was to protect and provide emotional support to the patient, and the doctor’s was to maintain hope in the patient.\textsuperscript{323}

1989 polls of public preferences (public opinion polls and mass media polls)\textsuperscript{324} found that a majority (54\%) wanted to be informed of a cancer diagnosis. This trend increased to 60\% in 1991 and 69.6\% in 1993.\textsuperscript{325} In the 1990s, those who did want to know often cited the need to prepare and the desire for open communication. Those who did not want to know stated anxiety about knowing that death was approaching and doubt about how they would really feel when the time came.\textsuperscript{326} The family’s role during this time continued to be that of protector (as reflected in public opinion polls about family preferences for patient disclosure). In 1993, only 28.5\% of respondents reported that they would convey a cancer diagnosis to a family member, while a 1996 survey found that only 19\% of people thought the physician should tell the patient, holding that disclosure depends on patient feelings and external situational conditions.\textsuperscript{327}

Studies of preferences in the late 1990s and early 2000s further complicate the role of the family and reveal hesitancy about disclosure. In a 1999 survey of 304 urban Nagoya residents, 63.4\% responded that a physician should not disclose an incurable stomach cancer diagnosis to a 60-year-old man. 35.6\% favored verbal prognosis, 31.2\% non-verbal, and 33.2\% responded that the diagnosis should not be communicated at all.

\textsuperscript{323} Ibid., 2103.
\textsuperscript{324} As in my survey of the U.S. data, I have excluded studies that only consider the preferences of cancer patients (considering data from cancer patients who have been told they have cancer as unreliable for judging whether or not cancer diagnoses should be disclosed), but have included studies that surveyed patients as to their experiences post-disclosure and their expectations of physicians and nurses.
\textsuperscript{326} Long, “Family Surrogacy,” 33-34.
\textsuperscript{327} Ibid., 36-37.
23.4% thought that decisionally-capacitated patients should make their own decisions, 27.6% responded that such decisions should be shared by the physician, patient, and family, 18.6% chose the physician and family, and the remainder were split between patient and family, patient and physician, family alone, and physician alone. A 2002 study of 357 Japanese in rural Gifu found that 63% wanted personally to be told if they had a cancer diagnosis, while 36.4% thought that, in general, doctors should tell patients when they have cancer. 65.4% of those surveyed were likely to associate the word “cancer” with death. Finally, a 2004 study of 134 diabetes patients in Kyoto found that, when given hypothetical scenarios involving cancer, pneumonia, and gangrene, the majority did want to be informed (all but one) and wanted to make treatment decisions together with their physicians. In the cancer scenario, as many as 70% of respondents wanted their families involved in decision-making (compared with 42% for pneumonia and 41% for gangrene). However, the majority (60%) would defer to the physician for the final decision of treatment option — even when it conflicted with their own preferences.

By 2005, a survey of 427 Tokyo residents found that 86.1% would want to be told a cancer diagnosis, while a survey of 222 residents of an unnamed prefecture found that 69.5% absolutely wanted to be told the diagnosis but 25.7% wanted diagnosis disclosure to be conditional on the possibility of treatment. Reasons for wanting to know were

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328 Matsumura, “Acculturation of Attitudes Towards End of Life Care,” 536.
331 Probably Kumamoto Prefecture, given that that is where all the authors worked. Taniguchi et al., “Factors Affecting People’s attitudes Concerning Being Told a Cancer
consistent with those expressed in the 1990s, such as planning for the future and selection of treatment, as well as a pure desire to know (*jibun no koto dakara* [because it is my issue]). Reasons for not wanting to know were also unchanged: fear of shock, helplessness, and being unable to handle the news. The ideas most frequently associated with cancer were “if you find it early it can be treated/cured (*naoru*)” (77.6%) and “fear (*kowai*)” (48.1%). 57.4% reported knowing very little about cancer (*amari ni shiranai*).

When asked about the role of their families, 74.2% said they wanted to know even if their families were opposed to it because it is their personal responsibility (*jibun no sekinin de shiritai*), while 20.5% said they would follow the will of their family. Only 21% thought their families would surely tell them; 47.1% thought their families might tell them; and 30.5% thought their families would withhold disclosure. The majority (58.6%) reported not talking with their families about cancer.

At this time, a divide in preferences between life expectancy and prognosis disclosure also began to appear. 32.8% wanted to receive “full disclosure without delay” of prognosis information, and 30.2% wanted full disclosure of life expectancy. The majority preferred partial or gradual full disclosure of prognosis (64.5%) and life expectancy (66.1%).

A 2007 study echoed this finding, reporting that while 97% of 529 Japanese cancer patients in Tokyo wanted the physician to tell them of treatment plans, only 50.4% wanted information on life expectancy. 78% wanted to be told their diagnoses in a setting with their families.  

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332 Miyata et al., “Disclosure Preferences Regarding Cancer Diagnosis and Prognosis: To Tell or Not to Tell?” 449.
Despite this ambivalence about prognoses, Japanese do increasingly want information about their diagnoses: a 2010 study showed that 97% of Japanese surveyed wanted to know their diagnoses, and 94.4% wanted information on recovery rate and life expectancy.\(^{334}\) In addition, people without cancer said that if they were diagnosed, the first thing they would worry about would be finances, with family and death as close seconds. For patients who knew they had cancer, their first biggest concern was death, with recurrence and their families close seconds. For patients currently receiving treatment, their biggest worry was recurrence, with family and finances distant seconds.

Many studies have looked at public preferences; fewer have analyzed patient reactions. A study of 129 cancer patients from 1987-1990 found that 52% of patients were shocked but adjusted, 24% had expected the news somewhat so they were not so shocked, and 16% were so shocked they “blacked out” (shokku de me no mae ga makkura). A study in 1990 of 112 patients with early stage stomach cancer found that 53% recovered from the shock within one week and 23% took one week to one month; the rest did not answer or took longer.\(^{335}\) More recent studies have charted patients’ narratives following disclosure in order to identify appropriate support. Almost all of these studies are in the field of nursing, such as a 1996 book by a nurse and cancer patient, *Gan Kokuchi Igo* [Following Cancer Disclosure].\(^{336}\) In addition, a 2012 study

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\(^{334}\) Aflac (2010).

\(^{335}\) Muto, “*Gan no Kokuchi* [Cancer Disclosure].”

\(^{336}\) Suda et al., “*Gan Kokuchi Go ni Shujutsuhou wo Ukeru Kanjiya no Sutoresu Taiken to Sono Henka*,” Takesako et al., “A Review of Studies on Psychological Change in Patients and Families Following Lung Cancer Disclosure and Nurse Intervention.”
found that patients who were given a life expectancy prognosis were shocked by the abrupt or quantitative nature of the disclosure.\textsuperscript{337}

Most concerning is the National Cancer Institute’s recent report, covered widely in the Japanese news, that newly diagnosed cancer patients are 20 times more likely to commit suicide in the year following their diagnosis than healthy Japanese.\textsuperscript{338} By comparison, the rate in Sweden of suicide within one week of disclosure is 13 times higher than the healthy population, and within one year of disclosure, 3 times higher; the U.S. does not report a higher risk of suicide for cancer patients.\textsuperscript{339} The study leader at the National Center of Neurology and Psychiatry, Yamauchi Takashi, explained that

There is a tendency, even in international research, for risk of suicide to increase immediately following diagnosis. In the year after diagnosis, lifestyle greatly changes due to treatment and stress increases. In addition to psychological care, it is necessary to provide social support.\textsuperscript{340}

The head of the palliative care department of the National Cancer Center’s Central Hospital also said,

This shocking result demonstrates once again the extent of patients’ distress. All physicians who engage in cancer treatment understand the importance of support

\textsuperscript{337} Sato et. al., “The Meaning of Life Prognosis Disclosure for Cancer Patients.”
\textsuperscript{338} The news first appeared on the homepage of the Mainichi Shinbun website on April 22, 2014, and was picked up by other national newspapers the next day (Yomiuri Shinbun, April 23, 2014; Asahi Shinbun, April 23, 2013; Nikkei Shinbun, April 23, 2014). Yamauchi et al. “Death by suicide and other externally caused injuries following a cancer diagnosis,” (2014).
\textsuperscript{339} Mainichi Shinbun, April 22, 2014.
\textsuperscript{340} Asahi Shinbun, April 23, 2014. The national government has recently targeted employment support for patients as one area that needs further investigation (Nikkei Shinbun, February 25, 2014, my translation)
for the social lives and the psychological distress of those living with cancer, and
after the diagnosis stage deal with providing comfort care.\textsuperscript{341}

This report highlights the difficulty that cancer patients have following disclosure, and
foreshadows the following discussion of social support for cancer patients in Japan.

\textit{4.3.4 Other Players and Social Support}

Japan has a Psycho-Oncology Association (JPOS), founded in 1987 with
couragement from Jimmie Holland, leader of the International Psycho-Oncology
Society. As of 1999, the JPOS had more than 500 members (mostly physicians and
urses),\textsuperscript{342} although at that time, only a few cancer center hospitals in Japan had psycho-
oncology professionals on staff, and they only offered psychosocial interventions when
cancer patients uninformed of their true diagnoses showed abnormal behavior or severe
distress. A member of the JPOS links this lack of support directly to the cancer disclosure
issue, writing that there is “a need to establish a mental-health service run by psycho-
oncology professionals with the aim of supporting communication between medical
professionals and cancer patients and their families after cancer disclosure.” He further
suggests that the participation of psychologists and social workers in medicine may be
limited because they are not certified by the government.\textsuperscript{343}

Professional certifications, however, are available. The Japan Association of
Certified Social Workers (JACSW), created in 1993, reported in 2013 that it had 35,140

\textsuperscript{341} Mainichi Shinbun, April 22, 2014 (my translation).
\textsuperscript{342} Uchitomi, “Psycho-oncology,” 412.
\textsuperscript{343} Ibid., 412.
members, although most of these were not medical social workers.\textsuperscript{344} According to a 2009 article, the role of medical social workers is to explain otherwise confusing aspects of diagnosis and treatment; most work at so-called cancer discussion centers within hospitals.\textsuperscript{345} Clinical psychologists are now also certified. The Japanese Society of Certified Clinical Psychologists (JSCCP) was established in 1988 and as of 2013 had 23,629 members.\textsuperscript{346} According to an article on the role of clinical psychologists in medicine, they can assist cancer patients and their families and support their decision-making.\textsuperscript{347}

Despite this growth in social work and clinical psychology, the participation of these professionals in medicine is limited, especially in cancer care. Accordingly, the JPOS still remains at about 600 members, including physicians, nurses, educators, clinical psychologists, and psychiatrists.\textsuperscript{348} Their website states that participation of clinical psychologists, psychiatrists, and others who specialize in the patient psychology is quite low, suggesting that

Problems like cancer disclosure in clinical settings still face great obstacles.

Currently, issues like the creation of guidelines for cancer patients’ psychological care, education and training for methods of support following cancer disclosure, and communication practice for physicians are being raised.\textsuperscript{349}

\textsuperscript{344} JACSW, http://www.jacsw.or.jp/01_csw/03_kokajoho/common/03_shibubetsukaiin.html.
\textsuperscript{345} Nikkei Shinbun, “Medical Social Workers” (2009).
\textsuperscript{346} JSCCP, http://www.jsccp.jp/about/concept.php
\textsuperscript{347} Nikkei Shinbun, “Clinical Psychologists,” (2013).
\textsuperscript{348} JPOS, http://jpos-society.org/about/history.php.
\textsuperscript{349} Ibid.
While new professions like medical social work and clinical psychology are growing in Japan, lack of patient support is still an issue in cancer disclosure. The Mainichi Shinbun reported that the Ministry of Health, Labor, and Welfare (MHLW) released its “Basic Plan for the Implementation of Cancer Counter-Measures” (gan taisaku suishin kihon keikaku) in 2000 to systematically provide patients and families comfort care (kanwa kea), including care for emotional agony. However, as of November 2013, only 63% of the 397 hospitals designated by the MHLW as “Cooperative Cancer Treatment Centers” (gan shinryō renkei kyoten byōin) had psychiatry departments, and less than 40% had comfort care teams for hospitalized patients. Even now, the misconception that comfort care equals end of life is deep-rooted, and care is not proactive from the side of the physician or the patient.

Japan is working to enhance support by redefining the roles of medical professionals like oncology nurses, who often provide patient support, as shown in the previous chapter. A 2000 study reported that nurses are almost always present when a diagnosis is disclosed, playing the roles of coordinators between physicians and patients and emotional supporters for patients. According to a report issued by a large hospital in Yokohama in 2012, physicians increasingly ask nurses to attend diagnosis disclosures and to check on patients afterwards. Patients increasingly seek nurse consultation on cancer, concerned with topics such as the nature of the disease and treatment, recuperation, consultation by the family, and emotional distress. A 2012 study found that

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350 Nikkei Shinbun, “Cancer Nursing Specialist Nurses.”
351 Kobayashi et al., “Haigan Kanjya no Infōmudo Konsento to Kangōfu no Yakuwari [Informed Consent with Lung Cancer Patients and the Nurses’ Role].”
352 Mitsuhori et al., Gan Kokuchi Kara Shumakki Made Kanjya/Kazoku wo Sasaeru Tameni [For supporting the patient/family from cancer disclosure to the final stages].
cancer patients expected nurses’ reliable support (shinrai dekiru taiō), including quick responses to their physical needs and questions, as well as words of encouragement, sincere concern, and hope for the future. Patients did not want nurses to actively intervene without prompting, nor did they want to be made re-aware of their condition, perhaps indicating that patients want to be in charge of the kind of support they receive.353

Finally, recognition of the psychological effects of cancer and the need for psychological care may be increasing in Japan. Recent newspaper articles focus on medical social workers’ roles and patients’ psychosocial needs.354 A 2014 survey conducted among readers of the “cancer navigation” section of the Nikkei Newspaper found that of 168 respondents, 48.8% wanted to see more articles on psychological care (kokoro no kea), although this was less than interest expressed in treatment, palliative care, and recent medical advancements.

4.3.5 Summary

According to the surveys cited above, for a long time physicians in Japan did not uniformly inform patients of cancer diagnoses. Although most now do, they allow for exceptions and decide to disclose on a case-by-case basis, expressing concern for patients’ welfare and feeling responsible for maintaining patients’ hope. They are also concerned about the lack of support for patients and are anxious about their own communicative abilities.

The majority of Japanese patients desire information about their diagnoses, but are dissatisfied with the information they receive. Less concerned with the details of prognoses, they expect physicians to maintain their hope and to bear responsibility for treatment decisions, although they do want to be involved in the decision-making process, and they want to control the type of support they receive. Their concerns about being able to handle a diagnosis seem well founded; in Japan cancer is the leading cause of death. Until 1998, the most common cancer was stomach cancer, which is particularly lethal. People are more likely to think that cancer leads to death, and they have more negative associations with cancer.355

The role of the family complicates decision-making for both physicians and patients. Physicians frequently cite ethical dilemmas and conflicts in dealing with families; very few will disclose against the family’s wishes. Family members often see their role as protecting and encouraging the patient. The percentage of people who would tell a family member they have cancer still remains much lower than the percentage who would want to be told. Many people say they would want to be told their diagnoses even if their families opposed it, but the majority thinks that their families would not tell them. Many also report not talking with their families about cancer or their wishes regarding disclosure.

355 There have been recent attempts to change this perception. For example, in 2012 the book, Douse Shinunara “Gan” Ga Ii [If you have to die anyway, cancer is pretty good], (Nakamura Jinichi and Kondō Makoto, Takajima publishing) was published and became quite popular. In it, the authors, both former physicians, enumerate the common misconceptions about cancer, explain why modern medical treatment and elongation of life is not without problems, and consider the relationship between Japanese people and death. They conclude that cancer is not such a bad death after all, and that perhaps people should not go to such great lengths to fight cancer.
Finally, physicians and patients find the lack of support for patients’ psychosocial needs problematic. Although support networks, medical social workers, and clinical psychologists are improving, the significant stigmas of psychological care prevent their services from being routinely offered. This may lead physicians and nurses to take on further responsibility for patients’ emotional support despite not being trained to provide such support. They accept this responsibility because there may be no other options. If they do not provide this support themselves, they often shift it to families.

In the next section, I turn to a comparison of the two countries and the implications for our understanding of informed consent and nondisclosure practices. This clarifies why Japanese physicians might choose to withhold cancer diagnoses from patients.

4.4 Social Factors Affecting Informed Consent in Cancer Disclosure

Two central themes that emerge from this comparative review are responsibility and support. The majority of patients in the U.S. seem willing to participate in and take responsibility for medical decision-making, as evidenced by their desire for information, their preference to be alone when their diagnoses are disclosed, and their assessment of the quality of their disclosure in terms of the information they receive. Many patients in Japan, on the other hand, have displayed hesitancy about emotional aspects of disclosure, citing worries about how they will be able to handle the news, although now almost all Japanese desire disclosure in order to make treatment selections and future plans. A large majority prefers their families to be present when diagnoses are disclosed, and most favor decision-making that is accomplished together with their families and their physicians.
Most Japanese patients expect their physicians to modify the manner of disclosure to suit them. Likewise, the high value they place on physicians’ maintenance of their hope suggests they may hold physicians responsible for their emotional state. So, whereas responsibility for a smooth decision-making process falls on patients in the U.S., it falls on physicians (or nurses) in Japan.

American patients value physicians’ technical expertise over their supportiveness. There is very little discussion of physicians’ emotional support for patients in the literature, perhaps because this is not part of the physician’s professional role in the U.S. Nevertheless, support is available, and patients rate the support available to both patients and caregivers highly. The U.S. has an extensive system of social, mental, and emotional support for cancer patients, dating back to the establishment of the first national cancer centers in the country’s oldest hospitals. While there is still some stigma to psychosocial treatment, it does not create a barrier to patient care.

In Japan, on the other hand, both patients and the public have repeatedly voiced desires for more emotional support from their physicians and nurses. Conversely, many physicians have expressed anxiety about their abilities to provide support and concerns about Japan’s lack of psychosocial services. Japan does not have an extensive patient support network, and although psychosocial professionals are emerging, they are not yet integrated with oncology. The lingering stigma attached to psychosocial support can prevent the growth of these services, although this may be improving. Without adequate support services, the burden often falls on families who may themselves be unavailable or unprepared to take responsibility for the emotional aspects of patient care. While American support for cancer patients is well established, in Japan both patients and
physicians recognize the need for improvement, as underscored by the high suicide rate of Japanese in the year following a cancer diagnosis.

This analysis of cancer disclosure in the U.S. and Japan reflects the differences in institutional policies of informed consent found in chapter 2: patients in the U.S. take responsibility for medical decisions and seek information that will aid them in the decision-making process, while physicians almost uniformly disclose cancer diagnoses, citing respect for their patients’ autonomy. In Japan, while more patients want to know their diagnoses now than thirty years ago, their reliance on physicians for determining the scope of disclosure, especially in terms of prognosis, shows reluctance to take responsibility for decisions. Physicians in Japan in turn try to respond to their patients’ needs, but often feel unprepared for the task.

In short, American patients seem to be more independent and proactive in seeking information from physicians, who comply with their requests. In Japan, patients express ambivalence about the amount of information they desire, so physicians feel responsible for determining the scope of the disclosure.

It must be stressed that not all physicians and patients in either the U.S. or Japan fit these characterizations, nor are these attitudes essential features of American or Japanese culture. Rather, they are part of the complex system of institutional rules, social practices, and general discourses of each country, and they are in accordance with the differences in informed consent policies, namely, the reasonable prudent patient standard in the U.S. and the professional and subjective standard of Japan. Yet, this does not necessarily mean that these institutional standards respond to the social needs identified in this chapter and in chapter 3. The following section addresses this concern.
4.5 Cancer Disclosure and Informed Consent: Untangling the Web

It is not surprising that, as a result of this review, responsibility appears as a central theme in the discussion on disclosure and consent. Indeed, as we have seen in chapter 2, the legal and medical structures shaping informed consent in both the U.S. and Japan have defined it mainly in terms of a patient’s right to make determinations about his or her body (i.e., to take responsibility for one’s body) and a physician’s responsibility to ensure that a patient can make these self-determinations. I will have more to say about responsibility in chapter 5. But for now, why is patient support also a significant theme in informed consent seen through the lens of cancer disclosure? Why is substantial support available to American patients, who seem more independent, and not to Japanese patients, who express more need of it? Is this connected to Japanese physicians’ reticence to uniformly disclose diagnoses of cancer to their patients? I suggest that the presence of support networks explains both American physicians’ and patients’ confidence about cancer disclosure and Japanese physicians’ and patients’ uncertainty.356

Early in the cancer disclosure debate, American physicians were most concerned with the psychological effects of disclosure. However, increased attention to and study of patients’ reactions to cancer diagnoses led to a better understanding of patients’ psychosocial needs. As more effective systems were put in place to meet these needs, disclosure to patients became “safer.” Physicians could be more confident that informing patients of their diagnoses would not cause them significant harm. In Japan, on the other

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356 There is temporal congruence here as well, although correlation does not, of course, prove causation. It was precisely from 1960-1979, when American physicians reversed their policy from nondisclosure of cancer to disclosure, that the U.S. increased support services for cancer patients.
hand, there have been fewer major studies of patients’ reactions to disclosure, and as a result there is less understanding of how systematized approaches can meet patients’ psychosocial needs. Given that oncologists are not likely to have an established relationship with patients at the time of diagnosis, they often rely on families to determine whether patients can handle the news and how to convey it. While including families in decision-making often causes complications, perhaps given families’ tendencies to try to protect patients from bad news, many physicians may feel it is the only route available to them. Yet physicians lack confidence in their communication skills, and in a country where there is a high risk of suicide following cancer diagnoses, it is not surprising that cancer disclosure rates in Japan have not risen to the universal level seen in the United States.\textsuperscript{357} Indeed, despite evidence from my interviews that cancer diagnoses are now “always told,” when in 2015 I went to an appointment at the office of a gastroenterologist in Kyoto, Japan, I was met with the following question on the intake form: “In the case that we find a malignant tumor (such as cancer), do you want to be told? (1) I absolutely want to be told, (2) I don’t want to be told, (3) If you can help me then I want to be told.”\textsuperscript{358} Data from my interviews combined with such evidence suggests that the issue of cancer diagnosis disclosures in Japan is not yet settled.

Both physicians and patients in Japan are concerned about cancer patients’ reactions to diagnoses because they know that receiving this news is not easy. However,

\textsuperscript{357} Yamauchi et al., “Death by suicide and other externally caused injuries following a cancer diagnosis,” (2014).
\textsuperscript{358} Akusei shuyō (gan nado) wo mitsukatta baai, anata wa kokuchi wo kibō saremasuka? 1) zehi kokuchi shite hoshii, 2) kokuchi shite hoshikunai, 3) tasukaru kanōsei ga areba kokuchi shite hoshii 悪性腫瘍（癌など）をみつかった場合、あなたは告知を希望されますか？1）是非告知して欲しい、2）告知して欲しくない、3）助かる可能性があれば告知して欲しい。
in the absence of reliable support services, Japanese physicians feel responsible for their patients’ physical and emotional welfare, and patients trust them to maintain their hope and provide support through the treatment process. Yet physicians are not confident in their communication skills due to inadequate communication training, so they are uncertain about disclosing diagnoses and prognoses.

In allowing for exceptions in diagnosis disclosures, Japan’s policy of informed consent reflects the immediate need for physicians to make case-by-case judgments, but it fails to address the underlying social factor making these decisions so difficult: the lack of reliable support for patients with cancer and similarly life-changing illnesses. Patient support is crucial because when patients have emotional and social support for receiving troubling information and making difficult decisions, physicians can be more confident that conveying bad news will not cause harm, and patients can more readily accept decision-making responsibility. This support is present in the United States, but it is neither acknowledged in the discourse nor is its value recognized. The predominant discourse in the U.S. is one of patient autonomy as the freedom to make one’s own decisions, although more physicians are becoming aware of the “human needs of the vulnerable patient.” In Japan, the role of patient support is beginning to be recognized, but its absence in the bioethical discourse reflects conditions in the U.S., where support can be taken for granted without major repercussions. The lack of discussion on patient support has more serious consequences in Japan, where support services are not integrated into patient care, leading to a real risk of harm following disclosure.

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359 Zitter, “Who Can Speak For The Patient?”
The revelation of the importance of patient support also influences how we understand informed consent. For much of the twentieth century, informed consent and autonomy have been closely intertwined, and informed consent has been the baseline requirement in medical practice. According to this requirement, a decisionally-capacitated adult is autonomous and has the right to make his or her decisions freely and without coercion. However, focusing on this aspect of informed consent alone hides an underlying precondition for informed consent in the context of medical treatment: emotional and social support for receiving troubling information and making difficult decisions. Patient support is an under-recognized element in the institutional framework and the philosophical discussion on informed consent. Indeed, the inconsistent use of the term “autonomy” by physicians in justifying their decisions should make us question the validity and efficacy of the discourse that focuses on “autonomy” alone.\(^{360}\)

While current bioethical arguments use respect for autonomy through informed consent as the litmus test for ethical cancer disclosure, cancer disclosure in Japan suggests compelling reasons for reappraising informed consent theory. In the absence of appropriate support mechanisms for patients diagnosed with a disease as impactful as cancer, it would be irresponsible for physicians to adopt a blanket policy of disclosure without taking into account particular patients’ emotional and mental states and social networks. For some patients, an adequate support network is a precondition for being able to participate in medical decision-making. I will return to this issue in chapter 5, where I consider the conceptual implications of what we have learned about informed consent and cancer disclosure in Japan in chapters 2, 3, and 4.

\(^{360}\) Fried et al., “Limits of Patient Autonomy.”
For now, I would like to highlight the finding that Japan’s distinctive culture is not at fault for its incomplete incorporation of respect for patients’ voluntary consent into the Japanese medical system. Rather, overreliance on “Japanese culture” as an explanation for why “American” informed consent does not work in Japan has led to a blind spot in the discourse; a blind spot which, ironically, highlights the extent to which Japanese society exhibits high levels of relationality and emotional dependency. The failures of bioethicists and policymakers to respond to these aspects of Japanese society have made cancer disclosure a very real problem for Japanese physicians and patients - not any theoretical clash between Japanese and American autonomy. The change of cancer disclosure policy in the U.S. and Japan is due less to reinforcing informed consent through increased respect for patient’s autonomy and individual rights, than to supporting patients when emotional and mental stress threaten their very abilities to act autonomously.

In this chapter I have identified support as the main issue concerning informed consent in Japan by analyzing the history of the practice on a detailed, practical level, building off my examination of the institutional standards for consent in chapter 2 and its practical manifestation in chapter 3. In short, support is an essential albeit under-recognized element of the discussion on informed consent practices. This has implications not just for how informed consent is practiced in Japan, but also for how informed consent is conceptualized in the U.S. and other countries with informed consent standards. In the next chapter, I ask why support has not been part of the theoretical discussion on informed consent and evaluate whether current theories of informed consent can account for the significance of support for medical decision-making.
Chapter 5: Responsibility and Dominant Theories of Informed Consent

“Japan is not a contractual society. The purpose of informed consent is to create a trusting relationship with the patient.”

--Interview with a Japanese Physician, 2014

“If someone is the responsible decision-maker, then other people may not want to talk to them, because if they were to affect their decision, that would imply that they had responsibility. The physician’s explanation transfers responsibility onto the patient. This shift of responsibility can be really hard on physicians when they see their patients doing things they know are wrong, like a patient with diabetes not taking care of his or her body.”

--Interview with a Japanese Physician, 2014

“There are physicians who work with patients and physicians who just tell patients to decide. Maybe in Japan, there is more sympathizing/intuiting (sassuru) between physicians and patients. But physicians are really busy, so this is difficult in practice. ”

--Interview with a Japanese Nurse, 2014

Introduction

The previous three chapters have highlighted similarities and differences in the institutional standards and social practices of informed consent in the U.S. and Japan. Chapter 2 showed that Japanese and American institutional standards of informed consent have many features in common but are based on fundamentally different premises about their respective societies and patients, namely that Japanese physicians are responsible for medical decision-making (ostensibly to protect patients), while American patients are responsible for medical decision-making (ostensibly to prevent physicians’ paternalism). Chapter 3 identified distinguishing features of Japanese informed consent practices as well as current challenges, such as the different stages of the informed consent process, the involvement of multiple parties, poor communication training for physicians, and lack of cooperation. Chapter 4 compared the history of cancer
diagnosis disclosures in Japan and the United States, concluding that support is a significant yet under-recognized element of informed consent. In this chapter, I ask if current theories of informed consent acknowledge support for patient decision-making or if support is hidden by this theoretical discourse. This will identify ethical tools that can be used to evaluate informed consent practices in Japan and worldwide.

This analysis shows that the autonomous authorization theory (the most popular theory of informed consent in the U.S. and the one most often used in non-Western countries) treats informed consent as a means of exchanging information and assigning individual responsibility for decisions. Two other theories of informed consent, the communicative transaction theory and the fiduciary exchange theory, incorporate physicians’ roles in ensuring successful communication of options and in deliberatively arriving at decisions that fit patients’ life goals. However, for both theories, informed consent is still based on individual responsibility for decisions. This ignores the effects of support and patients’ psychosocial reactions on patient decision-making.

Furthermore, while the informed consent discourse concentrates on the meaning and exercise of patient autonomy, my review suggests that autonomy is not the central concept in informed consent. A legalistic conception of responsibility does most of the work in these three theories, and as I will argue, making a patient responsible for her decisions does not necessarily entail that her decisions are made autonomously. This elision of autonomy and responsibility may stem from informed consent’s legal heritage in the U.S., which professes respect for patient autonomy and self-determination but functionally relies on a narrow conception of responsibility as liability, as shown in chapter 2. This model of responsibility, which I term the individual-outcome model,
focuses on individual liability for decisions and ignores supportive and emotional aspects of professional-patient communication. I propose that another model for responsibility, the relation-process model,\(^{361}\) better explains the ethical significance of psychosocial support.

The dominant theories considered in the present chapter are not the only theoretical approaches to informed consent. I will describe other Western and Japanese theories of informed consent that take support and other psychosocial factors into account using the relation-process model of responsibility, tempering but not entirely rejecting the legalistic individual-outcome model for responsibility. This chapter suggests that we can use insights from these theories to explain the ethics of informed consent in more comprehensive terms. Chapter 6 develops this comprehensive theoretical approach in the context of Japanese informed consent theories and standards and identifies aspects of American informed consent that are hidden by the individual-outcome model but revealed from a relation-process perspective. This analysis then suggests necessary changes to Japanese and American informed consent practices.

### 5.1 Dominant Theories of Informed Consent

Dominant theories of informed consent can be categorized roughly into three groups: (1) informed consent as an autonomous authorization,\(^{362}\) (2) informed consent as a communicative transaction,\(^{363}\) and (3) informed consent as an exchange in a fiduciary

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\(^{361}\) This model is not derived from Whiteheadian metaphysics, which also employs the term “relation-process.”


relationship. While other theories of informed consent and connections between the three types of theories outlined here exist, conceptual lines can be most clearly drawn between these three types. These three theories’ conceptions of the means and goals of informed consent differ, so analyzing these theories along these conceptual lines distinguishes the ways in which informed consent is justified. In this section, I will analyze each of these three types in turn.

5.1.1 Informed Consent as an Autonomous Authorization

Informed consent is most commonly discussed in terms of the theory of autonomous authorization advanced in Beauchamp and Childress’s canonical *Principles of Medical Ethics* and used in Faden and Beauchamp’s *A History and Theory of Informed Consent*. Both texts will be used to sketch the theory’s three general features: (1) an attempt to avoid a legalistic definition, (2) a consideration of informed consent as a species of the broader category of autonomous action, and (3) an emphasis on individual autonomy and freedom as ethically fundamental. The goal of this theory of informed consent is to respect patients’ autonomy by transferring authority and responsibility from physicians to patients.

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365 Berg et al. also distinguish between three “senses” of informed consent: the policy-oriented conception, the philosophical conception, and the shared decision making conception as promoted by the President’s Commission for the Study of Ethical Problems in Medicine in the U.S. However, there are not strong conceptual distinctions between these three senses. Both the philosophical conception and the shared decision-making conception use the idea of autonomous authorization, which is also the justification for most of the policies Berg et al. consider. Accordingly, their three senses of informed consent fall within the first type of informed consent described here: informed consent as an autonomous authorization.
Faden and Beauchamp begin by rejecting the definition of informed consent in terms of five elements that were generally agreed upon within American bioethical literature in the 1980s: disclosure, comprehension, voluntariness, competence, and consent. They suggest that these elements reflect biased concerns with disclosure and responsibility in medical convention and malpractice law and are unhelpful for a conceptual analysis of informed consent as a general theory. In other words, these elements focus on whether or not disclosure occurred and whether or not responsibility for decision-making was successfully transferred from the physician to the patient, often crucial questions in medical malpractice lawsuits, as shown in chapter 2.

At the time of Faden and Beauchamp’s writing, these five elements were the most commonly recognized components of a valid consent. However, Faden and Beauchamp argue that common recognition entails neither logical nor normative necessity. As to the first, they conceive of logical necessity as proceeding from first principles. The five-factor definition of informed consent is not logically necessary because it emerges from the contingent, historical conditions of American medical and legal institutions. As to the second, they object that this common understanding of informed consent cannot answer normative questions, such as: Must a physician always obtain valid consent? And must a patient always provide it? According to Faden and Beauchamp, a more rigorous conceptual analysis of informed consent must satisfy both logical and normative theoretical requirements.

Faden and Beauchamp begin their positive definition by distinguishing between two dominant conceptions of informed consent: sense 1, in which informed consent is

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366 F&B 274.
367 F&B 275.
“analyzable as a particular kind of action by individual patients and subjects” — an autonomous authorization — and sense₂, in which informed consent is analyzable in terms of the web of cultural and policy rules that collectively form the social practice of informed consent in institutional contexts where groups of patients and subjects must be treated in accordance with rules, policies, and standard practices.³⁶⁸

While sense₂ as a particular social manifestation of informed consent may not be normatively required, it is at least generally socially required; it is valid or effective only in social contexts.³⁶⁹ Since chapter 2 dealt with some of the ways in which informed consent is institutionalized and codified in the U.S. and Japan in line with sense₂, now something more than an historical genealogy of informed consent is necessary to address present issues in the practice. Accordingly, here I focus on Faden and Beauchamp’s definition of informed consent according to sense₁: an autonomous authorization. It is important to note that, according to Faden and Beauchamp’s theory, an informed consent in sense₁ can be ineffective in sense₂. The logically valid definition of informed consent will not always be socially effective, and vice versa.³⁷⁰ Their philosophical/conceptual definition of an autonomous authorization is independent of epistemic social conditions — a presumption that, as I will show, there are good reasons to question, given that it follows directly from American case law.

Faden and Beauchamp conceive of sense₁ of informed consent, hereafter referred to as an autonomous authorization, as a species of the larger category of autonomous

³⁶⁸ F&B 277.
³⁶⁹ Ibid., 280.
³⁷⁰ Ibid., 281.
action, a concept they explore in an earlier chapter of *A History and Theory of Informed Consent*. To act autonomously is to act: (1) intentionally, (2) with understanding, and (3) without controlling influences. These conditions are not black and white. Actions are more or less autonomous depending on the degree to which they are understood and un-coerced. Yet the first condition and the fulcrum of Faden and Beauchamp’s autonomous authorization theory – intentionality – does not occur along a spectrum. For Faden and Beauchamp, acts are either intentional or not, and only this condition of intentionality gives an informed consent the character of an authorization. Without intentionality, one could merely assent or acquiesce to a proposal with no authority over the decision. Based on this condition of intentionality, informed consent is an autonomous authorization of a professional to take a certain action that will affect one as a patient (the opposite is informed refusal).

Furthermore, to act intentionally by giving authorization is to take responsibility for one’s decision; “one must understand that one is assuming responsibility and warranting another to proceed.” Faden and Beauchamp suggest that this need not mean that the patient become solely responsible. They allow that the patient and physician may share responsibility for the outcome (as I will discuss later). However, this is not to say that the physician and patient have “reasoned together.” Faden and Beauchamp expressly reject the 1982 President’s Commission’s proposal that the physician and patient can

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371 Ibid., 277.
372 Ibid., 238, B&C 104.
373 F&B 278.
374 Ibid., 280.
share decision-making. Rather, they write that “it is the essence of informed consent in sense\textsubscript{1} only that the patient or subject authorizes autonomously; it is a matter of indifference where or how the proposal being authorized originates.” While the patient’s decision may arise out of conversation and dialogue with the physician, Faden and Beauchamp argue that this does not affect the determination of whether or not the decision is an autonomous authorization.

Although Faden and Beauchamp profess in A History and Theory of Informed Consent that their conceptual analysis of informed consent as autonomous authorization makes no normative claims, it is clear from Principles of Biomedical Ethics that this is also a normative theory. Faden and Beauchamp imply that autonomy ought to be respected via informed consent as autonomous authorization (indeed, they state that informed consent in sense\textsubscript{1} – an autonomous authorization – should serve as the evaluative standard for sense\textsubscript{2} – specific policies and institutional rules). According to Beauchamp and Childress, respect for autonomy entails both positive and negative obligations: a positive obligation to provide “respectful treatment in disclosing information and actions that foster autonomous decision making” and a negative obligation not to subject autonomous actions [or better: actions intended to be autonomous] to controlling constraints. Autonomous authorization is the practical manifestation of the normative requirement to respect autonomy. When pressed as to the

\begin{itemize}
\item[375] President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.
\item[376] F&B 279.
\item[377] F&B 286-287.
\item[378] B&C 107.
\end{itemize}
normative grounding of respect for autonomy, Beauchamp and Childress turn to “common morality,” a proposal that was criticized in chapter 1.

Others have tied informed consent as autonomous authorization to normative theory more successfully than Beauchamp and Childress. Indeed, this conception of informed consent is usually discussed in the context of normative theory. For example, Berg et al. defend informed consent along both Kantian and Millian lines. Kant defends the right of self-determination and Mill requires the freedom from external constraints. Such normative defenses respect individual autonomy because rational autonomy is thought to be fundamental to a meaningful human life.

In their emphases on rights to autonomy and freedom from coercion, Faden and Beauchamp uphold the conception of responsibility as transferred from physician to patient through the informed consent process. The autonomous authorization theory places responsibility firmly on the patient’s shoulders, unless the patient freely invites the physician into the inner circle of decision-making. While this theory attempts to avoid a legalistic focus on disclosure and responsibility, given the emphasis on a patient’s full understanding and ability to assume responsibility, it does not seem to accomplish this goal. As Faden and Beauchamp write, “In authorizing, one assumes responsibility for what one has authorized and transfers to another one’s authority to implement it.” Thus the autonomous authorization theory conceives of informed consent primarily as a

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379 It is revealing that Berg et al. attempt to ground informed consent as autonomous authorization in normative theory only after explaining its social historical importance in the United States. It seems likely that Berg et al. believe that normative theory will provide a stronger grounding for autonomous decision-making than the need for such autonomy in a given social climate or era.

380 The Belmont Report is the paramount application of this normative requirement.

381 F&B 280.
transfer of authority and responsibility, dependent on full understanding. This echoes American case law’s focus on disclosure, patient understanding, and patient responsibility and overlooks supportive and psychosocial aspects of informed consent.

Within their four principles approach to biomedical ethics, Beauchamp and Childress prioritize respect for autonomy by placing patient freedom at the center of their web of professional obligations. This effectively ensures that providing psychosocial support for shocked, scared, nervous, or lonely patients will be less of a priority than giving them the space in which they can make their own decisions. Proponents of the autonomous authorization theory, concerned with transferring authority and responsibility, overlook psychosocial support in diagnosis disclosure and patient decision-making.

This will be made clearest with an example. Let us say that Claire is a patient of Diane. During routine tests Diane discovers that Claire has early stage ovarian cancer, the most common treatment of which is surgery to remove the affected ovary. Diane does not think it is necessary to remove the other ovary, uterus, and fallopian tubes, although this is sometimes done. However, Diane also knows that Claire’s aunt died of ovarian cancer and that since her aunt’s death Claire has been anxious about whether or not she will also develop the disease. Given the untimely death of the aunt, Diane's delivery of the diagnosis risks putting Claire into a panic or depression. Claire is 25 years old and married with no children. Diane suspects that if she tells Claire that she has discovered ovarian cancer and proposes surgery to remove the ovary alone, Claire will elect to have surgery to remove her other ovary, uterus, and fallopian tubes. This more extensive surgery is not, strictly speaking, unnecessary, but it will make it impossible for Claire and
her husband to have children, something Diane knows that they are planning to begin in a few years. According to the autonomous authorization theory, how ought Diane to proceed?

Following this theory’s logic, the most important element of informed consent is Claire’s autonomous authorization of her chosen treatment. This means that she must make her choice intentionally, with understanding, and without controlling influences. All that is required of Diane is to make sure that Claire has all the information and understands her condition. Diane is not required to discuss Claire’s fears with her and may even be discouraged from doing so, should such a discussion influence Claire’s decision. Even though Diane suspects that Claire may regret the full surgery later, the autonomous authorization theory offers no way for her to broach this topic in the decision-making process. This may be unproblematic if Diane knows that Claire is confident in her decision: Claire wants the full surgery and she and her husband both accept that this decision comes at the price of not having children of their own. Yet let us say that Claire cannot decide. She wants to have children, but knows that she will be anxious if she does not have the full surgery. In this case, Diane is left in a quandary. How ought the decision to be made? It seems that the autonomous authorization theory can neither explain nor assist these more complex cases.

Beauchamp and Childress do acknowledge that autonomously authorizing may be a developed capacity rather than an inherent ability. They propose that respect for autonomy “includes, in some contexts, building up or maintaining others’ capacities for autonomous choice while helping to allay fears and other conditions that destroy or disrupt autonomous action” and “obliges professionals…to foster adequate decision
making” by assisting others in achieving their ends, not merely avoiding treating them solely as means to ends. However, they omit this capacity-based approach from their theoretical conception of informed consent. Their chapter on “Respect for Autonomy” addresses elements of informed consent, including competence, voluntariness, disclosure, recommendation, understanding, decision, and authorization, as well as standards to determine disclosure of information, levels of patient understanding, and forms of influence on the patient, but nowhere do they mention how to build the capacity for autonomous choice.

Claire is competent, she is acting voluntarily, and she has received Diane’s disclosure of her diagnosis and her recommendation for treatment, which she understands. Yet she is stuck at the decision-making stage. In this case, what is “adequate decision-making”? If Diane tries to allay Claire’s fears about her cancer spreading, is she acting as a controlling influence? Is Diane permitted to contact Claire’s husband so that the three of them can discuss the issue together? Without answering these questions, this theoretical account remains incomplete. Although Beauchamp and Childress occasionally touch on decision aids and tools for patient understanding, the autonomous authorization theory does not acknowledge these psychosocial aspects of informed consent.

In the next section, we will see whether adherents of the communicative transaction theory of informed consent better recognize the importance of support for patient decision-making.

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382 B&C 107.
5.1.2 Informed Consent as a Communicative Transaction

The main proponents of the communicative transaction theory are Neil Manson and Onora O’Neill. In *Rethinking Informed Consent*, they define this theory in terms of two general features: (1) a recognition that a communicative transaction involves two parties, both of whom are responsible for the success of their speech acts, and (2) a definition of consent as a situation-specific waiver of normative requirements that would otherwise hold in that situation. These features support their conception of informed consent as a communicative transaction that waives situation-specific normative requirements through successful speech acts.

Like Faden and Beauchamp, Manson and O’Neill begin their definition negatively. They propose that informed consent should be thought of not as disclosure for decision-making on a conduit/container model of information, but rather as a communicative transaction between agents on an agency model of communication. They point out that, according to the former model (features of which are recognizable as the autonomous authorization theory), obtaining informed consent entails ensuring that “the relevant information flows to – is disclosed to – those who have to decide to choose whether to consent.” They indicate a range of assumptions in this model that undermine its claim to support patient autonomy:

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383 O’Neill is also well known for her work analyzing the Kantian approach to autonomy and exploring its implications for informed consent (O’Neill, “Some Limits of Informed Consent,” and O’Neill, *Autonomy and Trust in Bioethics*).
384 M&O 69. In defining informed consent in this way, O’Neill and Manson rely heavily on speech act theory, the main proponent of which was J.L. Austin, in *How to Do Things with Words*.
385 Ibid., 69.
It is assumed that clinicians and researchers will not intend to injure their patients, and that they will not propose interventions that they think useless, unprofessional, too risky or illegal. Rather, they will propose only those interventions that they take to be lawful and professionally acceptable, reasonably likely to benefit…and unlikely to injure. These assumptions tacitly limit the choices patients and research subjects are offered to “approved” options. Reliance on these assumptions is in great tension with the thought that informed consent procedures are fundamental to clinical and research ethics because they ensure respect for individual autonomy.\(^{386}\)

This criticism suggests that autonomous authorization theory overlooks physicians’ contributions to the decision-making process. Indeed, as we saw with Faden and Beauchamp above, “it is a matter of indifference where or how the proposal being authorized originates.”\(^{387}\) Beauchamp and Childress further describe patients’ understanding in terms of acquiring pertinent information, having relevant beliefs about the nature and consequences of their actions, and grasping the central facts.\(^{388}\) The physician’s role is to disclose information based on the reasonable person standard, supplemented by an investigation into the informational needs of the particular patient.\(^{389}\)

Beauchamp and Childress do not address how the physician determines what is reasonable to disclose and how to check whether the patient understands the disclosure. Since physicians’ choices of which treatments to propose and in what terms to describe

\(^{386}\) Ibid., 71.
\(^{387}\) F&B 279.
\(^{388}\) B&C 131-132.
\(^{389}\) Ibid., 127.
them affect the scope of patients’ decision-making, Manson and O’Neill suggest that this contribution cannot be omitted from a theory of consent that aims to be comprehensive.

In contrast to an autonomous authorization, informed consent as a communicative transaction emphasizes “what is said and what is done both by those who request consent and by those who respond by giving or refusing their consent.”\(^{390}\) The foundation for this model of informed consent is the recognition that a consent transaction functions as a waiver:

In consenting we waive certain requirements on others not to treat us in certain ways… or we set aside certain expectations, or license action that would otherwise be ethically or legally unacceptable. Informed consent has a role only where activity is already subject to ethical, legal, or other requirements. We do not have to seek others’ consent to action that we have every right to do, or to meet others’ legitimate expectations.\(^{391}\)

While the details of these ethical, legal, and other requirements are situation-specific, Manson and O’Neill note that there is convergence on a number of areas, including the prohibition of force, fraud, duress, coercion, deception, and manipulation.

Manson and O’Neill’s informed consent is not ethically fundamental (a departure from autonomous authorization theory’s respect for autonomy), but is “a way of justifying action that would otherwise violate important norms, standards, or expectations.”\(^{392}\) In other words, consent is not morally required in every medical situation. Furthermore, because actions and norms differ depending on the expectations

\(^{390}\) M&O 71.
\(^{391}\) M&O 72.
\(^{392}\) Ibid., 75.
involved, Manson and O’Neill doubt that any uniform standard for an informed consent transaction or procedure could be successful. For example, “in complex, risky, unfamiliar cases there may be good reason to seek relatively explicit and relatively specific consent.” In more familiar cases, a relatively implicit and vague consent might suffice. They conclude that

There is no simple way of fixing the scope of consent requirements, beyond noting that consent will always be irrelevant where no important norms would be breached. Equally there is no simple way of fixing the standards for consent procedures: consent procedures must be robust enough to ensure that action that would otherwise breach norms is not performed unless those norms have been waived – and this may demand different standards in different cases.

According to this understanding, informed consent permits an action that is otherwise ethically or legally prohibited. While force or intrusion upon one’s person is not allowed in normal circumstances, an informed consent can make such an action permissible.

To this “patient’s consent as waiver” foundation, Manson and O’Neill add the requirement that the physician’s speech act of informing must count as successful communication. As they note, “intelligibility and relevance are not always enough for successful communication.” Rather, “informed consent transactions incorporate truth claims, so succeed only if they respect the norms for making successful truth claims.”

Mere disclosure is not necessarily communication, because disclosure does not always lead to understanding. Manson and O’Neill write:

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393 Ibid., 82.
394 M&O 83.
395 Ibid., 85.
396 Ibid., 87.
By focusing on disclosure at the expense of a fuller account of requirements for communicative transactions, they... ignore the importance of reciprocal communication and the opportunities it provides to check and challenge, to correct and defend truth-claims... Adequate accuracy is more important than illusory completeness for communicating the truth-claims that are integral to the successive stages of successful informed consent transactions. 397

To this end, physicians cannot simply explain procedures and disclose the risks before obtaining consent – they must confirm their patients’ comprehension.

This model suggests that consent is not composed solely of truth-claims; it also signals a commitment on behalf of those asking for consent to perform the actions described if consent is given. Similarly, those giving consent signal their commitment not to complain about, object to, nor sue in response to the action to which they have consented. To clarify these dimensions of successful speech acts, Manson and O’Neill analyze consents and refusals in terms of three functions: (1) they communicate the consenter’s grasp of the proposed action, (2) they signal a conditional commitment, and (3) they communicate an actual commitment or a lack of commitment. Manson and O’Neill argue that these standards are clearer and more differentiated than respect for individual autonomy or appeals to be maximally explicit or specific. According to their standards for consent and refusal, “communication that complies with these norms supports genuine consent or genuine refusal, without placing too much weight either on the cognitive capacities of patients and research subjects or on their capacities for

397 Ibid., 90.
voluntary action and choice." In short, physicians have an obligation to make themselves understood to their patients, not just to assess their patients’ capacities for understanding their options.

The primary merit of this communicative transaction model is its recognition of the role that physicians’ communicative abilities play in patients’ understanding of their options, which, as we saw in chapter 3, can critically affect patients’ decision-making processes. A secondary benefit is that it more thoroughly incorporates situational specificity into the informed consent paradigm. If patients’ consents as waivers depend on the ethical, legal, and social expectations of the situation, then no one general informed consent requirement is effective in all situations. This would allow different ethical standards to be relevant in cases of cancer, ALS, and dementia.

These are certainly improvements over the autonomous authorization model, which may be too concerned with the logical conditions of consent to be practicable. Nevertheless, even though Manson and O’Neill’s theory differs significantly from the autonomous authorization theory, their communicative transaction theory also mirrors much of the American case law considered in chapter 2. Consent is required only in cases where the action in question would be a battery, were there no consent (or without full disclosure of risks, the action would not have taken place at all, as in negligence). This makes intuitive sense – to give consent is to permit a non-standard action, and thus deserves special consideration.

However, this theory does not adequately consider the psychosocial dimensions of the informed consent process, but rather understands the physician’s informing and the

\[398 \text{M&O 91}\]
patient’s consenting as a rational communicative exchange of speech acts. That the physician may need to comfort the patient should the diagnosis prove alarming and that failure to do so may affect the success of the physician’s speech act is not considered. If we return to the example of Claire and Diane, Diane may successfully disclose Claire’s diagnosis to her, explain her treatment recommendations, and communicate her commitment to undertake Claire’s chosen surgery. Equally, Claire may be ready to consent to the full surgery and to waive Diane’s liability for the risks associated with it, including the inability to have children. Yet if Diane does not discuss Claire’s anxiety about ovarian cancer and her desire to have children, does she not fail to respond adequately to Claire’s needs? The communicative transaction theory offers no help in answering this question.

This is because the communicative transaction theory also assumes that the primary ethical issue in informed consent is the patient’s assumption of liability for disclosed risks associated with the decision to undergo medical treatment. The communicative exchange theory thus sits squarely within the framework of informed consent case law and its vocabulary of disclosure, transaction, and waiver. While such a conception of informed consent may satisfy the legal requirements for patient-professional interaction, it may not fulfill all of the relevant ethical requirements. In the next section, I consider a third alternative, the theory of informed consent as a fiduciary exchange, and I analyze its attempt to incorporate features of interpersonal relationships into the theoretical discussion on informed consent.
5.1.3. Informed Consent as a Fiduciary Exchange

Several authors have suggested that informed consent is best understood in the context of the trusting nature of the physician-patient relationship, as opposed to simply its legalistic informational or contractual aspects. This fiduciary exchange theory has been most clearly advanced by Steven Joffe and Robert Truog, as well as by Nir Eyal, Sissela Bok, and Torbjorn Tannsjo.\(^{399}\) It is characterized by two primary features: (1) a recognition of the physician’s role in helping the patient to reason towards a decision that satisfies the patient’s value perspective, and (2) an emphasis on trust as a social good worth promoting within the physician-patient relationship. Joffe and Truog explicate the first feature, while Bok, Tannsjo, and Eyal explain the second.

Joffe and Truog are partly in keeping with the autonomous authorization theory: they acknowledge the five elements of a valid consent discussed by Faden and Beauchamp above (voluntariness, competency, disclosure, understanding, authorization), folding them into the concept of an autonomous authorization,\(^{400}\) and they reject the shared decision-making model of informed consent put forth by Jay Katz and the President’s Commission.\(^{401}\) What is novel is their use of Emanuel and Emanuel’s distinction of the four conceptual models of the physician-patient relationship (agential/paternalistic, informative, interpretive, adviser/deliberative) to define their

\(^{399}\) Onora O’Neill has also supported this account, which need not necessarily conflict with her communicative exchange theory. However, given that the two theories conceive of the means and goals of informed consent differently, for the purpose of this analysis they are separated.

\(^{400}\) Joffe and Truog, “Consent to Medical Care,” 350. Hereafter J&T. One wonders whether they misunderstood the context in which Faden and Beauchamp referenced these five elements. As explained above, Faden and Beauchamp cite them to highlight their defects, not to incorporate them into their own theory of informed consent.

\(^{401}\) J&T 349.
approach to informed consent theory, which conceives of the means and goals of informed consent practices differently than the autonomous authorization theory.\textsuperscript{402}

Joffe and Truog depart from Faden and Beauchamp in their consideration of “the ways in which the fiduciary character of the physician-patient relationship should influence conceptions of informed consent for medical care.”\textsuperscript{403} They interpret the physician-patient relationship as one in which physicians act as trusted advisers to their patients. According to this picture, the physician must “help the patient make choices that cohere with and advance his individual life plan” – the adviser/deliberative model. This surpasses merely disclosing information to the patient – the informative model – and acting for the patient’s welfare – the agential/paternalistic model (what Beauchamp and Childress would term the paternalistic/beneficent model).\textsuperscript{404} In addition to providing information, physicians must ensure that patients have sufficient understanding to make decisions in line with their values.

Joffe and Truog do not reject the model of the physician as agent for the patient’s welfare. Rather, they suggest that in each physician-patient relationship, the physician’s role will range somewhere on a spectrum from adviser to agent, and that the “specific blend” will be the product of an “ongoing negotiation.”\textsuperscript{405} This negotiation is significant. Whether the physician acts as an agent or adviser depends on where authority for decision-making primarily falls within the particular physician-patient relationship. In the agent model, the physician has authority, whereas in the adviser model, the patient has authority. In any particular relationship the authority will slide between these two ends.

\textsuperscript{402} Emanuel and Emanuel, “Four Models of the Physician-Patient Relationship.”
\textsuperscript{403} J&T 351.
\textsuperscript{404} Ibid., 355.
\textsuperscript{405} J&T 355.
This question of authority is also one of responsibility for decisions. However, allocation of responsibility depends on the object of the decision. Medical choices can be choices about ends or choices about means – choices about desired results, or choices about how to achieve those desired results. To distinguish the two, Joffe and Truog suggest that patients’ values inform decisions about ends, while technical considerations (medical expertise) determine decisions about means. Of course the ends and means will change depending on the disease and the treatment options, so the informed consent process will also vary with the circumstances of the decision and the particular nature of the physician-patient relationship.\textsuperscript{406}

Joffe and Truog elucidate the means/ends distinction of the physician-patient relationship as follows:

1) Patients are always responsible for medical decisions about the ultimate ends or goals of therapy, which necessarily involves weighing of values,

2) Patients are presumptively responsible for decisions about the means to those ends, to the extent that such decisions entail value-laden choices among subsidiary ends, and

3) Physicians may assume presumptive responsibility for those decisions about means that are unlikely to entail value-laden choices between subsidiary ends (for example, decisions between two procedures that do not lead to divergently valued ends).\textsuperscript{407}

Joffe and Truog distinguish this ethical framework, which emphasizes patients’ ends, from the legal mandate to informed consent, which emphasizes discussions about

\textsuperscript{406} Ibid., 359.
\textsuperscript{407} J&T 360.
means. Furthermore, they identify three questions that are answerable within this framework: (1) Is there an objectively determinable normative threshold in the hierarchy of decisions beneath which important ends are no longer at stake, or does this threshold vary from one case to the next? (2) If the threshold varies, who has the ultimate authority to determinate whether or not ends are at stake in a particular decision, and (3) Is explicit agreement always required, or can physicians identify and pursue means on the basis of implicit agreement with patients about ends? Joffe and Truog propose that answers to these questions will be negotiated among the parties involved.

Joffe and Truog’s theory explains how informed consent might be reconceived in terms of fiduciary physician-patient relationships, but does not explain why these relationships should be fiduciary, rather than paternalistic or informative. One possible justification is that trust is a social good. Nir Eyal’s theory of trust in medical relationships clarifies this goal-related aspect of the fiduciary exchange theory.

Eyal describes informed consent as a safeguard for trust in these terms: (1) Social trust in caretakers and medical institutions is necessary so that people seek medical advice, comply with it, and participate in medical research. Therefore, (2) it is usually wrong to jeopardize that trust. (3) Coercion, deception, manipulation and other violations of standard informed consent requirements would seriously jeopardize that trust. Thus, (4) standard informed consent requirements are justified.

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408 Ibid., 370.
409 Ibid., 361.
410 Eyal’s argument considers both arguments for and against this theory. As the primary interest here is in the ability of this theory to accommodate the factors introduced in chapters 3 and 4, his criticisms will not be dealt with explicitly.
In accounting for the “trust-promotion argument for informed consent” in these terms, Eyal builds on previous work by Torbjorn Tannsjo and Sissela Bok. Eyal notes that the trust-promotion argument is utilitarian; it considers trust as a social good worth promoting for population health, greater satisfaction, more successful treatment and research, and so on.\(^{412}\) Tannsjo’s argument is simpler than its characterization by Eyal. For Tannsjo, trust is an essential feature of the medical system because, if patients cannot trust that they will be treated as they want to be treated, they will not seek medical help for their ailments and the medical system will fall apart.\(^{413}\) Trust in the medical system is not inherently good, but it is necessary for systemic stability.

Eyal, Tannsjo, and Bok’s formulations of the “trust-promotion argument for informed consent” differ from that of Joffe and Truog, but are similar in their focus on trust as a relational quality of the physician-patient relationship that affects the informed consent process. For Joffe and Truog, physicians can act as potential advisers who help patients live in accord with their values. For Eyal, Tannsjo, and Bok, physicians’ behavior is essential for the maintenance of the medical system.

While the former Joffe-Truog formulation takes trust to be inherently desirable and the latter understands it as instrumentally so, both versions of the fiduciary exchange theory recognize that patients’ feelings about their physicians affect their attitudes towards physicians’ explanations and recommendations, and subsequently affect their decision-making processes. This is a substantial advance from the case law derived treatments of informed consent by the previous two theories. According to this theory, informed consent is based on trust, not because the patient has authorized the physician to

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\(^{412}\) Ibid., 438.

\(^{413}\) Tannsjo, “Utilitarianism and Informed Consent,” 445.
perform an act that otherwise ought not to be done, but because the physician advises the patient about how best to obtain his or her desired ends. To achieve these ends, the physician must take the patient’s ends seriously and the patient must trust that the physician will do so.

This acknowledgment that the physician-related aspects of patients’ psychosocial conditions can affect the decision-making process is an improvement over the previous two theories. However, there are a variety of psychosocial factors that will not be addressed by discussing patients’ values with them, including shock or relief at their diagnoses, hopes or fears for their futures, and desires to appease or rebel against their loved ones, as well as physicians’ anxiety or confidence in breaking bad news, hesitancy or readiness in communicating risks, and empathy with or distance from patients’ personal situations.

In addition, the trusting relationship between physicians and patients is not primarily established through physicians assisting in patients’ rational deliberations about their options. Rather, physicians’ abilities to comfort anxious or distraught patients surely contribute to patients’ attitudes towards physicians’ recommendations and affect their decision-making processes. Returning to the case of Claire and Diane once more, the fiduciary exchange theory would suggest that Diane have a discussion with Claire about her values and what type of life she would like to lead. Let us say that Diane initiates such a discussion, and it becomes clear that Claire would like to have children. Diane thus recommends holding off on the full surgery and having just one ovary removed. She emphasizes that Claire can always elect to have the full surgery later. This seems like the best option given Claire’s life goals, and Diane feels confident that she is fulfilling her
fiduciary obligation to Claire. But what of Claire’s anxiety? Will her fear of developing cancer in her uterus or her other ovary affect her everyday life? Claire may feel confident in Diane’s recommendation that the best way to achieve her goal of having children is to have the conservative surgery. She may further trust that Diane is taking her ends seriously. Yet if Diane does not also understand and respond to Claire’s fear about developing cancer, will Claire not feel that Diane has failed her in some way? Claire may indeed find that she is disappointed in Diane, leading her to seek out a different doctor. It is possible that this other physician will listen to and empathize with Claire’s situation, in addition to helping her to deliberate about how to live in accordance with her values. It is equally possible that Claire, unable to find a suitable physician, will choose one out of desperation and be worse off than if Diane had fully responded to Claire’s needs at the outset. While Claire’s search for another physician need not necessarily be problematic, it does signal an insufficiency in Diane’s approach that has the potential to waste physician time and cause additional stress to the patient.

For a theory to be comprehensive, it must acknowledge these non-deliberative, psychosocial aspects of the physician-patient relationship. The fiduciary exchange theory comes close to satisfying this requirement but in conceiving of trust as a feature of relationships accomplished by rational deliberation rather than empathetic understanding and emotional support, it also fails as a comprehensive theory of informed consent.

This section analyzed three dominant theories of informed consent, finding that none provide a satisfactory account of psychosocial support. The next section argues that the concept of responsibility used by these theories precludes recognition of the psychosocial elements of informed consent. I propose that a different model of
responsibility more comprehensively addresses the ethical dimensions of informed consent practices.

5.2 Responsibility and Theories of Informed Consent

Many analysts of informed consent have taken patient autonomy to be the most significant concept underlying the ethics of informed consent. Critics of contemporary theories and practices of informed consent have thus typically targeted autonomy, suggesting either that it does not provide a sound theoretical foundation for informed consent, or that it is a goal that current practices of informed consent cannot realize.

Whether for or against, the discourse on informed consent has concentrated on autonomy. I would like to suggest that this concentration is mistaken, and that in fact autonomy is not the crux of informed consent. While it is true that patient autonomy is valuable and that contemporary informed consent practices were substantially influenced by arguments for increasing patients’ self-determination and giving them authority over personal decisions, responsibility seems to be the more substantive ethical concept in theories of informed consent. Indeed, only one of the theories considered above (the autonomous authorization theory) makes respect for patient autonomy the explicit goal of informed consent. The other two, communication theory and fiduciary exchange theory, conceive of informed consent as waiving otherwise relevant normative requirements and promoting trust as a systemic social good. Yet all three theories maintain that patients

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have primary responsibility for their treatment-related decisions. This is the common foundation of the dominant informed consent theories.

For the autonomous authorization theory, informed consent is required because it reflects the physician’s respect for the patient’s autonomy. Autonomy entails that the patient assumes responsibility for medical decisions. While proponents of the theory allow for shared responsibility of the outcome of treatment between physician and patient, ostensibly because the physician maintains responsibility for professionally administering the chosen treatment while the patient makes the choice of treatment, they do not allow that the decision to undertake a given treatment can be shared. Rather, to authorize autonomously is to be solely responsible for one’s decision to proceed. Thus, this theory appears to be based on respect for patients’ autonomy but is really premised on patients’ responsibility for their own decisions.

Importantly, to be autonomous and to be responsible are not necessarily the same thing. Making a patient responsible for her decisions is very different from that patient taking responsibility for her decisions – a patient can be made responsible for a decision she is not ready to take responsibility for, as shown by some of the narratives described in chapter 3. The former does not entail autonomy; the latter does. On the one hand, we have a systemic assignment of responsibility in the manner of liability, and on the other, a personal acceptance of responsibility akin to ownership. In conflating these two notions of responsibility, the autonomous authorization theory fails to engage with ownership responsibility — which would be related to autonomy — and argues in favor of liability responsibility instead. For example, in the case of Claire and Diane, the medical and legal

\[415\] For another formulation of this point, see Oshana, “The Misguided Marriage of Responsibility and Autonomy.”
systems may require that Claire be assigned sole responsibility for her decisions, despite her anxiety preventing her from taking responsibility for these decisions. Claire is liable for her decisions, but she cannot take ownership of them.

The other two theories, informed consent as a communicative transaction and as a fiduciary exchange, incorporate physicians’ perspectives, but maintain the individualistic liability approach to responsibility. In the communicative transaction approach, the physician and the patient are independently responsible for ensuring the success of their respective speech acts – the physician’s informing, on the one hand, and the patient’s consenting, on the other. This approach expands recognition of responsibility only by doubling individual responsibility to include both physician and patient responsibility. Informed consent is conceived as a transaction in which both sides are responsible for the success of their contributions, but hold no joint responsibility.

The theory of informed consent as a fiduciary exchange balances the other two theories. According to this theory, patients maintain ultimate responsibility for their ends-related decisions. Physicians aid this process by acting as trusted advisers in patients’ deliberations and occasionally by assuming responsibility for means-only decisions. This theory recognizes physicians’ responsibility for the technical aspects of medical treatment and patients’ responsibility for the personal dimensions of treatment decisions, while attempting to incorporate a role for physicians to play in patients’ deliberations about their ends and values. Despite this focus on physicians’ supportive roles in deliberation, the theory nevertheless presupposes that responsibility is split between the physician as an adviser and the patient as the ultimate decider.
These three theories’ notions of responsibility share two general features: (1) responsibility is for the outcome of decision-making processes – that is, the final decision, and (2) responsibility is individual and independent – no two agents can share responsibility for a single decision, although both may contribute to the deliberation process. Reexamining the function of responsibility in these theories will reveal why it precludes recognition of patient support. This will allow for an exploration of alternative approaches that better capture the complex ethical considerations in informed consent and patient decision-making.

In the following analysis, I demonstrate that these assumed features of responsibility are historically conditioned by American case law, leading to what I term the individual-outcome model of responsibility. I explain why this model has difficulty recognizing the significance of psychosocial aspects of medical decision-making. I then suggest that the relation-process model is a better model for responsibility in informed consent that can account for the ethical significance of psychosocial support in decision-making processes. This model of responsibility underlies the Japanese legal standard for informed consent as well as many Japanese professionals’ intuitions about how informed consent ought to be practiced. This observation will contribute to my analysis of the ethical justification of Japanese informed consent practices in chapter 6.

These features have been described by Elise Springer (in the context of speech act theory, which the communicative transaction theory of informed consent is a variety of) as the two axioms of temporal closure and agent-closure. My criticism here is in sympathy with her approach. As Springer rightly notes, limiting consideration to acts that fit these two axioms may lead to a coherent theory, but not a comprehensive one (Springer, Communicating Moral Concern, 101).
5.2.1 Case Law and the Individual-Outcome Model of Responsibility

This dissertation is not the first work to recognize that informed consent theories rely heavily on American case law.\footnote{417} Indeed, no philosophical treatment of informed consent would be complete without acknowledging a number of legal decisions. However, while previous analyses of informed consent have focused on these cases’ concepts of self-determination, autonomy, and paternalism,\footnote{418} here I concentrate on their concept of responsibility.\footnote{419}

Responsibility in American informed consent case law takes the form of liability.\footnote{420} This function is clearest in the early tension between the negligence and battery standards. As discussed in chapter 2, a battery case depends on injury caused by bodily infringement without patient consent, while a negligence case depends on whether an undisclosed risk that would have been material to the patient’s decision led to injury. In a battery case, consent signals one’s decision to allow a physician to perform an action

\footnote{417}{For example, see Katz, The Silent World of Doctor and Patient, Faden and Beauchamp, A History and Theory of Informed Consent, and Schneider, The Practice of Autonomy.}
\footnote{418}{For example, see Schneider, The Practice of Autonomy, Gaylin and Jennings, The Perversion of Autonomy, and Traphagan, Rethinking Autonomy.}
\footnote{419}{Nor am I the first to focus on responsibility in the context of informed consent. Joel Feinberg and Alfred I. Tauber have written extensively on law, medicine, and responsibility. However, my analysis importantly differs from theirs in that Feinberg focuses on concepts of responsibility in relation to their legal use, while Tauber conceives of responsibility as a professional ethical principle similar to beneficence. Here, I am concerned with how legal conceptions of responsibility preclude a full appreciation of different ethical conceptions of responsibility.}
\footnote{420}{Joel Feinberg has distinguished between five meanings of the phrase “ascription of responsibility”: straightforward ascriptions of causality, such as “the low pressure system caused the storm”; ascriptions of causal agency, such as “Peter opened the door and startled Paul”; ascriptions of simple agency, such as “I moved my finger”; imputations of fault, such as “He is to blame”; and ascriptions of liability, such as “I’ll take responsibility for that” (Feinberg, Doing and Deserving, 136). The legal notion of liability I discuss here combines aspects of the final two meanings of responsibility: to find one at fault and to find one liable.}
that otherwise could be considered a wrong. Such consent is premised on the hope that the bodily infringement will be in the interest of the patient’s health, as in the case of a medically necessary surgical procedure like an appendectomy. In these circumstances, the physician maintains responsibility for the outcome of the procedure. The physician is liable if there are medical mistakes, but not for the normal effects of a procedure successfully carried out. In a negligence case, consent signals that one understands the possibility of a bad outcome and accepts responsibility, should such an outcome materialize. Here consent relates not just to normal effects of relatively safe procedures, but also to the risks of non-routine procedures. For these non-routine procedures, the negligence standard recognizes that the possibility of harm over and above the simple act of bodily infringement requires the patient’s understanding of those risks. In this context, the patient’s responsibility for the treatment decision effectively waives the physician’s liability for non-negligent harm.

In chapter 2, I suggested that, while the movement towards the negligence standard in Natanson v. Kline (1960) and the subsequent development of this standard in Canterbury v. Spence (1972) was ostensibly in favor of patient self-determination, this is not achieved in practice. This negligence standard emphasizes patients’ rights and responsibilities to make their own treatment decisions. While the battery standard focuses on patients’ rights to consent to physicians’ proposed treatments, the negligence standard emphasizes responsibility over mere consent.

The negligence standard moves away from the physician’s responsibility for the outcome of a procedure and towards the patient’s responsibility, on the premise that the patient understands the risks and decides of his or her own volition. Responsibility here is
responsibility for a decision, and the emphasis on the patient’s right to free self-
determination signals that the physician participates in the decision-making process only
by explaining treatment options and their respective risks and merits. As stated in the
decision of *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957):

> A physician violates his duty to his patient and subjects himself to liability if he
> withholds any facts which are necessary to form the basis of an intelligent consent
> by the patient to the proposed treatment.\(^{421}\)

Likewise, we find in *Cobbs v. Grant* (1972):

> A medical doctor, being the expert, appreciates the risks inherent in the procedure
> he is prescribing, the risks of a decision not to undergo the treatment, and the
> probability of a successful outcome of the treatment…The weighing of these
> risks against the individual subjective fears and hopes of the patient is not an
> expert skill. Such evaluation and decision is a nonmedical judgment reserved to
> the patient alone.\(^{422}\)

Both of these cases establish that the patient is solely responsible for the final decision of
which treatment to pursue. If the physician withholds information or weighs the risks and
merits himself, he “subjects himself to liability.” The physician’s responsibility is to
provide information so that the patient can fulfill his or her responsibility to make a
decision. The crux of American informed consent is this balance of the physician’s
responsibility to provide information with the patient’s responsibility to consider the

\(^{421}\) *Salgo v. Leland Stanford Jr. University Board of Trustees*, 154 Cal. App. 2d 560, 213
P.2d 170 (1957).

options and make a final decision. The patient’s responsibility for accepting risks waives the physician’s liability for injuries that may occur within those risks.

Informed consent in American case law understands responsibility as individual – belonging to the patient or physician alone – and discrete – a medical judgment about potential treatments or a non-medical judgment to undergo such treatment or not. This understanding is based on the individual-outcome model of responsibility. Adoption of this model is directly responsible for the failure to address support in theoretical discussions of the ethics of informed consent, as I argue below.

5.2.2 The Individual-Outcome Model of Responsibility and Psychosocial Support

First, if responsibility is for the outcome of decision-making, psychosocial support for that decision-making process becomes a liability. As shown in the Cobbs v. Grant decision, the weighing of “individual subjective hopes and fears” is a task reserved for the patient alone. When this model of responsibility grounds informed consent, physicians have little reason to assist patients in the consideration of these hopes and fears and may even have strong incentives to refrain from becoming involved, should such involvement impinge on patients’ freedom.

Second, attributing responsibility solely to individuals creates a dichotomy between individual self-determination and other-determination, like the autonomy versus paternalism divide so often discussed in the context of American informed consent theory and case law. If only the physician or the patient alone is responsible for a decision or a choice, then either the patient decides autonomously or the physician decides paternalistically. As Gerald Dworkin writes,
Any sensible view has to distinguish between good done to agents at their request or with their consent, and good thrust upon them against their will. So the normative options seem to be just two. Either we are never permitted to aim at doing good for others against their wishes, and in ways which limit their liberty, or we are permitted to do so.\textsuperscript{423}

This either-or results from the focus on individual freedom as the locus of ethical value. If interfering with individual freedom is justifiable or not, then paternalism is either justifiable or it is not. However, to better assess various types of decision-making, we need to distinguish a lack of full autonomy from a definitive judgment of paternalism. In other words, interpersonal relationships are complex and cannot be divided exclusively into cases where an individual decides for himself and cases where someone else decides in his place: there are gray areas between the two. We cannot assume that if an individual is not expressly making his own decisions, then someone else is deciding for him against his will. Likewise, we cannot assume that if someone is influencing another’s decision-making process, then this is necessarily a paternalistic action. Such a false dichotomy overlooks cases where one person assists another person’s decision-making without imposing their judgment on the other person and depriving them of freedom. Lack of full self-expression at the moment of decision-making does not necessarily imply paternalism; responsibility for decision-making can be shared. Not all influence is paternalistic, nor is all autonomy individual.

\textsuperscript{423} Dworkin, “Paternalism.”
This shared responsibility need not be described in terms of the adviser/decider or means/ends dichotomies suggested by the dominant informed consent theories. Another model for responsibility, the relation-process model, enables a more comprehensive theory of informed consent. While not often invoked in bioethical discourse, it remedies the deficits of the dominant informed consent theories and makes sense of the Japanese legal standards and practices of informed consent.

5.2.3 The Relation-Process Model of Responsibility

The relation-process model of responsibility holds that one is responsible not just for the content of one’s choices – that is, for one’s decisions to “do the right thing,” but also for the manner in which one acts – that is, for “getting involved in the right way.” Admittedly, this is a more amorphous model for responsibility than the legalistic individual-outcome model, but it is one that is truer to our everyday experiences and our intuitions about what is needed in informed consent practices.

First, this model of responsibility understands ethical requirements as diachronic – evolving over time. In contrast to the synchronic individual-outcome model, where one acts ethically if one discharges responsibility upon acting, the relation-process model

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424 In the past 10-15 years, shared decision-making has become popular in bioethics, despite being rejected by all but the fiduciary exchange theory of informed consent. According to this theory, “decision-making is a complex process that takes place over time and can involve many individuals rather than an event that takes place at a fixed point in time and is restricted to the physician-patient dyad” (Charles, “Decision-Making in the Physician-Patient Encounter,” 660). The relation-process approach to responsibility I describe resembles the shared decision-making theory, with one important difference: the shared decision-making theory considers decision-making to be primarily a rational process, whereas I work to incorporate the emotional and psychosocial aspects of decision-making. Nevertheless, future research could explore the possibility of incorporating these aspects into the shared decision-making theory (for example, see Olthuis, “Why Shared Decision Making is Not Good Enough”).
ethically requires an ongoing commitment to take into account and care for others.
Second, by locating ethical responsibility in processes rather than actions as discrete
events, this model captures commonsense understandings of professional responsibility to
respond to vulnerable patients’ needs.\footnote{Hilde Lindemann and James Nelson have conducted an extensive study of how these
two areas of responsibilities (medical professional and parental) overlap (Lindemann Nelson and Lindemann Nelson, \textit{The Patient in the Family}).}

In the context of informed consent theory, this model suggests that medical
professionals cannot discharge their responsibilities to patients simply by explaining
treatment options. Rather, in their professional relationships, they continue to be
responsible for responding to patients’ psychosocial needs, especially those that are
unique to the process of medical diagnosis and treatment, such as grief, fear, hope, and
shock. In addition, responsibility for whether or not the informed consent process goes
well is not located in professionals or in patients independently, but is shared between
them. Just as the professional is responsible for responding to the patient’s hopes and
fears, so is the patient responsible for making these hopes and fears known, and for
working with the professional towards a more bearable situation.\footnote{This shared form of responsibility is significant in communication studies (Arnett, Harden Fritz, and Bell, “Interpersonal Communication Ethics”).}

This model for responsibility differs significantly from that of the dominant
theories of informed consent considered in this chapter. In contrast to the focus on
responsibility as individual and outcome-based, it emphasizes the interpersonal and
ongoing nature of the medical decision-making process. Interestingly, it also makes sense
of certain intuitive aspects of medical professional codes of ethics, such as the AMA’s
guideline VIII, which states, “A physician shall, while caring for a patient, regard
responsibility to the patient as paramount.” This statement acknowledges the physician’s ethical responsibility to the patient as a person with complex needs and interests, few of which are informational. I explain this aspect of the relation-process model for responsibility in more detail in chapter 6, which demonstrates how this model clarifies Japan’s legal standards and practices of informed consent.

5.3 Conclusion

This chapter has shown that the three dominant theories of informed consent – the autonomous authorization theory, the communicative transaction theory, and the fiduciary exchange theory – all fail to recognize the ethical significance of psychosocial support due to their use of the individual-outcome model of responsibility, which springs directly from American case law. Reformulating responsibility in informed consent in terms of the relation-process model results in a more comprehensive theory that supports concrete recommendations.

The next chapter examines possibilities for rethinking informed consent in light of this new model for responsibility. Indeed, this model is implied by Japanese theories of informed consent and Japan’s legal standards for informed consent and is also reflected in Japanese medical professionals’ concerns about their responsibilities towards their patients. I use this model to propose changes to the Japanese practice of informed consent that will bring it in line with the theoretical approach underlying its own standards. Finally, I suggest that this analysis of Japanese informed consent has implications for how informed consent is theorized and practiced in the United States as well.

427 AMA, Principles of Medical Ethics.
Chapter 6: Japanese Informed Consent: Clarification and Justification

“Among Japanese people, the thinking about physicians and medicine is very diverse, so one rule, something like a golden rule or decided by a golden procedure, something where if it is done everyone will be happy, this kind of guideline that is done at every hospital and makes everyone happy, maybe there aren’t any rules like this. Informed consent is more of a personal event, so, while there are parts that are determined by guidelines, these parts are not so great.”

--Interview with a Clinical Psychologist in Japan, 2014

“In the 1990s, the opinion that you ought to tell [a cancer diagnosis] was mixed with the opinion that you ought not to tell. For people who thought you ought not to tell, it was quite aesthetic (美学 bigaku). The patient noticed that nobody was telling them but that they really had cancer. So the family and the nurses, everyone was lying to them, and the patient noticed, but they wouldn’t say it. If they said it, they would have to talk about how hard everyone was working for the patient, how difficult it was, it would be noisy, it would be difficult, and to know this without saying it is a happy situation (幸せ shiawase). So for people who weren’t told, they probably noticed the truth, but then they could have a stronger trusting relationship, and while it’s strange to say that to tell a lie is basis for trust, it showed that everyone was thinking a lot about the patient, and they wouldn’t mention the patient’s diagnosis; they would use a different expression.”

--Interview with a Japanese Physician, 2014

Introduction

The previous chapter suggested that reliance on the individual-outcome model of responsibility causes dominant theories of informed consent to fail to recognize the significance of psychosocial support for informed consent and the medical decision-making process. Instead, I proposed that responsibility be conceptualized with a relation-process model, according to which responsibility is not liability or legal responsibility for the outcome of a decision by an individual, but is shared responsibility for whether or not a decision-making process goes well.

In this chapter, I analyze how the relation-process model of responsibility contributes to informed consent theories, legal standards, and practices in Japan. I show that while this relation-process model is often used in Japan, it is not clearly distinguished
from the individual-outcome model in medical decision-making processes, resulting in a lack of clarity about the means and goals of informed consent. I argue that because of this confusion over means and goals, many Japanese informed consent practices are currently not justified. I suggest not that the individual-outcome model should be replaced by the relation-process model, but that together they can contribute to a more comprehensive theory of informed consent. I then propose revisions to the Japanese practice of informed consent so as to reflect the significance of relation-process responsibility and to respond to the psychosocial needs of patients and caregivers. Finally, I suggest that these revisions do not apply to Japan alone; they are also needed in American practices of informed consent.

6.1 Relation-Process Responsibility in Japan

6.1.1 Responsibility in Japanese Theories of Informed Consent

Many theories of informed consent in Japan are similar to the dominant Western theories considered in chapter 5. I have already briefly touched on this in chapter 1, where I introduced Akira Akabayashi’s family-facilitated model of informed consent. Akabayashi’s approach to informed consent shares the defining feature of the autonomous authorization theory: informed consent is normatively required because it minimizes physician paternalism and respects patient preferences – in other words, it

ensures respect for autonomy. As Akabayashi writes, “the concept of autonomy…underlies the ideal practice of informed consent.”

In chapter 5, I argued that autonomy is not the best conceptual tool by which to analyze theories of informed consent. Instead, I proposed that responsibility is more salient and that a relation-process model of responsibility better accounts for Japanese informed consent practices than an individual-outcome based model. This section expands the discussion and considers other theoretical treatments of informed consent in Japanese academic discourse. These theories develop informed consent theory beyond the dominant approaches outlined in chapter 5, utilizing the relation-process model of responsibility. In doing so, they suggest how psychosocial factors and patient support might be incorporated into a more comprehensive theory of informed consent. While the creation of a new comprehensive theory of informed consent is beyond the scope of this chapter, this analysis will clarify how the relation-process model of responsibility functions in Japanese theories of informed consent, supplementing but not completely replacing the dominant approaches evaluated in chapter 5. This clarification will then indicate revisions to informed consent discourses and practices in Japan and the U.S.

6.1.1.1 Informed Consent as a Two-Stage Process

The Japanese Bioethics Series (Shiri-zu Seimei Rinrigaku シリーズ生命倫理学) is one of the most prominent publications on bioethics in Japan. According to the editors, “This series shows the current point reached by Japanese bioethics…Specifically, it compiles results of the most cutting-edge research on various important bioethical

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themes, and is the first such project in Japan. Informed consent is dealt with in the volume *The Basic Composition of Bioethics (Seimei Rinrigaku no Kihon Kōzu 生命倫理学の基本構図)*, which presents the standard approach to informed consent – including American case law, respect for autonomy, and so on – before offering a novel theoretical interpretation.

In the discussion of informed consent in chapter 11, “The Physician-Patient Relationship,” Nagaoka Shigeo acknowledges that medical professionals’ obligations to disclose information to patients in the appropriate/proper (*datōna*) manner and to respect patients’ self-determination have been widely accepted, but suggests that focusing on these obligations alone has both practical and theoretical problems. Practically, he observes that physicians’ explanations are difficult to understand and that patients’ expectations of what treatment will be like (e.g., painfulness and effect on daily life) can affect their decision-making. Theoretically, he admits that the theory of self-determination, which suggests that patients make decisions based on their personal values and their normal ways of thinking in their everyday lives, might not capture how patients approach a devastating illness or a difficult treatment decision.

Three examples illustrate these issues: a 2005 *New York Times* article about the burden of patient decision-making and two Japanese cancer patients’ narratives. The *New York Times* article, cited in chapter 3 of this dissertation, describes a number of cases that demonstrate the difficulty of decision-making in modern medicine. The original article highlights the increasing burden on patients to navigate the medical system, obtain...

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430 Japanese Bioethics Series Editorial Committee, “Preface.”
431 Each chapter of this volume has a different author.
information, and make their own decisions, but Nagaoka interprets the significance of the article somewhat differently. He focuses on the narrative of Meg Gaines, who had difficulty deciding whether to pursue chemotherapy or cryosurgery for her cancer treatment. She understood the benefits and risks of each option, she recognized that the decision was hers alone, and she received recommendations from physicians for either chemotherapy or cryosurgery. The choice was hers, but her final decision did not directly result from any of these factors. Rather, recalling her family’s experience in World War II, she chose both options: to “bring in the air force and bomb the hell out of the tumors and weaken them, then go in with the infantry.”

According to Nagaoka, this story shows that modern medical decisions are ultimately a gamble or a bet; the final decision depends on which wager feels best. The other two narratives support this interpretation. In the first, a physician with ample experience treating cancer patients observes that even very intelligent patients (interi dansei, “intellectual men”) become weak or indecisive (the Japanese word, moroi 脆い, suggests fragility or tenderness) in the face of medical decisions. Due to this situational vulnerability, these types of patients use rationalization as an emotional support, a crutch.

In the second narrative, a physician-turned-patient (Yanagihara Kazuko) consults with former patients and specialists about whether or not to pursue chemotherapy. She cannot decide; while she thinks she needs the treatment, she can neither forget criticisms

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433 Hoffman, “Awash in Information, Patients Face a Lonely, Uncertain Road.”
435 This narrative is from Nakashima Michi’s record of her cancer treatment experience, “Gan to Tataku, Gan kara Manabu, Gan to Ikiru [Fighting Cancer, Learning from Cancer, Living with Cancer].”
436 This narrative is taken from Yanagihara’s three-volume record of her experiences as a cancer patient, titled “Gan Kanjiya Gaku I, II, III [Cancer Patient Studies I, II, and III].”
of the treatment nor the agony of her own friends. What ultimately prompts her decision is the observation of a physician friend: “medicine also proceeds in its own way.” In other words, no treatment is certain. A high success rate does not guarantee success in any particular case. The only thing transcending statistics, data, and numbers is sympathy and a feeling of fellowship. She realizes that because her treatment will proceed in its own way, she should not decide based on success rate, but based on the care (shinmi 親身) with which the physician in charge will consider her (hairyo 配慮).

Drawing on these examples, Nagaoka proposes that there are two stages of informed consent, divided by a crucial point. First, there is the information management stage, when patients must speak with physicians and assemble information independently. Ultimately, however, when patients make a decision, they are gambling on a given path for which there is no certainty of success. After making a decision, patients enter the second stage of hope or prayer (inori 祈り), when they are no longer acquiring information, but are hoping that their chosen treatments will be successful.

Nagaoka distinguishes this two-stage theory from the one-stage standard for informed consent. The one-stage theoretical standard is the commonly cited set of requirements that, in order for patients to make an autonomous decision in the informed consent process, they must understand the information provided, relate it to their own values, and make a decision. At this stage, patients need as much information as possible about their choices, including merits and demerits. According to the two-stage theory, the second stage begins after a decision has been made. After this point, patients do not want to think about the demerits of the option that they selected and the merits of the options that they did not; they need reassurance, not critical analysis. Because patients’ thinking
changes so significantly once a decision has been made, Nagaoka argues that informed consent processes and patient decision-making must be understood in terms of these two stages.

Nagaoka identifies further differences in how the one-stage theory and the two-stage theory approach four aspects of informed consent: the value of information, the *omakase* system (in which decisions are entrusted to an expert), the establishment of patient-physician trust, and the flow of informed consent procedures.\(^{437}\) On the first point, the standard theory suggests that more information is always better. However, for patients who have made their decisions, it is better not to think about unchosen options and possibilities; they want faith or hope that things will go well. So according to the two-stage theory, patients need more information on the first stage but less on the second.

The second point deals with approaches to patients who want to entrust decisions to their physicians (patients who prefer *omakase*).\(^{438}\) The standard informed consent theory requires full involvement from physicians and patients: physicians must explain the situation well, and patients must endeavor to understand. In this one-stage theory, patients who choose not to choose are not ideal; they shirk their responsibilities. However, in the two-stage theory, Nagaoka suggests that if the decision is just a gamble, and if the only difference is how much information patients in the decision-making process have, then it is up to patients themselves to go about the decision-making process how they want to and to determine what will help them to cope as they move forward. Whether or not patients acquire a large amount of information before making a decision, the success

\(^{437}\) Nagaoka, “*Kanjiya-Iryōsha Kankei,*” 196.
\(^{438}\) Ibid., 196-197.
of treatment is a matter of chance, so there is no ethical difference between patients who leave this decision to their physicians and those who make it themselves.

The third point is trust between physician and patient.\(^{439}\) The standard one-stage theory treats trust as the basis for a good physician-patient relationship; once established, it suffuses the relationship. The two-stage theory suggests that trust is situational; trust matters most when patients cannot make decisions alone. In these cases, trust is based on patients’ feelings that even if they were to die, their physicians would have done everything possible. Nagaoka suggests that this “trust” cannot be fundamental to a relationship and be transported from case to case. Trust depends on how physicians deal with patients in specific cases. In essence, trust-building begins with each new diagnosis.

The fourth point is the procedural structure of informed consent. The one-stage theory takes informed consent as a movement from disclosure, to understanding, to a decision.\(^{440}\) The success of informed consent is measured by the degree of patient understanding leading up to, and at the time of, a decision. However, the two-stage theory suggests that patients’ understanding and feelings change post-decision, during treatment, and post-treatment, and that these changes are also significant to the success of the informed consent process.

This two-stage theory is unique, concerned less with abstract interactions between theoretical patients and more with how patients change over time and what this means for patients’ and physicians’ roles in the decision-making process. Informed consent is a process that takes place in time, not a requirement that can be satisfied instantaneously by a consent form or a verbal agreement. Moreover, it is not strictly a rational process. It


\(^{440}\) Ibid., 198.
should come as no surprise that irrationality and affect are common reactions to serious illnesses. Rather than trying to explain these responses away, this theory anticipates them so as to respond to actual patients’ complex needs. The goal of informed consent in this theory is different from the dominant Western theories. Informed consent is not just an issue of patient autonomy, communicative transparency, nor maintenance of trust; it is a process that can go either well or poorly, and whether or not it goes well depends on how the physician and the patient enact their relationship at each point in time.

Importantly, this theory incorporates both the traditional individual-outcome model and the relation-process model of responsibility. While it recognizes that informed consent is ultimately a process that occurs in the context of professional-patient relationships, it also preserves the singular informed consent event that serves as the fulcrum between the two distinct levels of the process. In this sense, the two-stage theory does not throw out previous understandings of informed consent, but supplements them with relational and processual considerations.

This recognition of informed consent as a complex practice that depends on shifting places, times, and agents is better able to account for psychosocial factors in informed consent and medical decision-making. It acknowledges that there might not always be a right decision, but that there may be a way of making decisions that allows patients to cope with their diagnoses, endure treatment, and maintain their values.

However, this theory has a number of problems. First is the lack of definitive evidence for the descriptive claims about patients’ decision-making. Some studies have suggested that while increasing the information provided to patients throughout treatment does not improve the decision-making process, emotional and social support does
facilitate decision-making and increase patient and family satisfaction. Nevertheless, research on patients’ mental states pre- and post-decision has not yielded solid conclusions about when patients need information, when they need support, and what kind of support different patients need. Of course, this is part of Nagaoka’s point – the dominance of the one-stage theory has resulted in a lack of research on the temporal and situational context of informed consent. Nevertheless, without such research this theory remains speculative.

Second, this theory is primarily descriptive. It explains why psychosocial factors are relevant to informed consent practices, but not whether considering psychosocial factors is ethically required. A merit of the dominant Western moral theories is that they explain why informed consent must be theorized in their terms: because autonomy must be respected, or because the medical system must be secure. Can attending to patients’ and physicians’ psychosocial needs be normatively required, and not just supererogatory? The next section will take up this question by considering another Japanese theoretical approach to informed consent.

6.1.1.2 Informed Consent as an Empathetic Communication

The volume Informed Consent: From Sympathy/Empathy to Agreement/Mutual Understanding (Infōmudo Konsento: Kyōkan kara Gōi he) hints at where the normative force of the two-stage theory might be found. It is a collaborative volume, produced by

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441 For example, see the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT), conducted from 1989-1994 (SUPPORT Principal Investigators, “A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients,” 1995). Other studies are discussed in White, “Uncharted Terrain: Preference Construction at the End of Life,” 2014 and Howe, “How to Help Patients and Families Make Better End-of-Life Decisions,” 2014.
the Kantō (East Japan) region of the Japanese Society for Philosophical and Ethical Research in Medicine. The chapter by Tanahashi Minoru, “Towards ‘Empathy’” (kyōkan ni mukete), is especially helpful. Tanahashi uses a Levinasian ethical perspective to suggest not only that physicians can respond to patients’ psychosocial needs, but also that they must – that it is a fundamental ethical responsibility. According to this perspective, ethical responsibilities can never be completely discharged, although we satisfy them through ethical engagement. As Alfred A. Tauber has suggested (in Levinasian terms):

An “ethics of responsibility” better addresses the moral intimacy of the doctor-patient relationship. It calls on the primordial recognition of the other, or in other words, an ethics of responsibility is metaphysically situated as a response to an other.\(^\text{442}\)

This suggestion holds the key to normative justification for the relation-process model for responsibility. For Levinas, to be responsible is not to seek to understand another person completely (as one would approach an object) but to engage in a participatory, communicative relationship with another person as an irreducibly particular, ongoing individual who is fundamentally different from oneself. An example of the former type of responsibility is to assess a patient’s decisional capacity, provide relevant information about treatment, and instruct her to choose an option. For Levinas, such an attitude does not respond to the patient as a person, but as a task to be categorized and completed. By contrast, to ask the patient about her concerns, values, and plans before working with her to assess treatment options and set a course of action, and to continue to communicate

\(^{442}\) Tauber, *Patient Autonomy and the Ethics of Responsibility.*
with her throughout treatment, is to take her seriously as another person with thoughts, feelings, and experiences of her own.

While for Levinas this relationship is more ontological than practical, Levinasian ethics has been invoked as a possible source of medical ethical requirements by a number of scholars, and is also often used in the field of communication and rhetorical studies, where his philosophy grounds an approach known as “interpersonal communication ethics.” According to Douwe Tiemersma, Levinasian ethics suggests that

The authentic medical situation is…the appearance of a suffering fellow-man in need of help. This action arises from compassion and responsibility, before reflection, thematizing, and deliberation…I can do nothing but take the suffering upon me, or at least stay next to the other in his suffering and help…The medical, ethical and juridical rules come later than my responsibility.

In other words, one’s primary responsibility to one’s fellow human beings is to try to empathetically understand their experiences. The medical context, distinguished from everyday life by the amount and extent of suffering, requires a higher degree of such empathetic understanding by those who work in it. This does not mean that medical professionals must hold sole responsibility for interpersonal understanding. Indeed, interpersonal communication ethics emphasizes that the focus “is not about ‘me’ or ‘you’; it is about a co-constituted communicative benchmark that makes both parties accountable for the quality and the depth of the relationship.”

443 Arnett et al., “Interpersonal Communication Ethics.”
445 Arnett et al., “Interpersonal Communication Ethics,” 120.
Nor do the ethics of empathetic communication require medical professionals to actually sympathize with every patient.\footnote{Tauber, \textit{Patient Autonomy and the Ethics of Responsibility}, 196.} Whereas sympathy is the ability to share another’s feelings, empathy requires only that their feelings are understood.\footnote{Empathy and sympathy are often discussed as the reverse: empathy as feeling another’s feelings and sympathy as understanding those feelings. For the sake of simplicity, I do not consider this other interpretation here.} As discussed by Coulehan et al., “in clinical medicine, empathy is the ability to understand the patient’s situation, perspective, and feelings and to communicate that understanding to the patient.”\footnote{Tauber, \textit{Patient Autonomy and the Ethics of Responsibility}, 199.} Were medical professionals to sympathize with each patient, that is, to actually share their patients’ worries, fears, and anxieties, they would quickly experience burnout. The ethics of empathetic communication only normatively require that professionals make an effort to understand these experiences.

Levinas sees such responsibility as continuous and relational; to be responsible in one’s relationships with another person is to be open to that person’s complexity as a being who is fundamentally different from oneself and to seek engagement with that complex being through ongoing, expressive, empathetic discourse. This is normatively required because this relationship with the other is fundamental to being human. To put it practically, this form of responsibility is inherent in interpersonal relationships – the question is whether we choose to recognize it or to ignore it.

Recognizing and attempting to understand the other as a person with complex experiences, ideas, and feelings exhibits an ethical orientation to interpersonal relationships that differs substantially from an ethics of respect for individual, autonomous agents. We should be wary of the historical contingency of the dominant
theories’ prioritizing of individual freedom and autonomy. As Alfred Tauber has observed, the centrality of autonomy to medical ethics is culturally and historically dependent, in that “the cultural preoccupation with individual autonomy is a distinctly post-World War II social phenomenon…Contemporary American bioethics developed in that milieu.”\textsuperscript{449} Rather than being theoretically fundamental, respect for individual autonomy is very much a product of American culture and the discourse on individual rights.\textsuperscript{450} This historical contingency does not mean that autonomy is not valuable, but that we should be open to seeking out alternative perspectives that offer greater opportunities for improvement in practice.

In contrast to the relatively recent ascension of respect for autonomy, a Levinasian ethics of responsibility through empathetic communication resonates with early Anglo-American medical ethics as well as with Japanese philosophical ethics. John Gregory, recognized as a forefather of Anglo-American medical ethics, built his eighteenth century medical ethics on sympathy \textit{as} empathy, “a kind of self-reflective modality, where the empathy aroused in the physician for another’s pleasure or pain evoked a moral evaluation of those feelings.”\textsuperscript{451} This “moral evaluation” was not just a rational appraisal of one’s feelings, but was also a reflective appreciation of the links between reason, sympathy, and benevolence.\textsuperscript{452} This perspective resonates with the 1847 AMA code of ethics, which (as noted in chapter 2) understands the physician as “the minister of hope and comfort to the sick.”\textsuperscript{453} Somewhat later, Richard C. Cabot argued in

\textsuperscript{449} Tauber, \textit{Patient Autonomy and the Ethics of Responsibility}, 16.  
\textsuperscript{450} Tauber, “Historical and Philosophical Reflections on Patient Autonomy.”  
\textsuperscript{451} Tauber, \textit{Patient Autonomy and the Ethics of Responsibility}, 69.  
\textsuperscript{452} Ibid., 70.  
\textsuperscript{453} AMA, \textit{Code of Ethics} (1847).
the early twentieth century that clinical competence must include “appreciation of the personal and social needs of the patient,” and in the current AMA code of ethics we find that physicians should “have compassion and respect for human dignity and rights” and should “regard responsibility to the patient as paramount.” While there are certainly those who disagree with this empathetic approach, its place in American medical ethics cannot be ignored.

In the Japanese context, perhaps Watsuji Tetsurō has developed ethics the farthest. Watsuji argues that “the standpoint of isolated subjectivity…is… forcibly applied to the questions of ethics,” but that this is an artificial application. Rather, “the locus of ethical problems lies in the in-betweenness of person and person” and “ethics is the study of ningen.” Using this concept of ningen (人間 human being), Watsuji shows how human beings are dynamically interconnected through acts that necessarily exhibit relationality with others. This dynamic interconnectedness is ethically maintained through recognizing and respecting the significance of interpersonal communication for ones’ relationships and also for oneself. Watsuji’s emphasis on the importance of interpersonal communication complements the Anglo-American recognition of empathy in medical ethics; both resemble the Levinasian ethics of responsibility.

Beyond the role that this ethics of responsibility plays in Japanese theories of informed consent, there are good reasons to reexamine the significance of empathetic communication for clinical ethics. These reasons include evidence that empathy and other

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455 AMA, *Principles of Medical Ethics*.
457 Ibid., 10.
social emotions affect informed consent and medical decision-making\(^{458}\) and suggestions that without empathy, physicians will be unable to meet the needs of their patients.\(^{459}\) Indeed, some argue that physicians’ cultivation of empathy and other social emotions more effectively affect patients’ behaviors in clinical encounters than information provision alone.\(^{460}\) In the next section, I will show how Japanese case law attempts to retain this relational and processual ethical orientation, largely absent from American case law.

6.1.2 Responsibility in Japanese Case Law

This relation-process approach to responsibility can be seen in Japanese case law and also in Japanese professional standards for informed consent (although they employ elements of the individual-outcome model as well; the two are not mutually exclusive).

As shown in chapter 2, early Japanese case law is similar to American case law in that rulings depend on whether or not patients gave consent to intrusive medical procedures. However, rather than favoring patient responsibility for decision-making and shifting from the battery to the negligence standard, Japanese courts have given broad allowances to physician discretion, employing a “subjective standard” for informed consent. In principle, this standard requires that physicians’ use their professional judgment to determine the scope of disclosure, although they can be judged on whether their use of this discretionary power successfully meets the needs of their patients.

\(^{458}\) According to one neuroethical study of informed consent, there is an empirical relationship between decision-making, informed consent and empathy and emotions (Supady et al., “How is Informed Consent Related to Emotions and Empathy?”).

\(^{459}\) Rosenberg and Towers, “The Practice of Empathy as a Prerequisite for Informed Consent.”

\(^{460}\) Halpern and Little, “Empathy and the Normative Activity of Coping.”
In addition, Japanese courts have made physicians responsible for responding to unique aspects of each patient relationship, including the degree of trust in the relationship, the patient’s character, the patient’s or family’s need for guidance, and the family environment. Other Japanese court decisions have suggested that it is part of the physician’s responsibility to gather this information about the patient and family and that the physician has a duty to monitor the patient’s reaction to bad news.

In addition, Japanese courts interpret physician responsibility as multi-staged, similar to the two-stage theory considered above. Physicians are responsible for gathering information about their patients’ particular needs, for aiding in patients’ decision-making processes, and for monitoring patients’ reactions to information and treatment. This fits the relation-process model of responsibility, not the individual-outcome model explained in chapter 5.

However, Japanese case law does not rely solely on the relation-process model of responsibility; it also understands responsibility as individual and outcome-based. Japanese physicians’ responsibility for the relational and processual aspects of informed consent is not a basic ethical responsibility (as in Levinas), but is a juridic basis for legal liability. In other words, Japanese physicians are responsible for responding to patients’ psychosocial needs, but there is no accompanying requirement for patients to make these

461 Nagoya High Court, October 31, 1990, 43(3) Minshū 178, 1373 Hanji 68, 44 Hanta 182.
462 Supreme Court, April 25, 1995, 49(4) Minshū 1163, 1530 Hanji 53, 877 Hanta 171.
463 Fukuoka District Court, December 19, 1990, 1394 Hanji 137.
464 Tokyo District Court, March 30, 1994, 1522 Hanji 104.
465 Akita Branch, Sendai High Court, March 9, 1998, 1679 Hanji 40.
466 Kawagoe Branch, Saitama District Court, October 30, 2003, 1185 Hanta 252.
needs clear. Patients need only cooperate with physicians’ recommendations. As the expert authorities in the medical situation, physicians maintain sole responsibility for whether or not the decision-making process goes well. The only case that exempts them from this responsibility is if patients proactively make their own decisions.

The Japanese medical professional standard for informed consent reflects a similar understanding of responsibility to that of Japanese court decisions. The 1984 Japanese Declaration of Patients’ Rights gives patients the right to “support and assistance from medical practitioners at any time necessary” and the 1990 JMA report on informed consent emphasizes trust and ongoing cooperation between physicians and patients. Likewise, the 2008 JMA guidelines describe the physician-patient relationship as one of cooperation to “overcome the disease.” The importance of support is especially clear in the National Cancer Research Center’s 1997 policy on disclosure, revised in 2004, which states that the main issue in cancer disclosure is “how to convey the truth, and after this how to support and aid the patient.” This understanding of responsibility is relational and processual: patients and physicians cooperate to achieve good outcomes. However, there are ways in which this might be problematic. Physicians bear the burden of understanding patients’ needs and monitoring patients following disclosures, and patients may feel pressure to acquiesce to physicians’ recommendations rather than express their own preferences.

I show in the next section that these problems result from an intertwining of the individual-outcome and relation-process models of responsibility. This leads to confusion

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467 National Cancer Center (Japan), *Gan Manuaru*. 
among physicians and between professionals and patients about who is responsible for medical decisions and how this responsibility is determined.

6.1.3 Responsibility in Japanese Informed Consent Practices

In my interviews, Japanese medical professionals occasionally described informed consent as transferring responsibility from the physician to the patient. However, this sense of responsibility was not the only way in which responsibility was used.\textsuperscript{468} In fact, my interviews showed that there are at least three different, yet not mutually exclusive, ways in which Japanese medical professionals conceive of responsibility in their informed consent practices.

6.1.3.1 Legal Responsibility

In this first use of responsibility, informed consent is a transfer of legal responsibility from the physician to the patient. Informed consent ensures that the patient has understood the risks of the proposed treatment and has chosen to move forward. This sense of responsibility is reflected in the expression “informed consent \textit{suru}” or “to do informed consent.” Several interviewees suggested that “informed consent \textit{shita}” – “I did informed consent” – transfers responsibility to the patient by affirming that the physician has fulfilled the duty to explain. It removes liability from the physician so that treatment can progress.

\textsuperscript{468} This analysis develops and expands on previous studies of responsibility and informed consent practices in Japan, which interpret responsibility as a burden that is born by one party in the decision-making process (e.g. Elwyn et. al., “Responsibility and Cancer Disclosure in Japan”).
This understanding of responsibility transfer accords with the lawsuit-based individual-outcome model of informed consent. Informed consent is an event that signals that the patient alone takes on responsibility for the decision to pursue a given course of treatment. For this reason, many interviewees said that informed consent is effective in risk management and quality assurance; it is thought to ensure that patients are satisfied with the care they are given. One physician mentioned that there are few lawsuits in Japan, but lawsuits relating to medicine are very difficult to resolve. In this context, informed consent has become an easy way to exempt liability – if the patient knew of the risks before the procedure, then the physician is not liable. This use of responsibility encourages physicians to practice informed consent for legal reasons, although several interviewees suggested that understanding informed consent in this way harms the physician-patient relationship. If informed consent is just an exchange of legal responsibility, then the physician-patient relationship cannot become one of personal concern. This becomes clearer in the following two uses of responsibility.

6.1.3.2 Communicative Responsibility

Some interviewees suggested that if the physician initiates a more communicative relationship with the patient and/or the family, then the physician also accepts responsibility for whether or not the situation goes well. This is a different use of responsibility than the legal responsibility described above, although there is overlap. If physicians communicate openly with patients and families, physicians become more personally responsible for the decision-making process than if they make the decision themselves or if the patient and the family decide independently. One physician said that
to open lines of communication with the patient and family burdens the physician, especially in difficult cases. Increased communication requires that the physician accept responsibility not just for transmitting the information needed to make a decision, but also for whether or not the patient and the family understand the explanation provided. In this sense, the physician retains individual-outcome responsibility. In difficult cases, the physician will have to spend considerable time working with the patient and family throughout the decision-making process.

Yet the physician’s responsibility for increased communication cannot be transferred, as in legal responsibility. This is because communicative responsibility is also based on the relation-process model: it is ongoing and situational, such that physicians who fully engage with their patients in decision-making come to bear responsibility for patients’ and families’ mental and emotional states. The extent of involvement determines the weight of the responsibility. This responsibility can be shared with patients and families, but it may also be unevenly born by the physician, especially if the patient and/or family are unwilling to accept responsibility for their understanding of the situation. This seems to be the case in Japan, where patients are not often thought to have obligations to their physicians other than obedience.

The situation described above may lead to a problematic overlap with the individual-outcome model of responsibility and related liability concerns. One physician suggested that some physicians avoid communication with patients during the decision-making process (other than explanation), because they could be seen as influencing the patient’s decision, and this would lead them to bear responsibility for both the decision-making process and its outcome. This usage of responsibility leads some physicians to
refrain from fully engaging with patients and families in the decision-making process, either out of fear that they will influence the decision (and thus shoulder some of the legal responsibility described above), or due to a lack of confidence about their ability to handle the more difficult situations occasioned by increased communication.

6.1.3.3 Fiduciary Responsibility

Legal and communicative responsibilities in informed consent manifest as liability for decisions, or for patients and families’ mental and emotional states. In both cases, the burden of responsibility falls on one side of the relationship, depending on who is more proactive in the decision-making process. More relational than legal or communicative responsibility, fiduciary responsibility presumes both parties’ mutual participation.469 Indeed, several interviewees suggested that, in contrast with what they perceived as the contractual understanding of informed consent in the U.S., the purpose of informed consent in Japan should be to create a trusting interpersonal relationship with the patient.

Unfortunately, it is difficult to give a positive account of fiduciary responsibility, perhaps because trusting relationships are so difficult to create in the current Japanese medical system. Interviewees described fiduciary relationships primarily in terms of what they are not. For example, several interviewees suggested that increased overt communication is a sign of decreased trust. In other words, when patients are cared for by physicians whom they trust, they do not need to make every need explicit; rather, they

469 In this section, I intend the idea of “fiduciary responsibility” to connect with philosophical theories on trusting relationships (see the fiduciary model for informed consent discussed in chapter 5), not necessarily to fiduciary relationships in the context of agency law.
can trust that the physician will provide the care they need. Below, I unpack this suggestion in more detail.

The current reliance on the patient’s chart for inter-professional and physician-patient communication about informed consent was frequently cited as a catalyst for the decline in trusting medical relationships. Informed consent used to be required only when a patient was admitted to the hospital. The admitting physician would write on the patient’s chart that informed consent was done (informed consent *shita*), but would not necessarily write the details of what was explained. Now this is all written in the patient’s electronic chart; it became legally mandatory to write everything down approximately 10 years ago. According to one nurse, even information about patients’ personalities is now written on their charts. This ostensibly supports patients’ legal rights and respects their autonomy. Since patients now also have access to their charts (a landmark legal change in Japan), there are no secrets about their medical situation. Detailed charts also increase awareness of patients’ psychosocial issues among medical staff.

However, several nurses and a few physicians said that more detailed record keeping has actually harmed trust, both among medical professionals and also between professionals and patients. Many nurses said that exchanging information through charts has meant that nurses and physicians communicate less. They are “offline” in their personal encounters because so much of their communication is “online” through electronic charts, which provide fewer opportunities to develop trusting professional relationships. There is also less trust between professionals and patients. If patients know that all aspects of their interaction will be written down, including personal details, they may feel that physicians’ goal is just to record that “informed consent was done”
(informed consent *shita*) and move on with treatment. As a result, patients come to trust physicians less. While my interviewees suggested that this means that less information should be openly shared, what they instead seem to be pointing to is the fact that trust, once established, does not need to be constantly proved. However, establishing trust does require personal, verbal communication, and increased documentation requirements could hinder this if physicians are more concerned with comprehensive electronic documentation than with comprehensive understanding of their patients’ experiences.

If trust is felt more than directly communicated, and if increased documentation actually harms trust in Japan, then this understanding of responsibility as fiduciary may be at odds with informed consent as it is currently practiced. Indeed, informed consent seems to have arisen at a time when trust in physicians was lowest (in both the U.S. and Japan, physicians were performing surgeries without consulting their patients, as described in chapter 2). The goal was not necessarily to increase trust, but to ensure that even those physicians who could not be trusted behaved ethically. Several of my interviewees raised this issue, and suggested that informed consent can have a detrimental effect on trust in the physician-patient relationship. As shown in the previous sense of responsibility, fear of liability premised on the individual-outcome model of responsibility can lead physicians to avoid communication with patients and families that surpasses the minimum of what is required to shift responsibility onto the patient. Likewise, creating an atmosphere of unspoken, felt trust with patients can open

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470 Alfred Tauber has also noted how bioethics as a whole is “a response to new demands for physician accountability” (Tauber, *Patient Autonomy and the Ethics of Responsibility*, 7).
physicians to liability, as this kind of atmosphere can neither be documented nor proven in a court of law.

My interview data show that Japanese medical professionals perceive both individual-outcome and relation-process models of responsibility as significant. However, without differentiation, these two models mutually frustrate each other’s aims and complicate the informed consent process, leading medical professionals to identify three different types of responsibility within their practices of informed consent: legal responsibility, communicative responsibility, and fiduciary responsibility. While Japanese professionals may have strong personal motivations to respond to patients’ occasionally unspoken needs on the relation-process model of responsibility, fear of liability on the individual-outcome model often dissuades them from either establishing the types of relationships that would make such non-verbal trust possible or openly communicating with their patients about non-treatment related issues.

In the next section, I explain how this analysis of Japanese informed consent theory, case law, and professional practices in terms of responsibility clarifies the crucial ethical issues in informed consent in Japan. This facilitates an assessment of the justification of Japanese informed consent practices and also suggests implications for practices in the U.S.

6.2 Clarifying Japanese Informed Consent

According to the analysis above, we can understand Japanese informed consent as a combination of the individual-outcome and relation-process models for responsibility. Informed consent theories, case law, and concrete practices incorporate both rational
decision-making requirements and psychosocial coping requirements because the two go hand-in-hand. It is hard to make a decision if one does not feel good about one’s choice, especially if one is already anxious or stressed about one’s medical situation. This suggests a need for professionals to be attentive to patients’ emotional and rational states throughout the decision-making process. Japanese courts have upheld physicians’ responsibility for this situational attentiveness at the same time that they have recognized the legal significance of obtaining patients’ consents.

Japanese informed consent can also be interpreted according to a Levinasian theoretical ethical approach, in which the normative grounds of professionals’ responsibility to patients is the fact that they are suffering persons who cannot be dismissed with a signature on a form or a record in a digital chart. The refusal to communicate or engage with patients’ psychosocial needs is as much an ethical choice as the decision to inform them about the merits and demerits of treatment options.

However, the intertwining of the two models of responsibility in informed consent complicates physicians’ practices. The individual-outcome model supports liability-based judgments and can be useful in deciding legal cases, but it can also be an obstacle to recognition of relation-process responsibilities. Pursuing an empathetic, communicative relationship with patients can be construed as interfering with their freedom to make their own decisions, and can also put physicians at risk for lawsuits. In this context, Japanese medical professionals are not sure whether they should leave Japanese patients and their families to their own decision-making or assist them in this process through empathetic communication and psychosocial support. While they want to establish trusting relationships with their patients, they may feel more bound to legal or administrative
requirements than normative ones. Thus Japanese professionals are not certain about how or why they should practice informed consent.

6.3 Justifying Japanese Informed Consent

As shown in the previous section, there are a number of conceptual and practical problems with informed consent in Japan. Conceptually, the mix of the individual-outcome model and the relation-process models confuses the means and ends of informed consent. Is the goal to transfer responsibility as liability by providing information and requiring confirmation of the patient’s decision, or is it to ensure that the decision-making process goes well by responding to the patient’s psychosocial needs? In thinking of informed consent, Japanese medical professionals, especially physicians, have been pulled in these two directions. Confusion and misunderstanding in theory and discourse have resulted in inconsistent practices.

Due to the conceptual confusion, adequate structures are not in place to support successful functioning of either of the two models of informed consent in Japanese informed consent practices. Japanese physicians are taught neither how to communicate complex medical information to their patients nor how to confirm whether their patients have understood this information. This means that they are unprepared for the relation-process responsibility of the decision-making process. Likewise, Japanese patients are not well informed about their medical options, so they are unable to take on individual-outcome based responsibility for these decisions, nor can they participate in the decision-making process to the extent that relation-process responsibility requires.
Complicating matters are the lack of support staff and the failure to distinguish between different professional roles. Given physicians’ busy schedules and without support staff, no one is available to listen to patients’ complex histories before treatment or to check on how they are coping with their diagnosis and their treatment. Even when support staff are available, their work is accomplished behind the scenes; physicians are generally unaware that they can use the support staff as a resource for informed consent. Because physicians tend to interact more closely with families than with support staff, they often turn to family members to help them communicate difficult information to patients.

These factors make Japanese informed consent an uneven and unreliable practice that neither clarifies the distribution of responsibility as liability nor supports the creation and maintenance of the kinds of interpersonal relationships that fulfill relation-process responsibility. As a result, Japanese physicians are not certain whether they should disclose diagnoses to patients, patients do not always want to take on the burden of individual decision-making, and families demonstrate concern for their loved ones’ welfare by attempting to shield them from potentially harmful truths.

Japanese informed consent can be explained, but it is not justified. In short, if patients are not told their diagnoses, this is not because Japan has a unique concept of autonomy, but because Japanese physicians and patients are ill equipped for the responsibilities of interpersonal communication in the medical context – responsibilities that the Japanese medical system nevertheless assigns to them. If families are told diagnoses before patients, it is not because families are more valued in Japan than in the U.S., but because there is a systemic lack of institutional support in the Japanese medical
system. In the following section, I will suggest how these shortcomings can be improved. While these recommendations should influence institutional policy development and could influence legal standards, they are intended as general ethical recommendations and not as detailed proposals ready for practical implementation.

6.4 Improving Japanese Informed Consent

What is needed to make Japanese informed consent into a justifiable practice in terms of both individual-outcome and relation-process responsibility? Because many of the current difficulties stem from a lack of clarity about the function and distribution of these two models, we must begin by clearly distinguishing where and how they apply to informed consent practices. These issues are obscured by the informed consent discourse that primarily relies on the individual-outcome model, but the addition of the relation-process model allows a reframing of Japanese informed consent from which suggestions for solutions and improvements to current problems flow more easily.

First, the individual-outcome based model for responsibility is primarily relevant for decisions about treatments, tests, or medical procedures. As such, this model clarifies liability for the decision (should something go wrong) and validates the location of this liability through a written or verbal consent. The relation-process model for responsibility, on the other hand, is relevant not only prior to treatment and during the decision-making process, but also post-decision and post-treatment. While the relational and processual aspects of responsibility continue beyond the moment of decision-making, at the precise moment a decision is made the individual-outcome model for responsibility is more salient. This requires that either the physician or patient take legal responsibility
for the decision to administer or undergo treatment, but this assumption of legal responsibility should be clearly delineated from relational responsibilities to foster communication and mutual understanding throughout the decision-making process.

Second, this distinction between types of responsibility should be supported by practical measures. At the moment of decision-making, physicians’ abilities to communicate complex medical information and patients’ abilities to understand this information are of the utmost importance. Both physicians and patients require education to prepare them for this. Physicians need communication training, and the public needs education in making medical decisions they are likely to face. For the former, mock patients may be useful in medical school training.\textsuperscript{471} For the latter, outreach efforts such as informal community groups and classes can prove effective.\textsuperscript{472}

The decision-making process, from decisions through treatment, requires support staff with clearly delineated duties. Physicians are too busy to provide psychosocial care to patients or to anticipate their needs. This recommendation differs from that of many critics of informed consent, who suggest that physicians can and should respond to the psychosocial needs of their patients.\textsuperscript{473} While possible in principle, physicians’ extensive training in medical science, not conversation, coupled with the significant amount of time required by their medical practice, suggests that showing concern for their patients’ psychosocial needs is supererogatory. Such concerns are better left to support staff with the dedicated time and specialized training to effectively respond to these needs. To this

\textsuperscript{471} There is evidence that this kind of training works: see Joshi, “Doctor, Shut Up and Listen.”
\textsuperscript{472} For example, in Kyoto I attended an experimental class for local residents that educated them about how to make good health and medical decisions.
\textsuperscript{473} For instance, Rosenberg and Towers, “The Practice of Empathy as a Prerequisite for Informed Consent.”
end, physicians should be trained to facilitate the support work undertaken by nurses and other professionals. Making support staff available will also substantially lift the burden of support from families. The assumption that at least one member of the family will always be available to provide home care no longer holds and may even damage the family’s economic and psychological well-being.

Nurses, medical social workers, clinical psychologists, and clinical ethicists should be integrated into the medical team and made responsible for the relation-process aspects of patient care, free from legal liability. In other words, to ensure that communication and non-verbal trust do not conflict with liability, support staff cannot be held responsible for patients’ decisions on the legal, individual-outcome model. They must have the freedom to act as patient advocates and confidantes throughout decision-making, treatment, and recovery processes. This is not to say that support staff should not be held responsible at all; they should hold responsibility on the relation-process model. If they are not listening to patients, not taking their concerns seriously, or are contributing to patient anxiety and distress, they should be penalized for failing their ethical responsibilities to their patients – as long as they have been given sufficient training and themselves receive systemic support.

Drawing these conceptual and practical distinctions between the individual-outcome and relation-process models of informed consent should improve Japanese informed consent practices. Japanese physicians will not be liable for dimensions of the decision-making process that they have neither the training nor the time to take on, and patients will not have to rely on their families alone for psychosocial support in
distressing circumstances. These changes would improve the Japanese practice of
informed consent, and they should also be implemented in the U.S., as I argue below.

6.5 Revising American Informed Consent

This dissertation has considered how case law, the medical profession, the
philosophical community, and the larger society have contributed to shaping the practices
and discourses of informed consent in the U.S. and Japan. I have argued that the
American and Japanese structural foundations of informed consent support different
processes of medical decision-making that reflect divergent understandings of how to
ensure that this process goes well. I have also shown that these two systems are based on
different premises about expectations, needs, and attitudes in American and Japanese
society. This comparative study has offered suggestions for how Japanese informed
consent can better reflect the ethical requirements of the relation-process model of
responsibility, as opposed to the individual-outcome based model.

Yet Japan’s practical struggles with informed consent are not unique to Japan. The U.S.
faces an increasingly legalistic and medicalized health system to the detriment
of patient care, and many commentators have criticized the American bioethical
discourse on practices such as informed consent for being overly concerned with the legal
and institutional aspects of these practices to the exclusion of their social and emotional
aspects. So the American discourse and practice could also benefit from the
recommendations for Japanese informed consent made in this chapter. Below, I focus on
five ways in which we can improve the discourse and practice of informed consent in the
U.S.
First and foremost, many American physicians have difficulties with communication similar to those faced by Japanese physicians, as noted in chapter 3.\textsuperscript{474} They need better training in interpersonal skills. However, as is the case in Japan, the complex task of communicating with patients and families should not be left to physicians alone. While the U.S. has developed support systems for patients, these support networks are often poorly integrated into the medical system itself and remain outside it as secondary sources of care. This makes it more difficult to bring in needed support staff and complicates insurance claims for these services. Communication specialists such as medical social workers and clinical psychologists should be part of the medical team from the time of admission. If these professionals are part of patients’ medical teams, someone well trained in interpersonal skills should be available for patients to talk to at any time, rather than when they are already experiencing feelings of frustration or isolation.

Second, many patients are overwhelmed by the information and time management skills required in the American medical system.\textsuperscript{475} While this dissertation is not the place to lessen this informational burden, one possible improvement is to increase the informational and decisional support available to patients as they navigate difficult decisions. While insurance companies have been relatively proactive about providing health advice to their patients, professionals unattached to insurance providers should also be available. Patients should receive health advice from, and work through decision-


\textsuperscript{475} Hoffman, “Awash in Information,” and Hertz, “Why We Make Bad Decisions.”
making with, professionals who are not influenced by whether or not their chosen services will be reimbursed.

Third, there have been numerous calls for better recognition of the psychosocial aspects of contemporary medical care. These aspects include the roles played by psychosocial staff such as medical social workers and clinical psychologists, family dynamics in patient care and decision-making, and emotional and social support for patients, families, and medical professionals. For example, Americans do not seem as individualistic as often assumed. There is evidence that Americans prefer shared decision-making accomplished along with families, caregivers, and professionals. Practices such as informed consent are not just ways of transferring information and making treatment decisions, but are processes of forming different types of relationships with people in diverse professional and personal roles. The more we study how these different elements of informed consent interact and develop, the more we will be able to improve peoples’ experiences during medical care.

Fourth, many critics have noted that the discourse on American informed consent practices is overly focused on the legal meaning of informed consent as liability. This is not to say that the American legalistic informed consent discourse is inherently wrong, but that prioritizing the individual-outcome model of informed consent can isolate individuals in the medical setting, pitting physicians against patients in the fight to

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determine who is at fault should anything go wrong. To avoid this, the legal discourse on informed consent should be supplemented with an ethics based on relation-process responsibility that focuses on our shared responsibilities in difficult situations, rather than on our legal rights against one another. Such an ethics is in the same spirit as Jay Katz’s “new ideology of professionalism that is more firmly grounded in a commitment to mutual equality, in a trusting recognition of common dependence.”\textsuperscript{479} According to Katz, this new ideology, the “conversation model,”\textsuperscript{480} is based on communication between physicians and patients that encourages awareness of the factors that affect their decision-making processes and choices. The relation-process model of responsibility encourages such frank communication, while the individual-outcome model of responsibility as liability discourages it. The legal standard of informed consent is institutionally necessary, but we should take care that the ethics of informed consent do not reduce to legal arguments in the U.S. It is possible that this ethical perspective could, in turn, influence the legal conception of informed consent.

Fifth and finally, several theorists have noted that the current emphasis on respecting individual autonomy in U.S. culture may preclude action based on compassion and empathy. As Gaylin and Jennings observe in the broader context of contemporary American culture,

\textbf{Autonomy has also penetrated deeply into our everyday lives. Too many people experience relationships as encroachments…When people support public policies and social practices that maximize personal freedom of choice, no matter what the moral or financial cost to society and no matter how self-destructive the behavior,}

\textsuperscript{479} Katz, \textit{The Silent World of Doctor and Patient}, 103.
\textsuperscript{480} Brody, \textit{The Healer’s Power}, 92.
they are responding to the seduction of autonomy as well. Rejection of commitments, relationships, discipline and duty are openly celebrated.\textsuperscript{481}

Turning the conversation away from individual-outcome based responsibility to relation-process responsibility helps to alleviate these problems. When we focus less on maintaining our freedom from others and concern ourselves more with being responsible for our social contexts and relationships, we come to recognize the ways in which human flourishing and realization occur with others in relationships. As Gaylin and Jennings further note, this leads us to see the significance of “need, vulnerability, frailty, fallibility, weakness, and mortality,” and encourages us to develop our social emotions, not just our self-centered ones.\textsuperscript{482} This ethical sense can impact informed consent practices if we cease to understand such practices primarily as waivers of liability. If they are instead understood as practices of compassion, we become able to address the needs and vulnerabilities of patients and their families, rather than abandoning them to their own decisions. Carl Schneider has described this as a shift from the consumer-choice model of modern medicine to the consumer-welfare model, in which kindness becomes a crucial aspect of medical practice.\textsuperscript{483} We should focus more on the acts of kindness that already occur in medical practice, especially those accomplished by support staff, and we should ensure that such acts are duly recognized and rewarded. Indeed, a recent study by researchers at the University of Texas MD Anderson Cancer Center found that the level of compassion in physician-patient communication affects both the content of diagnosis

\textsuperscript{481} Gaylin and Jennings, “The Perversion of Autonomy,” 252.
\textsuperscript{482} Gaylin and Jennings, “The Perversion of Autonomy,” 253
\textsuperscript{483} Schneider, \textit{The Practice of Autonomy}. 

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disclosure and the decision-making process itself.\textsuperscript{484} The more we understand these interpersonal, emotional aspects of bioethical issues, the better we will be able to meet both physicians’ and patients’ needs.

As in Japanese informed consent, I have argued that American informed consent practices also need improvement. By attending to similarities and differences between the problems that are faced by both practices, we can ensure that cross-cultural studies are neither simplistic nor one-sided. The initial formulations of the ethical claims defending East Asian informed consent practices – that informed consent ought to be done with the patient or the family due to differing notions of autonomy – were too simple to justify these practices. This dissertation has not only illuminated the full spectrum of reasons rendering these practices problematic, it has also proposed avenues for improvement. The value of this particularist approach to comparative bioethics is its ability to highlight under-recognized issues, including supposedly universal theoretical assumptions and intuitively acceptable yet unexamined practices.

\textsuperscript{484} Tanco et al., “Patient Perception of Physician Compassion after a More Optimistic vs. a Less Optimistic Message: A Randomized Clinical Trial.”
Conclusion: Improving Practices of Informed Consent Globally

This dissertation began with the question of whether or not the Japanese practice of informed consent, in which diagnoses may be disclosed to families before patients, can be ethically justified. In chapter 1, I questioned the principlist methodology that is commonly used to answer this question, arguing that a particularist analysis better illuminates the complex issues involved. Proceeding with my particularist analysis in chapters 2 through 4, I showed how Japanese informed consent court decisions, professional guidelines, and concrete practices of informed consent differ from those in the U.S. I emphasized that many differences stem not from fundamentally different ethical perspectives, but from responses to unique social, historical, and epidemiological factors, many of them relating to the two countries’ divergent experiences with cancer. This analysis highlighted the Japanese struggle to provide support for patients’ psychosocial needs. Although the importance of this support is recognized in Japan, it is neither institutionalized nor put into practice. By contrast, the American system does not recognize the importance of psychosocial support, but provides for it institutionally and in practice.

To uncover the sources of this difference, I analyzed three dominant global theories of informed consent in chapter 5, showing that their reliance on an individual-outcome model of responsibility obscures recognition of patients’ psychosocial needs. I suggested that a relation-process model of responsibility would better account for these needs. In chapter 6, I explained how these needs are acknowledged by Japanese theories of informed consent, court decisions, and medical professionals, but I suggested that there are structural reasons why they are difficult to respond to in practice. Therefore, I
proposed changes to Japanese informed consent that could produce a more cohesive, effective, and ethical practice. Finally, I suggested that American informed consent practices could also benefit from the kinds of revisions needed in Japan.

This particularist, cross-cultural examination of informed consent has shown how Japanese and American legal and medical institutions struggle to balance patients’ rights to decide their own futures with physicians’ obligations to take patients’ interests seriously. The American response, on the part of both judges and the medical profession, has been to delineate the information that reasonable, prudent patients need in their decision-making processes and to place increasingly specific demands on physicians to provide this information. In doing so, American informed consent practices have emphasized patient self-determination at the expense of mutual support among patients, families, and medical professionals.

The Japanese response has been to protect patients’ rights to voluntary consent by making physicians responsible for responding to individual patients’ particular needs. This emphasis on professional discretion can be understood not as empowering the medical profession over and against the patient, but as placing support for patients’ psychological and emotional needs within the scope of physician responsibility. The premise of Japan’s system is that physicians should know how to assess their patients’ potential emotional and psychological responses, as well as their informational needs, and that patients expect them to do so. However, this study has shown that physicians are not prepared to take on this responsibility and so the burden of psychosocial care often falls on families. Other medical professionals such as nurses, medical social workers, and
clinical psychologists should be better trained and incorporated into medical systems to ensure that patients and families receive the support they need.

At the heart of the tensions between these two local informed consent practices is an equivocation over the concept of responsibility – not over autonomy, as many critics have suggested. Rather, a failure to differentiate individual-outcome based responsibility from relation-process responsibility has led an inadequate practice in Japan and a one-sided practice in the U.S. Distinguishing these two conceptual approaches to responsibility clarifies the ethical issues in informed consent and diagnosis disclosure. This comprehensive perspective on informed consent in turn suggests improvements to practices, while also serving as a model for ethical justification across cultures.
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