Insuring Against Infertility: Expanding State Infertility Mandates to Include Fertility Preservation Technology for Cancer Patients

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Melanie was 29-years-old, married, and hoping to start a family when she discovered a lump in her pelvis. She was diagnosed with non-Hodgkin lymphoma. But one of her biggest fears upon learning of her diagnosis was the possibility of loosing her ability to have children. When Melanie asked her oncologist and radiation oncologist about the risk cancer treatment posed to her fertility, they told her it was small, as only one ovary would be destroyed during the radiation. Deciding to ask for another opinion, she sought out a reproductive endocrinologist, who told her, contrary to what her oncologists had said, that women like her typically did have problems conceiving after radiation treatment on their pelvis. One of the hardest parts of dealing with her dual diagnosis, Melanie later recalled, was the unknown: "I didn't know if my treatment would definitely render me infertile."[1]

But even if she had been told the radiation and chemotherapy needed to irradiate her cancer would absolutely leave her infertile, Melanie still would not have met the medical definition for infertility. Currently, the standard medical definition for infertility, per the American Society for Reproductive Medicine, is engaging in regular, unprotected sex for one year without conception occurring.[2] Because of this, even if Melanie had lived in a state where insurance companies were mandated to pay for services to treat infertility through assisted reproductive technologies (ARTs), she would not have qualified under this mandate to access fertility preservation treatments prior to undergoing treatment for her cancer.[3] Melanie could have appealed to her insurance company to cover fertility preservation technology (FPT) — there has been success in such endeavors[4] — but doing so may not have occurred to her; moreover, it could have seemed too complex of an undertaking for an individual, especially one just diagnosed with cancer. Additionally, timing may have been an issue.

Fertility preservation treatments can be expensive; cost and the lack of insurance coverage are often the major reasons given by oncologists for why they do not provide information on fertility preservation options to their patients.[5] One method of ensuring people in their reproductive years or children who are diagnosed with cancer have access to and insurance coverage for FPT is to legally treat them as a distinct group from people diagnosed with infertility. For example, there could be a law mandating insurance coverage for people with a genetic predisposition to cancer allowing use of FPT prior to risk reduction surgery. In this paper, however, we propose to work within the current medical definition of infertility but seek to expand it to cover people who may become infertile because of

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medical treatment for a disease such as, but not necessarily limited to, cancer. We make this proposal with a specific objective in mind: to expand infertility insurance mandates to guarantee that people like Melanie can receive FPT prior to medical treatments that may induce infertility.

We do so by using one state as an example. Massachusetts passed its infertility mandate in October 1987. While not the first state in the nation to do so, the Bay State went further than Maryland had two years prior.[6] Massachusetts' infertility mandate was and remains one of the most inclusive health insurance mandates regulating coverage for infertility services in the United States; because of its breadth, we use it as a model to expand insurance mandates to include people whose medical treatments for other diseases, such as cancer, may induce infertility. The Massachusetts mandate creates a review system that allows for additional infertility services to be covered as medical technology advances and procedures move from experimental to routine. In addition, unlike other states, Massachusetts' mandate places few limitations on covered procedures, such as the number of in vitro fertilization cycles. However, despite the law's intention to be inclusive and evolving, the mandate still fails to include patients like Melanie who face infertility due to cancer treatment. This paper analyzes current definitions of infertility, the shortcomings of the Massachusetts mandate, the population currently excluded, and possible routes to coverage. While we use Massachusetts as a model, our arguments and analysis of possible routes to coverage can be applied to all states seeking inclusive coverage for infertility treatment.

Fertility preservation treatments can be expensive; cost and the lack of insurance coverage are often the major reasons given by oncologists for why they do not provide information on fertility preservation options to their patients. One method of ensuring people in their reproductive years or children who are diagnosed with cancer have access to and insurance coverage for FPT is to legally treat them as a distinct group from people diagnosed with infertility.

Current Definitions of Infertility

According to major national and international health organizations, a necessary criterion for being diagnosed as infertile is failure to achieve pregnancy over a specified period of time, typically one year, in which the person is engaging in regular, unprotected sex[7] (see Tables 1 and 2). Using these definitions, people with cancer are not technically infertile at the time of their diagnosis, as they do not meet the time requirement for unsuccessful conception. Among others, these definitions of infertility exclude individuals with future foreseeable infertility, like cancer patients, who want to protect their fertility using FPT before commencing cancer treatment that could potentially cause infertility or sterility.[8] Some definitions of infertility also seem to exclude cancer patients. For instance, the Massachusetts mandate states that infertility is a "condition of a presumably healthy individual."[9] Unfortunately, the Massachusetts mandate does not specify what it means for an individual to be healthy and whether an individual who most would agree is not healthy (e.g., a cancer patient) could still be considered infertile and eligible for infertility service coverage. Massachusetts' Division of Insurance also does not specify a definition for non-healthy individuals seeking an infertility diagnosis. In sum, the Massachusetts mandate's definition of infertility cannot accommodate cancer patients because it requires individuals to both be unable to conceive for one year and to be healthy.

The Massachusetts Mandate

Massachusetts passed the *Act Providing a Medical Definition of Infertility* (hereafter referred to as the mandate or the act) in 1987, nine years after the birth of the first baby using in vitro fertilization (IVF), and six years after the birth of Elizabeth Carr, the first baby born using IVF in the United States. Between Carr's birth and 1986, the year the mandate was first introduced in Massachusetts, the number of infertility clinics in the United States grew dramatically.[10] Importantly, infertility clinics grew in the marketplace during the years before the Massachusetts mandate. Though the original intent of IVF was to help women with blocked fallopian tubes conceive, by the 1980s infertility treatment was largely being undertaken by women

who did not necessarily have this as their primary basis for seeking care.[11] ARTs such as IVF were seen as a consumer-driven, not medically-driven, treatment; they were regarded popularly as elective procedures. This was largely because of the population most often using ARTs: middle-class, educated white women who had "delayed" pregnancy. Though the media in the 1980s pursued a story line that there was an "epidemic" of infertility among educated, middle-class white women, this was erroneous. This demographic, however, were the ones who could afford ARTs, and were therefore the ones who were using it.[12]

It was in this historical context in which RESOLVE, a national infertility advocacy group based in Massachusetts, began pushing for an insurance mandate, and it was largely because of this context that they did so quietly. RESOLVE purposely did not seek support from women's or physician groups, or seek media attention, in order to meet two objectives for the legislation. First, they wanted to keep the mandate from seeming "like some cause for a bunch of affluent yuppie couples," as then-president of RESOLVE, Martha Griffin, stated.[13] And secondly, they wanted infertility to be labeled as a medical condition necessitating treatment, thus removing it from the category of a "cosmetic problem," as one RESOLVE advocate phrased it.[14]

Prior to the legislation, health insurance coverage for infertility treatments was varied and unpredictable. There was no clear definition of infertility, and insurance companies provided a variety of reasons for denying claims that were infertility-related.[15] Therefore, members of RESOLVE decided that legislation was necessary to provide a clear definition of infertility. The definition was created by the authors of the mandate using standard medical definitions for infertility: one year of attempted conception without success.[16]

While RESOLVE purposely worked quietly toward passing the mandate, groups outside of RESOLVE were aware of the mandate. The Catholic Church opposed the legislation, citing its opposition to artificial insemination and in vitro fertilization. It was also actively opposed by the insurance industry, which cited the possibility of high costs of treating infertility. Regardless, the Catholic-dominated legislature passed the mandate, with the House voting 2 to 1 for it, and the Catholic governor signing it.[17] By doing so, they amended several sections of the Massachusetts General Law to include insurance coverage requirements for infertility services at the same level as pregnancy-related services.[18] The mandate stated that coverage should be provided for "medically necessary expenses of diagnosis and treatment of infertility."[19] The legislation gave the Massachusetts Commissioner of Insurance (hereafter referred to as the Commissioner) the authority to establish a list of required and optional infertility benefits along with the authority to oversee the process of adding new procedures to what would be covered.[20] In order for a new procedure to be added to the required benefits list, an individual must petition the Commissioner to recognize the procedure as non-experimental. According to the mandate, a procedure is considered non-experimental when it is recognized as such by the American College of Obstetricians

Table 1
Definitions of Infertility

Organization	Definition of Infertility
Massachusetts Mandate	The condition of a presumably healthy individual who is unable to conceive or produce conception during a period of one year. [7]
World Health Organization (WHO)	A disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse. [27]
National Institute of Health (NIH)	Infertility means not being able to become pregnant after a year of trying. If a woman keeps having miscarriages, it is also called infertility.[28]
RESOLVE	Infertility is defined as the inability to conceive after one year of unprotected intercourse (six months if the woman is over age 35) or the inability to carry a pregnancy to live birth.[29]
American Society of Reproductive Medicine (ASRM)	Infertility is the result of a disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the male or female reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery. The duration of unprotected intercourse with failure to conceive should be about 12 months before an infertility evaluation is undertaken, unless medical history, age, or physical findings dictate earlier evaluation and treatment.[30]

and Gynecologists (ACOG), the American Society for Reproductive Medicine (ASRM), or another infertility expert approved by the Commissioner.[21] Using this process, the Commissioner was able to assess and add new procedures.[22] Importantly, this process has allowed for the mandate to evolve as medical technology advances without the need for further legislative action. As of March 2010, required benefits include IVF, artificial insemination, gamete intra fallopian transfer, and zygote intra fallopian transfer.[23]

The Currently Excluded Population

While ostensibly covering everyone, the mandate primarily affects those who have health insurance and who meet the definition of infertility as it currently stands. Others have examined the important issue of why it has been largely white, middle-class women who use (and are encouraged to use) infertility services in the United States,[24] but in this article, as our focus is on expanding the definition to include those who may become infertile as a result of medical treatment for a condition like cancer, we will examine why such a redefinition is necessary, using cancer as our disease example.

Cancer is generally perceived as a condition affecting men and women past their child-bearing years, but nearly 10% of those diagnosed are under age 45.[25] Indeed, some of those diagnosed with cancer are still children. In 2006, an estimated 9,500 new cases of pediatric cancer were diagnosed in the United States.[26] The ability to more aggressively treat cancer, particularly in those under age 45, has enabled more people to survive. But these treatments have also resulted in some patients experiencing impaired fertility or sterility.[27] Oncofertility — the intersection of cancer treatment and fertility preservation — recently emerged in response to the challenge of improving cancer patients' opportunities to become a biological parent post-cancer treatment.[28]

Given the number of children and adults within their child-bearing years diagnosed with, treated for, and surviving cancer, fertility concerns have emerged as a quality of life issue important to cancer survivors and their families. In one study of cancer survivors, 76% of those who were childless expressed a desire to have biological children in the future.[29] Impaired fertility as a result of cancer treatment has physical as well as psychological effects. The existing literature on women whose fertility was impaired as a result of cancer treatment reveals an intense psychological distress; for these women, "psychological distress may result from, not only the loss of the physical ability to conceive, but also a symbolic loss of the option or idea of fertility, regardless of whether this would have been acted upon or achievable."[30] Some studies on men have revealed similar levels of long-term distress over their impaired fertility as a result of cancer treatments.[31] The increased survival rate of cancer patients in their reproductive years is a main reason for the higher demand for FPT; today, preserving one's fertility before cancer treatment is often seen as a quality of life issue.

Expanding Coverage

While one may agree that the technology exists to preserve cancer patients' fertility and that FPT should be offered to cancer patients, the question remains as to whether infertility state mandates should be expanded to include FPT for cancer patients. In this section we discuss why we think they should.

Table 2
Infertility Definitions Overview

Organization	Year Requirement	Labeled a Disease?	Miscarriages Recognized?	Definition for "Healthy" People
Massachusetts Mandate	1 year			X
World Health Organization (WHO)	1 year	X		
National Institute of Health (NIH)	1 year		X	
RESOLVE	1 year, 6 months if age>35		X	
American Society of Reproductive Medicine (ASRM)	1 year	X	X	X

Cancer patients are not included under the current definition of infertility because they are neither physiologically nor medically regarded as infertile at the time when fertility preservation treatment would take place (right before the commencement of cancer treatment). The current definition of infertility is problematic[32] because it assumes medicine is always reactive — i.e., treating conditions that already exist — and does not acknowledge that medicine is also proactive – i.e., preventing conditions from existing in the future. Health care providers not only treat people who are currently experiencing a medical problem (e.g., antibiotics for a bacterial infection, surgery for an appendicitis), they also prescribe medication and perform treatments to minimize their patients' likelihood of experiencing future medical problems (e.g., taking blood pressure medicine to prevent heart attacks, removing moles to prevent skin cancer).

In particular, health care providers often recommend certain measures to prevent iatrogenic (treatment-induced) conditions from occurring. For cancer patients these prophylactic procedures can include antiemetics for nausea and dental evaluations for osteoradionecrosis. Using FPT before cancer treatment is another type of preventive treatment to guard against infertility as an adverse iatrogenic outcome. Indeed, freezing one's embryos or gametes (sperm or eggs) in case of future infertility is analogous to storing one's blood as a prophylactic precaution in case of an emergency transfusion. People who freeze embryos or gametes and people who store blood are both preparing for the worst case scenario — infertility or emergency blood transfusion — by setting aside a reserve of what they will need to treat the possible iatrogenic condition. While some iatrogenic conditions may be rare or their probability may be difficult to predict, infertility is an unfortunate inevitability for many cancer patients. While one cannot precisely predict the chance of infertility, some treatments for cancer induce infertility rates of eighty percent or more. Indeed, some estimate that up to 90 percent of cancer patients in their reproductive years will be rendered infertile from treatment.[33] Given the high potential for future infertility and the limited timeframe for treatment, in some ways cancer patients' need for infertility treatment is greater than those who do meet the standard definition of infertility. Unlike traditional infertility patients who are often able to receive infertility treatment until they conceive, cancer patients frequently only have one chance at preserving their fertility because it must occur before they begin cancer treatment. Cancer patients typically start treatment immediately before or shortly after their diagnosis. Consequently, cancer patients have only a small window of time in which they can utilize FPT. Once their cancer treatment commences, the opportunity to preserve their fertility closes. Couples undergoing infertility treatment are typically not as pressed for time as cancer patients. Though some women may feel a time crunch because their increasing age makes it more difficult to conceive, they have multiple chances to use infertility treatments and some couples continue using them for months or even years.[34]

One possible objection to including FPT in infertility mandates is the fear this technology will then have to become available to all women, not just those with cancer or certain other diseases, because all women have foreseeable future infertility: menopause. In other words, one may be concerned that including FPT for cancer patients will lead to a slippery slope in which individuals without cancer or any other disease will eventually be included in the mandate. Yet a line — perhaps not perfectly clear, but clear enough — can be drawn between using FPT for medical reasons and social reasons. Indeed, women who have foreseeable future infertility due to a disease (e.g., Turner's Syndrome) or treatment for a disease (e.g., chemotherapy) can be distinguished from women wanting to use FPT for delaying childbearing.

Some have asserted that an easy way to differentiate between medical and social reasons for using FPT is causal responsibility for infertility: in the former, the woman is generally not thought to be responsible for her infertility, while in the latter she often is seen as responsible. When women use FPT to prevent age-related infertility, they are usually labeled as causally responsible for their infertility because they "chose" to delay childbearing.[35] Despite the fact that the woman with cancer is the one who decides to have the cancer treatment that could leave her infertile, typically she is not seen as causally responsible for her infertility. In many cases, the occurrence of certain diseases is often attributed to bad luck, not to the action of a particular agent. It was bad luck that a woman developed cancer in the first place and, moreover, that treatment options for cancer often lead to infertility. Consequently, if she decides to pursue treatment intended to save her life, she may have no option but to risk her fertility. This is a no-win situation, as she must choose between treatment options where there is always a risk of loss — either loss of her life and/or loss of her fertility.[36] In short, while the woman is (hopefully) the one making the decision about her treatment and thus is causally responsible in the sense that her choice leads to an event (the treatment) that engenders her infertility, we typically do not understand her to be causally responsible for her infertility because we see her cancer and

the difficult decision she must make as both not her fault and beyond her control.

Causal responsibility is just one method for determining who should have access to FPT under an infertility mandate. Other, perhaps less contentious, options are also possible (e.g., assigning a bioethics panel to make these decisions or creating a formula based on a patient's age, chance of infertility, and remaining years of fertility). We do not want to go into these other suggestions in detail. Rather, in response to concerns about a slippery slope, our goal is to highlight that feasible options exist that would set boundaries on who is eligible for FPT. Equipped with methods for determining who should be permitted to use FPT, infertility mandates should expand to include this technology. The current definition of infertility is too limited and thus unable to recognize and accommodate the needs of cancer patients who face the unique situation of a strong potential for foreseeable iatrogenic infertility and a limited timeframe in which to preserve their fertility.

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Legislative Routes to Coverage

Continuing to use Massachusetts as our example, in this section we outline four legislative routes[37] that could be taken to expand the definition of infertility to include cancer patients, highlighting possible complications and moral dilemmas that might arise from each. All four routes would require Massachusetts' legislature to either amend the existing mandate or adopt a new mandate. While legislation is often introduced without success, we believe seeking coverage through a legislative route is politically viable.

Health insurance mandates have become commonplace, especially cancer-related mandates, in state law since the 1990s. As of 2009, there were 2,133 individual mandates regulating providers and/or benefits. Massachusetts is responsible for 52 of these mandates.[38] From 2000 to 2002, an average of 76 health insurance mandates were passed per year in the United States, which rose from 59 mandates per year during the 1990s.[39] While these mandates address issues ranging from telemedicine to vaccinations, every state has at least one mandate addressing cancer. For example, all states now have legislation regulating coverage for breast reconstruction surgery after recovering from breast cancer and many also address coverage for diagnosing prostate cancer.[40] Given the recent trends in adopting and modifying health insurance mandates, it is plausible that new legislation could be adopted so cancer patients could meet the definition of infertility and thus have access to infertility treatment, including fertility preservation treatment. We recognize, however, that the current economic climate and passage of national health reform could present challenges that did not exist during the relatively quick passage of the initial infertility mandate in Massachusetts.

Allowing the Commissioner of Insurance to Set the Definition

Changing the definition of infertility could be delegated to the Commissioner of Insurance. Using Massachusetts as a model, a state's Commissioner of Insurance could update the definition of infertility as medicine and science evolve. Under a similar approach, the Commissioner could allow for petitions to amend the definition of infertility and examine them using ASRM and ACOG expertise along with other recognized experts. Although this route could provide a more accurate definition of infertility over time, it could lead to a shift, or perhaps the perception of shift, in the definition of infertility from a medical definition to a political definition. Indeed, there is a potential tension between the law's original intent to provide a medical definition of infertility devoid of political context and its intent to change alongside medical advancements. Furthermore, placing the power to change the definition of infertility into the hands of just one state employee may give the appearance that the definition of infertility is a political, and even a partisan, matter to be decided by politicians rather than medical professionals. There is also the concern that health care providers who belong to ASRM or ACOG could push to categorize certain procedures as non-experimental so that they could make more money; the logic here is that if the procedures were included in the mandate,

more people would choose to have them and providers would benefit financially.

Including a Clause Specifically for Cancer Patients
As previously mentioned, Massachusetts' current definition of infertility only applies for a "presumably health individual." Yet, those who have cancer are not likely to be categorized as healthy. One route to coverage for these individuals is to amend the current mandate by adding a clause addressing the population of people facing infertility due to cancer treatment. Rather than modifying the current definition to be more inclusive, this route tacks on a different definition of infertility specifically for cancer survivors. Such a clause is advantageous not only because it would explicitly include cancer patients, but also because it would provide separate criteria for cancer patients to meet the definition of infertility. Indeed, this option acknowledges the unique situation cancer patients face: they have a limited window of opportunity to preserve their fertility before beginning treatment that is likely to render them infertile. Yet, the narrow focus of this clause is also a disadvantage in that individuals with other medical conditions that could lead to infertility would be excluded. Relying on this route could be tedious and inefficient given that Massachusetts would have to add a specific clause each time they decide to extend coverage to another group of currently excluded individuals.

Adopting ASRM or ACOG Definitions
Another possible route is for the mandate to rely upon the ASRM or ACOG definition of infertility rather than a state having its own definition. While the previous two routes kept the definition strictly within governmental control, this route would depend upon specialized medical societies to provide the definition of infertility. On the one hand, using the ASRM or ACOG definition of infertility enables the mandate to be based on the most up-to-date medical definition of infertility. Moreover, this route does not require any process or mechanism to update the definition; rather, the mandate definition automatically changes with the ASRM or ACOG definition. On the other hand, deferring to medical societies definition of infertility minimizes Massachusetts' control over how this mandate grows and changes, which could lead to unintended and even undesirable consequences (e.g., the definition expanding to include fertility preservation for "social" reasons, ASRM or ACOG classifying procedures as non-experimental so health care providers profit from increased business, etc.).

Adopting a New Mandate
While the previous routes to coverage work within the confines of the current mandate to fulfill its intention of being inclusive, this route would create a new mandate defining infertility services for individuals facing cancer treatments. Massachusetts would be the first state to enact such legislation as no state or federal law currently addresses infertility services for individuals diagnosed with cancer. While creating a new mandate would allow the most flexibility for legislators to design a coverage program for cancer patients, creating a new law could potentially be less politically viable than amending current state law. As previously discussed, there was strong opposition during the original creation of the law from health insurance companies; however, due to the dearth of media attention — and RESOLVE's work to make this so — the debates stayed within the legislative hearings. Given the current nature of health care politics, it is unlikely that a new mandate could pass without significant media attention. So, while this option would set a precedent for all states and could be used as a model, it may face more political challenges than the other routes.

Conclusion

Because of its expansive means for deciding who and what should be covered under its mandate, we used Massachusetts as an example other states with mandates could follow. All four of the routes outlined would expand the definition of infertility in a way to include cancer patients like Melanie, who was introduced at the beginning of this article. There are, as we briefly suggested at the beginning of this article, other routes for increasing coverage for infertility treatment, and none of the four routes we propose are without problems. However, we introduce these routes to show plausible ways to broaden the definition of infertility to encompass cancer patients and allow them covered access to fertility preservation treatments. The current definition of infertility can neither account for, nor accommodate the needs of, cancer patients who may be rendered infertile by their cancer treatment. Our argument could also be applied to other groups of patients who may experience future infertility from treatment for their conditions. The Massachusetts mandate was a bold step forward in treating infertility as a medical condition. We believe it is time to take another step forward by expanding infertility coverage mandates to include FPT for cancer patients.

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40. See Bunce and Wieske, *supra* note 38.