

Presumed Consent With Opt-Out: An Ethical Consent Approach to Automatically Refer Patients With Cancer to Tobacco Treatment Services

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Continued smoking after cancer diagnosis increases the risk of cancer recurrence, treatment-related toxicities, treatment failure, and death.¹⁻⁹ Apart from disease site and stage, continued smoking is the strongest predictor of mortality in patients with cancer.^{9,10} Quitting smoking can increase long-term survival, reduce total symptom burden, decrease treatment toxicity, optimize postoperative outcomes in patients requiring surgery, and improve quality of life.^{3,5,11-15}

Despite these considerable benefits, multiple challenges remain to helping patients with cancer quit smoking. In particular, most do not receive evidence-based tobacco treatment services. Clinical practice guidelines recommend that oncologists assess patient readiness to quit and assist in making a quit attempt, yet < 40% of oncologists report treating or referring their patients to tobacco treatment.¹⁶ If patients do not express interest in quitting, typically, referrals to treatment are not made. Thus, receipt of treatment is entirely dependent on patient readiness to opt in to treatment. However, patients can benefit from treatment even if they do not have an initial desire to quit.¹⁷ Tobacco treatment doubles the likelihood of abstinence even among patients unwilling to quit at initial assessment, an effect size similar to that among patients who wanted to quit.¹⁸ Thus, opt-out approaches to tobacco treatment in cancer care have been proposed.¹⁹ In this approach, which is based on the concept of presumed consent, all patients with cancer who smoke are automatically referred to tobacco treatment, irrespective of their intent to quit. Presumed consent assumes that individuals want to participate in services that may improve their health unless they expressly decline (ie, opt out); failure to oppose treatment is considered as consent. The opt-out approach also has the practical advantage of not depending upon clinicians initiating discretionary referrals.

To improve the reach of tobacco treatment services, the National Cancer Institute launched the Cancer

Center Cessation Initiative to integrate tobacco treatment as a routine element of cancer care.²⁰ Several participating cancer centers have begun using an opt-out approach to refer all patients to tobacco treatment, with encouraging results in terms of increasing the reach and effectiveness of tobacco treatment for patients with cancer.²¹⁻²⁵ Although the potential benefits of referral are clear, there are also important questions about the ethical justifiability of such practices, such as whether doing so violates patient autonomy or results in unintended consequences. Although the seminal paper proposing the opt-out approach discussed some of these issues, and generated lively correspondence, no study has yet explored in detail the ethical considerations in implementing this approach.^{19,26-28}

In this work, we examine several ethical considerations in using a presumed consent with opt-out approach to tobacco treatment, referred to hereafter as opt-out. Ethics involves weighing consequences, goods, and the rights of moral agents. The opt-out approach presupposes that certain goods and consequences are worth pursuing in general, while preserving a way for patients to refuse services if they so choose. We argue that although the opt-out approach shapes how patients exercise their liberty and choice, it is rooted in patient welfare in terms of improved outcomes. This intention aligns with the duty of health professionals (beneficence) and implies that systems may be set up toward that end so long as a right to refuse is preserved (autonomy). We also argue that practice protections can ensure patient choices are honored and the dignity of patients with cancer who choose not to pursue treatment is preserved. As a point of reference, the arguments in this work are summarized in [Table 1](#).

DOES THE OPT-OUT APPROACH TO TOBACCO TREATMENT REFERRAL VIOLATE PATIENT AUTONOMY?

Opt-out approaches can influence health behavior and positively impact patient care.^{29,30} In medical settings,

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TABLE 1. Summary of Concerns Regarding the Opt-Out Approach to Tobacco Treatment in Cancer Care and Responses to These Concerns

Concerns That Opt-Out for Tobacco Treatment May:	Response
Violate patient autonomy	The ability to opt out preserves autonomy, while serving the best health interests of the patient (ie, honors the principle of beneficence).
Place emotional burden on patients	Opt-out can be emotionally beneficial by: (1) promoting a positive change in lifestyle choices that can immediately impact their treatment; and (2) empowering patients to have control over their cancer care.
Impose a financial burden on patients	The Affordable Care Act requires health plans to cover tobacco cessation interventions and waive any out-of-pocket expenses, as does Medicare and Medicaid. Offering free tobacco treatment or referral to free public tobacco treatment programs is also an option for the uninsured or if plans are not compliant.
Add to a patient's treatment burden through multiple additional appointments	Opt-out does not require a series of treatment appointments; the first can be presented as an opportunity to discuss options for and benefits of treatment with a tobacco treatment specialist so that patients can make an informed decision about how to proceed. Patients retain the right to forego scheduled appointments if those do not fit with their life.
Strain the clinician-patient relationship	Providing a consistent message that referral to tobacco treatment is a routine part of cancer care can strengthen the clinician-patient relationship by demonstrating that clinicians view their patients as more than just a cancer case, but as a person with a life apart from cancer.

examples of opt-out approaches include mandatory influenza vaccination for healthcare workers, routine administration of pneumococcal vaccine for eligible hospitalized patients, default registration for organ donation, and obtaining patient samples for population biobanks as part of routine care.³¹⁻³⁴ The utilization of the opt-out approach among cancer centers has steadily increased. It shows promising results in terms of increasing patient attendance to tobacco treatment and subsequent quit rates compared with the traditional opt-in approach, although further work is necessary to evaluate long-term cessation efficacy.^{21-25,35-37} Although increasing quit rates among patients with cancer is clearly beneficial, the possibility of interfering with patient autonomy is real.

Autonomy is defined as the ability of an individual to act freely in accordance with a self-chosen plan such that they are free of controlling influences that determine their action or inhibit self-directedness.³⁸ The act of referring a patient who uses tobacco without taking into consideration intent to quit, or obtaining explicit consent prior to referral, is inherently controlling. Opt-out may thus appear to limit patient choice. Instead of actively choosing to consent or immediately decline a tobacco treatment appointment, patients are required to take additional steps to refuse treatment. The opt-out approach leverages medical authority and the position of power to divert patients toward an action they did not actively choose. Such limitations of patient autonomy could lead to what has been called a dignitary harm—someone being wronged by virtue of the disrespect implied in delimiting their choices. Additionally, patients may believe that the provision of care could be jeopardized if they do not comply.

However, we argue that patients still retain freedom of choice and that the opt-out approach differs from a mandate. We also argue that it is not coercive—denying

smokers cancer treatment until they quit smoking would be coercive. It is reasonable that clinicians presume that patients want to improve their health. Although clinicians may sometimes misestimate which services will achieve this goal, there is no doubt that quitting is beneficial. The opt-out approach intentionally structures choices, the so called choice architecture, on the basis of a presumption of beneficence—a central ethical principle in medicine to maximize patient welfare.^{34,39} It is based on soft paternalism—shaping choices while maintaining freedom.^{34,40} Clinicians often assume that patients want proven interventions, such as mammograms, colonoscopies, and vaccines, among others. Systems for preventive care are designed on this assumption, as the act of pursuing medical care implies the desire to maximize health outcomes. The opt-out approach provides patients access to evidence-based treatment that will maximize the possibility of successful cancer treatment—while still allowing patients to exercise autonomy by not scheduling or canceling a tobacco treatment appointment.

Potential threats to autonomy with the opt-out approach can be managed. Respecting autonomy requires clinicians to honor patient agency by avoiding undue influence or coercion and respecting individual rights.³⁸ Moreover, protections need to be in place to honor and respect the dignity of patients who decide to continue to smoke during cancer treatment. To limit dignitary harms, patients should be made aware of their right to decline (opt out) without real or perceived negative consequences to their care and be provided practical opportunities to do so.

UNINTENDED CONSEQUENCES OF THE OPT-OUT APPROACH

Practical consequences must be considered prior to implementing an opt-out approach. One concern is the emotional burden opt-out may place on patients, such as

emotional guilt, shame, or embarrassment for their actions.⁴¹⁻⁴³ Patients may blame themselves or perceive that their clinician blames them for getting cancer, increasing anxiety and fear.⁴³ However, we argue that the opt-out approach is unlikely to cause an additional emotional burden as many patients who use tobacco already feel shame or guilt resulting from an internal belief that their lifestyle may have contributed to their cancer.⁴¹ Rather, referral to tobacco treatment promotes a positive change in lifestyle choices that can immediately impact their treatment and may empower patients to have some measure of control over their cancer care, which may in turn be emotionally beneficial.

The opt-out approach may impose a financial burden on some patients. Patients of low socioeconomic status or uninsured (who tend to have a higher prevalence of tobacco use) may be at greater risk of financial strain if tobacco treatment generates out-of-pocket costs, potentially worsening healthcare inequalities arising from tobacco use.⁴⁴ Conversely, opt-out could reduce disparities by reducing clinician referral bias and other barriers to treatment. The Affordable Care Act requires health plans to cover tobacco cessation interventions and waive any out-of-pocket expenses.⁴⁵ In practice, tobacco treatment is not always totally covered. One approach would be to waive these co-payments for patients as elimination of Medicare co-payments increases enrollment into tobacco treatment among lower-income patients.^{27,46} Offering free tobacco treatment is an option for the uninsured or if plans are not compliant. If offering free tobacco treatment is not feasible, patients can be referred to free public tobacco treatment programs, such as online support from sites like that in [ref. 47](#) and telephone support from state quitlines. Finally, costs associated with tobacco treatment may be recovered if cessation is achieved, even if only temporarily, by reducing the purchase of tobacco products and risk of future tobacco-related healthcare expenses.

Other consequences include potential forms of psychological and dignitary harms, such as adding to a patient's treatment burden through additional appointments; the potential to strain the clinician-patient relationship; and shame, embarrassment, or loss of self-esteem if they do not succeed in quitting. As a result, patients may become discouraged or annoyed and lose confidence in their clinician, healthcare team, or the medical institution. This may further impact their desire to comply with not only tobacco treatment but other treatments as well. However, our own experience has found that consistent messages from clinicians and other members of the healthcare team that a referral is a routine part of cancer care can in fact strengthen the clinician-patient relationship by demonstrating that clinicians view their patients as more than just a cancer case.²⁵ Indeed, referral can be presented as an

opportunity to discuss options for and benefits of treatment with a tobacco treatment specialist so that patients can make an informed decision about how to proceed. However, more research is necessary to explore these potential deleterious effects and devise consistent mitigating strategies.

There are also potential beneficial consequences. Making autonomous decisions requires patients with capacity to weigh options and choose one that is aligned with their values and desires. Patients with cancer who use tobacco are confronted with an additional challenge on the basis of logistics of when clinicians assess readiness to quit. Receiving news of a cancer diagnosis is an emotionally difficult situation. In this situation, patients are challenged with concentrating on crucial information such as cancer stage and treatment options.⁴⁸ At such a juncture, the patient may well be unable to adequately assess the information being conveyed about the benefits of quitting, limiting their capacity to make decisions when assessed for readiness to quit, and consequently may refuse tobacco treatment. The opt-out approach does not require an immediate decision to pursue tobacco treatment. It permits a patient's cancer treatment to move forward but offers them time to consider relevant facts, process the information, and discuss tobacco treatment further with tobacco treatment specialists after the initial emotional shock subsides, without a commitment to quit.

In conclusion, we consider the primary ethical concern with using the opt-out approach for tobacco treatment as balancing the preservation of autonomy with the principle of beneficence. The medical community has a duty to promote the well-being of patients while allowing them to accept or refuse care. The benefits of improved cancer treatment outcomes outweigh any inconvenience to a patient if they choose to opt out of their tobacco treatment appointment. The traditional approach to tobacco treatment requires patients to actively opt in to care—placing a greater importance on autonomy at the potential expense of beneficence. The opt-out approach honors both principles, serving the best health interests of the patient while protecting autonomy. As with any treatment approach, there are potential unintended consequences, including psychological, financial, or dignitary harms. However, experience to date suggests that these consequences are manageable and are outweighed by the benefits of this approach. Each healthcare system implementing this approach needs to assess their practice, and their patient population, to understand how best to technically implement automatic referrals and minimize unintended consequences. We conclude that implementing a presumed consent with opt-out approach for tobacco treatment is ethically justifiable and should be seriously considered by healthcare systems that serve patients with cancer.

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