COVID-19 vaccination in incapacitated, unrepresented patients

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Over 70,000 incapacitated, unrepresented patients need care in the United States each year.1 The majority of these individuals are underserved, and providing them timely, high-quality care—while challenging—is a moral imperative that requires balancing competing ethical principles. The coronavirus disease (COVID-19) pandemic has unearthed underlying and long-standing inequities in our healthcare system, with underserved patients suffering morbidity and mortality at rates that exceed those of their peers.2 Central to mitigating the disproportionate harm of COVID-19 on underserved populations is ensuring broad vaccination to eligible groups. This is a particular challenge when caring for incapacitated, unrepresented individuals, most of whom are currently eligible for COVID-19 vaccination based on age and comorbidity.

Clinical care for these (and all) patients is driven by the five ethical pillars of bioethics: respect for patient autonomy, beneficence, nonmaleficence, distributive justice, and parsimony (Figure 1).3 By definition, for incapacitated individuals, lack of a medical decision-maker impairs autonomy. For decisions that are not time sensitive, conservatorship made to the County Office of the Public Guardian allows surrogate decision-making. Applying for conservatorship maximizes an individual’s autonomy by securing a definitive, legally approved surrogate decision-maker. Even though an individual may not have decision-making capacity, care can be guided by previous data about their preferences. These include prior statements (made when they had capacity), advance directives, Physician Orders for Life-Sustaining Treatments, and other documented conversations about goals of care. Absent such direction, we must rely upon surrogate decision-makers to make decisions in that individual’s best interest. These may include family, friends, or other acquaintances, but for over 70,000 incapacitated patients in the United States, none are available. However, conservatorship through the Office of the Public Guardian typically takes 12–18 months to complete, possibly longer during COVID-19. In the interim, individuals who are eligible to receive the COVID-19 vaccine are at risk for becoming infected while appropriate surrogate decision-making is pursued.

Given the average age of incapacitated, unrepresented patients, the COVID-19 infection fatality rate is estimated at greater than 12%, and more than 19% if a nursing home is required.1,4 In the absence of conservatorship, “administrative consent” is an option. The specific mechanism to achieve this varies across healthcare settings. In the Department of Veterans’ Affairs, for instance, this involves the attending clinician of record and the chief of service cooperating as medical decision-makers, using a best-interest standard. They weigh prior preferences, risks, benefits, and alternatives the same way other surrogate decision-makers would. Other healthcare settings in the United States have similar policy-driven approaches to providing “informed consent by staff committee” for such patients.

Although federal law does not require informed consent for most vaccines, several state laws do, and the particular harms imposed by COVID-19 render the decision to vaccinate exceptionally crucial. Federal law requires signature on a Vaccine Injury Statement (VIS) form for the purposes of satisfying the vaccine injury act, whereas Veterans’ Administration national policy stipulates that vaccines only
require oral consent. For incapacitated, unrepresented patients, either oral consent or VIS signature is unreliable, and elevated deliberation of competing priorities by way of informed consent is most appropriate.

The available COVID-19 vaccines have quantifiable risks and benefits, and although they received Emergency Use Authorization under section 564 of the Federal Food, Drug, and Cosmetic Act, they are not currently approved by the Food and Drug Administration.\textsuperscript{5,6} In balancing beneficence and nonmaleficence, the benefits and drawbacks need to be weighed. Published data from a large randomized controlled trial demonstrated excellent efficacy: 95\% effective in preventing moderate to severe COVID-19 infections and with adverse events similar in drug and placebo arms.\textsuperscript{7} Distributive justice compels us to weigh the potential risks and demonstrable benefits in a timely fashion and not allow a decision to be delayed because of a lack of capacity or representation. If other individuals of similar age and comorbidity, but with capacity or representation, would make a decision regarding COVID-19 vaccination in a matter of days, we are compelled not to delay vaccination if other ethical principles point toward vaccination. Finally, when applying the principle of parsimony, it is generally accepted that a highly effective preventative health measure, such as vaccination, against a significantly morbid disease that frequently requires intensive care is not wasteful and in fact conserves scarce resources.

With consideration of the impediment to autonomy, the primary ethical pillar relevant to care for incapacitated, unrepresented individuals is the beneficence of the COVID-19 vaccine. The mild substantiated maleficence of the COVID-19 vaccine is outweighed by the beneficence of vaccination. Importantly, the only risks to be considered are proven, scientifically accurate risks. Although disinformation may inform individual preferences, only accurate data should be considered in clinical decisions. Beneficence thus guides us to vaccinate eligible patients as soon as they are eligible, and the conservatorship process is prohibitively long; thus, the vaccine should be provided through administrative consent.

Health equity compels us to advocate for and aggressively protect our most vulnerable populations.\textsuperscript{2} That they have disproportionately suffered from the COVID-19 pandemic is a stain on our healthcare system and a call for action to develop specific, systematic care plans to ensure high-quality care for all. Protecting unrepresented, incapacitated individuals is a great place to start.

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**CONFLICT OF INTEREST**

None.
AUTHOR CONTRIBUTIONS
All authors contributed equally to this submission.

SPONSOR'S ROLE
None.

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