points raised with respect to the need to address medication delivery systems for clinical decision-making. Our Clinical Practice Guideline relied on the available literature to date to perform a rigorous, PICO (Population, Intervention, Comparator, and Outcomes)-driven distillation of scientific evidence to provide recommendations pertaining to key questions regarding the pharmacologic treatment of chronic obstructive pulmonary disease. However, the available evidence did not allow us to address the merits of specific medication delivery devices. As per the committee discussions, we raised the issues of feasibility and acceptability as playing a role in the decision to prescribe various types of inhalers. Though we noted issues such as cost and burden of use of inhalers, we did not specifically identify cognitive ability, dexterity, coordination, and inspiratory flow as additional issues to be addressed. We thank the authors for raising these important considerations in this forum and look forward to future randomized trials that address matching medication delivery devices to specific patient characteristics. ■

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Linda Nici, M.D.*
Providence Veterans Affairs Medical Center
Providence, Rhode Island
and
The Warren Alpert Medical School of Brown University
Providence, Rhode Island

Shawn D. Aaron, M.D.
The Ottawa Hospital Research Institute at the University of Ottawa
Ottawa, Ontario, Canada

*Corresponding author (e-mail: linda_nici@brown.edu).

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Treatment Decisions for Unrepresented Patients: American Thoracic Society/American Geriatrics Society Policy Statement Lacks Sufficient Guidance

To the Editor:

The *Journal* recently published a joint statement of the American Thoracic Society and the American Geriatrics Society on medical decision-making for unrepresented patients in the critical care setting (1). This statement is an important contribution, but it neglects at least one significant aspect of the decision-making process for unrepresented patients, as follows: how to identify the point in an unrepresented patient's treatment course at which an alternative decision-making process should be implemented. A comprehensive approach to supporting the decision-making process for these patients requires that this question be answered systematically, and this statement is a missed opportunity in this regard.

There are many ways that this issue can present itself in the clinical setting. For example, in some cases, an unrepresented patient may need a line placement, a blood transfusion, or some other nonemergency but consent-requiring procedure. Should an alternative decision-making process be initiated under such conditions? Is it *really* necessary for the physician to justify the need for a peripherally inserted central catheter line in a hypotensive patient, for example? Some clinical ethicists answer in the affirmative—the procedure requires informed consent, so an alternative process is always required. But this seems a terrible waste of time and resources for all involved, and it can undermine clinician willingness to engage with appropriate processes when more urgently necessary. This sort of challenge is not considered by this statement, except to flag it as something they do not intend to address. Guidance on when to initiate an alternative decision-making process would help clinicians to better navigate these circumstances, and comprehensive guidelines on medical decision-making for unrepresented patients should address this issue.

A lack of implementation guidance also creates the possibility of moving too quickly or too slowly to an alternative decision-making process for unrepresented patients, which may lead to avoidable violations of patient autonomy. For example, a patient with a life-threatening thrombus may benefit from surgical intervention, but this may turn out to be an unwanted intervention once the patient's surrogate decision-maker, perhaps a difficult-to-locate relative, is identified. In this type of case, moving too quickly to an alternative decision-making process can lead to unwanted care. Similarly, an unrepresented patient for whom comfort-focused care is medically and ethically appropriate may end up receiving aggressive care before an alternative decision-making process can be implemented. When the decision-making process is too slow for the developing clinical circumstances, the medical team may feel compelled to provide potentially inappropriate care to unrepresented patients (2).

These are difficult but familiar situations for clinicians to navigate, and a policy statement that declines to offer any guidance about how to address such concerns must ultimately be regarded as incomplete. The issue can be approached conservatively or aggressively or via a nuanced process that considers the many clinical and ethical considerations that might be involved. But neglecting the question altogether is a missed opportunity to provide helpful and much needed guidance for front-line clinicians. ■

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Eli Weber, Ph.D., M.A., H.C.E.C.-C.*
Kaiser Permanente
San Bernardino County Area, California

*Corresponding author (e-mail: elijah.j.weber@kp.org).

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Reply to Weber

From the Authors:

We thank Dr. Weber for his acclamation and important comments regarding our recent policy statement, in which our interprofessional, multidisciplinary expert committee provides clinicians and hospital administrators with recommendations for decision-making on behalf of unrepresented patients in the critical care setting (1).

We agree with Dr. Weber that the policy statement does not provide an algorithm for determining the exact point in every patient's treatment course at which an alternative decision-making process should be implemented. Dr. Weber wants a "comprehensive" and "systematic" approach to answering this question. But for two reasons, providing that type and level of direction dwelled outside the scope and purpose of this policy statement.

First, professional organization policy statements generally leave significant flexibility to individual institutions to adapt guidance to their local circumstances and conditions. For example, prior American Thoracic Society policy statements on healthcare policy, ethics, and end-of-life care are explicit that they offer only a "framework" or "proposed components of an institutional policy" (2–4). Similarly, this policy statement omits certain fine-grained details, noting that its six recommendations must be "tailored to the capabilities of the individual institution" and that "institutions should have flexibility" in how they implement the guidance. Indeed, at the heart of this policy statement is an explicit tradeoff between "excessive and insufficient procedural safeguards" (1). Although this policy statement sets some broad parameters, it is appropriate that various institutions will strike the balance between fairness and feasibility differently.

Second, as Dr. Weber notes, this policy statement is focused on making life-sustaining treatment decisions for unrepresented patients in the ICU setting. Within this context, we describe an alternative decision-making process and unambiguously recommend its use except in time-pressured situations. Outside the context of life-sustaining treatment, the policy statement does not address when to use an alternative decision-making process. But we do suggest that "minor interventions that are less consequential. . . may require less process and oversight." Most state laws and professional organization guidance agree that an alternative decision-making process is not required for routine treatments and procedures that are low-risk and within broadly accepted standards of medical practice (5). In sum, to answer Dr. Weber's direct question, an alternative decision-making process is required for decisions about life-sustaining treatment and is not required for decisions about routine treatment.

But Dr. Weber focuses on a third tier of interventions—"nonemergency but consent-requiring procedure[s]." He is correct that the policy statement does not directly address these interventions. But even if the policy statement does not provide precise trigger points, it still provides two types of helpful guidance in this domain. First, the recommendations on prevention remain the same. Because many seemingly unrepresented patients are not actually unrepresented, institutions should implement strategies for careful capacity assessments, diligent searches for potential surrogates, and proactive advance care planning.

Second, whether a decision concerns major medical treatment or life-sustaining treatment, the decision-making process should promote the same five ethical goals (1). At least for the subset of consent-requiring procedures that involve significant risk, institutions should approximate the decision-making process that the policy statement provides for life-sustaining treatment. This is the approach taken in several state statutes that specify separate levels of rules, which require increasing amounts of oversight for decisions about routine, major, and life-sustaining treatment (5).

Unrepresented patients are among the most vulnerable in the healthcare system (1). For decades, the dominant approach has prioritized efficiency over fairness and procedural due process. Dr. Weber is right to call attention to the need for recalibrating that balance not only with respect to life-sustaining treatment but also with respect to major medical treatment. ■

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Thaddeus M. Pope, J.D., Ph.D., H.E.C.-C.*
Mitchell Hamline School of Law
Saint Paul, Minnesota

Lynette Cederquist, M.D.
University of California San Diego Health
San Diego, California

Paula Goodman-Crews, M.S.W., L.C.S.W.
Kaiser Permanente Southern California
Pasadena, California

Douglas B. White, M.D., M.A.S.
University of Pittsburgh Medical Center
Pittsburgh, Pennsylvania