

Antimicrobial Stewardship

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FROM THE EDITOR

What Is Antimicrobial Stewardship?

Olivia S. Kates, MD, MA

Last month's issue of the *AMA Journal of Ethics* explored antimicrobial resistance (AMR) as a complex challenge emblematic of the interconnectedness of living systems—from the smallest microorganisms to enduring global ecosystems—all linking back to human action, health, and disease. It is this interconnectedness that demands a unique, collaborative approach to finding solutions. This issue examines antimicrobial stewardship, a response to the threat of AMR. Antimicrobial stewardship is a tool kit of structured interventions generally operating at the same levels as AMR, with individual-, clinician-, and **patient-level tools**, organizational tools, and social and public health tools.¹ The purpose of stewardship at every level is to guide the use of antimicrobials—but toward what end?

The Centers for Disease Control and Prevention's Core Elements of Antibiotic Stewardship recommendations highlight 3 ends of antimicrobial stewardship programs: "to effectively treat infections, protect patients from harms ... and combat antibiotic resistance."² We know that antimicrobial use drives AMR. This is a descriptive, scientific claim, supported by high-quality empirical data.³ But antimicrobial stewardship seeks not to end antimicrobial use but rather to target "misuse," "overuse," or "inappropriate" or "irresponsible" use of antimicrobials. These characterizations of certain examples of antimicrobial use make normative claims—claims about what is right or wrong, good or ... not so good. The ethical practice of antimicrobial stewardship depends on defining "good" antimicrobial use (in relation to misuse or overuse, for example), building consensus around those definitions, navigating the uncertainty inherent in antimicrobial decision making, and balancing good antimicrobial use with other values like patient and **professional autonomy**. If normative characterizations of antimicrobial use are incompletely defined and imperfectly understood, so, too, are the conceptual frameworks for balancing the diverse ends of antimicrobial stewardship. As you explore this issue, be mindful of the language used to describe both the values of antimicrobial stewardship and the approaches to resolving competing values.

- **Stewardship as correctness.** In its simplest form, antimicrobial stewardship promotes the correct—that is, the *empirically* correct—use of antimicrobials via clinicians choosing an antimicrobial that is effective against the target microorganism and able to penetrate the affected body tissue; administering that drug at a dose appropriate to the patient's condition, size, and metabolism; and continuing the treatment for the duration needed to achieve the therapeutic goal.⁴ Certainly, there are empirically wrong choices for a given therapeutic goal, and stewardship seeks to avoid them. But the sheer complexity of patient, disease, and drug characteristics may make it hard to identify a single "right" or "best" choice based only on empirical data.

- *Stewardship as refinement.* Presented with many at least passable options, stewardship may seek to refine antimicrobial use on the margins by using small, incremental changes or nudges to fine-tune antimicrobial decision making. For example, a stewardship program might implement reminders about antimicrobial dose adjustment for kidney function in the electronic health record.⁵ This perspective frames stewardship as subtle, gentle, and minimally intrusive. But is marginal refinement a sufficient response to the threat of AMR?
- *Stewardship as optimization.* Taken further, refinement may become optimization. A kind of quantifiable perfection, optimization is less gentle than refinement and more ambitious. Instead of just any step in the right direction, optimization asks us to go as far as we can toward “ideal” or “perfect” antimicrobial use. But optimization depends on a unified understanding of the good and bad aspects of antimicrobial use. As prevalent as the language of optimization is in the conversation about antimicrobial stewardship, such a unified understanding is elusive. We cannot simultaneously optimize 2 competing goods—maximization of therapeutic benefits of antimicrobials *and* minimization of the risks of emergence of resistance, for example, without agreeing how these goods should be weighed against one another.
- *Stewardship as moderation.* Perhaps rather than optimization, stewardship demands moderation. Moderation is a virtue between the opposing extremes of excess and austerity. Less quantitative and more subjective than optimization, moderation in antibiotic use might be akin to other virtuous traits and behaviors: wisdom, patience, and courage. We see these deeply rooted character traits in the thoughts, speech, and actions of our role models, who have aspired to and practiced these virtues over long and distinguished careers, such that they have become effortless. Instilling and nurturing these virtues has long been a priority of the apprenticeship model of medical training.⁶ But, like other virtues, the virtue of moderation might appear different to different observers. Some might see moderation in the choice of oral rather than intravenous antibiotics, others in the use of an intravenous antibiotic with a narrower spectrum like oxacillin rather than in an oral antibiotic with a broader spectrum like levofloxacin. Antimicrobial stewardship **calls upon health professionals** in diverse roles at *all* levels of training to embrace new data and strive for moderation, meaning that stewardship knowledge is not only transmitted from expert to apprentice but also from peer to peer and even from junior to senior.
- *Stewardship as conservation.* Antimicrobial stewardship can be seen as a part of an even larger paradigm shift, a focus on sustainability and conservation. Much as human activity has driven climate change, habitat destruction, and extinction, human activity (in the form of antimicrobial use) has driven AMR. Antimicrobial stewardship, then, can be seen as a conservation intervention whose purpose is to better preserve the current microbe and antimicrobial ecology for years to come.⁷ Just as environmental conservation seeks to conserve vanishing habitats and waning species so that future generations can enjoy a world of rich biodiversity and stable ecosystems, so antimicrobial conservation seeks to conserve effective treatments for diseases so that future generations can enjoy a world where common infections are still treatable and not lethal and where treatments—elective surgery, chemotherapy, organ transplantation—potentially complicated by infections are still safe and feasible. This focus on the future demands change, often sacrifice, in the present. But while it may seem reasonable to demand sacrifices of convenience—such as

many single-use plastics or vanities like private jets and yachts—delineating ethical “sacrifices” in health is more complicated.

In this issue of the *AMA Journal of Ethics*, contributors explore what antimicrobial stewardship is and suggest ethics’ pivotal roles in antimicrobial stewardship scholarship, practice, and advocacy.

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CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

How Should Clinicians Navigate Interprofessional Tension in Their Roles as Antimicrobial Stewards?

James B. Cutrell, MD and James M. Sanders, PhD, PharmD

Abstract

Pharmacists and physicians play key roles in antimicrobial stewardship. This commentary on a case describes these health professionals' need to collaborate to optimize therapeutic use of antimicrobials in clinical settings. Prescription preauthorization is one antimicrobial stewardship strategy that can meet with some physicians' frustration and generate conflict between pharmacists and prescribing physicians, particularly when pharmacists make alternative treatment recommendations. This commentary considers interprofessional tension concerning prescription preauthorization and suggests strategies for navigating such conflict.

Case

RX is an infectious diseases (ID) pharmacist reviewing a list of antimicrobials pending prior authorization. RX calls Dr H, a hospitalist physician colleague, to discuss their prescription for meropenem, a broad-spectrum antibiotic, for JJ, an 89-year-old patient with delirium whom Dr H admitted this morning. JJ has mild hypertension and osteoporosis but is generally healthy and has not been hospitalized for several years.

During the call, Dr H explains that the order for meropenem is for empiric coverage pending further diagnostic workup, including urine cultures, to guide definitive therapy for possible sepsis from a urinary tract infection (UTI) that Dr H believes is the cause of JJ's delirium. RX queries Dr H specifically about whether the bland urinalysis, pending urine culture, and lack of leukocytosis make UTI an unlikely cause of JJ's delirium, particularly from a multidrug-resistant organism that would require meropenem. Dr H responds, "If JJ has an infection, a poor clinical outcome will be my professional responsibility, so I won't change the prescription." RX acknowledges Dr H's perspective and responsibility for the patient's care. But RX also shares their own assessment of the patient informed by (1) the organization's UTI guidance, which discusses risk factors necessitating broad-spectrum empiric antibiotics (absent in this case) and (2) local susceptibility patterns (ie, hospital antibiogram) for common UTI pathogens. Dr H responds, "I agree that the information RX provided suggests that an alternative agent might work, but I remain concerned about JJ's clinical status, so I prefer to use the broadest agent possible. I'll switch when JJ's urine cultures are back in a couple of days."

RX then states that, in cases of disagreement like this one, the next step in the organization's prescription preauthorization protocol is to consult the antimicrobial stewardship program's medical director, Dr MD. Dr MD's review of JJ's record supports RX's findings and recommendation to utilize ceftriaxone, a narrower-spectrum agent with excellent activity against common UTI pathogens based on hospital antibiogram. Dr MD calls Dr H, who now agrees to changing meropenem to ceftriaxone. Dr H adds that they do not appreciate pharmacists "acting like antibiotic police" about their empiric antimicrobial prescribing decisions. Dr MD counters, "We are all working on the same team toward the same goal to take the best care of our patients."

After the interaction, Dr MD wonders how to improve collegiality and promote more efficient, productive interprofessional collaboration.

Commentary

Antimicrobial stewardship programs (ASP) employ a systematic approach that draws on medical and pharmaceutical expertise and practice "to optimize clinical outcomes while minimizing unintended consequences of antimicrobial use."¹ These programs are typically led jointly by an ID physician and pharmacist, but to be most effective they require a multidisciplinary and collaborative approach that includes stakeholders from a diverse group of individuals: inpatient and outpatient prescribers, non-ID pharmacists, infection preventionists, nurses, microbiologists, patients, and many others.¹ While all of these individuals have an essential and important role in antimicrobial stewardship, in this commentary, we will use the term *stewards* to refer specifically to physicians and pharmacists who have a formal role in an established ASP. The case presented epitomizes the ID pharmacist conducting one of several core ASP activities, formulary restriction and prescription preauthorization.¹ In executing these activities, it is commonplace for pharmacists to face difficult situations that might challenge their professional duty, code of ethics, and moral obligations.^{2,3} In an era of increasing antimicrobial resistance, antimicrobial stewards must weigh the needs of current patients to receive optimal antimicrobial coverage for potentially serious infections against the needs of future patients to avoid a "post-antibiotic era" driven by rampant antimicrobial resistance.^{4,5} When combined with other medical, fiscal, and legal demands, this ethical calculus imposes major burdens on antimicrobial stewards.⁶

Another contributing factor that can exacerbate this internal struggle is the interprofessional tension sometimes experienced by prescribers and pharmacists working together, all of whom have key **antimicrobial stewardship roles** to play. Stewardship pharmacists can find themselves at odds with—and labeled as a "disconnected outsider" by—prescribers who prefer a "just-in-case" approach, as pharmacists try to uphold a firmly held moral obligation of protecting not only the patient at hand but also future patients that antimicrobial resistance might affect.⁶ Prescribers might perceive giving consideration to future patients as favoritism that prevents the pharmacist from fully factoring the current patient's needs into the equation. Thus, routine antimicrobial preauthorization review can lead to perceptions of infringement on prescriber and patient autonomy.^{4,6,7} Ideally, antimicrobial stewardship pharmacists seek to balance prescribers' professional autonomy and their own duty to determine whether the ordered medication is the most appropriate choice. For the pharmacist, these internal and external tensions contribute to the cognitive dissonance that underpins moral distress.⁸

Moral Injury in Health Care

The topic of **moral distress** experienced by health care practitioners, including pharmacists, has recently received increased attention.^{9,10} Isolated incidents of moral distress, in and of themselves, can be overcome in passing, especially in individuals with moral resilience.¹¹ Unfortunately, many antimicrobial stewards experience a buildup or accumulation of moral distress from repeated negative encounters in the form of moral residue, which exists along a continuum with moral injury, increasing burnout rates among stewards.^{9,11,12,13} Moral injury, a concept first developed to explain persistent moral struggles in combat soldiers, has been classically defined as “perpetrating, failing to prevent, or bearing witness to acts that transgress deeply held moral beliefs and expectations.”¹⁴ Similar to other health care professionals, pharmacists can encounter morally distressing scenarios with a frequency or severity that results in moral injury, ultimately leading to their disengagement from ethical duties once the pendulum swings to burnout.¹¹ The end result of burnout has increasingly been the premature attrition of clinical pharmacists, including those in the field of antimicrobial stewardship.¹⁵ Moral distress and burnout experienced by stewardship pharmacists can also be aroused by stressors other than daily clinical activities, such as presented in this case; additional administrative duties (eg, formulary review, drug shortage management) might result in additional moral distress for pharmacists charged with allocating costly and scarce resources for an entire institution or community.^{1,8}

Several potential mediating factors have been described in the literature that make individuals more vulnerable to moral injury, including constraints specific to a task or institution, as well as social determinants of health.^{8,16} Factors that place ID pharmacists at heightened risk of moral injury include the following: (a) their inherent position in the **decisional hierarchy** of medical practice; (b) their complex role in balancing direct clinical and administrative responsibilities; (c) others’ negative perception of their role as stewards, leading to their being dismissed and labeled with the pejorative terms *gatekeeper* and *antibiotic police*; and (d) their insufficient awareness of and training in bioethical principles during pharmacy education.^{6,17,18}

Antimicrobial stewardship physicians and pharmacists need to better identify and implement strategies to prevent and mitigate moral injury. Unfortunately, pharmacists, especially those in long-standing practice, often completed their terminal training without substantial formal pedagogy in bioethics, limiting their abilities and resources to navigate moral and ethical dilemmas.¹⁷ Prior calls for expansion of bioethics curricula in pharmacy education have yet to be answered with such curricula’s widespread adoption.^{17,19,20} However, a renewed urgency to implement this training is critical, given the rising tide of moral injury, burnout, and premature exodus from the field of antimicrobial stewardship.

A final aspect highlighted by this case is the role of physician ASP leaders. Although they clearly experience moral distress and injury along with their pharmacy counterparts, they are situated differently in the medical decisional hierarchy, as illustrated by the contrasting responses of Dr H to RX and MD in this case. Therefore, their role as a bystander is critical in situations such as the one illustrated here of flagrant professional disrespect shown to the pharmacist.²¹ Although some physician ASP leaders might silently become complicit “to keep the peace,” further exacerbating their pharmacy colleague’s moral injury, others might courageously speak up in support of the ID pharmacist to external parties, thereby uplifting them as an equally important member of the ASP team and mitigating morally injurious events. Through skilled and intentional

communication, ASP leaders can convey stewardship recommendations to their physician colleagues while also highlighting the unique expertise that they contribute to enhancing patient outcomes. In turn, this approach can help foster more collaborative interprofessional interactions essential for effective antimicrobial stewardship.

Stewardship Interprofessional Interactions

Having established the reality of moral injury and need for collaboration in stewardship, what ethical frameworks and resources can be brought to bear on this issue? The principlist medical ethics approach popularized by Beauchamp and Childress, with its reliance on 4 ethical principles—respect for autonomy, nonmaleficence, beneficence, and justice—has recently been applied specifically to the field of antimicrobial stewardship and can offer assistance in resolving major ethical dilemmas.²² However, we propose that the complex interplay of clinical decision making, interprofessional communication, and multifaceted motivations at play in daily stewardship activities are best addressed through one of the most ancient ethical frameworks: virtue ethics.

Originating from the work of ancient Greek philosophers such as Aristotle, virtue ethics has seen a recent resurgence in the modern bioethics literature.^{23,24,25} At its core, virtue ethics stakes the claim that **moral character and virtue** are central to justifying the right or ethical course of action; put another way, “a right action is one that a virtuous person would do in the circumstances.”²⁴ While no comprehensive list of virtues pertinent to stewardship exists, some commonly cited virtues relevant to stewardship include trustworthiness, integrity, discernment, and justice.²³ Trustworthiness is “a disposition to take responsibility for whatever is (appropriately) entrusted” to an individual, which fits well within the concept of stewardship.²⁶ Integrity requires honesty and acting consistently with one’s moral principles, while discernment requires using practical wisdom to evaluate and decide between different actions.²³ Finally, justice entails fairness in the allocation and distribution of rights and resources—specifically, antimicrobials in the case of stewardship.²³ A distinctive feature of the virtue ethics approach is its emphasis on the role of emotions and motivations,²³ as right action “involves not merely the performance of certain acts, but requires acting from certain dispositions and (in many cases) certain motives.”²⁴ Another important contribution is its focus on the social and communal aspects of ethical action.²⁷ As Gardiner aptly penned, virtue ethics “has a deep understanding of the social and interpersonal nature of our human existence and how this can affect and be influenced by our moral behaviour.”²³ Finally, for the virtue ethicist, the ultimate goal of any right action (and all of life) is the pursuit of a state of *eudaemonia*, most often translated as “human flourishing.”²³

What would it look like to apply virtue ethics in an antimicrobial stewardship context? We believe that it would entail the cultivation of a health care team environment where all members, both the antimicrobial stewards and those they interact with, pursued the virtues and corresponding actions that promote flourishing for their patients and the entire community. While much constructive work remains to be done to develop this concept more fully, such a health care community might include the following characteristics:

1. All members are valued as equal contributors with unique knowledge and skills to share in caring for patients, as was highlighted in the case vignette.
2. All members share responsibility for and commitment to the common goal of the best possible outcome(s) for the individual patient and broader community.

3. All members seek to carry out their roles actuated by “right” motives, while assuming the best intentions of others wherever possible.
4. All members strive for fairness and equity when using the available health care resources to benefit the individual patient and broader community.
5. All members can confidently share their voice and perspective *and* listen with humility and empathy to others, including patients.

While the outlined vision of a “virtuous” health care community might seem largely aspirational, we believe that the epidemic of moral injury and burnout among health care professionals, including antimicrobial stewards, demands bold action. The lack of constructive work on this specific topic in the literature will require experts from both bioethics and stewardship to better define the problems and develop strategies to combat them. In the meantime, frontline clinicians and antimicrobial stewards should spur each other on to embody the character and virtues conducive to an environment where their patients and the broader community can truly flourish.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

What Does Disability Justice Require of Antimicrobial Stewardship?

Katie Savin, PhD, MSW, Laura Guidry-Grimes, PhD, HEC-C, and Olivia S. Kates, MD, MA

Abstract

This commentary on a case argues that antimicrobial stewardship requires an intersectional disability justice approach if it is to be equitable, particularly for multiply marginalized patients with disabilities residing in nursing homes, who are more susceptible to antibiotic under- and overtreatment. Disability justice concepts emphasize resistance to structural and capitalist roots of ableism and prioritize leadership by disabled persons. A disability justice perspective on antimicrobial stewardship means prioritizing clarification of presumptive diagnoses of infection in vulnerable patients, clinician education led by disabled persons, and data collection.

Case

Dr S is a resident physician responsible for admitting patients overnight. A patient, M, is being transferred from a nursing home (NH) for tachycardia and hypotension. The NH's physician, Dr P, started M on a broad-spectrum antibiotic prior to M's transfer. Dr S notices in M's record that M has had multiple episodes of being treated with antibiotics in-hospital or in the NH, but with no specific infection diagnosis. Dr S worries about exacerbating this pattern of possible excessive antibiotic use that might expose M to unnecessary toxicity and threat of antibiotic resistance. Dr S plans to be judicious with antibiotics when treating M.

M arrives on the unit and is now under Dr S's care. M is 57 years old with a history of cardiac arrest resulting in anoxic brain injury. M has a tracheostomy and normally breathes on her own without a ventilator; however, for transport from the NH to the hospital, she has been connected to a ventilator. M turns her head to look at Dr S when Dr S speaks to M, but M cannot speak while connected to the ventilator, appears to Dr S to be uncomfortable, and does not reliably signal "yes" or "no" in response to Dr S's questions. Now that Dr S has met M, Dr S questions her initial instinct to limit antibiotics for M.

Commentary

Up to 70% of NH residents are prescribed antibiotics over the course of a year, and 40% to 75% of such prescriptions may be inappropriate or unnecessary.¹ Many residents live

in NHs for years, compounding the effects of prescribing practices.² Factors driving antibiotic overprescription in NHs include the complexity and frailty of the patient population and concerns about infection control in a congregate setting. On-site testing for infectious diseases is not reliably available, leading to empirical treatment without definitive diagnosis; furthermore, prescribers are typically off-site, leading to treatment decisions that are often based on nurses' evaluations.^{2,3,4,5}

While there is extensive literature on the particular importance of antimicrobial stewardship in NHs, the issue has not been addressed from the perspective of disability as a social identity. Disabled people⁶ (a term we use in place of "people with disabilities," in recognition of the stated preference for identify-first language of multiple disabled activists and scholars) are at risk for both over- and underprescribing of antibiotics and subsequent antimicrobial resistance (AMR). People with certain disabilities, such as **intellectual and developmental disabilities** and functional disabilities requiring heavy nursing contact, are particularly vulnerable to AMR.^{7,8} Furthermore, NH residents are a vulnerable group of disabled people facing disproportionately high rates of AMR.⁷ Principles of disability justice (DJ) hold significance for understanding disabled people's vulnerability to both over- and underprescribing of antibiotics by framing disability oppression from intersectional, historicized, and structural perspectives. In particular, the principles of *intersectionality*, *leadership by those most impacted*, and *anticapitalist politics* inform this article.⁹

Disability Justice and Nursing Homes

From a DJ perspective that foregrounds systemic forms of ableism in a capitalist society, we consider what makes disabled persons like M susceptible to infections and to AMR in the first place. The DJ commitment to anticapitalist politics refers to resistance to exploitative wealth accumulation and labor productivity as a measure of human worth. This resistance comes readily to many disabled people who face exclusion from labor markets. Perceptions of disabled people as non-contributors to market economies drives prejudice, including against increased numbers of people who are institutionalized outside their communities. Access to community-based long-term care is limited by long wait lists and states' allocation of Medicaid funding to NHs as opposed to community care.¹⁰ Systemic prioritization of NH care results in disabled people's relegation to congregate care sites where their susceptibility to both infection and antibiotic misuse increases. NHs are a setting for pathogenic vulnerabilities, which arise when something "intended to ameliorate vulnerability has the paradoxical effect of exacerbating existing vulnerabilities or generating new ones."¹¹

Disabled people also face barriers to outpatient care that may lead to underuse as well as overuse of antibiotics, such as lack of physical access to clinicians' offices or outpatient diagnostic evaluations, in addition to experiences of ableism that lead to avoidance of primary and preventive care. Biased views among physicians that might lead to such avoidance are well documented, as are accessibility needs.^{12,13} Both dangers of antibiotic over- and underprescribing are present in the case of M: the NH doctor gives broad-spectrum antibiotics before any diagnostic workup, and Dr S considers withholding antibiotics in reaction to a pattern of overprescribing.

DJ requires overhauling systems of care that perpetuate pathogenic vulnerabilities, as well as social disparities.¹⁴ Attitudinal, architectural, and institutional barriers to health care contribute more generally to disability-based health disparities and to delayed care and undertreatment of disabled people.^{12,15,16,17} Disabled people of color are more likely

than their White counterparts to be in lower-quality NHs, which have performance deficiencies, higher occupancy, lower nurse staffing, and fewer financial resources.¹⁸ Moreover, institutional racial segregation among NHs is associated with negative facility-level quality indicators, as demonstrated by exacerbated racial inequities among NH residents during the COVID-19 pandemic.^{18,19,20} Underinvestment and inequity may also have downstream effects on AMR, as the COVID-19 pandemic was associated with high rates of antimicrobial misuse, especially in low- and middle-income countries.²¹ Disability activists have raised concerns for years about for-profit NH facilities, including deficiencies in funding, staffing, regulatory and accountability mechanisms, and opportunities for patient self-determination. The NH industry has resisted regulatory action based on this activism for decades.^{22,23}

Caring for Patient M

Bioethicist Jackie Leach Scully argues that nondisabled people tend to assume that if a disabled person is vulnerable in one area of life, they are globally vulnerable in all areas of life, a phenomenon that “is especially pernicious because of the insidious damage it does to other people’s attitudes toward disabled people’s own agency.”²⁴ In M’s case, the ascription of global vulnerability could lead to false assumptions that M is incapable of communicating or participating in decision making. M’s anoxic brain injury and her initial inability to indicate “yes” or “no” reliably could mean her decisional capacity is diminished, temporarily or permanently. Nevertheless, with additional support, M could potentially relay key information about her experiences, what she values, and whom she trusts to a surrogate decision-maker. (Even if M or a surrogate would not then dictate all aspects of antibiotic treatment, such input has diagnostic and therapeutic utility.) Participation in treatment discussions is a health care right that can be neglected when patients have cognitive- or speech-related disabilities, especially when **institutional resources are limited**.^{24,25} Dr S’s team should work to safely remove the temporary ventilator and explore other means of communication and sources of information to facilitate M’s agency. Infections, antimicrobial side effects, pain, and delirium also affect cognition, underscoring the urgency of addressing M’s medical issues properly.

Resident Dr S faces a challenging situation in determining whether to provide or withhold antimicrobials for M. M’s medical record lacks important details about the causes or types of infections she has experienced; she has quickly received antimicrobials and then been transferred back to the NH without clarification on these points. Without clarification of the presumptive diagnosis of infection, NH residents like M—particularly those multiply marginalized by race, class, and insurance status—will become stuck in a hospitalization carousel, suffer preventable harms from both infections and medications, and contribute to AMR risks for other NH residents.

At a 2019 conference hosted by The Joint Commission and Pew Charitable Trusts, the expert panel emphasized “diagnostic stewardship,” which includes reducing testing that could have false positive or difficult-to-interpret results and thereby lead to unnecessary antimicrobial prescribing.²⁶ We contend that another diagnostic stewardship priority should be ensuring equitable, thorough investigation of infections in vulnerable patients before starting broad-spectrum antibiotics and ongoing evaluation to consider stopping antibiotics. The option for continued intravenous medication administration in NHs makes it easier to transition patients back to their facility without seriously interrogating whether antibiotics should be stopped.

These complex considerations make it clear that it is problematic to have an overnight resident take on all the responsibilities of antimicrobial stewardship and caring for M. We recommend that Dr S reattempt communication with M in collaboration with a consulting speech pathologist, identify alternative sources of information about M's interests, and start a thorough diagnostic evaluation for causes of hypotension and tachycardia, including but not limited to infections. Beyond the individual case, residents like Dr S should be supported with hospital leadership commitment, multidisciplinary expertise, and decisional aids, all informed by principles of DJ and overseen by the hospital's antibiotic stewardship program.

Stewardship Recommendations

The Centers for Disease Control and Prevention recommends tracking data related to antibiotic prescriptions and indicators of AMR as one mechanism to monitor adherence to stewardship guidelines.¹ In accordance with the DJ principle of intersectionality, we recommend incorporating demographic data related to disability status as well as other social identity factors, such as race and class, that shape how people's disabilities are interpreted and what explicit or implicit biases they may face in health care systems.^{27,28,29,30} Given well-documented inequities in myriad health care settings where antibiotics are prescribed, we can expect these inequities to manifest in antibiotic prescribing practices.³¹ Since inequitable care may show up as both under- and overprescribing, data tracking and analysis processes must incorporate data on the health care side (prescription and prescriber details, diagnostic workup, and treatment outcomes), as well as on the patient side (disability status and other sociodemographic details).

To improve care and mitigate disability-related bias, we further recommend **anti-ableism training for health care professionals** in connection with antibiotic stewardship programs.^{32,33} Training should be provided by members of disability communities in alignment with the DJ principle of leadership by those most impacted. Interaction with disabled people in contexts outside of the patient-clinician dynamic can disrupt stereotypical perspectives of disabled people. Such training might include identification of common harmful assumptions about disability, such as global vulnerability. Clinicians should be cautioned to avoid conflating speech disabilities or nonverbal communication with impaired decision-making capacity. Although underused in hospital settings, augmentative and alternative communication strategies are important for providing equitable care to patients who are nonspeaking due to disability or critical illness, particularly for pain management and for communication about treatment goals.^{34,35,36} Finally, training should incorporate intersectional perspectives on disability and explain how racial and ethnic biases influence disability-related biases. For example, danger and criminality are associated with men of color with disabilities,³⁷ particularly those with intellectual and developmental disabilities, psychiatric disabilities, and substance use disorders,^{37,38,39} and higher tolerance for pain is associated with Black people, as evidenced by the disproportionate undertreatment of pain in Black patients with chronic pain.^{40,41,42}

Conclusion

A DJ perspective on antimicrobial stewardship entails diagnostic stewardship that prioritizes clarification of presumptive diagnoses of infection in vulnerable patients, clinician education led by disabled people, and data collection incorporating disability status as part of intersectional analyses of antimicrobial stewardship practices, each of which promotes anti-ableist practices and more equitable health care for disabled

people. Communication with patients about their symptoms, medical history, and goals for care is essential, particularly among multiply marginalized patients, even and especially if it takes additional steps to find the appropriate support. When it comes to mitigating disparate outcomes for disabled patients like M, time, though always at a premium for health care professionals, may be one of the few tools to redress long-standing health inequities and optimize antimicrobial prescribing.

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CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

When Should Patients at the End of Life Get Antimicrobials?

Noah Boton, MD and Jeffrey Larnard, MD

Abstract

Although antimicrobial medications are commonly prescribed to patients at the end of life (EOL), clinicians might not discuss the benefits and harms of antimicrobials with their patients in the advance care planning process. This commentary on a case discusses challenges and strategies in antimicrobial decision making for patients at the EOL. As antimicrobial use can harm some patients, and as antimicrobial resistance remains an urgent public health issue, this article advocates for ethical reasoning to guide antimicrobial decision making for patients at the EOL.

Case

LK is a 75-year-old woman with metastatic lung cancer who is admitted for pneumonia. She is administered broad-spectrum intravenous antibiotics with subsequent improvement of her fever and hypoxia. Imaging of the chest reveals a tumor obstructing the right lower lobe bronchus. Due to the extent of metastatic disease, frequent infections, and generalized weakness, LK is not a candidate for additional surgery or other cancer-directed therapies. The decision is made to focus on comfort, and LK discusses her treatment preferences during transition to hospice care. While many of her preferences were previously outlined when completing her advance directive, she has not yet discussed the use of antimicrobials. LK asks if she should continue taking antibiotics when she returns home.

Commentary

End of life (EOL) is a term used in health care to describe the final days, weeks, or months of a patient's life. During this time, patients make many important decisions about their medical care. Often absent from goals-of-care discussions is the use of antimicrobials, which are administered to a significant proportion of patients at the EOL.^{1,2} In particular, high rates of antimicrobial use have been reported in patients transitioning to comfort-focused care or enrolling in hospice services.^{3,4,5,6} Patients at the EOL are predisposed to infection due to foreign bodies, disruption of host barriers, immobility, and malnutrition,^{7,8,9} all of which likely contribute to the high rate of antimicrobial use. However, antibiotics are also prescribed at the EOL in the absence of confirmed infection.^{6,10} In addition, antimicrobial use at the EOL can be influenced by the desire to palliate symptoms, as well as by patient or family preferences.^{11,12,13}

As LK transitions to hospice care, she is faced with several important decisions regarding her medical care, including current and future use of antimicrobials. To guide LK, clinicians need to elicit her values, goals, and preferences, while ensuring that the potential benefits and harms of continued antimicrobial therapy are presented accurately to her. In LK's case, the use of antimicrobials alone without an intervention to relieve the obstruction in her lungs might not cure her infection. However, antimicrobials could suppress the infection and potentially improve her comfort. Clinicians might also be concerned that ongoing antimicrobial use in the presence of her persistent nidus of infection would promote development of antimicrobial resistance. Determining the appropriateness of antimicrobials for patients like LK involves a nuanced approach, especially given the lack of clear guidelines and limited evidence for patients at the EOL. This article, written from the perspective of infectious disease physicians, explores strategies based on the principles of beneficence, nonmaleficence, autonomy, and justice that clinicians can use to navigate these difficult clinical scenarios.

Weighing Benefits and Harms

When contemplating antimicrobial prescribing at the EOL, clinicians should use a patient-centered approach that balances beneficence and nonmaleficence. When patients at the EOL are suffering from an infection and there is reasonable confidence that antimicrobial treatment will alleviate their symptoms, prescribing a trial of antimicrobials aligns with the principle of beneficence.¹⁴ While this approach is simple in theory, clinical practice is not often straightforward. Observational studies have shown varied success rates in symptom improvement with antimicrobials for patients at the EOL.¹⁵ Older observational studies suggested that antimicrobials might be more effective at palliating symptoms of urinary tract infections than other infections at the EOL.^{16,17,18} However, a more recent study that retrospectively applied an appropriate use tool to antibiotic prescriptions found that the rate of symptom improvement for urinary tract infections was similar to that for other infections.¹⁰ Moreover, symptom improvement was only seen in about 60% of patients.¹⁰ Observational studies have also indicated that antimicrobials might be less effective in palliating symptoms in the final weeks of life.^{19,20} Overall, there remain significant limitations in the available data, and clinicians need to rely on their judgment to assess potential benefits of antimicrobials on a case-by-case basis.

Although clinicians might be familiar with many of the potential harms associated with antimicrobial use, when the goals of care are focused on palliation, particular attention should be paid to nonmaleficence. Potential harms of antimicrobial use include symptoms of intolerance, such as gastrointestinal distress, as well as allergic reactions. Specific toxicities are associated with certain antimicrobials, such as encephalopathy with beta-lactam use.²¹ The frequency of these events can be significant, including for patients at the EOL. For example, of patients with advanced cancer receiving palliative chemotherapy who were exposed to an antimicrobial during their hospital stay, 35% developed an adverse drug event.²² Furthermore, antimicrobial use is a risk factor for acquisition of *Clostridioides difficile* infection, including at the EOL.^{3,23} The use of intravenous antimicrobials can additionally lead to indirect harms such as pain, infections, and thrombi at intravenous sites,^{24,25} and antibiotic use in acute care settings at the EOL has been associated with increased length of stay.²⁶ In light of these risks, ethical prescribing at the EOL requires carefully balancing the potential benefits (ie, symptom relief or extended duration of life) and the likelihood of adverse effects.

Due to the heterogenous nature of the EOL population and differing goals of care, antimicrobial prescribing must be tailored to each patient's unique situation and care objectives. If the goal of antimicrobials is symptom palliation, clinicians should first consider carefully whether a bacterial infection is present and whether that infection is leading to bothersome symptoms. Additionally, clinicians should ask whether antimicrobials could realistically lead to symptom improvement and whether it would be more or less than what could be expected from a non-antimicrobial medication, such as acetaminophen. These considerations need to be weighed against the risk of direct harms from antimicrobials, which depend on the specific agent used. As an example, the need for central venous access and intensive lab monitoring involved in prescribing intravenous vancomycin exposes patients to more potential harms than prescribing oral amoxicillin. Finally, and perhaps most importantly, realistic expectations of benefits and harms should be presented clearly to the patient and family.

Clinical Decision Making

The implications of antimicrobial prescribing for patients at the EOL extend **beyond individual patients**. Antimicrobial use promotes the development of antimicrobial resistance in health care facilities and in the community.^{27,28} The downstream effects of antimicrobial resistance, including increased patient mortality and rising health care costs, are urgent global problems.^{29,30} A significant contributing factor is the prevalence of unnecessary or inappropriate antimicrobial prescriptions, estimated in 2013 to be as high as 50%.³¹ These unnecessary prescribing practices extend to patients at the EOL. For example, one nationwide analysis showed that only 15% of patients receiving antibiotics during the last week of life had a documented infectious diagnosis.⁶ This issue highlights the principle of justice, which necessitates a fair distribution of health care resources, giving consideration to the needs of both individual patients and society.¹⁴ In the context of rising antimicrobial resistance, this principle necessitates preserving the effectiveness of antimicrobials for society now and in the future.

Applying the principle of justice to antimicrobial prescribing at the EOL presents significant challenges for clinicians. One critical issue is the limited evidence of which specific antimicrobial prescribing practices do the most to promote resistance among this patient population. Observational data suggest that antimicrobial use for patients receiving EOL care in intensive care units is associated with increased resistance.³² However, the broader impact of antimicrobial use for EOL patients in health care facilities and in the community is not well elucidated. Another challenge is the complex microbiologic landscape of antimicrobial resistance. There are many different pathways to resistance depending on the specific pathogen-antimicrobial interaction. For example, while the emergence of resistance to vancomycin in enterococci is not likely to occur during therapy, bacteria such as *Pseudomonas aeruginosa* can rapidly develop resistance during treatment when exposed to multiple classes of antimicrobials.³³

Recognizing these challenges, clinicians can apply the principle of justice, as exemplified by LK's case. For example, if LK's respiratory cultures reveal an infection caused by an extended-spectrum beta-lactamase-producing *Klebsiella pneumoniae*, antimicrobial options are limited to the use of broad-spectrum agents, such as fluoroquinolones or carbapenems. However, given the obstruction in LK's lungs, which might prevent complete resolution of her infection, clinicians must answer an important question: Will antimicrobials actually benefit her? If clinical judgment suggests limited or no benefit, then the ethical implications of continuing antibiotics could extend beyond LK's individual care. Continued use of broad-spectrum agents can contribute to higher

levels of antimicrobial resistance, potentially affecting other patients through transmission of resistant organisms. When prescribing antimicrobials at the EOL, we believe clinicians have an obligation to incorporate the risk of antimicrobial resistance in their decision making, particularly when antimicrobials are suspected to have little benefit. Moreover, care should be taken to review the available microbiology data and local antimicrobial resistance patterns to avoid prescribing antimicrobials with unnecessary broad-spectrum activity.

Advance Care Planning

In LK's case, it might not be clear if antimicrobials will improve the symptoms of her pneumonia as she transitions to hospice care. After discussing the benefits and risks of ongoing antimicrobials and making a recommendation, her clinicians have a responsibility to respect her right to make a decision. LK is in a position to make an informed choice. However, many terminally ill patients might not have the capacity to fully engage in these conversations. For these patients, incorporating discussions about antimicrobial use in **advance care planning** (ACP) is one strategy that can improve patient autonomy by aligning future prescribing practices with patients' goals of care.

However, discussion of antimicrobial use in ACP is not yet widely adopted.^{1,34} Clinicians have cited several reasons for not discussing antimicrobials in ACP processes, including concerns about overwhelming patients or families and about having insufficient training to discuss antimicrobials at the EOL.³⁴ Other topics commonly included in ACP, such as the use of life support interventions and identifying a health care surrogate, already involve complex discussions, so discussing antimicrobial use during this process may seem arduous for clinicians, patients, and families.

Despite these concerns, we believe that antimicrobial use deserves a place in ACP, given the frequency with which antimicrobials are used at the EOL and their potential for significant benefit and harm. Integrating discussions of antimicrobial use into ACP facilitates more informed choices and provides patients and families more time to understand potential impacts of these treatments. Importantly, the objective of these discussions should not be to convince patients to avoid antimicrobials at the EOL but rather to ensure antimicrobial prescribing practices align with patients' values and preferences. Research suggests that this strategy can be practical and impactful, as completing a Physician Orders for Life Sustaining Treatment (POLST) form with a preference for limited antimicrobial use was shown to reduce use of antimicrobials in the last 30 days of life.¹ However, it should be noted that not all state POLST forms include a section to indicate antimicrobial preferences.¹

Conclusion

Prescribing antimicrobials at the EOL is rarely straightforward, and clinicians need to weigh multiple ethical considerations. Clinicians must consider the patient's individual values, goals of care, underlying disease, and current infectious process when deciding if antimicrobials would be beneficial. Moreover, clinicians need to consider the potential harms of antimicrobials to the patient and the broader effects of antimicrobial overuse on society. In states that include antimicrobial preferences on POLST forms, ACP can be an impactful tool to guide prescribing.¹ Clinicians should take particular care at the EOL to assess the potential benefits and harms of antimicrobials in the context of patients' specific goals of care and clinical scenarios and then communicate those benefits and harms clearly to patients and families. If clinicians believe antimicrobials will not be

helpful in realizing their patients' known wishes—and could instead be detrimental—a recommendation to withhold or stop antibiotics can be given.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.



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HEALTH LAW: PEER-REVIEWED ARTICLE

How Might Antibiotic Stewardship Programs Influence Clinicians' Autonomy and Organizations' Liability?

George Maliha, MD, JD, Keith Robert Thomas, JD, Mary Ellen Nepps, JD, and Keith W. Hamilton, MD

Abstract

Federal and state governments mandate some health care organizations to implement antibiotic stewardship programs (ASPs). Some early adopters developed model ASPs that have helped set industry standards; other benchmarks will likely be forged in subsequent regulation, legislation, and jurisprudence. This article considers how ASP designs can affect professional autonomy, especially of frontline antibiotic stewards who are usually physicians and pharmacists. This article also considers how ASP development and implementation might influence standards of care and malpractice liability.

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Stewardship Programs

Antibiotic stewardship programs (ASPs) aim to track the use of antibiotics, to encourage data sharing by providing high-level expertise on these drugs, and to improve care by guiding appropriate prescribing practices.¹ Although these programs are designed to help clinicians and have been shown to improve patient outcomes, reduce costs, and prevent the development of antibiotic resistance,¹ some stewardship interventions might be perceived as limiting clinician autonomy and raise complex, as-yet unsettled questions of malpractice liability for primary clinicians, ASPs and their personnel, and health care institutions.² Without clearer prospective laws, regulations, or other standards, the inevitable controversies arising from ASP implementation—with implications for clinician autonomy and the professional and medico-legal **allocation of responsibility** between primary clinicians and ASPs and their personnel—will be shuttled to other fora, such as trial courts that litigate malpractice claims on an ad hoc, case-by-case basis.³ This article explores existing legal authorities concerning antibiotic stewardship and analyzes the implications that ASP implementation might have for clinician autonomy and malpractice liability, especially in light of the potentially unpredictable ways that rules or standards derived from malpractice suits may develop.

Responsibility for ASPs

Federal rules and national standard-setting organizations have encouraged the development of ASPs, but many of the debates on the contours of ASPs occur outside the government and its regulatory agencies. In a series of rules in the 2010s, the Centers for Medicare and Medicaid Services (CMS) essentially mandated ASPs in most inpatient and long-term care settings, including one notable final rule published on September 30, 2019.^{4,5} These rules were sparse on detail but mandated basic program infrastructure and activities. CMS did notably express in its September 2019 rule that it sought to “build flexibility into the regulation by proposing language that requires hospitals to demonstrate adherence to nationally recognized guidance and guidelines, rather than any specific guidance, guideline, or set of guidelines, for best practices in infection prevention and control and for implementing antibiotic stewardship programs.”⁴ Although certain hospitals “may have less resources available,” CMS did “encourage” those hospitals “to utilize the existing available resources to ensure the antibiotic stewardship requirements are met” because “antibiotic stewardship is no less important in these settings.”⁴

Standard-setting organizations and quasi-governmental actors have provided much more detail on guidelines for implementing ASPs. For instance, the Joint Commission has outlined the structure and resources that should be devoted to ASPs in its 2023 revisions to its standards.⁶ Furthermore, the Centers for Disease Control and Prevention (CDC),⁷ Society for Healthcare Epidemiology of America,¹ and Infectious Diseases Society of America¹ have provided guidelines and resources for programs, some of which are mentioned in Medicare’s guidance as sources of assistance.⁴

That said, ASPs represent only one aspect of the federal and national response to the problem of antibiotic resistance—and thus only a part of the law addressing these areas. The federal government is often interested in information acquisition from ASPs,⁸ and, to that end, CMS required hospital antimicrobial use and resistance data to be shared with the CDC starting in 2024.⁹ Moreover, complementing the goal of ASPs, other parts of the federal government have focused on ensuring a pipeline of new antibiotic candidates to help overcome resistance, targeting novel biological threats, and preventing the widespread use of antibiotics in animals.^{10,11}

Given that the federal government and national organizations are concerned with the broader problem of antibiotic resistance and less suited to account for multiple contingencies and local practice settings, state regulators will likely provide more detailed guidance to health care institutions—and may provide the fora to address novel issues and problems for ASPs. To be sure, some states have followed the lead of the federal government and have mandated antimicrobial stewardship regional advisory committees,¹² and others have gone further to protect against the development of antibiotic resistance.¹³ But traditional state malpractice liability may still become an important method to regulate ASPs where regulatory voids exist.

Malpractice Liability

Malpractice litigation is a familiar legal mechanism by which health care practitioners and institutions can be held accountable for alleged medical errors. Indeed, **malpractice cases** can themselves serve as a form of regulation by establishing legal precedent that may influence future medical practice. Briefly, the elements of a malpractice claim consist of a duty of a health care practitioner or institution to a patient, a breach of that duty, and an injury to a patient caused by that breach of duty. Breach of duty is

determined by reference to an established standard of care: how similarly-situated practitioners would act in similar clinical circumstances.¹⁴

The decision making of ASPs is not immune from malpractice exposure. Since ASPs can influence patient care and outcomes, it would be reasonable to believe that ASPs would be liable for those actions and subject to malpractice litigation.³ However, because members of ASPs often do not interact directly with patients and because a clear standard of care has yet to be established by case law, each one of these elements could be contested.

ASPs and their activities come in many forms, and the different ASP roles implicate different liability and clinician autonomy issues, including prior authorization of selected antibiotics, prospective audit and feedback, benchmarking, medical record clinical decision support, formulary restriction, dose optimization, assistance with parenteral to oral conversion, and guideline development.¹ As a result, there is a kaleidoscope of different lenses through which courts could view ASPs and their activities—and thus influence how ASPs are integrated into preexisting health care infrastructure. Although each issue would carry a different liability implication, health care institutions would focus on balancing potential legal exposure and clinical autonomy.

Stewardship and Sources of Liability

There are several possible patient scenarios, of varying plausibility, out of which a malpractice suit might arise^{15,16,17}: (1) patients who allege that they were inadequately treated because of an antibiotic or lack thereof, (2) patients who allege that they suffered harmful side effects because of an antibiotic, and (3) patients who allege that they suffered an infection from a resistant organism that would have otherwise been preventable but for insufficient antibiotic stewardship.

First, patients might allege that they were inadequately treated because they were prescribed an inappropriate antibiotic or because they were not prescribed an antibiotic at all. There are at least 2 variations of this scenario: a patient who is prescribed an antibiotic that an ASP recommended and a patient who is prescribed a different antibiotic by a primary clinician notwithstanding the ASP's recommendation. In the first variation, the patient might sue the ASP and its personnel because their recommendation was followed by the primary clinician who may have otherwise prescribed a more appropriate antibiotic. In the second variation, the patient might sue the primary clinician who failed to heed the ASP's recommendation, potentially causing harm. In either case, the patient might sue the health care institution for failing to design its ASP in a way that might have prevented the alleged harm. Second, and relatedly, patients might allege that they suffered harmful side effects because of an antibiotic that they were prescribed. The possible sources of malpractice liability are similar to the first scenario and its variations. Finally, patients might allege that they suffered an infection that would have otherwise been preventable in the presence of more effective antibiotic stewardship.

These scenarios are more than theoretical sources of liability. One such scenario may occur directly as the result of antibiotic use in a single patient, the most likely of which may be the patient's acquiring a *Clostridioides difficile* (*C difficile*) infection. Because the risk of this infection is increased by health care and antibiotic exposure,¹⁸ the prescriber may be held liable for the infection if the antibiotic prescribed was inappropriate. Similar arguments could be made for other resistant organisms in which infection acquisition is

associated with antibiotic use. Many of these resistant organisms, such as *C difficile*, can also spread horizontally to multiple patients within a health care facility. Moreover, higher rates of antibiotic use in health care units are associated with higher rates of *C difficile* on those units.¹⁹ Even if a patient did not receive an antibiotic, it could be argued that their acquisition of an antibiotic-resistant infection was the result of insufficient antibiotic stewardship. Such a theory of malpractice liability might be the basis of a proceeding brought by individual patients or might be brought by several or many patients as, for example, a mass tort or class action.

ASPs and Their Legal Implications

There are at least 4 possible conceptualizations of ASPs and their roles in a health care institution: (1) as a consultant for a particular patient; (2) as a guardian of scarce antibiotic resources; (3) as an educational resource providing general antibiotic guidance and serving as a repository of useful clinical information related to appropriate antibiotic prescribing; and (4) as a mechanism by which to aggregate, organize, and develop relevant resources to guide antibiotic use. These conceptualizations are not mutually exclusive. Each conceptualization, however, might imply different relationships between ASPs and their members, be they antibiotic stewardship personnel, on one hand, or primary clinicians, on the other. Furthermore, each conceptualization may give rise to several possible sources of malpractice liability for the ASPs, their personnel, primary clinicians, and health care institutions.

ASPs as consultants. The ASP may be viewed as acting as a sort of consultant, providing an opinion on a particular patient care issue, such as when an ASP provides a prospective audit and feedback by making recommendations to primary clinicians based on information ASP personnel review in the medical record, local antibiotic susceptibility data, and applicable guidelines. This ASP role might be akin to that of a pathologist or radiologist who does not directly interact with a patient but who nonetheless opines on a particular aspect of care. Ignoring these trusted consultants might carry medical and legal risks for primary clinicians. Because most primary clinicians cannot independently assess studies with the same degree of rigor as specialists, clinicians who consult ASPs sacrifice some of their autonomy. However, primary clinicians do have some capacity to disagree with a specialist if the reasons are well founded and well documented in the medical record, especially because primary clinicians' proximity to the patient confers a unique vantage point. Indeed, good documentation by ASPs and their personnel—as well as by primary clinicians—and explaining and justifying assessments and recommendations might mitigate possible malpractice liability while also promoting clinician autonomy, especially in the event of disagreements.²⁰ On the other hand, minimizing clinicians' ability to disagree with specialists or the ASP could channel liability to one decision maker—namely, to a specialist or to the ASP.

Open questions remain as to the precise nature of the consulting role of ASPs. For example, might ASPs be considered legally analogous to a formal infectious disease consultation? Or might ASPs be considered more analogous to something commonly known as a “curbside” consult, as when one clinician asks another a question in passing about a specific patient? Even if ASPs are found to function in a legally analogous way to curbside consults, such curbside consults have attracted some scrutiny by legal authorities, given that they may influence patient care.²¹

Absent further prospective legal or regulatory clarity, the question of the precise nature of the consulting role of ASPs would likely be resolved—and its implications for where

and when liability exists clarified—through the piecemeal, case-by-case development of the law through malpractice suits. Indeed, ASPs-as-consultants might give rise to liability for primary clinicians for failing to heed ASP guidance, for ASPs and their personnel for flawed recommendations, or for health care institutions regarding their institutional protocols and policies for ASPs and their relationship with primary clinicians.

ASPs as gatekeepers. The ASP may be seen as guarding a specialized or scarce resource when it sponsors prior authorization systems—that is, when, due to factors such as drug cost and spectrum of activity, clinicians require approval from ASP personnel to use certain antibiotics. In general, “[t]he intent of prior authorizations is to ensure that drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines.”²² The ASP’s role as gatekeeper is much like that of an oncologist selecting chemotherapeutic agents for a targeted cancer treatment plan or that of an intensivist faced with a limited number of critical care beds whose role is to improve outcomes for individual patients and to maximize benefit for the entire population of patients eligible for these resources. Primary clinicians not trained in these specialties typically do not solely decide cancer treatment plans or triage critically ill patients. Analogously, primary clinicians may not be expected to have as much expertise in antibiotic prescribing and stewardship as ASP personnel. In cases in which ASPs act as gatekeepers, patients might be denied access to an antibiotic or given another one that their primary clinician might not otherwise have prescribed had it not been for an ASP’s recommendation. The existence and distribution of malpractice liability in this regard—among primary clinicians, ASPs, and health care institutions—would likely depend on several factors, including whether primary clinicians have discretion to heed or disregard an ASP’s recommendations or whether an ASP’s recommendations are binding rather than merely suggestive. Furthermore, it might be prudent for health care institutions to consider implementing **clear escalation protocols** if a primary clinician should disagree with the recommendations of an ASP, perhaps a recommendation to formally consult an infectious disease specialist or a physician-director of the ASP itself.

ASPs as educators. The ASP can act as an educational resource by providing general antibiotic guidance and serving as a repository of clinical information related to appropriate antibiotic prescribing and stewardship protocols. For example, a clinician may ask physicians or pharmacists from the ASP for advice on choosing an oral antibiotic that is equivalent to an intravenous antibiotic or for a good choice to treat pyelonephritis in a patient with a specific antibiotic allergy. Such queries would be different from a consultation because these questions may not require ASP personnel to review a particular patient’s medical record if they are framed in theoretical or hypothetical terms, not unlike a case vignette. These questions may have consensus answers that may not be accessible to or remembered by busy clinicians.

In these situations, seeking answers to hypothetical or case vignette questions that do not directly refer to a patient being cared for at the moment differs from a formal consultation with infectious disease specialists, which might also entail seeing a specific patient or reviewing a patient’s medical records in order to answer a specific and potentially treatment-guiding question. These scenarios likewise differ from the ASP consultation role as well as from patient-specific curbside consults discussed above. However, in these scenarios, ASPs might still enhance primary clinicians’ autonomy by providing relevant and specialist knowledge and thereby facilitating the growth of primary clinicians’ fund of knowledge. The precise implications clinicians’ subsequent actions might have for malpractice liability—for primary clinicians themselves, for ASPs

and their personnel, or for health care institutions—will, of course, in part, depend on the evolving status and precise medico-legal definition of curbside consults, and, once again, on the institutional practices and policies regarding how ASPs work at a given institution, their relationship with primary clinicians, and the nature—suggested or required—of their recommendations.

ASPs as aggregators. ASPs can provide mechanisms by which to aggregate and organize relevant information regarding antibiotics, including local and national guidelines. In this role, ASPs might also contribute to developing institutional guidelines and, therefore, helping to inform the local standard of care by adapting guidelines from public health authorities or professional societies. Here, failure to follow institutional or other relevant local or regional practice guidelines without compelling clinical reasons, such as a novel situation or unique patient factors, could lead to liability exposure for primary clinicians. Yet courts have been clear that guidelines do not automatically set the standard for malpractice,²³ so guidelines can also be seen as channeling autonomy by proscribing some actions while maintaining space for clinicians' discretion in specific clinical situations. That said, failure to follow guidelines without sufficient documented justification can be a basis for liability.

Evolving ASPs

Given these different conceptions of ASPs, health system leaders have a menu of options to tailor an ASP to the local liability environment and to clinician autonomy considerations. However, each conception of an ASP has its own malpractice and autonomy implications, as do different institutional choices regarding the design of an ASP. The lack of clear prospective legal requirements concerning the structure of ASPs, including the nature of their day-to-day functions in a health care institution and their relationships with existing care protocols, permits variability in ASP design, implementation, and administration.

Institutions, such as hospitals, will therefore need to create their own protocols, guided by the general direction provided by relevant laws and regulations, including national guidelines and regulations from relevant authorities. These choices will have implications for clinician and institutional responsibility and clinician autonomy and, therefore, for malpractice liability. Indeed, such lack of clarity and the implied flexibility means that many questions about the evolving roles of ASPs—and their relationships with clinicians—may end up being clarified through the case-by-case process of malpractice-based litigation against primary clinicians, ASPs and their personnel, or health care institutions.

It is thus crucial for health care institutions and health care practitioners involved in the design, implementation, and administration of ASPs to consider possible theoretical roles of ASPs and possible theoretical sources of malpractice liability that might arise from these different roles in the context of antibiotic prescribing in order to mitigate risks associated with malpractice liability while still preserving clinician autonomy and providing optimal patient care. Such considerations will ideally evolve in light of ongoing developments concerning best practices for ASP design and implementation and in light of new legal and regulatory requirements arising through malpractice litigation and otherwise. For instance, in thinking about the ASP as a consultant, program designers need to consider where to draw the line between ASP involvement and the need for a formal infectious disease consultant. For an ASP as aggregator, vigilance regarding new developments that may require updates to guidance is required. Of course, malpractice

is not the only legal consideration in ASP design and its implications for individual practitioner autonomy; for instance, scope of practice rules affect how and through whom ASPs implement recommendations. Nonetheless, evolving legal mandates and institutions will likely contribute to the ongoing and evolving conversation concerning the proper role and function of ASPs.

Malpractice litigation by its very nature will develop new rules and standards on an ad hoc, case-by-case basis; indeed, different courts in different jurisdictions may adopt different and perhaps even conflicting rules or standards, which, in general, is how the common law tends to develop. While such a manner of legal development has its own merits, it also has its flaws, not the least of which is the lack of clarity, consistency, and predictability. As such, to avoid the malpractice system and its possible vagaries from dominating the development of rules concerning ASPs, health care institutions, physicians, and other stakeholders should consider working toward clearer national standards and rules. In the meantime, however, those same institutions and clinicians will need to build and reform their ASPs while keeping possible malpractice liability in mind, which will require thinking seriously about possible sources of that liability and their implications for care team protocols and clinician autonomy.

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POLICY FORUM: PEER-REVIEWED ARTICLE

Why Assuring the Quality of Antimicrobials Is a Global Imperative

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Abstract

Poor-quality antimicrobial medicines continue to proliferate across supply chains, threatening patients' health and safety, especially in low- and middle-income regions. This article discusses consequences and risks of antimicrobial resistance and other ways in which antimicrobial medicines can be of poor quality and recommends regulatory and policy reforms to help maintain supply chain resilience and quality of antimicrobial medicines.

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Introduction

The World Health Organization (WHO) has declared antimicrobial resistance (AMR) one of the top global public health threats facing humanity.¹ In the United States, more than 2.8 million antibiotic-resistant infections occur each year, resulting in more than 35 000 deaths,² and a recent study estimated that nearly 5 million people died worldwide in 2019 due to causes associated with AMR, with over 1 million deaths directly attributable to AMR.^{3,4}

Poor-quality antimicrobials continue to proliferate across the medicines supply chain, threatening patient health and possibly increasing the incidence of AMR.^{5,6} A 2017 WHO study estimated that approximately 1 in 10 medicines in **low- and middle-income countries** (LMICs) are substandard or falsified (SF),⁵ with more recent estimates suggesting that approximately 17% of the global antibiotic supply may be SF.⁶ SF antimicrobials can lead to failure in patient outcomes and substantial economic costs. The WHO estimated that between 72 430 and 169 271 excess child pneumonia deaths are due to SF antibiotic use.⁵ Another national-level modeling study estimated that poor-quality antimalarials were responsible for over 12 000 deaths of children under 5 years of age and more than \$890 million in costs annually in Nigeria.⁷ Incorporating antimalarial resistance, the model estimated that, in Nigeria, annual deaths among patients under 5 years of age would increase by 7700 and that annual costs would increase by another \$839 million.⁷ Consequently, it is a moral imperative for countries to work together to sustain a supply of effective, quality-assured antimicrobials that is

both resilient to supply chain disruptions and that patients around the world can access in an equitable manner.

What Are Substandard Medicines?

While misuse and overuse of antimicrobial medicines are major drivers of AMR,⁸ another often-overlooked cause of AMR is the presence of SF antimicrobials. Substandard medicines are products authorized for use that fail to meet quality standards or their specifications, or both.⁵ For example, in substandard antimicrobial formulations, the active pharmaceutical ingredient (API)—the biologically active component of a drug—may be present in a lesser dose than is required to treat the infection.⁶ Poor-quality excipients, impurities, or degradation can also affect the medicine's solubility, bioavailability, and antimicrobial activity. Falsified medicines deliberately or fraudulently misrepresent their identity, composition, or source.⁵ In the case of substandard antibiotics, antimicrobial characteristics and antimicrobials' subsequent interactions with bacteria can result in bacteria becoming altered, leading to AMR development.

Why Antimicrobial Quality Matters Everywhere

In the United States, legislative proposals are under consideration and public-private partnerships have been formed to provide investments to ensure the availability of quality medicines.^{9,10,11,12} However, the problem of medicine quality must be viewed through a multidisciplinary global lens, which includes evidence-based research on the impact of poor-quality antimicrobials on AMR.

Experimental research from the United States Pharmacopeia's Quality Institute, which sponsors independent research to inform policy decisions, helps build the evidence base that poor-quality antibiotics can drive bacteria to become multidrug resistant.¹³ One such study found that exposure to low levels of API (in ciprofloxacin) led to multidrug resistance development that was below the clinical cut-off for resistance—which means resistance may go unreported or undetected until it is a significant problem.¹⁴ Low-level resistance can serve to establish a reservoir of bacteria primed for further development of resistance.¹⁴ This finding has important policy implications, as early emergence of resistance, especially in locations with high incidence of SF antibiotics, might be missed in current surveillance strategies. Research has also shown that exposure to impurities and degradation products—unwanted chemicals or by-products that can develop during the manufacturing, transportation, and storage of drugs—can promote AMR and interfere with content assays that aim to measure the quantity of API in a medicine.^{15,16} Maintaining good storage and distribution practices along the medicines supply chain is also critical for maintaining quality medicines.

Tackling medicinal quality is critical to achieving universal health coverage (UHC), which the United Nations (UN) has identified as a global target. Sustainable Development Goal (SDG) 3.8 seeks to “achieve universal health coverage, including financial risk protection, access to quality essential health-care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all.”^{17,18} While access to quality medicines is mentioned under SDG 3.8, medicine quality itself is not one of the indicators of progress towards UHC.¹⁹ This is a blind spot. The UN Interagency Coordination Group on Antimicrobial Resistance highlights the need for UHC schemes to promote not only access to quality-assured medicines but also appropriate use of antimicrobials to reduce AMR.²⁰

Prior to the emergence of SARS-CoV-2, the virus that causes coronavirus disease (COVID-19) and that led to the ensuing global pandemic, AMR was one of the world's most concerning public health issues. As emergency declarations end and the threat of severe disease, hospitalization, or death from COVID-19 continues to decline, AMR has the potential to become the next major public health emergency. However, apathy toward discovery of new antibiotics in high-income countries persists.²¹ Many pharmaceutical companies have stopped investing in research and development of antibiotics due to low financial projections. Increased funding for academic institutions and smaller start-ups to develop new antibiotics is promising though somewhat fragmented; however, scientific discovery is inherently slow, and getting a product onto the market requires substantial clinical work.²² Thus, it is critical to maintain the quality of the antibiotics that we currently utilize. Additionally, medicine quality is rarely studied in high-income countries, where a lack of published SF prevalence data, despite documented recalls of poor-quality products, has led to gaps in our knowledge.²³ The COVID-19 pandemic has demonstrated that infectious diseases and supply chain disruptions are not isolated and can rapidly spread across the globe. Addressing the issue of medicine quality and AMR requires global investment and collaborative work at the local, regional, national, and global levels that relies on shared and effective communication, collaboration, and coordination.

Supply Resilience and Quality Assurance

Several factors contribute to supply chain vulnerabilities that can exacerbate the proliferation of SF medicines. Increasingly common shortages of antimicrobials—including antibiotics like amoxicillin—and consequent increase in demand can create an incentive for actors to introduce SF products into the supply chain.²⁴ While LMICs experience drug shortages most acutely, the consequences, especially for AMR development, are global. Additionally, API manufacturing is geographically concentrated in a few locations, and concerns over antibiotic API quality have been another source of **vulnerability in the supply chain**, especially with the increase of extreme weather events that can cause product degradation or cut off supply.^{25,26} However, attributing poor medicine quality to origin of manufacture, without evidence, should be avoided.

Global stakeholders, such as policy makers, national regulatory authorities, and public health authorities, have a responsibility to ensure equitable access to quality-assured antibiotics, especially by vulnerable populations. Medicine shortages and the proliferation of unauthorized sellers in many places undermine this goal. In many LMICs, people seeking medical treatment may access medicines from unlicensed outlets associated with poor-quality medicines and practices.^{19,27,28} There would be less economic incentive to produce poor-quality antimicrobials if patients were ensured access to quality-assured antimicrobials.

Increased Efforts to Incorporate Quality Dimensions in National Action Plans

For effective AMR stewardship, countries need to develop and implement a national strategy to combat AMR that integrates medicine quality. In 2015, the World Health Assembly encouraged member states to develop individual national action plans (NAPs) to fight AMR.²⁹ Since that time, many countries have developed NAPs, and several have incorporated quality dimensions in their plans. A review of publicly available NAPs in 2018 found that 27 of 41 NAPs included medicine quality.³⁰ Applying the cornerstone WHO “prevent, detect and respond” framework,⁵ NAPs have outlined medicine quality activities, including implementing good manufacturing practices; coordinating quality control; **establishing national surveillance**; strengthening laboratory systems;

implementing a single drug regulatory system across human, animal, and aquaculture sectors; and removing SF medicines from the market.^{30,31}

Additional work is necessary to convey the importance of AMR NAPs and their inclusion of quality considerations. It is also imperative that the global community continue to provide financial and technical resources to develop and implement national AMR strategies. Since resistance knows no borders, resistance in one country will remain a problem globally.

Global Call to Action

Given the negative effects of poor-quality antimicrobials on AMR and public health, sustaining a resilient supply of quality antimicrobials is a global health imperative. Policy makers, regulators, manufacturers, distributors, and other stakeholders should build and maintain a resilient supply of quality-assured antimicrobials. These efforts are difficult and expensive and will require international cooperation and continued capital investment. We recommend 3 specific policy and regulatory reforms.

1. Prioritizing the building of resiliency into the global antimicrobial supply chain, including by fostering broader geographic distribution (less concentration) and more sources of API production.
2. Building capabilities among global stakeholders (eg, national regulatory agencies) to reduce the proliferation of poor-quality antimicrobials and to ensure access to effective antimicrobials by taking these steps:
 - a. Adhering to science-based public quality standards.
 - b. Increasing the use of AMR surveillance tools and strategies to track the emergence of resistance and provide targeted action.
 - c. Increasing the development of proactive risk-based tools and risk-based testing for quality along multiple points of the supply chain.^{32,33}
 - d. Developing and strengthening quality assurance of local and regional API and finished product manufacturing by providing incentives in order to diversify the supply chain and build capacity.
 - e. Increasing information sharing and transparency through regulatory reliance and recognition agreements among national regulatory authorities to help facilitate bilateral cooperation.
3. Implementing steps to increase funding to incentivize research and development on the next generation of products while assuring the quality of the current antimicrobial armamentarium.

Conclusion

Antimicrobials are lifesaving drugs that all countries need to protect the health of their populations. It is necessary to continue to raise awareness of the role that poor-quality medicines play in AMR. The global community should provide additional financial and technical resources as countries continue to implement AMR NAPs. Importantly, securing a resilient supply of antimicrobials made with quality APIs and excipients is imperative to ensuring that patients have access to effective therapies.

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MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

How Should We Think About Clinicians' Individual Antibiotic Stewardship Duties?

Travis N. Rieder, PhD and Chelsea Modlin, MD

Abstract

The language of antibiotic stewardship is often used to capture the moral importance of individual prescribers doing their part to combat antibiotic resistance. “Stewardship” as an ethics concept borrows from collective action problems—those that cannot be solved by individuals only—like those discussed in the environmental ethics literature. This article suggests that hyper focus on stewardship, however, risks misunderstanding individual prescribers' reasons to limit antibiotic use.

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Stewardship as an Ethics Concept

The language of antibiotic stewardship can be helpful and powerful, as it frames the challenge of responding to the global rise in antibiotic resistance as a collective action problem in which the uncoordinated actions of millions or billions of people lead to a problem that can only be solved through coordination and working together. Thus, individual clinicians are called on to be good stewards of a precious resource, contributing to a larger, global effort in order to mitigate the collective harm that comes from overuse.¹ This framing plays off an analogy with other collective action problems—in particular, with the natural environment.² In response to massive, catastrophic threats like climate change, freshwater depletion, biodiversity loss, and so on, each of us individually is called upon to do our part in conserving our natural resources. Although none of us can solve such massive, structural threats on our own, each of us can do our part by being good stewards of natural resources.

Although there is something attractive about this framing, we will argue that it comes with costs. The responsibilities associated with stewardship are arguably not as strict as the responsibilities expected of prescribers. To see this perspective, consider whether each action you take that utilizes unnecessary fossil fuel seems like a violation of duty. If you drive when you could have biked, did you violate a duty? If you travel to see family, did you do something wrong? What about if you travel for an academic conference? Most people think that they are not strictly obligated to minimize their carbon footprints, even though it would be *good* to bike or reduce the amount of travel. All of us have

latitude when it comes to our small contributions to collective efforts that clinicians do not have in prescribing and using antibiotics. This constraint does not mean that stewardship as a concept is not helpful. It does mean that multiple normative frameworks should be explored for conceiving what it means to prescribe and use antibiotics responsibly.

Environmental Stewardship

Stewardship is an important concept in **environmental ethics**³ because environmental problems are so large and complex that the relevant harms tend not to be solvable by individuals. In a case in which a single company is pouring toxins into a river and making people downstream sick, we don't need to employ the idea that the company should be a good steward of the river; it simply shouldn't cause harm. Stewardship, then, is invoked when the river becomes toxic and makes people sick as a result of the uncoordinated dumping of many people's waste (no one of which dumpings is sufficient to cause harm). In such a case, the harm is caused by a collective, and so we need each individual to be a good steward and limit their dumping of waste into the river. This need for coordination explains why problems of collective action are best solved by governments or other institutions with the power to set and enforce policy. Yes, each individual *should* be a good steward; but individual stewardship efforts won't solve the problem. Policy will.

The environment provides many examples of harms caused by the collective actions of millions or billions of people, with climate change perhaps being the paradigmatic example. Due to the scale and complexity of climate change, no single individual causes the harms of climate disruption through their emissions.⁴ As a result, it seems the harm-producing mechanisms of climate change are insensitive to most individual choices.

Due to this insensitivity, both ethicists and the public have asked whether individuals really have a duty *not* to contribute to climate change in the absence of policy or regulation. If one's personal emissions don't meaningfully contribute to any harm, what could justify such a duty?⁵ Although many potential answers to this question have been offered, the first author on this paper (T.N.R.) has argued that the causal disconnect between individual action and collective harm entails that most individuals do not have a strict duty to reduce emissions, as duties are much too demanding a moral concept to be justified by our miniscule contributions to the problem.^{6,7} However, we certainly have good *reasons* not to contribute to the emission of greenhouse gases, and those reasons can be explained by what we might think of as "softer" moral concepts, such as virtue, integrity, standing in solidarity, and—most relevant to this paper—being a good steward.^{6,7}

In general, we all have good moral reasons to do our part to promote collective goods and avoid collective harms, even when our part is quite small. But having a *reason* is different from having a *duty*. It is clearly good to reduce one's carbon footprint, but individuals aren't ethically required to take every opportunity to do so. This is why we praise those who live modestly for environmental reasons but don't think our friends and family who take nonessential flights are bad people (though they would be if they dumped toxic waste into a river, directly making those downstream sick).

An Analogy to Antibiotics

One way to explore stewardship in the context of antibiotic resistance, then, is to ask whether and to what extent such resistance is really analogous to environmental

challenges like climate change. We focus on antibiotics and antibacterial resistance as a subset of antimicrobials and antimicrobial resistance here because of the contributions that both appropriate use and overuse of antibiotics make to emerging public health threats.⁸ We would have good reason to employ the concept of stewardship if and to the degree that antibiotic resistance is best described as a kind of collective action problem for which other moral concepts aren't comfortably applicable.

On the one hand, the analogy seems apt because (1) antibiotic resistance is a large, public health threat; (2) the prescribing of antibiotics contributes to this large, collective threat; but (3) no individual decision by a clinician not to prescribe antibiotics would solve the collective problem. Thus, it seems that we should collectively limit antibiotic use and that we can individualize that responsibility by asking clinicians to be good stewards of the collective antibiotic resource.⁹

On the other hand, however, there are features of antibiotic prescribing and consumption that are potentially different from the environmental case in morally relevant ways. Here, we will focus on the question of whether an individual prescribing action can make a meaningful difference to the harms of antibiotic resistance in a way that would make it disanalogous to the case of, say, climate change and individual emissions.

Risk of harm to patients. In some cases, there is a direct causal pathway between prescribing antibiotics and risk of harm to the patient. Consuming antibiotics alters the composition of commensal bacteria—the bacteria that are a normal part of the human body—such as those that live in the digestive tract and on the surface of the skin. The antibiotic eliminates bacteria susceptible to it, leaving behind those with intrinsic antibiotic resistance to grow and thrive, including some commensal bacteria.¹⁰ This effect itself is often justifiable, given the medical need for the antibiotic. It does not always cause direct harm, is slowly reversible once the antibiotic prescription is complete, and is highly dependent on the type of antibiotic prescribed. However, it does mean there is often a window of time when a patient's commensal bacteria have a more antibiotic-resistant profile. Most infections occur when commensal bacteria travel to sites where they shouldn't be, like to the bladder or kidneys where they cause a urinary tract infection, or underneath the skin where they cause a soft tissue infection. If an infection is acquired during this window of a person's having more resistant commensal bacteria, the infection is more likely to be caused by resistant bacteria and require broader-spectrum antibiotics to treat it. This cycle of antibiotics and worsening resistance therefore starts anew and can occur repeatedly within a singular patient.

A common example of this self-reinforcing cycle of resistance is inflammation of the colon and diarrhea from *Clostridium difficile* infection (CDI), for which previous antibiotic exposure is a significant risk factor.¹¹ Patients with a history of CDI are at higher risk of CDI recurrence if they are continued on non-*Clostridium difficile* antibiotics after diagnosis of CDI or prescribed antibiotics in the future.¹²

Prescribing antibiotics also comes with a host of patient-related risks aside from alteration of the commensal bacteria. These range from adverse drug reactions, such as nausea and vomiting, to mistaking a rash after penicillin is prescribed for an allergic reaction rather than a manifestation of an original viral infection. The subsequent labeling of the patient as "penicillin-allergic" limits downstream antibiotic treatment options, with suboptimal regimens initiating and perpetuating the same cycle of

worsening bacterial resistance mentioned previously. As the second author (C.M) argues elsewhere in this issue, the risk of general antibiotic resistance for the individual patient, along with other risks that come with antibiotic use, should undergird the risk-benefit determination physicians use to decide when to prescribe antibiotics. And if the risk of prescribing is too high to justify for a particular patient, then choosing to prescribe in that case violates strict duties not to risk harm to a patient for insufficient benefit.

Risk of harm to others. Beyond risks to the individual patient receiving antibiotics, there are also causal pathways from the individual patient to particular, identifiable others. This is because commensal bacteria are **transmitted among close contacts**. If a patient's commensal bacteria are more resistant from either antibiotic use or recent hospitalization, those bacteria are likely going to spread to individuals within the same household or to individuals sharing hospital rooms or health care practitioners. This spread of antibiotic-resistant bacteria has been seen among patients with commensal methicillin-resistant *Staphylococcus aureus* (MRSA)¹³ and extended-spectrum beta-lactamase *Escherichia coli* (ESBL-E)¹⁴ following discharge from the hospital. Both MRSA and ESBL-E are increasingly causing infection among patients in the community who do not have recent hospital exposure, with the transmission among close contacts serving as an alternative explanation for why they have an antibiotic-resistant infection.^{15,16} Similarly, household members of patients with recent CDI or commensal *Clostridium difficile* are at higher risk of requiring hospitalization for CDI.^{17,18} These examples demonstrate that resistant bacteria that are part of the commensal bacterial profile of an individual patient can be transmitted to others and cause direct harm to third parties, and this transmission can be prevented to a certain degree by strict duties not to risk such harm unnecessarily.

Thus, there are more traditional justifications for cautious prescribing that go beyond just a reason to promote the collective good by imposing a strict duty to prescribe antibiotics responsibly; in particular, duties of nonmaleficence require clinicians not to cause harm to their patients and to particular others.

An Upshot for Bioethics

Antibiotic resistance is a pressing problem and demands a serious response. Although the idea of stewardship is clearly important—all clinicians have good reason to do their part to protect our collective antibiotic resource—it's also a relatively weak concept. While we should all be stewards of the environment, stewardship doesn't seem to translate into a strict duty not to, say, travel for a vacation, to see family, or for an academic conference. Such travel creates "luxury emissions," but those emissions do not directly cause meaningful harm, and travel is a valuable part of many people's lives. Thus, part of the challenge of environmental ethics is that it's unclear how demanding a responsibility it is to be a good steward.

In the context of antibiotic prescribing by clinicians, it seems plausible that something stronger is needed: clinicians are *obligated* to prescribe in a certain way. For instance, in cases in which an infection is overwhelmingly likely to be caused by a virus, it is *wrong* to prescribe an antibiotic to a patient just because, for instance, the patient demands it. While such a prescription would be a violation of stewardship, the environmental analogy suggests that stewardship cannot support the weight of justifying a duty. But we have argued that stewardship need not, as classical bioethical reasoning concerning a duty of nonmaleficence can do the work. And invoking third parties need not require thinking of clinicians as having a public health duty to "the community" in an abstract;

rather, they are simply required not to risk harm to a patient's family, roommates, and other close contacts.

When it comes to antibiotic resistance, we should employ all of our bioethical tools to get a handle on the situation. It seems fairly well accepted that clinicians should be good stewards, and the health care system should continue to encourage that mindset. But if stewardship were the only justification for responsible antibiotic prescribing, we may have to admit that we're in a place similar to that of climate change: we certainly need institutions to act (by creating policies and regulation that *will* solve the problem), and it's clearly *good* for individuals to be stewards of a precious resource, but in the absence of **policy or regulation**, individuals don't have a strict duty one way or the other. We have argued that this analogy does not seem to be correct in the case of antibiotics. While it's certainly true that clinicians should see themselves as contributing to a collective effort, and thereby acting as stewards, the risk of direct harm to patients and third parties justifies a strict obligation to prescribe responsibly.

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MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

How Should Focus Be Shifted From Individual Preference to Collective Wisdom for Patients at the End of Life With Antimicrobial-Resistant Infections?

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Abstract

Despite growth in numbers of organizational antimicrobial stewardship programs, antimicrobial resistance continues to escalate. Interprofessional education and collaboration are needed to make these programs appropriately responsive to the ethically and clinically complex needs of patients at the end of life whose care plans still require antimicrobial management.

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End-of-Life Antimicrobial Stewardship

More than 2.8 million antimicrobial-resistant infections and 35 000 deaths from antibiotic resistance are reported to occur annually.¹ Escalating rates of antimicrobial resistance have called attention to the need for antimicrobial stewardship programs and infection control measures.^{2,3,4} Although antimicrobial misuse is a problem across the lifespan, overtreatment with antibacterials is common at the end of life.⁵ The proportion of end-of-life or comfort-care patients receiving an antimicrobial has been estimated to be as high as 77%,^{6,7,8} yet only 15% meet criteria for antimicrobial treatment.⁹ In particular, nonbeneficial antimicrobial therapy is provided to a substantial number of end-of-life patients with advanced stage cancer,¹⁰ with advanced dementia,¹¹ and who are on comfort-care protocols.^{6,9,12,13} Despite implementation of antimicrobial stewardship programs,¹⁴ prescribing and using antimicrobials for individuals at the end of life is complicated by a number of ethics questions that affect all of us.¹⁵ Failure to identify key features of antimicrobial misuse results in ineffective treatments, more multidrug-resistant organisms, prolonged suffering, and increased systemic burden.^{5,16}

Recent research on [antimicrobial use at the end of life](#) has focused on prescribing patterns and factors contributing to them rather than generating evidence-based interventions.^{6,7,10,17,18,19} Antimicrobial drug overuse and misuse often result from clinicians' inadequate education about antimicrobial drug stewardship,²⁰ tendencies to

treat symptoms rather than identified microorganisms,²¹ and yielding to patients' and families' non-evidence-based desires for treatment.^{18,22} Antimicrobial treatments at the end of life persist despite the fact that they are often ineffective, do not alleviate symptoms,^{7,8} and do not result in a significant increase in the quality or length of life.²³

It is imperative to implement systems to overcome these challenges. Some tool kits have resulted in more responsible antimicrobial use, but it is unknown whether those changes are sustainable.^{8,24} Recent increases in rates of antimicrobial resistance²⁵ suggest that the tool kits have not curbed resistance. In addition, recent changes to the nurse, physician, and pharmacy workforces as a result of the COVID-19 pandemic could have undermined previous work on antimicrobial stewardship and antimicrobial resistance.^{26,27,28,29,30}

Stewardship Demands

Antimicrobial stewardship can improve effectiveness in treatment of infectious diseases and protect against the harm associated with antimicrobial misuse in the care of patients, especially those at end of life. However, limiting antimicrobial use can present an ethical dilemma for some clinicians. Because clinicians work closely with patients, they are often morally and emotionally compelled to focus on patients' individual rights and well-being rather than on the well-being of the public as a whole.

This tension between helping one and helping many agents is a common one in public health ethics, particularly in individualistic societies, and addressing this tension in end-of-life care requires a shift from serving individuals (an autonomy focus) toward serving the collective (an equity focus) to achieve the goals of stewardship.³¹ Theoretical work in environmental sciences has explored the importance of care and relational values, which reflect the centrality of the collective in fostering stewardship.^{32,33} Building on a framework with 3 elements of stewardship—care, knowledge, and agency³² we propose a framework of sustainability that adds a fourth element—equity—which could have utility in the promotion of antimicrobial stewardship (see Table). Care, as a normative and subjective element of the framework, is necessary because it motivates an individual to attend to, or care about, an issue such as antimicrobial resistance and its impact on humanity. Knowledge, another core element of stewardship actions, may currently be inadequate to combat antimicrobial resistance,²⁰ making education for clinicians and the public critical to the promotion of stewardship.³⁴ Agency, the third element of the framework, denotes the capacity of people to affect change, particularly through collective action. Equity, as applied to end-of-life care, highlights the ambiguity inherent in medicine and the need for not only a forthright discussion of what it means for patients to be at the end of their lives, but also potential consideration of the impact of antimicrobial use on antimicrobial resistance. The misuse of antimicrobials at the end of life is not easily combatted by individuals alone but instead will require a collective approach regarding common practices and expectations for the end of life that are equitable. Care, knowledge, and agency are intertwined.³³ Adding an explicit discussion of **equity** rather than a focus on autonomy makes all these framework elements necessary to advance stewardship.

Table. Framework of Sustainability Applied to Antimicrobial Stewardship

Care

Ability of individuals, families, and clinicians to accept change and be concerned about antimicrobial prescribing practices

Knowledge

Education of and communication among individuals, families, and clinicians about antimicrobial use

Agency

Evidence-based individual, family, and clinician decision making and action regarding the use of antimicrobials

Equity

Antimicrobial prescribing practice that is ethical and equitable for all individuals, families, and communities

End-of-Life Care

Despite a desire to have discussions with their clinicians about end-of-life care, many patients do not engage in these discussions.³⁵ Patients who are at risk for a life-threatening clinical event due to a serious life-limiting medical condition can benefit from advance care planning, such as by completing the Physician Orders for Life Sustaining Treatment.³⁶ However, focusing on documents may undermine efforts to engage in **meaningful conversations** about advance care planning for patients nearing the end of their lives.³⁷ There is consensus that comprehensive advance care planning should include intentional discussion about infection management.²⁰ If a patient's goals are comfort at the end of life, antimicrobial use may unnecessarily complicate achieving those goals.^{38,39}

Use of antimicrobials has become ubiquitous in modern medicine—so much so that patients often expect and pressure physicians to prescribe antimicrobials even when they are not indicated.⁴⁰ Acquiescing to patients' requests for antimicrobials when they are not medically indicated illustrates an overemphasis on patient autonomy. An equitable approach to antimicrobial stewardship should redirect the focus from respect for autonomy to that of the common good. However, inconsistent information on antimicrobial effectiveness for treating symptoms or prolonging life^{8,41} contributes to the challenges of establishing ethical and equitable antimicrobial use for patients who likely are facing the end of life. Given that the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America identify antibiotic therapy as aggressive care at the end of life,⁴² it's potentially inappropriate if it cannot achieve the intended goals of care.⁴³ Rather than focus on individual preferences about specific treatment options, physicians should consider using an algorithm⁵ or a decision support aid when considering antimicrobial use in end-of-life situations.²⁴ Treating an infection as part of end-of-life care could delay a shift to a more comfort-focused plan of care and thus contribute to additional suffering of a patient who may survive the infection only to experience additional discomfort from the underlying disease process.⁵

A Call to Action

Minimizing long-term harms of antimicrobial resistance requires a rapid coordinated response, including the mounting of rigorous surveillance systems to monitor antimicrobial resistance patterns, implementation of antimicrobial drug stewardship

protocols aimed at decreasing the overuse and misuse of antimicrobials, and scaling up of quality infection prevention and control systems.^{17,44} The US National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025, stresses that evidence-based interventions are essential to control antimicrobial resistance and combat its sequelae.⁴⁵

Further work is needed to (1) assess the effect of antimicrobial stewardship protocols on antimicrobial use at the end of life, (2) analyze the impact of antimicrobial use on symptom management, (3) explore quality-of-life implications of antimicrobial use, (4) develop decision support tools to advance informed ethical decisions about antimicrobial use at the end of life, (5) standardize clinician education on antimicrobial stewardship and ethical considerations at the end of life, and (6) implement ethical and equitable standards for end-of-life care that could inform future antimicrobial stewardship programs.

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MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

How to Mitigate Community Harms of Antibacterial Resistance With Patient-Centered Care

Chelsea Modlin, MD

Abstract

Overprescription of antibiotics in cases in which bacterial infection is clinically uncertain contributes to increased prevalence of multidrug-resistant bacteria. Ethically, merits and drawbacks of stricter prescription practice oversight should be weighed against risks of untreatable bacterial infections to patients and communities. This article considers how to balance this set of ideas and values.

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Resistance as an Ethical Problem

The rise of antibacterial resistance worldwide, combined with the projected increase in morbidity and mortality that patients will suffer in consequence,¹ has prompted many clinicians and ethicists to rethink their approach to antibiotic use. The problem of antibacterial resistance originates from complex and multifactorial challenges that extend well beyond the hospital or clinical setting. However, overuse of antibiotics within clinical encounters remains a major contributor to the development of drug-resistant bacteria.² Even appropriate use of antibiotics contributes to a minute but collectively gradual loss of their effectiveness for patients, communities, and members of future generations. Stewardship measures pertaining to antibiotic prescribing practices and policies need to address underlying **ethical tensions**, including the medical need of an individual patient and the minimization of antibacterial resistance for the community.

Uncertainty

In order to characterize the need of an individual patient as it pertains to antibiotic prescribing, it helps to stratify a patient's risk of bacterial infection into 1 of 3 categories: (1) clinical suspicion of bacterial infection is near or at 100%, such that it is ethically and medically mandatory to prescribe antibiotics; (2) there is no clinical suspicion of bacterial infection—it is ethically and medically mandatory to *not* prescribe antibiotics; and (3) clinical suspicion of bacterial infection is uncertain, and it is ethically permissible and medically justifiable to prescribe antibiotics. It is unlikely that anyone would say the first category is problematic. Although antibiotics are inappropriately prescribed for viral infections and noninfectious conditions,^{3,4} the second category

described, with risk of bacterial infection known with confidence to be nonexistent, is not particularly ethically challenging, either. So why do many patients with viral illnesses leave their clinic appointment with antibiotic prescriptions in hand?⁵

When clinicians view antibiotic prescribing through the lens of uncertainty, there is a tendency to favor minimizing the risk of *potential* bacterial infection. Even if a viral infection is more likely, the clinician's duty to prevent harm seemingly supports providing antibiotics because the risk of bacterial infection is not zero. This response is likely both a result of, and a direct contributor to, a culture of "zero tolerance" for avoidable infection-related harm that is reinforced by defensive antibiotic prescribing⁶ and cognitive biases that influence decision making. These biases include commission bias (favoring action over inaction), hyperbolic discounting (favoring small, immediate gains over long-term benefits or reduction in harm), and optimism bias (overestimating potential benefits and underestimating risks).⁷ An example of these biases influencing both patient expectations and clinician practices is the association between antibiotic prescribing volume and both patient demand and higher patient satisfaction scores,^{8,9} regardless of whether the antibiotic was medically necessary or not.

Prevention

Two of the prevailing ethical frameworks within antibiotic stewardship are a cost-benefit approach, most often represented as utilitarianism, and contractualism. While both frameworks are related to the central claim made here, which is that antibiotic stewardship should include a patient-centered, harm-reduction approach, a detailed discussion of different ethical theories as they pertain to antibiotic stewardship as a collective issue falls outside the scope of this work. Utilitarians¹⁰ would claim that clinicians are expected to weigh risks and benefits in terms of outcomes as they relate to everyone, not just the individual patient. In this instance, antibiotics should only be prescribed when the expected benefits to everyone outweigh the expected costs. Contractualists, discussed in the context of antibacterial resistance by Michael Millar,^{11,12} would state that the clinician should only prescribe antibiotics when guided by principles that no one could reasonably reject. Millar defines one such principle as prescribing antibiotics to prevent "substantial risk of irretrievable harm" in patients or their contacts and introduces the idea that the level of acceptable risk should be above the level of risk we consent to in our daily lives, such as in driving a car. Using antibiotics when the risk of harm is comparable to or lower than these activities should be avoided for the purpose of protecting the community from further antibacterial resistance.¹² Both the utilitarian and contractualist approaches require the clinician to account for the well-being of people other than their patient, whether these people compose the community or future generations.

However, both approaches undervalue the special relationship clinicians share with their patient. It seems both practically and ethically appropriate that clinicians have particular obligations to prevent harm to their patients rather than to prevent harm to everyone, even if the latter consideration should not be disregarded completely. Although Millar's suggested risk threshold for antibiotic use accounts for antibiotic-associated risk to the patient, it is difficult to empirically conceptualize and does not seem well suited to the context of clinical care with all its pragmatic complexities, including diagnostic uncertainty and clinical and epidemiological factors that increase or decrease confidence in a bacterial diagnosis on a patient-by-patient basis. Furthermore, clinicians have traditionally expressed extremely low tolerance for introducing even a small risk of avoidable harm to their patients,¹³ especially in the form of underdiagnosis or

undertreatment. The risk of introducing or enhancing antibacterial resistance is among the least important factors they account for when making antibiotic prescribing decisions.¹⁴

Centering Patients

Unless we can appeal to clinicians' duty to prevent *any* avoidable harm to their patients, there is little reason to think their gatekeeper-like influence over antibiotic prescribing will dramatically change. Utilitarian and contractualist approaches are unsatisfactory and unlikely to sway clinicians to change their antibiotic prescribing practices. However, discussions of trade-offs in antibiotic prescribing frequently rely on the assumption that antibiotics are inherently beneficial and that harm only occurs in their absence. Yet, as clinicians know, antibiotics can be a direct cause of adverse medical outcomes. The expected utility to an individual patient of receiving antibiotics can be lower than the expected utility of *not* receiving antibiotics, even when the risk of potential bacterial infection is more than zero. A clinical example of this scenario is when antibiotics are prescribed for patients with COVID-19, which is discussed in detail below. Reframing the justification for limiting antibiotic prescribing to one that focuses on harm reduction for a given patient—including risk of the potential for both bacterial infection and antibiotic-related adverse events—appeals to a clinician's duty to prevent harm while also indirectly benefiting the community by reducing low-utility antibiotic prescriptions.

Take the example of COVID-19, a viral infection. Differences between an isolated COVID-19 infection and a bacterial co-infection can be difficult to distinguish clinically. By several months into the pandemic, studies showed a wide range of bacterial co-infection rates in hospitalized COVID-19 patients, but a meta-analysis of multiple studies found an average co-infection rate of 7%.¹⁵ This rate decreased to 1% to 3% for mild and moderate COVID-19 cases.¹⁶ Yet, as many as 50% to 90% of patients admitted for COVID-19 during the first year of the pandemic received antibiotics.^{15,17,18} While a proportion of these prescriptions were appropriate for select patients at increased risk of having a bacterial co-infection, such as patients requiring admission to intensive care,^{19,20,21,22,23} the incidence of co-infection among these small but high-risk populations still did not approach the overall rates of empiric antibiotic use.

In order to compare the relative risks and benefits of prescribing or not prescribing antibiotics for an individual COVID-19 patient, we can conduct a thought experiment to estimate the expected utility of each therapeutic decision, as shown in Table 1. These expected utilities are admittedly subjective quantifications of potential utility selected to reflect the perspective of a clinician faced with the decision to give or not give antibiotics to a patient with COVID-19. For simplicity, this example assumes that the antibiotic prescribed is appropriate for co-infection. The utility of prescribing antibiotics when a bacterial co-infection is present is high (let us say +100), while the utility of not providing antibiotics for a bacterial co-infection is inversely proportional, if not worse (-150). In giving antibiotics for a purely viral process, there is an appreciable risk of negative utility in the form of an antibiotic adverse event (-20)—which is based on a study showing that 20% of hospital patients who receive an antibiotic experience an adverse antibiotic-related event²⁴—and a small positive utility in not giving antibiotics in the form of prevention of future antibacterial-resistant infection in the patient (+5). As shown in the right-most column, which multiplies this subjective expected utility by the rate of bacterial co-infections (7%) to generate overall expected utility, even abstaining from prescribing antibiotics for potential bacterial co-infection among routine COVID-19 infection cases comes with a degree of risk; it is in the patient's best interest not to

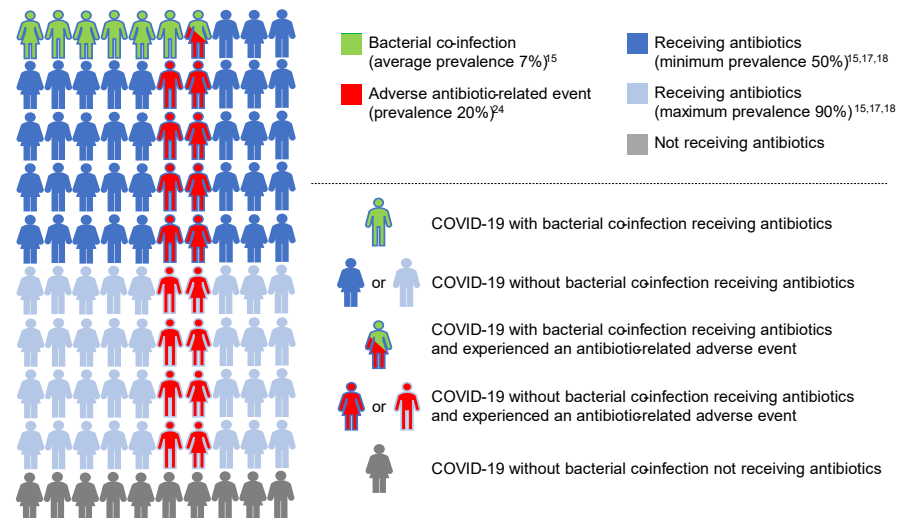
receive antibiotics empirically, without needing to directly account for any related community benefit.

Table 1. Expected Utility of Prescribing Antibiotics in Cases of Known COVID-19 Infection and Possible Bacterial Co-Infection

Decision	Utility if infected with COVID-19 only ($P = .93$) ¹⁵	Utility if infected with secondary bacterial co-infection ($P = 0.07$) ¹⁵	Expected utility
Give antibiotics	-20	100	$(-20 \times 0.93) + (100 \times 0.07)$ = -11.6
Do not give antibiotics	5	-150	$(5 \times 0.93) + (-150 \times 0.07)$ = -5.9

Some may disagree with this formulation because it relies on subjective quantifications of utility that vary based on clinician preferences, level of clinical uncertainty, or amount of information available. As an alternative, we can compare antibiotic-associated adverse outcomes among COVID-19 cases with and without bacterial co-infection. As mentioned previously, 20% of patients who receive antibiotics in the hospital experience at least one adverse drug reaction.²⁴ Extrapolating from this statistic, roughly 1 of every 5 COVID-19 patients receiving antibiotics without bacterial co-infection will suffer from an antibiotic-related adverse outcome without any relevant health gains (see Figure). Comparing these patients as a proportion of all patients without bacterial co-infection to those receiving antibiotics with bacterial co-infection, it can be concluded that antibiotics cause avoidable harm to COVID-19 inpatients without bacterial co-infection at a rate (eg, between 8 and 16 patients of every 93 patients, or between 9% to 17% based on the Figure) that is higher than the 7% of patients with COVID-19 who benefit from antibiotics because a clinician accurately diagnoses and treats their bacterial co-infection.

Figure. Prevalence of Bacterial Co-Infection, Antibiotic Use, and Antibiotic-Associated Adverse Events in Hospitalized Patients With Routine COVID-19 Infection



Green symbols with a blue outline represent patients receiving appropriate treatment. While a proportion of these patients will still have an antibiotic-associated adverse event (red and green symbol with blue outline), this risk is tolerable if not justifiable due to the need for antibiotics to prevent bacterial infection-related harm. Conversely, solid blue symbols represent patients receiving overtreatment with antibiotics in the absence of bacterial co-infection. A proportion of these patients will have one or more antibiotic-associated adverse events (red symbols with blue outline). It seems difficult to justify incurring this harm, given the lack of any benefit.

Table 2 enumerates other commonly encountered clinical scenarios in which antibiotics or antifungals are often prescribed despite not being indicated in most cases. However, for other situations that also fall under the category of uncertainty, the pretest probability of bacterial infection is higher, such as patients who are critically ill or who have immunocompromising conditions, which can justifiably tip the calculus in favor of prescribing antibiotics.

Table 2. Common Clinical Scenarios in Which Antibiotics Are Often Prescribed Despite a Well-Established Lack of Utility

Clinical presentation	Antimicrobials commonly prescribed (potential adverse effects) ²⁴
Asymptomatic bacteriuria in an elderly patient with delirium	<ul style="list-style-type: none"> • Ceftriaxone (gastrointestinal upset, <i>C difficile</i>, cytopenias) • Cefepime (gastrointestinal upset, <i>C difficile</i>, cytopenias, neurotoxicity) • Ciprofloxacin (<i>C difficile</i>, gastrointestinal upset, tendinopathy)
Asymptomatic candiduria in a patient with a urinary catheter	<ul style="list-style-type: none"> • Fluconazole (hepatotoxicity, gastrointestinal upset, QTc prolongation)²⁵
Coagulase-negative <i>Staphylococcus</i> contaminating blood cultures	<ul style="list-style-type: none"> • Vancomycin (nephrotoxicity, infusion reaction)
Fever, rash, and leukocytosis from mononucleosis	<ul style="list-style-type: none"> • Amoxicillin/clavulanate (gastrointestinal upset)
Lower-extremity venous stasis and ulceration	<ul style="list-style-type: none"> • Vancomycin (nephrotoxicity, infusion reaction) • Ampicillin/sulbactam (gastrointestinal upset, nephrotoxicity) • Cefazolin (cytopenias, nephrotoxicity)
Nosocomial tracheitis without evidence of lower respiratory tract disease	<ul style="list-style-type: none"> • All of the above

Abbreviation: *C difficile*, *Clostridium difficile*.

One limitation of the expected utility framework is that it does not address certain factors, such as patient preferences and expectations, that influence how a clinician weighs relative risk, benefit, and utility in antibiotic decision making. This shortcoming highlights one of the many areas in which a **robust antimicrobial stewardship program** can—by enacting processes such as antibiotic approvals, preset antibiotic durations, and individual clinician audits—prevent actions that result in overprescribing antibiotics, underestimating potential harm from side effects, or prescribing antibiotics that are too broad, are too narrow, or are used for too long of a duration, given the indication. These informed risk-benefit calculations can be discussed with patients in order to reach a decision that both patient and clinician feel is consistent with the patient’s best interest.

Conclusion

Addressing the rise in antibacterial resistance via antibiotic stewardship is an emerging priority for health systems and clinicians. There is certainly no straightforward solution, and there remains a distinct need for normative deliberation and empirically supported methods to reduce individual clinician prescribing practices that contribute to antibacterial resistance. Suggestions to increase, even slightly, the potential risk of avoidable harm to a patient for the sake of community benefit are incompatible with how a clinician’s duty to prevent harm is ingrained in professional norms. In health care systems where access to antibiotics is via prescription from a clinician, there is potential advantage in reframing restricting antibiotic prescribing as focusing on the patient and in revisiting how we conceptualize patient harm. When there is a degree of uncertainty

about a bacterial diagnosis, a utility calculus or harm-reduction approach can be useful for antibiotic decision making. In cases in which expected utility favors not prescribing antibiotics, there is both a direct benefit to the patient by reducing avoidable harm from antibiotics and an indirect benefit to the community by decreasing one of the major selective pressures that promote antibacterial resistance.

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VIEWPOINT

Should We Think of Early Career Cheaters as Capable of Stewardship?

Christy A. Rentmeester, PhD

Abstract

Resistance to acknowledging and curbing cheating should be seen as expressing academic organizations' dereliction of their tacit early career health professional self-regulatory duties. Cheating among students and trainees deserves ethical attention, scrutiny, and self-regulatory responses because cheating behaviors express characterological vices that undermine trust and trustworthiness, which, among other virtues, are key to good stewardship and other duties of health professionals.

Cheating as Early Career Self-Regulatory Failure

Cheating is not new in the index of human experience. It is not new in health professions education, and it happens all over the world.^{1,2,3,4} Cheating students and trainees grow into cheating clinicians and researchers,^{5,6,7} and that is a problem for all of us who rely on the integrity of health professions and health professionals.

As a philosopher who has taught for many years in academic settings, I've learned, directly and indirectly, of what some cheaters are characterologically capable. One student generated a fake death certificate for a member of their family. Another student exclaimed, upon learning that content in their assignment was found *verbatim* on a website, "I can't believe someone would put my case on their website!" Despite how outrageous these instances sound, some academic health organizations fail to use these and similar instances of cheating or kindred offences to enforce professional ethics standards, admonish or penalize offenders, or, in some cases, even wonder whether cheaters are characterologically worthy of public trust or able to execute their duties as clinicians, stewards of community health goods, and self-regulators of their professions.

These failures of academic health organizations are, what I will call herein, failures of early career health **professional self-regulation**, which tend to take the following forms: willful ignorance and naivete (eg, we do not need text replication detection programs because cheating has never been a problem here); denial that offences warrant serious concern (eg, these are minor offences); and overreliance on the ethical sufficiency of delayed self-regulatory response (eg, cheaters will be dealt with in good time and appropriately by their state licensure boards or professional societies).

Public Reliance and Professional Self-Regulation

There is little documented about what academic health organizations do or should be required to do about cheating. Even less seems to be documented about what is *not* done about cheating when these organizations fail to support faculty trying to pursue due diligence in response to suspected or verified cheating. What's been going on in practice for a long time has not, as far as I can tell, been tracked well by health professions education, health policy, health humanities, or health care ethics literatures.

How academic health organizations respond or fail to respond to early career cheating on examinations and assignments, falsification of information in applications, or other misconduct should get more ethical and self-regulatory attention. One reason for this is our tacit reliance upon and fiduciary trust in academic health organizations, for better or worse, to vet, select, teach, and train people whom we will, usually in 4 years, ask our states to license and credential as our clinicians. This is the same reason why academic health organizations have *de facto* early career self-regulatory obligations to health professions and to the public.

State boards are a more well-known species of health professional self-regulators, typically composed of professionals in the fields they self-regulate and members of the public. During my service on one of these boards, we deliberated on and made decisions about how to best protect members of the public from harms posed by licensees or their practices. Expressions of ethics concerns our board fielded were most frequently articulated as scope of practice questions (eg, *This clinician did or does X; is that appropriate?*) and as questions about clinicians' characters and behaviors (eg, *Is it appropriate for someone who did, does, said, or says X to practice this profession? or This clinician should have done X and they didn't; I'm reporting it and something needs to be done about it*). Sometimes queries we received generated our recommendations to the state attorney general's office or generated our responses (a **range of disciplinary or nondisciplinary actions**) to findings of the state attorney general's office's investigations into licensees' behaviors. For example, boards' self-regulatory functions can range from restricting clinicians' licenses, recommending issuance of cease-and-desist orders, recommending investigations, imposing practice supervision, requiring education and documentation of education on key topics, or levying a range of penalties or issuing a range of practice limitations in the interest of protecting the public from risk or harm posed by a licensee.

Prelicensure Vices and Virtues

But state boards have no authority to regulate health professions school graduates who are not yet licensed, other than to not grant a license to an applicant. One question to ask here is *When persons not yet licensed to practice their professions cheat, who or which bodies are better positioned than academic health organizations to do the jobs of early career professional self-regulation?*

Postlicensure self-regulatory bodies are not in the business of selecting who will have educational and training opportunities to become applicants for licensure. Nor are they in the business of professional or characterological formation. But academic health organizations are. When academic health organizations award degrees to cheaters, health professions' and health professionals' responsibilities to safeguard public trust and to self-regulate in the interest of public protection are not met. Instead, these responsibilities get passed along to public agencies, and at costs borne by all of us.

One way to understand cheating as professional malformation is in terms of the characterological vices cheating behaviors tend to express: insufficient self-governance, poor judgment, and lack of humility, which is, specifically, a failure to try to reckon honestly with the limits of one's content knowledge and to take ownership of limits in the scope of one's competence. Articulating cheating in ethical terms—that is, in terms of characterological vices—offers us opportunities to think, by contrast, about the kinds of virtues that good self-regulation, stewardship, and other key tasks of health professionalism require: self-governance, good judgment, and humility about the scope of one's knowledge and practice. If we generally accept that these vices and virtues have the kind of significance in health professional formation and malformation that I suggest here, then it's reasonable for us to think of conferral of a health professional degree and graduation as key early career self-regulatory functions that express academic health organizations' endorsement of an early career clinician's entry into a health profession.

Trustworthiness is Prior to Stewardship

It is certainly possible for the vicious to become virtuous and for the virtuous to become vicious. It is possible for cheaters to regret their behaviors and reform, and I remain hopeful that some of them can. An upshot of this essay, however, is that we should regard early career professional self-regulation as an explicit, not tacit, job of academic health professions education organizations. We rely upon these organizations to care about characterological transformations, for better or worse, of students and trainees because these educational and training organizations have key roles in recommending entire professions' and individual professionals' trustworthiness to the public. Trustworthiness should be regarded as prior to being trusted,⁸ and being trusted should be regarded as prior to being entrusted with key duties, such as stewardship . . . of **antimicrobials**, scarce resources and commodities, inpatient bed space, or anything else patients and communities need.

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