A Cross-Sectional Survey of Medical Trainee Experiences During Medication Shortages

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ABSTRACT

Background Medication shortages prevent patients from receiving optimal care. Despite the frequency with which medical trainees care for inpatients, no assessment of their experiences in medication shortage management has been performed.

Objective We evaluated trainees' experiences managing medication shortages.

Methods We performed a cross-sectional survey of trainees postgraduate year 2 (PGY-2) and above in medicine, anesthesiology, and emergency medicine departments at 2 academic centers in 2018–2019. Categorical and ordinal assessments evaluated shortage awareness, substitution availability, pharmacy and therapeutics committee-based restrictions, communication, and education. Regressions were performed to determine effect of PGY, department, and institution on responses.

Results A total of 168 of 273 subjects completed the survey (62% response rate). Most (95%, 159 of 168) reported managing medication shortages during training; 51% (86 of 168) described managing clinically relevant shortages daily or weekly. Seventy-seven percent (129 of 168) noted equivalent alternatives were unavailable at least one-quarter of the time, and 43% (72 of 168) reported clinically necessary medications were restricted at least weekly. Fifty-four percent (89 of 168) and 64% (106 of 167) of respondents discussed clinically relevant shortages with supervising physicians or patients "some of the time" or less, respectively. Most respondents (90%, 151 of 168) reported they would benefit from shortage management training, but few (13%, 21 of 168) reported prior training.

Conclusions Although trainees reported frequent involvement in clinically impactful shortage management, medication shortage communication between trainees and supervising physicians or patients appears sporadic. Medication shortage management training is uncommon but perceived as beneficial.

Introduction

Inpatient medication shortages in the United States are a widespread and ongoing problem that prevent patients from receiving optimal medical care.[1–4] Medication shortages stem from raw material scarcity, manufacturing disruptions, business decisions, and demand fluctuations.[5,6] Although the absolute numbers of shortages ostensibly improved after regulatory changes in 2012,[7–9] recent evidence has shown that shortages are now more protracted, more severe in multiple medication categories, lead to shortages of substitutes, and impact virtually every US hospital.[10–12]

Prior studies have investigated the etiologies of shortages, mitigation mechanisms, the impact of specific shortages on patient outcomes, and the merits of different ethical allocation frameworks.[1,10,13–19] A recent survey of US hospital-based pharmacists found that medication rationing episodes were common, decisions were often made without outside input, and patients were infrequently informed.[4] These findings raise ethical concerns over transparency, clinician decision-making and moral distress, and the accepted standard of shared decision-making. Research evaluating the impact of medication shortages on personnel has been limited to assessments of subspecialist and pharmacist management.[2,4,10]

Residents and fellows frequently care for inpatients throughout the United States. Despite the ubiquity of medication shortages, it is unclear how they perceive their ability to provide care during shortages, if and when they choose to communicate with supervising clinicians or patients, or if they have received or desire shortage-related training. Utilizing domains of interest identified from published data (awareness of and experiences managing shortages, use of alternatives, pharmacy and therapeutics (P&T) committee-based restrictions, and communication within the medical team and with patients),[4] we performed a cross-sectional survey of trainees to examine their experiences, beliefs, and preferences in these areas.

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Editor's Note: The online version of this article contains the final version of the 17-item survey; figures of frequencies of medication shortage management and shortage management communication results; and tables of awareness and personal shortage management experience, shortage management associations, shortage management communication associations, patient disclosure threshold results, and shortage training results.

Methods

Participants

The participants were postgraduate year 2 (PGY-2) and above in the departments of anesthesiology, medicine, and emergency medicine at The University of Chicago (UC) and Mayo Clinic. Sites were selected for their differences in setting (urban versus suburban/rural) and patient demographics (race, income, education).[20] Within each institution, departments were chosen because those trainees care for inpatients at the same hospital and therefore would be more likely to have a comparable medication supply. To ensure they had experience treating inpatients within their department and in their current role, eligible trainees were required to be at least PGY-2, and survey distribution did not begin until 3 months after the start of the academic year.

What was known and gap
Despite the frequency of medication shortages and the large number of residents and fellows who care for inpatients, there has not been an assessment of trainee experiences with shortage management.

What is new
A cross-sectional survey of trainees to evaluate shortage awareness, substitution availability, pharmacy and therapeutics committee-based restrictions, communication, and education.

Limitations
Survey was retrospective and subject to recall and social desirability bias.

Bottom line
Trainees regularly encounter medication shortages and frequently consider them to be clinically relevant, but shortage-related communication between trainees and supervising physicians or patients appears sporadic. Shortage management training is uncommon but perceived as beneficial.

Survey Development

Based on these domains, a 17-item survey with questions tailored to trainees was developed by the authors, which included 2 qualitative health services researchers, 2 medical ethicists, and a research pharmacist. Questions were worded based on common key phrases and terminology from the data and were pretested for clarity and potential areas of bias by 2 different health services researchers familiar with the subject. Final questions are provided as online supplemental material.

Recruitment

Lists of the 273 trainees were provided by participating departments. Paper surveys were distributed in person by 3 authors (A.H., A.M.E., T.T.N.) at mandatory graduate medical education conferences on clinical educational topics that the selected residency programs held at UC and Mayo Clinic between October 2018 and January 2019. Participants were not compensated. Informed consent forms were completed prior to participation. To ensure response accuracy, surveys were linked to individuals using unique identifiers.

Outcomes

The survey was designed to describe trainee awareness of and experience managing medication shortages, the use of alternatives, P&T committee-based restrictions, and communication within the medical team and with patients to evaluate response differences according to PGY, department, and institution.

The institutional review boards of UC and Mayo Clinic approved the study.

Analysis

Survey results were analyzed for descriptive statistics. Fisher's exact or χ^2 testing was used to compare differences between categorical variables, as appropriate. Logistic regression and ordinal logistic regression were performed to determine the effect of PGY, department, and institution on questions with categorical and ordinal variables, respectively. PGY was also divided into PGY-2 or PGY-3 and above to assess if trainees with more than 1 year as a senior resident were more independent in medication shortage management. P values $\leq .05$ were considered significant. Statistics were performed using STATA SE version 15.0 (StataCorp LLC, College Station, TX).

Results

Of 273 eligible subjects, 168 completed the survey (62% response rate). Subject nonresponse was similar across postgraduate year, department, and institution (46% to 77% response rate range). During regression, variance inflation factors were less than 5. Item response rate was greater than 99.9%; therefore, no imputation was performed. Respondent demographics are shown in the TABLE.

Overall, 96% (162 of 168) of respondents were aware of medication shortages, and 95% (159 of 168) reported personal experience managing shortages during their training period; responses were similar across institution, department, and PGY (see TABLE 1 in online supplemental material). Response percentages for the frequencies of shortage management also can be seen in FIGURE 1 in the online supplemental material.

TABLE
Respondent Demographics

Demographic	n (%) of Total Respondents	Response Rate, %
Institution		
University of Chicago	108 (64)	74
Mayo Clinic	60 (36)	48
Department		
Medicine	85 (51)	77
Emergency medicine	29 (17)	64
Anesthesiology	54 (32)	46
Postgraduate year		
2	82 (49)	65
> 2	86 (51)	59

Associations within shortage management, altering treatment choice, and self-described clinically relevant shortage questions are described in TABLE 2A in the online supplemental material. Trainees at UC reported an increased frequency of shortage management (OR = 3.40; 95% CI 2.33–4.68; $P < .001$), altering treatment choice (OR = 3.32; 95% CI 2.19–4.46; $P < .001$), and self-described clinically relevant shortages (OR = 3.14; 95% CI 2.02-4.29; $P < .001$) as compared to trainees from Mayo Clinic. A total of 43% (72 of 168) reported that the hospital P&T committee restricted clinically necessary medications from their use on at least a weekly basis. A majority (77%, 129 of 168) of respondents reported that clinically equivalent alternatives (defined by equivalence of efficacy, toxicity, familiarity, and route of administration) were not available at least 25% of the time. Associations according to institution, department, and PGY for these questions are reported in TABLE 2B in the online supplemental material. Frequent restriction and a lack of clinically equivalent alternatives were more common at UC than Mayo Clinic (OR = 7.50 and 2.08; 95% CI 6.24–8.90 and 1.40–2.72; $P = .001$ and $P = .012$).

Absolute response percentages for communication questions are shown in FIGURE 2 in the online supplemental material, with 68% (114 of 168) of those with prior management experience reported discussing episodes of management with their supervising physician "some of the time" or less. When the respondent deemed the medication shortage clinically relevant, this was 54% (89 of 168) of the time. If management was based on a P&T committee restriction, 77% (129 of 168) reported discussing the shortage with patients "some of the time" or less; when the shortage was considered clinically relevant, this was 64% (106 of 167). Associations according to institution, department, and PGY for communication questions are reported in TABLE 3 in the online supplemental material. Medicine trainees and PGY-3 and above trainees were less likely to discuss shortages they considered clinically relevant with their supervising physician (OR = 0.46 and 0.55; 95% CI 0.29–0.96 and 0.28–0.97; $P = .048$ and .050). Those from Mayo Clinic and those from either medicine department were more likely to frequently discuss shortages they considered clinically relevant with patients (OR = 2.02 and 1.61; 95% CI 1.54–2.65 and 1.25–1.85; $P = .009$ and .012).

Disclosure threshold responses and medication shortage management training responses are shown in TABLES 4 and 5, respectively, in the online supplemental material. Trainees who responded that patients should be informed of shortages based on the degree of a substitution's clinical difference (79% [133 of 168] of respondents) were asked the minimum level of clinical difference required to disclose. Only 33% (44 of 133) stated that they would disclose a shortage if there was any difference in efficacy or toxicity between the original medication and the alternative, 20% (27 of 133) reported that there should be at least a small difference, and 47% (62 of 133) responded that should be at least a moderate or major difference. Associations according to institution, department, and PGY for disclosure questions and shortage management training questions are reported in TABLES 4 and 5, respectively, in the online supplemental material. UC trainees and emergency medicine trainees at both institutions were more likely to require a higher degree of difference to consider disclosure necessary (OR = 1.84 and 1.96; 95% CI 1.45–2.11 and 1.19–2.80; $P = .009$ and .023).

Discussion

This is the first study to examine medical trainee experiences with medication shortages. This cross-sectional survey of 3 parallel departments at 2 academic centers describes the degree to which trainees perceive the impact of medication shortages, their communication practices during shortage management, and their shortage-related training. It also demonstrates that trainees believe shortages regularly affect clinical decision-making and result in the use of nonequivalent alternatives—experiences that reflect prior evaluations of pharmacists and subspecialty clinicians.[21] As medication shortages continue, this study adds to the recent literature demonstrating that cohesive management of and communication during shortages is uncommon and remains a clear gap in optimizing patient care.[4,10,21]

Although trainees in different departments and PGYs appear to manage medication shortages with

similar frequencies, trainees at different institutions reported dissimilar frequencies of shortage management. Several institutional differences may account for these results. First, while medication scarcity is widespread, specific shortages and their severity are known to vary between hospitals.[4,22] Second, participating institutions' patient populations may play a role. For example, ongoing parenteral opioid shortages may have a greater impact on UC trainees due to a larger population of patients with sickle cell disease in Chicago.[23] Third, there is no standardized management of medication shortages in US hospitals. Mitigation and management strategies vary, and the degree to which trainees recognize their use is likely to affect perceptions.[10,24]

These management strategies often include P&T committee-based ordering restrictions and mandated substitutions.[24] Notably, 77% of respondents stated that equivalent alternatives were unavailable at least one quarter of the time, and 43% were restricted from clinically necessary medications at least weekly. These definitions are clinician-dependent; however, it reflects the increasing difficulty hospitals have in obtaining equivalent substitutes and managing shortages.[2] The use of inferior alternatives is a troubling trend. While trainees are expected to familiarize themselves with different medications, their inexperience may compound risk factors for error—or result in inferior outcomes—when alternatives are frequently switched or are nonequivalent. Shortage-specific education and standardized P&T committee communication during mandated substitution may help improve this issue.

Over half of trainees reported frequent medication shortage management and infrequent communication with supervising physicians or patients. These data should be of concern to the graduate medical education field. The postgraduate period is when trainees are expected to learn and practice the clinical management skills and responsibilities necessary for independent practice. As few trainees reported prior shortage-related training, their independent management of shortages and disclosure decision-making are areas for educational improvement and innovation. As medication shortages are now a common part of clinical care during training and independent practice, inclusion of shortage management education into the systems-based practice competency of Accreditation Council for Graduate Medical Education Milestones should be considered.

Ethical concerns of medication shortages have been examined via bioethical frameworks and empirical studies; they also should be considered within trainee shortage management.[19,24] Both ethical theory and data on patient preference suggested that patients should, and want to, be told of shortages.[22,24] Arguments against patients being informed are due to the lack of alternatives, because clinicians regard substitution differences as insubstantial, or because clinicians think that patients will be unnecessarily concerned.[25,26] It appears that the complexity of shortages (variability, capricious availability of substitutions, and rationing via P&T committee-based restrictions) has made transparency during medication scarcity uncommon.[24] As the surveyed trainees only have experience during this era of medication shortages, they may not recognize that this decision-making is morally complex.

The limitations of this study include the inherently retrospective nature and associated recall bias of self-report surveys. The social desirability bias to report higher levels of communication suggests that the true level of trainee communication may in fact be lower than our data suggest. As we aimed to study the trainee perspective, we feel that the variable interpretation of terms like "clinical relevance" and "clinically necessary" are acceptable, but we acknowledge that they also may be limiting. Our future research includes a larger prospective evaluation of trainees and educational interventions. Though the use of prior work provided a clear basis for question domains, it may have unintentionally limited the scope. We also did not measure the corresponding perspective of supervising physicians, whose assessment is central to an ongoing evaluation.

Next steps should include assessments of interdisciplinary communication and how and when trainees manage medication shortages independently. These evaluations will aid in the eventual design of a graduate medical education medication shortage educational model, which may help mitigate ethically difficult practices.

Conclusions

This cross-sectional survey suggests that trainees regularly encounter medication shortages and that they frequently consider shortages to be clinically relevant. Respondents report regularly prescribing nonequivalent alternatives and being restricted from using medications they deem medically necessary. Additionally, they report managing shortages independent of their supervising clinician and not disclosing shortage management to patients, while simultaneously considering those shortages clinically relevant. Despite respondents' desire for training, few trainees in this sample had received medication shortage-related education.

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