American Academy of Allergy Asthma & Immunology

The Impact of Prior Authorization on Clinical Practice and Patient Care Outcomes: A Work Group Report of the AAAAI Prior Authorization Task Force

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What is already known about this topic? Prior authorization (PA) was originally developed to reduce medical costs and promote safe, efficient, evidence-based medical care but has emerged as a mechanism for regulating health care management.

What does this article add to our knowledge? The questionnaire responses from the American Academy of Allergy, Asthma & Immunology membership indicate that PAs can significantly affect patient care delivery and increase administrative burden on clinical practices, leading to adverse events in some circumstances.

How does this study impact current management guidelines? Findings from this study support responses from the 2021 AMA Survey that assessed the impact of PA on clinical care confirming that it is a serious health care problem affecting the clinical management of patients managed by allergists-immunologists.

The Prior Authorization Task Force of the American Academy of Allergy, Asthma & Immunology (AAAAI), a presidential initiative of David Khan, MD, FAAAI, was established to develop an AAAAI position statement outlining ways to improve health care for our patients, to support legislation that advocates for prior authorization (PA) reform and identify the impact PA

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Abbreviations used
AAAAI- American Academy of Allergy, Asthma & Immunology
AMA- American Medical Association
EHR- Electronic health record
ePA- Electronic prior authorization
HAE- Hereditary angioedema
IVIG- Intravenous immunoglobulin
PA- Prior authorization
PATF- Prior Authorization Task Force
SCIG- subcutaneous immunoglobulin
SCIT- Subcutaneous immunotherapy
SLIT- Sublingual immunotherapy

has on its membership using a questionnaire survey. This article describes the results of this survey. An electronic anonymous survey questionnaire was developed to assess the impact and burden of PA on AAAAI members and their staff and patients. Surveys were sent to randomly selected members and fellows of the AAAAI in the United States. Descriptive statistics were used to analyze the results by the Information Services team of the AAAAI and the authors of this work group report. The questionnaire responses from allergy immunology specialists demographically reflected the AAAAI membership and indicate that PAs can significantly affect patient care delivery and increase administrative burden to clinical practices, leading to serious adverse events in some circumstances. Differential responses regarding PAs for various medication classes likely reflect the physician's patient population, which can shift prescribing patterns. Prior authorization is a serious health care problem that is wasting financial resources and needlessly placing patients in danger when they are unable to access medications or medical services required for clinical management. The results of this questionnaire study support the recommendations made in the recent AAAAI position statement on PA. © **2024 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2024;12:1719-26)**

Key words: *Prior authorization reform; Health care problem; Burden to clinical practices; Guidelines; Treatment; Questionnaire survey*

INTRODUCTION

In the 1960s, with the passage of Medicare and Medicaid legislation, utilization reviews were established to ensure certain treatments during hospitalizations were appropriate for patient care. Prior authorization (PA) was developed with potential benefits including reducing medical costs while promoting safe, efficient, and evidence-based medical care. It was also designed to identify drugs that were known to have unsafe interactions with medications the patient was already taking, and drugs prescribed for unapproved indications.[1] Subsequently, PA was extended beyond hospital care to the medical community as a tool to reduce potential risk and harm to the patient by providing a critical safety net that prevented potentially dangerous prescribing decisions by physicians.[2] Other potential benefits of PA include the involvement of the allergy-immunology specialist in the recommendations of biologic therapy, providing some competition for drug pricing and encouraging pharmaceutical manufacturers to prove the effectiveness of new indications of drugs already approved for other indications. However, the PA process has evolved into a mechanism that insurance companies use to control costs by deterring or limiting the prescribing of brand name medications and those deemed high-cost. The justification of ensuring the reduction of low-value care (defined as being ineffective, harmful, or of marginal benefit at a disproportionately high cost) endures in broader forms including step therapy, the demonstration of medical necessity, peer-to-peer reviews, and PAs that extend to prescription drugs, medical equipment, and certain services and treatment plans.[1,3]

Prior authorizations are now a routine method used by third-party payers to regulate the management of patient care. The Center of Medicare and Medicaid Services defines PA as "a decision by your health insurer or plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary."[4] Also known as preauthorization, prior approval, or precertification, it is a tool requiring providers to establish and justify the clinical eligibility of a treatment before care can be delivered or often, continued. Pharmacists and health care professionals employed by the insurance company review PA requests from a patient's provider. They reportedly make determinations whether the selected course of action of a treatment is appropriate, based on the latest clinical evidence and considering the cost, safety, and alternatives. If they deem that the selected treatment is too expensive with available lower-cost alternatives or unnecessary, the PA is denied.[4] These internal policies are supposedly based on the latest clinical evidence, including guidelines from relevant medical specialty organizations. Treatments or medicines deemed unsafe, of low value, or with too high a cost may be denied or deferred until alternative treatment(s) have been trialed.[3,5]

Prior authorization requirements are not uniform and can differ based on a variety of ever-changing factors, including the payer, patterns of use, and state-specific government regulations. In addition, there is no uniform method for submitting a request; each payer has different avenues of submission, including fax, paper, and electronic. Often multiple contacts with the payer are required in the process. Although deemed a cost-control measure by payers, PAs are associated with significant indirect patient care administrative requirements for physicians and their staff.

Allergy-immunology physicians treat a variety of conditions including severe persistent asthma, eosinophilic disorders, inflammatory skin disorders, food allergy, immunodeficiency, and rare orphan diseases such as hereditary angioedema (HAE), for which there is a growing number of US Food and Drug Administration—approved treatments that have improved patient outcomes and quality of life. Many of these patients have experienced prolonged journeys involving seeing multiple doctors, receiving many ineffective therapies, and often having had avoidable emergency room visits and hospitalizations before seeing an allergy-immunology specialist knowledgeable in their care.[6-11] For example, patients with severe persistent asthma can be difficult to manage and often require advanced care with treatments such as a combination inhaler containing a long-acting β-agonist, inhaled corticosteroid, long-acting muscarinic agent, and/or biologic agent that may require PAs. Denials by third-party payers of these therapies further delay the ability to

manage patients with severe asthma, leading to avoidable morbidity and health care costs. A recent study reported that the PA process for biologics in the treatment of asthma is slow, with an approval duration from the time of submission to the first dose available for injection of 44.0 ± 23.2 days.[8] The authors concluded that "the prior authorization process for biologics was slow, and the subjects were at high risk of exacerbations during this time."[8]

The current work group report was developed as a project under the Prior Authorization Task Force (PATF) of the American Academy of Allergy, Asthma, and Immunology (AAAAI), a presidential initiative of David Khan, MD, FAAAI.[12] The PATF developed an AAAAI position statement on PAs that outlined six positions regarding PAs to improve health care for patients.[12] Another charge of the PATF was to develop a survey on the impact of PAs on AAAAI members. This article describes the results of this survey.

METHODS

We developed an electronic anonymous survey questionnaire to assess the impact and burden on AAAAI members and their staff and patients. Some questions reflected the recent American Medical Association (AMA) survey that addressed the impact on PA on health care issues across the spectrum of medical specialties and other questions related to specialty-specific areas (Table I). Surveys were sent to randomly selected members and fellows of the AAAAI in the United States at five separate 1- to 2-week intervals (approximately 4,844 members and fellows in total). Fellows-in-training were not invited to participate. Descriptive statistics were used to analyze the results by the Information Services team of the AAAAI and the authors of this work group report.

RESULTS

Respondent characteristics and clinical setting

A total of 259 members (approximately a 4% response rate) responded, representing 40 of 50 states; the greatest number of respondents come from California (n = 26), Texas (n = 20), New York (n = 19), Virginia (n = 14), Illinois (n = 13), Ohio (n = 13), Arizona (n = 11), and New Jersey (n = 10). Approximately 52% of respondents were male, 39% were female, and 9% did not disclose this information; 60% were White, 16% were Asian, 2% were Black, 3% were Hispanic or Latino, and 16% did not disclose this information. Approximately, 62% and 19% of respondents were from small allergy-immunology practices composed of one to five and five to 10 doctors, respectively. Approximately 6% of respondents were from practices composed of 10 to 25 allergists, and 6% from practices composed of 25 to 100 allergists. A smaller representation of respondents was from practices larger than 100 physicians. The greatest number of respondents was from single-specialty group practices (33.46%), followed by physicians in hospital health care systems (21.79%), solo practice (19.46%) and multiple-specialty group practice (12.45%). Fifty-six percent of practices were privately owned, whereas the remaining practices were owned by a hospital, health system, or asset management company. Approximately 71% of physicians worked 26 to 45 h/wk. Approximately 45%, 38%, and 15% respondents were trained in internal medicine, pediatric and combined internal medicine and pediatrics, respectively. Patients' age was evenly distributed among the participating practices. Although the response rate to this survey was lower than the 10% rate expected for similar surveys, demographics were reflective of the AAAAI membership and geographically distributed across the United States, indicating the generalizability of responses. Differences in responses may have varied by state depending on PA legislation and health care plan requirements, but this information was not obtainable from this survey.

MEDICATIONS REQUIRING PAs

Approximately 97% of physicians or their staff had performed PAs for prescription medications other than nonformulary mediations and biologics, 82% for immunoglobulin replacement therapy, 75% for medical services (eg, procedures, genetic studies, laboratory values, durable medical equipment, imaging), and 61.5% for HAE medications in the past week (Figure 1). A smaller percentage of respondents performed PAs for sublingual immunotherapy (SLIT) for aeroallergens or food allergy (ie, Palforzia; Aimmune therapeutics, Bridgewater, NJ.).

Responses were generally mixed when physicians were asked how difficult it was for them or their staff to predict whether a treatment required a PA, ranging from extremely easy to extremely difficult. However, most thought that it was somewhat or extremely difficult for prescription medications (69%) and medical services (52.95%), and less than 50% responded similarly for HAE medications (27%), biologics (44.6%), intravenous immunoglobulin (IVIG)/subcutaneous immunoglobulin (SCIG) (40.2%), SLIT (21.97%) and food allergy medications (18.59%). Interestingly, for this question, more responded that they did not know the answer for HAE medications, SLIT, or food allergy treatments, which could reflect the infrequency with which these medications were prescribed by some physicians.

BURDEN OF PAs

Most respondents described the burden of PA on clinical practice was as extremely high (71%) or high (26%) (Figure 2). The majority endorsed completing up to 25 PAs in the prior week (59%), which ranged between 67% and 87% for prescription medications other than nonformulary medications, biologics, IVIG/SCIG, HAE medications, SLIT, food allergy medications, or medical services. When asked how PA requests had changed over the past 5 years, most responded that it had increased significantly for prescription medications (other than nonformulary), biologics, and IVIG/SCIG, but responses were mixed, ranging from no change to increased somewhat and to increased significantly for food allergy treatment, SLIT, and medical services. When asked whether practices had dedicated staff who worked exclusively on PAs, the majority responded yes, which suggested that significant resources were being allocated by practices for this process (Figure 3).

IMPACT OF PAs ON PATIENT CARE

Most respondents (>80%) reported often to always experiencing delays in access to prescription medications and biologics, whereas the responses were more evenly distributed among sometimes, often, and always for HAE medications, IVIG/SCIG, SLIT, and medical services. Over 80% of respondents thought that PAs interfered with chronic treatment, and over 96% thought that PAs somewhat or significantly negatively affected clinical outcomes (Figure 4). Several questions focused on whether the PA process ever affected care delivery and led to a

TABLE I. Questionnaire survey

Screener questions
Which of the following options best describes you?
How many hours of direct patient care do you provide during a typical week of practice?
We have the state in which you practice listed as _____. Is that correct?
Please select your state from the following list.
We have your medical specialty listed as _____. Is that correct?
Please select your primary medical specialty from the following list.
Prior authorization questions
In a typical week of practice, do you or your staff complete prior authorizations for …?
How would you describe the burden associated with prior authorization in your practice?
Please provide your best estimate of the number of prescription and/or medical services prior authorizations completed by yourself and/or your staff for your patients in the past week. Do not include prior authorizations that practice staff completed for the patients of other physicians in your practice.
Thinking about all of the _____ prior authorizations you and your staff completed in the past week, please provide your best estimate of the number of hours spent on processing these prior authorizations. Do not include prior authorizations that practice staff completed for the patients of other physicians in your practice.
How has the number of prior authorizations required for prescription medications used in your patients' treatment changed over the past 5 years?
How has the number of prior authorizations required for medical services used in your patients' treatment changed over the past 5 years?
Do you have staff members in your practice who work exclusively on prior authorization?
Do any of the health plans with which you contract offer programs that exempt physicians from prior authorization requirements? (These exemptions can be based on performance [eg, gold card programs] or participation in risk-based payment models.)
Please provide the name(s) of the health plan(s) with which you contract that offer programs that exempt physicians from prior authorization requirements.
For those patients whose treatment requires prior authorization, how often does this process delay access to necessary care?
How often do issues related to the prior authorization process lead to patients abandoning their recommended course of treatment?
How often does the prior authorization process interfere with the continuity of ongoing care (eg, missed doses, interruptions in chronic treatment)?
For patients whose treatment requires prior authorization, what is your perception of the overall impact of this process on patient clinical outcomes?
In your experience, has the prior authorization process ever affected care delivery and led to a serious adverse event (eg, death, hospitalization, disability or permanent bodily damage, or other life-threatening event) for a patient in your care?
What serious adverse event(s) did the prior authorization process lead to for the patient(s) in your care? Select all that apply.
(Optional) Please use the space below to provide additional information about how prior authorization was associated with a serious adverse event for a patient in your care. Please note this question is optional.
Do you see patients aged 18 to 65 years who are members of the workforce (ie, individuals engaged in or available for work)?
Consider your patients in the workforce. Has the prior authorization process ever interfered with a patient's ability to perform his or her job responsibilities?
(Optional) Please use the space below to provide additional information about your experience(s) with the prior authorization process interfering with a patient's ability to perform his or her job responsibilities.
How difficult is it for you and/or your staff to determine whether a prescription medication requires prior authorization?
How difficult is it for you and/or your staff to determine whether a medical service requires prior authorization?
How often are health plans' prior authorization criteria based on evidence-based medicine and/or guidelines from national medical specialty societies?
Please indicate how often you and/or your staff use each of the following methods to complete prior authorizations for prescription medications.
Does your electronic health record (EHR)/electronic prescribing system allow you to process prior authorization requests for prescription medications without exiting the system to use a separate portal?
Please indicate how often you and/or your staff use each of the following methods to complete prior authorizations for medical services.
Do any of the health plans with which you currently contract require you to grant them access to your EHR to assist with the prior authorization process?
(Optional) Please provide the name of the health plan(s) with which you are currently contracting that require you to grant them access to your EHR to assist with the prior authorization process.
Are you willing to grant health plans full access to your EHR to assist with the prior authorization process?
If health plans are granted full access to your EHR to support the prior authorization process, how concerned are you that these health plans would access and use the data for other purposes?
Please indicate your level of support for federal and/or state legislation or regulation requiring health plans to offer programs that exempt physicians with high prior authorization approval rates from prior authorization requirements.
Demographic questions
Including yourself, how many physicians are in your practice? Please include all of your practice locations or sites in your answer. Please enter a number below.
Which of the following best describes your main practice?
Is your practice owned by a hospital or health system?
Are you willing to be contacted to discuss your experience with prior authorization?
Please provide your contact information:

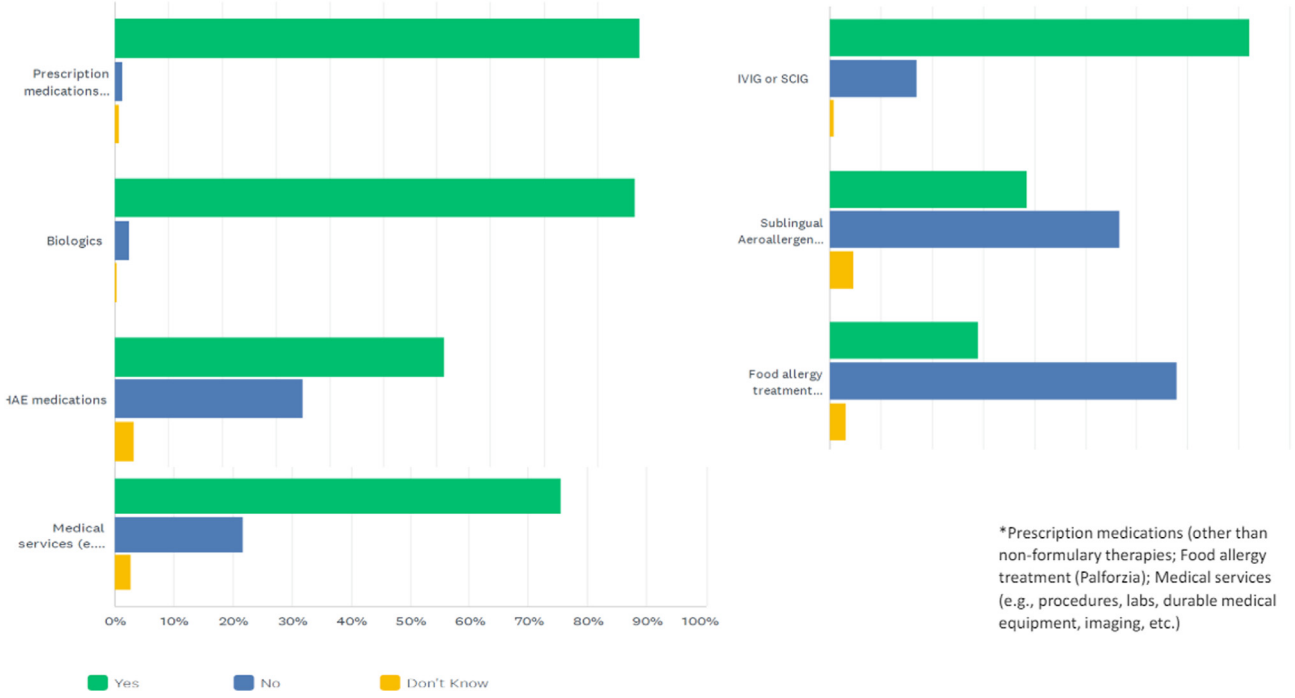

FIGURE 1. Experience by respondents with PA for different therapies. In a typical week of practice, do you or your staff complete prior authorizations for each of the following medications*? *Prescription medications (other than nonformulary therapies; food allergy treatment (Palforzia); medical services (eg, procedures, laboratory values, durable medical equipment, imaging, etc).

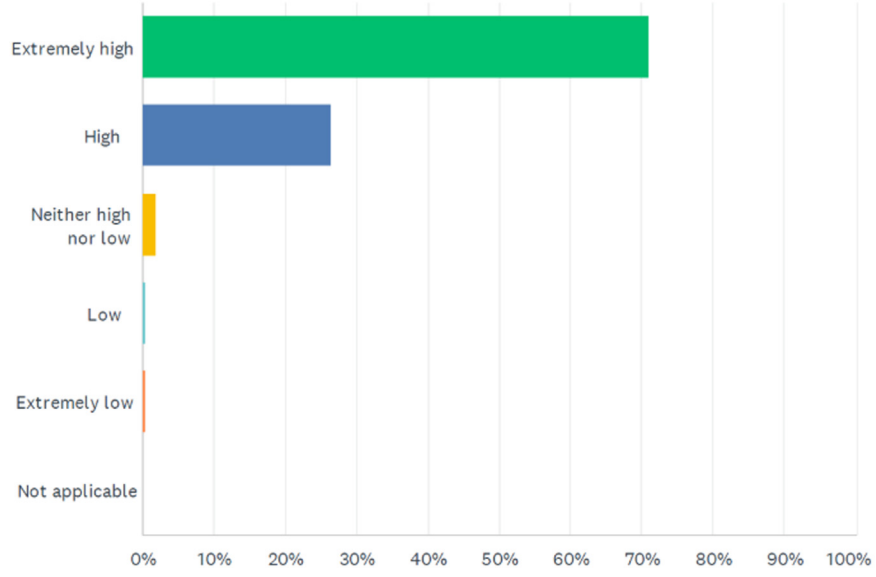

FIGURE 2. How would you describe the burden of prior authorization?

serious adverse event for a patient in their care, to which 44% indicated yes (Figure 5). Specifically, approximately 45% indicated that the adverse event was hospitalization; 18%, a life-threatening event; and 4%, death. Of note, approximately 13% of patients required an intervention to prevent permanent impairment or damage. Serious adverse events, reported by 40% of respondents, included missed work, emergency department visits, hospitalizations or use of oral corticosteroids for asthma exacerbations ,and life-threatening infections leading to death.

IMPACT OF PAs ON PATIENT WORK PRODUCTIVITY

Over 97% of physicians cared for patients aged 18 to 65 years who were in the workforce. Approximately 71% of these

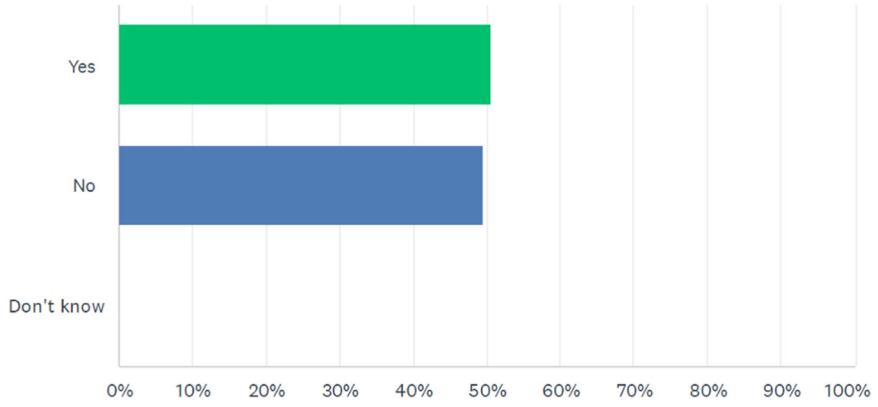

FIGURE 3. Do you have staff members in your office who work exclusively on prior authorization?

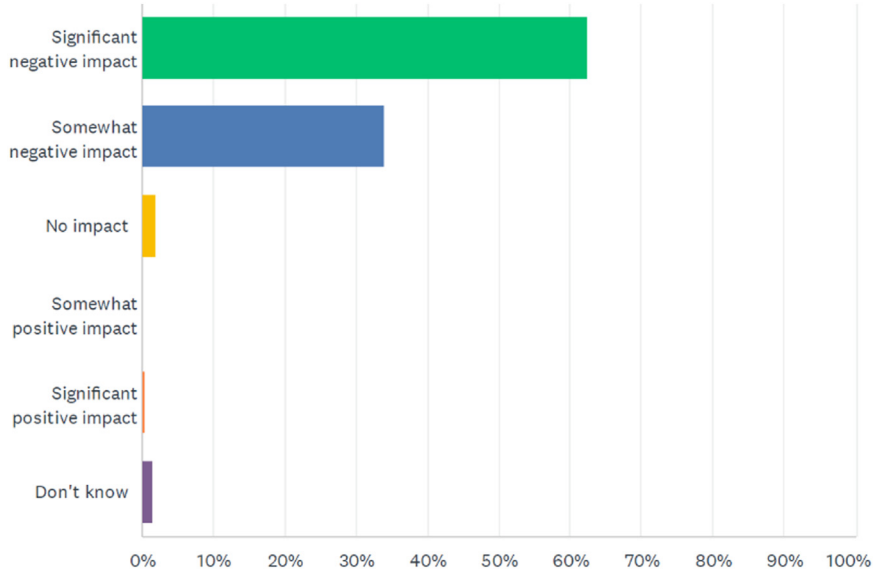

FIGURE 4. For those patients whose treatment requires prior authorization, what is your perception of the overall impact of this process on patient clinical outcomes?

physicians indicated that PA interfered with their patients' ability to work or perform their job responsibilities (Figure 6). This high response rate suggests that PAs have a significant indirect cost to patients in the workforce owing to lost wages.

OTHER ALLERGY-IMMUNOLOGY PERCEPTIONS ABOUT PAs

Regarding whether health care plan PA criteria were based on evidence-based medicine and/or national specialty guidelines, 75% responded sometimes or rarely, and an additional 8.8% responded never. Only 11.8% responded often or always. When asked whether health plans require access to the practice's electronic health record (EHR) to assist with the PA process, 60.3% responded no whereas only 9.8% responded yes. Interestingly, 8.8% of respondents did not have an EHR system. A spectrum of health care plans was reported to require EHR access, but it is unclear from the responses whether this was a statewide or regional requirement. Over 54% respondents were not willing to grant health plans access to their EHR system, compared with 24% who were. Over 83% of respondents were extremely or somewhat concerned that health plans would use this information for other purposes if the health plans had access to the EHR system. Only 4.4% of respondents' health plans offered programs that exempted physicians from PA requirements based on performance or participation in risk-based models. It was unclear from the information collected in this survey which health plans or states offered these programs. Most respondents (81.68%) were strongly or somewhat supportive of federal and/or state legislation or regulation requiring health plans to offer programs exempting physicians with high PA approval rates from PA requirements. Respondents were evenly split as to whether they would be willing to be contacted to discuss their PA experience.

DISCUSSION

The questionnaire responses from allergy-immunology specialists, which demographically reflect our membership, suggest

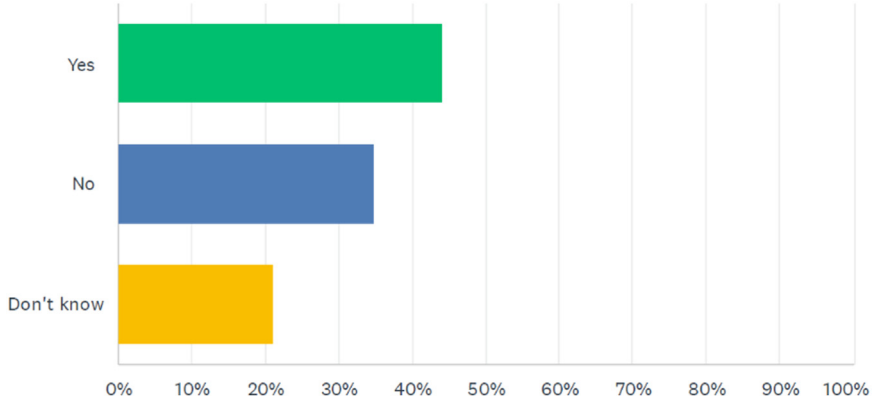

FIGURE 5. In your experience, has the prior authorization process ever affected care delivery and led to a serious adverse event (eg, death, hospitalization, disability or permanent bodily damage, or other life-threatening event) for a patient in your care?

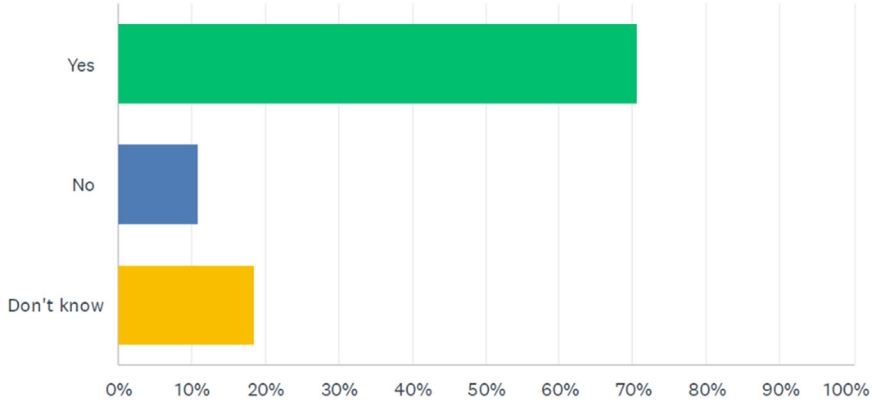

FIGURE 6. Consider your patients in the workforce. Has the prior authorization process-related delay in treatment ever interfered with a patient's ability to perform his or her job responsibilities?

that PAs can significantly affect patient care delivery and increase administrative burden to clinical practices, leading to serious adverse events in some circumstances. Differential responses regarding PA for different medication classes likely reflect the physician's patient population, which can shift prescribing patterns.

The findings from our survey correlate with responses from the recent AMA Survey in 2021[13] that assessed the impact of PA on clinical care. The results of the AMA survey revealed that 91% of physicians reported a negative impact on outcome measures when treatments required a PA. Thirty-four percent of physicians reported that the PA process led to a serious adverse event for their patients. This included 24% of survey respondents who stated that the PA process led to a patient's hospitalization and 18% who noted that PAs led to a life-threatening event or required disability or permanent bodily damage, congenital anomaly or birth defect, or death.[13] The data are similar to those of the 2018 AMA Prior Authorization Physician Survey of 1000 practicing physicians,[1] which revealed that 65% and 26% of physicians reported waiting on average at least 1 and 3 business days, respectively, for a response from the health plan, 91% reported that PA requirements caused delayed access to necessary care for their patients, and greater than 25% of physicians reported that PA procedures had led to a serious adverse event such as death, hospitalization, disability or permanent bodily damage, or another life-threatening events. These surveys demonstrate the burden of PAs on clinical practices across specialties. The results reported in the AMA 2021 survey were similar for allergists-immunologists reported in our survey.[1,13]

An additional unexpected outcome of PA is poor medication adherence by patients. The World Health Organization reported that medication adherence has a more direct impact on patient outcomes than the specific treatment itself. It is estimated that poor medication adherence contributes to more than $500 billion in avoidable health costs, including approximately 125,000 potential preventable deaths and up to 25% annual hospitalizations in the United States.[14] Prior authorization is often associated with poor medication adherence. Of the physicians surveyed by the AMA 2021 survey, 75% stated that PA-related issues caused their patients to abandon the recommended treatment.[13]

A recent study evaluated the impact of implementing an electronic PA (ePA) system on prescription filling in a large US health care system.[15] The authors found that 64.2% of ePA prescriptions were filled, compared with 68.8% of control prescriptions filled using standard procedures.[15] The authors

identified several limitations of ePA implementation, including software misfiring (PA requested when it was not required or did not initiate a PA when it was needed), changing of PA requirements, and insurance fragmentation that could not be addressed by the technology used.[15] Although future informatic systems may be able to address these barriers, they currently do not reduce the burden that PAs have on health care practices and on patient care.[15]

This survey study has several potential limitations including recall bias; selection bias, because respondents who participated may have had a disproportionately greater negative experience with PA than nonrespondents; and a low response rate. In addition, because the survey was read and responded to by only approximately 4% of the AAAAI membership, the responses to the questions may not be generalizable. However, the respondents were demographically distributed throughout the United States and the response rate was found to be proportionally greater than a similar survey on PA distributed by the AMA.[1]

This overview of the state of PA in the United States health care system supports the recent AAAAI position statement, which recommends (1) improving the transparency of PA, (2) reducing the number of allergy-immunology specialists subject to PA requirements, (3) using guideline-based criteria to improve access to approved biologics, (4) ensuring continuity of care for rare genetic disorders requiring life-saving medications, (5) instituting national electronic standards for PAs, and (6) preventing PAs from leading to delayed access to emergency care medications.[12] Patient and physician advocacy is needed to support legislative initiatives currently being considered in Congress to address PA reform. Prior authorization is a serious health care problem that is wasting financial resources and needlessly placing patients in danger when they are unable to access medications or medical services required for their clinical management.

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