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ORIGINAL RESEARCH ARTICLE

The Physician and Administrator-Reported Cost of Drug Utilization Management to Physician Practices: A Cross-Sectional Survey

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Abstract

Background The use of drug utilization management techniques such as formulary exclusions, prior authorizations, and step edits has risen sharply during the last decade, contributing to growing administrative costs for physician practices. However, limited data exist on the extent of these administrative costs, with previous studies relying on data from over a decade ago.

Objective The aim of this study was to assess physician and practice administrator experiences with drug utilization management.

Methods A national survey was conducted between 9 February and 30 March 2021, targeting 925 physicians and administrators working at medical practices in the US. Time spent by physicians and their staff on tasks related to drug utilization management for prescription medications was collected and used to calculate the dollar value of that time.

Results We estimated that physicians spent a median of 4.0 h per week on drug utilization management, while nurses spent 15.0 h and other staff spent between 3.6 and 10.0 h on drug utilization management per physician per week. This time was associated with a calculated median dollar value of $75,927 per physician per year. Extrapolating this estimate to a national scale suggests that time spent annually by physician practices on drug utilization management could be valued at more than $43 billion.

Conclusions Drug utilization management results in significant time spent by US physician practices, which in turn, results in meaningful costs to these practices. As the prevalence of drug utilization management continues to grow, the impact on physician practices will remain an important topic.

1 Introduction

Drug utilization management is designed to ensure patient safety and clinical appropriateness while helping to contain costs. It can include formulary restrictions, wherein certain drugs are not covered by a payer unless an exception is requested and approved; prior authorizations, which require physicians to document that a given patient has a medical condition that can be treated by a requested drug; and step edits, which require a patient to try cheaper alternatives before being approved for a more expensive specialty drug. However, the use of drug utilization management has risen sharply in the last decade as payers seek to temper the continued growth of healthcare and pharmaceutical spending in the US [1–3]. For example, formulary exclusions by the largest three pharmacy benefit managers expanded from 109 drugs excluded in 2014 to 846 in 2020 [4], while prior authorization requirements in Medicare Part D plans increased from 8% of drugs covered in 2007 to 24% in 2019 [2]. Similarly, one-third of large commercial payers now impose access restrictions on specialty drugs that are more stringent than those on the US FDA's label [5].

As the use of drug utilization management has increased, so has the administrative cost to physicians and their staff as they spend more time and resources obtaining payer approval for prescriptions. For example, a survey conducted by the American Medical Association (AMA) found that in

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Key Points for Decision Makers

Based on a national survey of 925 physicians and administrators, physicians spent a median of 4.0 h per week on drug utilization management, while nurses spent 15.0 h and other staff spent between 3.6 and 10.0 h per physician per week.

This time was associated with a calculated median dollar value of $75,927 per physician per year.

The findings from this study suggest that drug utilization management results in significant time spent by US physician practices, which in turn, results in meaningful costs.

2020, practices completed an average of 40 prior authorizations per physician per week, requiring 16 h of physician and staff time [6]. In addition, for every interaction that a physician has with a payer over drug utilization management, there is often a corresponding conversation with the patient whose prescription is in question, further adding to the time spent by physicians and their staff.

Previous studies have sought to quantify costs incurred by physician practices due to interactions with payers or time spent on administration. However, these studies either focused broadly on overall administrative costs [7–11] or narrowly on specific types of drug utilization management [6, 12–17]. Furthermore, the majority of these studies are based on data from over a decade ago, and greater complexity in plan benefit design, higher use of specialty medications, and growing use of drug utilization on management by payers have shifted this landscape considerably.

We conducted a national US survey of physicians and administrators inquiring about their experience with drug utilization management, including formulary restrictions, prior authorizations, step edits, and other or unknown payer policies. In particular, we examined the time spent by physicians and their staff on tasks related to utilization management for prescription medications and calculated the dollar value of that time.

2 Methods

2.1 Survey Instrument

A survey targeting US physicians and administrators was developed to assess the impact of drug utilization management on physician practices. This instrument was designed to capture information on drug utilization management related to retail prescriptions and physician-administered medications and was refined based on three pre-test interviews with a primary care physician, a specialist physician, and a specialty practice administrator. In particular, the instrument covered four distinct categories of drug utilization management, including formulary restrictions, prior authorizations, step edits, and other or unknown payer policies. It should be noted that drugs subject to step edits may also require prior authorization and be subject to other drug utilization management techniques such as quantity limits [18]. As such, the categorization used in this study may have resulted in a degree of double counting.

The survey included questions about respondent and practice characteristics such as years of experience, practice specialty and size, staff compensation, prescription volume and composition (e.g., branded vs. generic), patient volume and insurance types, and drug utilization management volume. The survey also included questions about respondent and practice experience with drug utilization management such as staff time spent working on tasks related to drug utilization management. Survey questions were tailored for physicians and administrators to account for their differing perspectives. The full survey instrument can be found in the appendix.

2.2 Sampling Strategy

The survey was fielded online to a large US-based panel maintained by M3 Global Research between 9 February and 30 March 2021. M3's panel includes physicians from all US states, with a distribution of age, sex, and practice type that is similar to the physicians registered with the AMA. Respondents were compensated at fair market value rates for completing the survey (see the Appendix for details). Respondents worked in primary care or select specialist outpatient practices and were required to know the approximate time their staff spent on tasks related to drug utilization management. Specialist practices included those the authors considered likely to face drug utilization management: allergy and immunology, cardiovascular disease, dermatology, endocrinology, family medicine/general practice, gastroenterology, geriatric medicine, oncology and hematology, internal medicine, nephrology, neurology, ophthalmology, pain medicine and pain management, psychiatry, pulmonary disease, rheumatology, and urology. Respondents working in specialties unlikely to encounter frequent drug utilization management and those working in the emergency room or inpatient settings were excluded. Furthermore, those working in outpatient military clinics, Veteran Affairs centers, or other government hospitals were removed due to their unique payer coverage policies.

Physician respondents were required to be licensed to practice medicine in the US. Administrators' job titles

included practice administrator, office manager, practice manager, and medical manager. Administrators also included clinical staff (e.g., nurse practitioner, physician assistant) who reported that the majority of their time was spent on administrative responsibilities. Recruitment quotas were established based on practice specialty and size in order to obtain an evenly distributed sample.

2.3 Analysis

To assess the frequency with which physician practices engage in tasks related to drug utilization management, we asked respondents about the volume of formulary restrictions, prior authorizations, step edits, and other/unknown drug utilization management encountered in a typical week. We also evaluated weekly hours spent on drug utilization management tasks by staff type, including physicians, nurses, other clinical staff (e.g., physician assistants), senior administrators, administrative/clerical staff, and pharmacy technicians or similar support staff. Tasks of interest were related to drug utilization management, for example processing/administrative tasks, preparing materials, discussing among staff, and follow-up work. We asked physician respondents to report time spent by staff on tasks related to their own patients only, while administrator respondents were asked to report time spent on tasks related to the practice locations that they oversee. Weekly staff time was converted to an annual dollar value using compensation data collected from the survey.

Two sensitivity analyses were conducted. First, to test the survey-reported staff compensation, we calculated the annual dollar value of staff time based on compensation estimates from the Bureau of Labor Statistics Occupational Employment and Wage Statistics (BLS OEWS) [19]. Second, to validate the hours reportedly spent on drug utilization management by staff type, we calculated the number of full-time equivalent (FTE) practice staff members who work on drug utilization management. FTE estimates were based on an assumed 40-h work week and the reported percentage of time that a typical member of each staff category spent overall on tasks related to drug utilization management, multiplied by the number of staff members in each category.

Outliers for key outcome variables were removed from the data based on a threshold of three times the standard deviation above the mean. We performed all analyses in R version 3.6.3 (The R Foundation for Statistical Computing, Vienna, Austria), and SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA). More details on our analytical approach are provided in the Appendix.

3 Results

3.1 Respondents and Practice Characteristics

A total of 25,308 physicians and administrators were invited to complete the survey. Among those invited, 2933 (11.6%) answered the survey eligibility questions. Of the 2933 physician and physician office administrator respondents who answered the survey eligibility questions, 1161 (39.6%) were eligible. It should be noted that out of the 1772 ineligible respondents, 370 (20.9%) were ineligible because the quota for their position, practice size, or specialty had already been filled. Of the eligible respondents, 925 (79.7%) completed the survey and were included in the final sample (see the Appendix).

Table 1 describes the characteristics of the survey respondents and their practices. The sample was comprised of physicians ($n = 742$) and administrators ($n = 183$). Per the study design, our sample was evenly divided by practice size, and between respondents working in primary care and one of 15 other specialties. Primary care respondents ($n = 463$) worked in family medicine/general practice (72.8%) and internal medicine (27.2%) offices. Among the specialist respondents ($n = 462$), the most common specialist types were ophthalmology (17.7%), dermatology (12.6%), and gastroenterology (9.5%).

A median of eight physicians were employed at the surveyed practices. Administrator respondents supported a median of five physicians at the practice locations that they oversaw. The majority of respondents (68.6%) worked in private practice and treated privately insured (46.7%) or Medicare (including Medicare Advantage; 32.4%) patients. Lastly, physicians reported seeing a median of 100 patients in a typical week.

Our sample was comparable to the US nationwide sample in terms of weekly patients seen by physicians (100 in our study vs. 101 in the US [20]); region (22.8% Midwest, 23.0% Northeast, 33.9% South, 20.2% West in our study vs. 20.7% Midwest, 17.2% Northeast, 38.3% South, 23.7% West [21]); and location (54.8% suburban in our study vs. 52.0% suburban in the US [22]). In terms of patient insurance breakdown, our sample reported 46.7% privately insured patients versus 66.5% privately insured patients in the US [23].

3.2 Prescription Characteristics

Table 2 summarizes the overall prescription characteristics for our survey respondents and their practices. Across all respondents, there was a median of 1.0 and a mean of 1.4 prescriptions per patient in a typical week. On average, the majority of prescriptions were for generic drugs (59.3%),

Table 1 Respondent and practice characteristics

	All respondents [$N = 925$]	Physicians [$n = 742$]	Administrators [$n = 183$]
Respondent characteristics			
No. of years in current position [mean (SD)]	12.9 (9.0)	13.0 (9.2)	12.6 (8.3)
Specialty[a] [*n* (%)]			
Primary care	463 (50.1)	369 (49.7)	94 (51.4)
Specialty medicine	462 (49.9)	373 (50.3)	89 (48.6)
Practice characteristics			
Practice size [*n* (%)]			
Small: 1–5 physicians	329 (35.6)	256 (34.5)	73 (39.9)
Medium: 6–19 physicians	328 (35.5)	259 (34.9)	69 (37.7)
Large: ≥20 physicians	268 (29.0)	227 (30.6)	41 (22.4)
No. of physicians employed at primary practice			
Mean (SD)	26.3 (59.1)	29.0 (64.4)	15.5 (26.8)
Median	8.0	9.0	7.0
Primary practice type [*n* (%)]			
Private practice	635 (68.6)	515 (69.4)	120 (65.6)
Community-based clinic	156 (16.9)	119 (16.0)	37 (20.2)
Academic institution	109 (11.8)	98 (13.2)	11 (6.0)
Hospital or hospital-owned (not VA or government)	133 (14.4)	92 (12.4)	41 (22.4)
Percentage breakdown of patient insurance types [mean[b] (SD)]			
Private, commercial	46.7 (20.3)	47.9 (20.5)	41.9 (18.9)
Medicare (including Medicare Advantage, Part B, Part D, etc.)	32.4 (15.8)	31.2 (15.4)	37.2 (16.5)
Medicaid	13.3 (14.5)	13.5 (14.7)	12.4 (13.4)
Uninsured	4.7 (7.0)	4.5 (6.9)	5.3 (7.5)
Other (e.g., VA, military)	2.9 (6.5)	2.9 (6.9)	3.1 (4.4)
No. of patients in a typical week			
Mean (SD)	185.2 (344.0)	112.9 (71.7)	475.4 (685.0)
Median	100.0	100.0	245.0

Source: Authors' analysis of data from the survey conducted for this study

SD standard deviation, *VA* Veterans' Affairs

[a]As part of the study design, a fixed number of oncologist physicians ($n = 20$) were recruited to ensure representation from this group

[b]Summary statistics for patient insurance types were reported among respondents who reported that they knew this information ($n = 906$)

followed by branded (25.4%), specialty (defined as high-cost oral or injectable drugs used to treat complex chronic conditions, often associated with high patient co-insurance; 10.1%), and physician-administered (5.2%) drugs. This survey was conducted during the coronavirus disease 2019 (COVID-19) pandemic, and as such, it should be noted that two-thirds of respondents reported that the pandemic affected their prescription volumes. Among those respondents, 38% reported prescription volume had not returned to a pre-pandemic level at the time of the survey, with average volume reportedly 21.5% lower than normal.

We also asked physicians to estimate the proportion of prescriptions in each of these drug categories that were subject to drug utilization management. On average, specialty and branded drugs were each reported to be subject to utilization management more than half of the time. About one in three physician-administered drugs and one in four generic drugs were subject to utilization management. Prior authorizations and formulary restrictions, reported to impact approximately one in five prescriptions on average, were more common than step edits and other or unknown types of drug utilization management (impacting ≤ 10% of prescriptions). Overall, physicians, answering for just their own patients reported weekly average volumes of 23.5 formulary restrictions, 19.7 prior authorizations, 12.6 step edits, and 7.9 other types of drug utilization management.

Specific to prior authorizations, respondents reported being able to anticipate and submit in advance prior authorization requirements approximately one-third of the time (33% of the time for branded drugs, 46% for specialty drugs, and 34% for physician-administered drugs) and that

Table 2 Prescription characteristics

	All respondents [$N = 925$]	Physicians [$n = 742$]	Administrators [$n = 183$]
Prescription characteristics[a]			
No. of drug prescriptions per patient in a typical week			
Mean (SD)	1.4 (1.0)	1.4 (1.0)	1.1 (0.9)
Median	1.0	1.2	0.8
Percentage breakdown of drug prescription types[b] [mean (SD)]			
Generic drugs	–	59.3 (21.4)	–
Branded drugs	–	25.4 (15.0)	–
Specialty drugs	–	10.1 (11.2)	–
Physician-administered drugs	–	5.2 (9.6)	–
Percentage of prescriptions subject to drug utilization management, by drug type [mean (SD)]			
Generic drugs	–	24.6 (28.1)	–
Branded drugs	–	50.8 (29.8)	–
Specialty drugs	–	61.4 (36.8)	–
Physician-administered drugs	–	35.6 (37.8)	–
Drug utilization management characteristics[c,d]			
Percentage of prescriptions subject to each type of drug utilization management [mean (SD)]			
Formulary restrictions	20.0 (20.4)	19.4 (19.9)	22.5 (22.1)
Prior authorizations	20.8 (21.9)	18.7 (20.7)	28.9 (24.5)
Step edits	10.0 (14.0)	9.6 (13.3)	11.5 (16.7)
Other or unknown types of drug utilization management	6.8 (11.8)	6.2 (11.2)	9.1 (13.5)
Prior authorization characteristics			
Proportion of prior authorizations that were electronic vs. manual [mean (SD)][e]			
Fully electronic	42.5 (33.4)	41.4 (33.6)	47.1 (32.0)
Partially electronic	26.9 (24.0)	26.4 (24.1)	28.9 (23.7)
Fully manual	30.6 (28.8)	32.2 (29.9)	24.0 (23.0)
Proportion of prior authorizations that were simple vs. complex [mean (SD)][f]			
Simple	61.8 (24.4)	61.7 (25.0)	62.3 (22.0)
Complex	38.2 (24.4)	38.3 (25.0)	37.7 (22.0)
Proportion of prior authorizations that were anticipated and submitted ahead of time [mean (SD)]			
Branded drug	33.0 (29.2)	31.9 (29.3)	36.1 (28.8)
Specialty drug	46.2 (35.6)	48.0 (36.4)	41.6 (33.4)
Physician-administered drug	33.7 (35.4)	34.3 (36.9)	32.7 (32.5)

Source: Authors' analysis of data from the survey conducted for this study

SD standard deviation

[a] 'Prescriptions' refer to both prescription drugs and physician-administered drugs

[b] Questions about prescription characteristics were only asked of physicians, not administrators; all physicians in the sample ($n = 742$) responded to these questions

[c] For drug utilization management characteristics, summary statistics were reported among the respondents who reported that they knew the volume of the given type of drug utilization management, and whose responses met data quality standards. Data quality was assessed by identifying extreme outliers reported for volume of a given type of drug utilization management, based on a threshold of three times the standard deviation

[d] Sample counts for each drug utilization management type: respondents with knowledge of formulary restriction volume, sample $n = 808$ (87.4%); respondents with knowledge of prior authorization volume, sample $n = 866$ (93.6%); respondents with knowledge of step edit volume, sample $n = 650$ (70.3%); respondents with knowledge of other types of drug utilization management, sample $n = 565$ (61.1%)

[e] In the survey question, the following examples were given for electronic versus manual prior authorizations: Fully electronic: automated transactions using the federally mandated electronic standards, e.g., prior authorization technology standards: ASC X12N 278/5010X217 278). Partially electronic: web portal, interactive voice. Fully manual: phone, fax, email

[f] In the survey question, the following examples were given for simple versus complex prior authorizations: Simple: automated submission process, limited person-to-person interaction, transparency about what is required in a submission. Complex: peer-to-peer reviews, supporting documentation required, multiple phones calls with health plans, lack of clarity about what is required in a submission

43% of prior authorizations were submitted fully electronically. Physicians in our survey reported facing complex prior authorizations 38% of the time, for example those requiring peer-to-peer reviews, detailed supporting documentation, and multiple phones calls with health plans. The remaining PAs were classified as simple; for example, those with an automated submission process and requiring limited person-to-person interaction (e.g., an attestation of clinical diagnosis).

3.3 Weekly Staff Time Spent on Drug Utilization Management, Per Physician

Table 3 presents the hours dedicated to drug utilization management by practice staff per physician in a typical week. Nurses spent the most time, with a median of 15.0 h per physician per week; other clinical staff spent 10.0 h and administrative/clerical staff spent 8.0 h. Physicians reported a median of 4.0 h per week. The means for each staff category were higher than the medians, driven by a small group of respondents who reported greater time spent relative to the broader sample. Specifically, the reported means for nurses, other clinical staff, administrative/clerical staff, and physicians were 39.6, 21.6, 16.6, and 4.9 weekly hours per physician, respectively.

Overall, formulary restrictions and prior authorizations were the most time-consuming types of drug utilization management, requiring a median of 14.7 and 13.8 h per physician per week, respectively. Moreover, nearly half of the respondents (48.6%) reported that their practices employed staff who work exclusively on tasks related to drug utilization management, with 33.0% employing at least one dedicated administrative/clerical staff member and 29.6% employing at least one dedicated nurse.

Table 3 Weekly staff time spent on drug utilization management, per physician

Weekly hours spent on drug utilization management, per physician[a–c]	Formulary restrictions [$n = 799$]	Prior authorizations [$n = 808$]	Step edits [$n = 734$]	Other types [$n = 632$]	Total [$n = 811$]
Physician					
Mean (SD)	1.8 (2.8)	1.4 (1.6)	1.0 (1.4)	1.0 (1.9)	4.9 (5.3)
Median	1.0	1.0	1.0	1.0	4.0
Nursing staff					
Mean (SD)	14.1 (37.8)	13.2 (28.5)	7.9 (27.9)	6.5 (16.6)	39.6 (92.8)
Median	5.0	5.0	2.0	2.0	15.0
Other clinical staff members					
Mean (SD)	7.8 (17.7)	7.0 (11.4)	3.9 (8.0)	3.9 (9.4)	21.6 (32.6)
Median	4.0	3.0	2.0	1.0	10.0
Senior administrators					
Mean (SD)	3.1 (5.8)	2.8 (4.7)	1.5 (4.0)	1.8 (6.0)	8.6 (17.4)
Median	1.2	1.1	0.5	0.5	3.6
Administrative/clerical staff					
Mean (SD)	5.0 (8.2)	7.1 (13.7)	3.0 (5.5)	2.5 (5.5)	16.6 (27.9)
Median	2.5	2.7	1.0	1.0	8.0
Pharmacy technician or other similar support staff					
Mean (SD)	3.1 (7.8)	3.1 (8.1)	2.0 (5.7)	1.3 (4.6)	8.9 (21.8)
Median	1.0	1.0	0.4	0.3	3.7

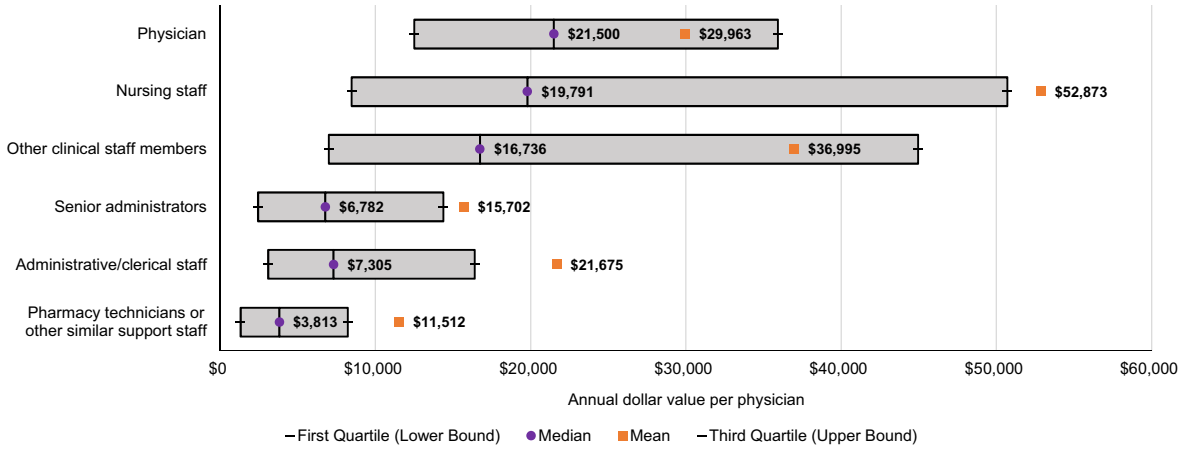
Source: Authors' analysis of data from the survey conducted for this study

SD standard deviation

[a]Summary statistics for each type of drug utilization management were reported among the respondents who reported non-zero volume of the given policy, and whose responses met data quality standards. Data quality was assessed by identifying extreme outliers reported for time spent on a given type of drug utilization management, based on a threshold of three times the standard deviation. The number of respondents with valid, non-missing data related to the time spent on each type of drug utilization management is reported underneath the column title for each type. The means for each type of drug utilization management, they do not sum to the mean in the total column due to missing data

[b]Values for physicians, nursing staff, and other clinical staff members were estimated from physician survey responses. Values for senior administrators, administrative/clerical staff, and pharmacy technicians or other similar support staff were estimated from administrator survey responses

[c]Administrator respondents were included in the senior administrator category. Administrator respondents' responses were initially reported for all the practice locations that they support. For this analysis, these responses were scaled down to the physician level using the number of physicians they reported supporting, with tasks related to drug utilization management



Source: Authors' analysis of data from survey conducted for this study. **Notes:** Summary statistics were reported among the respondents who reported a nonzero volume of drug utilization management, and whose responses met data quality standards. Data quality was assessed by identifying extreme outliers reported for time spent on a given type of drug utilization management, based on a threshold of three times the standard deviation.Respondents with valid, non-missing data related to the time spent on drug utilization management, sample N = 811 (87.7%). Dollar value estimates were based on the compensation data collected in the survey. For respondents who did not know compensation information for their staff but did report time estimates, compensation estimates were imputed based on the median estimates from the rest of the sample. For respondents who were only able to report wages estimates, not including benefits and bonuses, we scaled up their reported values to full compensation estimates using the ratio between the mean wage and mean full compensation that we observed in the data. Values for physicians, nursing staff, and other clinical staff members were estimated from physician survey responses. Values for senior administrators, administrative/clerical staff, and pharmacy technicians or other similar support staff were estimated from administrator survey responses. Administrator respondents were included in the senior administrator category. Administrator respondents' responses were initially reported for all the practice locations that they support. For this analysis, these responses were scaled down to the physician level using the number of physicians they reported supporting with tasks related to drug utilization management. Values reported are in 2021 USD.

Fig. 1 Annual dollar value of staff time spent on drug utilization management, per physician

As a sensitivity analysis, administrative cost was measured in terms of the overall number of FTE staff members working on drug utilization management per physician. This represents the sum of those working full time on drug utilization management (1 FTE), as well the time dedicated by staff who spend only part of their time on drug utilization management (e.g., 20% of a nurse's time = 0.2 FTE). The physician respondents reported a median of 1.56 and a mean of 3.26 FTE staff members working with them on tasks related to drug utilization management for their patients.

3.4 Annual Dollar Value of Staff Time Spent on Drug Utilization Management, Per Physician

Figure 1 presents the annual dollar value of time spent per physician on drug utilization management. This was calculated based on respondent-reported staff compensation and hours spent on drug utilization management. Time spent by clinical staff (i.e., physicians, nurses, and other clinical staff) was associated with a larger dollar value than time spent by administrative staff (i.e., senior administrators, administrative/clerical staff, and pharmacy technicians) due to higher compensation rates. Wide dollar value distributions were observed, especially among clinical staff, driven by a small number of respondents who reported large amounts of staff time. Referring to the median values, physician time represented the highest burden at $21,500 per year, followed by nurse time of $19,791 per physician per year. Mean values were higher, with nursing staff time representing the highest burden, valued at $52,873 per physician per year. Physicians' time spent on drug utilization management was valued at a mean of $29,963 per year.

Including all six staff categories examined, the total annual dollar value of drug utilization management per physician was $75,927 based on median reported staff hours, and $168,720 using mean reported hours. It should be noted that the median estimate of staff hours may be a better representation of the burden for a typical US practice than the mean values, which are raised by high-end estimates. In a sensitivity analysis using the median survey-reported staff hours with BLS OEWS compensation data for comparable staff categories (see the Appendix [24]), an annual value of $93,087 per physician was estimated.

4 Discussion

The data summarized in this study suggest that drug utilization management results in significant time spent by US physician practices. Based on a survey of over 900 physicians and administrators, we estimated that the median time spent on drug utilization management was 15.0 h per physician per week for nurses, 4.0 for physicians, 10.0 for other clinical staff, 8.0 for administrative/clerical staff, 3.7 for pharmacy technicians and other similar support staff, and 3.6 for senior administrators.

Our findings align with previous estimates and reflect the growing use of drug utilization management during the last decade. The most frequently cited data stem from a survey administered in 2006, where Morra et al. estimated an annual dollar value of $111,187 per physician (inflated to 2021 US$) in time spent by physician practices interacting with payers for both medical and prescription-related interactions. In particular, the authors summarized the number of hours by task associated with this time, suggesting that 43% of the dollar value could be attributed to utilization management-related interactions such as formularies and prior authorizations, a value in 2021 US$ of $47,512 per physician [13]. As such, our study represents a 60% increase over the estimate reported by Morra et al. It should be noted that both Morra et al. and our study used surveys that relied on the recall of our respondents. While studies quantifying the overall impact of drug utilization management on physician practices at a national level using alternative methods (e.g., time and motion study or time diaries) were not found in the peer-reviewed literature, Morley et al. reported the results of two 'card studies' specifically for prior authorizations experienced by nine practices in upstate New York (study 1) and three practices in southeastern Pennsylvania (study 2) [14]. Based on the findings of their study, practices spent an average of 1.2 and 1.5 h per physician per week on prior authorizations in 2010. This contrasts to our study, wherein we report a median of 13.8 h per physician per week spent on prior authorizations, consistent with the growing prevalence of prior authorizations and in alignment with recent surveys completed by the AMA [25]. This difference could also be reflective of variation in methods used to obtain the data, as well as regional differences compared with our national survey.

Extrapolated more broadly, our results suggest that the national burden of drug utilization management on physician practices may be significant. With a total of 892,856 active practicing physicians in the US [20], and assuming that 64% of them face drug utilization management [17], we can approximate that the aggregate annual dollar value associated with US physician practices' time spent on drug utilization management is about $43.4 billion. For context, this is 26.3% of the Himmelstein et al. 2020 $164.8 billion estimate (inflated to 2021 US$) of overall administrative costs incurred by physician offices due to interactions with payers for both medical and prescription-related interactions [7].

Beyond the impacts quantified in this study, some evidence suggests that the growing burden of drug utilization management has, for physicians, led to increasing frustration, stress, and burnout. A 2019 Medscape survey reported that 44% of physician respondents felt burned out, with 'too many bureaucratic tasks' contributing the most to their mindset (59%) [26]. For their patients, studies have found that medication coverage rejections due to drug utilization management are often overturned. For example, of 8.1 million Medicare Part D prior authorization requests for medications in 2017, 35% were initially rejected, but 73% of appealed denials were ultimately overturned [27]. However, drug utilization management costs a total of $35.8 billion annually in incremental cost sharing that is beyond the level of the average generic co-pay [17]. Moreover, numerous studies have found an association between drug utilization management and gaps and delays in treatment as well as adverse health outcomes [6, 28, 29]. Nonetheless, it is important to note that drug utilization management can be a valuable component of insurance benefit design. Data show that these techniques can save patients hundreds of dollars each year through generic and therapeutic substitution [30]. Drug utilization management is also associated with reductions in adverse drug events and improved safety and outcomes for patients [31].

With drug utilization management becoming more widespread, US practices and their patients will face continued exposure to these policies. To ease administrative costs associated with drug utilization management, some groups such as the Centers for Medicare & Medicaid Services, the Council for Affordable Quality Healthcare, and others, have advocated for standardizing and automating the process of completing drug utilization management requirements such as prior authorizations, with the Office of the National Coordinator for Health Information Technology (ONC) recently releasing a request for information on electronic prior authorization data standards [32–35]. Similarly, prior authorization 'gold carding' has been proposed, with Texas recently passing a first-of-its-kind law, wherein physicians who have a 90% prior authorization approval rate over 6 months will be exempt for those services [36]. Others have suggested greater collaboration and a greater role for pharmacies in the prior authorization process. For example, Bhakta et al. found that pharmacist-led centralization of prescription renewals and prior authorization processing had a positive effect on physician efficiency and satisfaction [37]. However, while these are all steps in the right direction, they do not address the core of the issue—that drug utilization management requirements are often inconsistent with the clinical value of the therapies clinicians prescribe.

According to the 2020 AMA physician survey, only 15% of physicians believe prior authorization criteria are 'always' or 'often' based on guidelines from national medical specialty societies. Instead, 32% of surveyed physicians reported that these criteria are rarely or never evidence-based [6]. As such, there is a clear need to define principles with which drug utilization management criteria are determined and evaluated. For instance, the AMA has released prior authorization and utilization management reform principles [38] and the National Pharmaceutical Council has published

stakeholder views on step therapy criteria [39–41]. Similarly, the Institute for Clinical and Economic Review has released criteria for fair coverage of prescription drugs and used these criteria to evaluate how payer policies align with their fair access criteria [42].

On a more systemic level, the current US drug pricing and access system is considered by many to be unsustainable, with the continued introduction of high-cost therapies from drug manufacturers leading to payers expanding their use of drug utilization management [17, 43]. As the use of drug utilization management has intensified, manufacturers have responded with programs that support patient access, which in turn has led to payers further tightening drug utilization management, and so on and so forth. What results is a system that relies on and encourages high list prices, substantial opaque rebates that are generally not passed through to patients, and significant administrative and cost-sharing barriers [44, 45]. As such, there is a need to develop alternative approaches. For example, Robinson et al.and Howell et al. have proposed a system in which a manufacturer's use of value-based pricing is linked to value-based patient access from a payer. In this framework, individual manufacturers voluntarily set prices based on benchmarks proposed by independent health technology assessment organizations. These prices are then linked to value-based access, where individual payers define drug utilization management based on clinical evidence and social values, again as developed by independent organizations such as those outlined above [17, 43]. This would serve to lower the use and subsequent burden of drug utilization management on all stakeholders, including physician practices and their patients.

Our study had several limitations. First, this study relied on survey responses, which may differ from actual staff time spent on drug utilization management and staff compensation due to recall bias and difficulty estimating the efforts of colleagues. This could lead to large variance in the reported data. As such, it would be beneficial for future studies to use alternative methods (e.g., time and motion study, time diaries), thereby providing a deeper understanding into the cost of drug utilization management to physician practices. Second, the survey was conducted during the first quarter of 2021 and as such, findings were impacted by the COVID-19 pandemic, likely representing a conservative estimate of the impact of drug utilization management. Third, there may be differing interpretations of the categories of drug utilization management included in the survey. We asked providers to estimate time spent by their staff on four distinct categories: formulary restrictions, prior authorizations, step edits, and other/unknown. However, there is a possibility of double counting across drug utilization management categories. Finally, data from this study were drawn from a convenience sample focused on a select subset of health care professionals working in an outpatient setting in specialties likely to regularly encounter drug utilization management. Although we set out to create a balanced sample of physicians in primary care and specialist practices working across different practice sizes, the results are not generalizable beyond the participants and settings represented in the study population.

5 Conclusion

In summary, drug utilization management results in significant time spent by US physician practices, which in turn results in meaningful costs to these practices. As the prevalence of drug utilization management, including formulary exclusions, prior authorizations, and step edits, continues to grow, the impact on physician practices will remain an important topic of discussion.

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Declarations

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Conflict of interest Marie Louise Edwards, Michael Kuehn, and Noam Kirson are employees of Analysis Group, Inc., and Perry T. Yin, Keith Bratti and Scott Howell are employees of Novartis Pharmaceuticals Corporations. Anupam Jena reports receiving (in the last 36 months) consulting fees unrelated to this work from Bioverativ, Merck/Sharp/Dohme, Janssen, Edwards Life Sciences, Novartis, Amgen, Eisai, Otsuka Pharmaceuticals, Vertex Pharmaceuticals, Celgene, Sanofi Aventis, Precision Health Economics, and Analysis Group. He also reports receiving (in the last 36 months) income unrelated to this work from hosting the podcast Freakonomics, M.D., and from book rights to Doubleday Books.

Ethics approval Institutional Review Board approval was not sought as the study was based on primary market research of office-based physicians and their administrative staff and did not involve any patient-level data.

Consent to participate Participants were informed about the aim of the study and participant consent was required to start the survey. Study participant consent covered compliance with adverse event and product complaint reporting if applicable, processing of personal data for the purposes of the study, and obtaining applicable permissions to take part in the study, e.g. if required by an employer. It should also be noted that the study did not collect personal information and respondent information was anonymized at data collection.

Consent for publication (from patients/participants) Participants were informed about the aim of this study, including the intent to publish findings, and participant consent was required to start the survey.

Availability of data and material The data underlying the results presented in the study are available from Analysis Group, Inc.

Code availability Not applicable.

Author contributions All authors were involved in the conceptualization and design of the study. MLE, PY, MK, and NK contributed to the acquisition, analysis, and interpretation of data. MLE and MK were involved in statistical analyses. All authors were involved in drafting the manuscript and critical revisions. PY, KB, NK, and SH provided supervision.

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