

SHORT COMMUNICATION



Impact of non-medical switching of prescription medications on health outcomes: an e-survey of high-volume medicare and medicaid physician providers

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ABSTRACT

Background: Non-medical switching refers to a change in a stable patient's prescribed medication to a clinically distinct, non-generic, alternative for reasons other than poor clinical response, side-effects or non-adherence.

Objective: To assess the perceptions of high-volume Medicare and/or Medicaid physician providers regarding the impact non-medical switching has on their patients' medication-related outcomes and health-care utilization.

Methods: We performed an e-survey of high-volume Medicare and/or Medicaid physicians (spending >50% of their time caring for Medicare and/or Medicaid patients), practicing for >2 years but <30 years post-residency and/or fellowship; working in a general, internal, family medicine or specialist setting; spending ≥40% of their time providing direct care and having received ≥1 request for a non-medical switch in the past 12 months. Physicians were queried on 15-items to assess perceptions regarding the impact non-medical switching on medication-related outcomes and health-care utilization.

Results: Three-hundred and fifty physicians were included. Respondents reported they felt non-medical switching, to some degree, increased side-effects (54.0%), medication errors (56.0%) and medication abandonment (60.3%), and ~50% believed it increased patients' out-of-pocket costs. Few physicians (≤13.4% for each) felt non-medical switching had a positive impact on effectiveness, adherence or patients' or physicians' confidence in the quality-of-care provided. Non-office visit and prescriber-pharmacy contact were most frequently thought to increase due to non-medical switching. One-third of physicians felt office visits were very frequently/frequently increased, and ~ 1-in-5 respondents believed laboratory testing and additional medication use very frequently/frequently increased following a non-medical switch. About 1-in-10 physicians felt non-medical switching very frequently/frequently increased the utilization of emergency department or in-hospital care.

Conclusion: This study suggests high-volume Medicare and/or Medicaid physician providers perceive multiple negative influences of non-medical switching on medication-related outcomes and health-care utilization.

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Introduction

Non-medical switching refers to a change in a stable patient's prescribed medication to a clinically distinct, non-generic, alternative for reasons other than poor clinical response, side-effects or non-adherence [1] (e.g., requiring a patient with gastroesophageal reflux disease with good, consistent symptom control on dexlansoprazole to switch to omeprazole). Non-medical switching is commonly the results of formulary changes or restrictions implemented by insurers and pharmacy

benefit managers (including step edits and prior authorization requirements) in order to lower their medication costs [2,3]. The medication cost-cutting steps implemented by insurers, and the subsequent nonmedical switching required, are based on the premise that switching between the originally prescribed and alternative, mandated medication will have no clinical impact [1–3]. However, whether this is the case with many non-medical switch mandates is unclear.

Due to their frequent lack of economic security, larger number of chronic medical conditions and

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subsequent need for multiple prescription medications, Medicare and Medicaid patients may be among the most vulnerable to the negative consequences of non-medical switching [4–6]. Here, we sought to assess the perceptions of high-volume Medicare and/or Medicaid physician providers regarding the impact non-medical switching has on their patients' medication-related outcomes and health-care utilization.

Materials and methods

We conducted a cross-sectional survey of high-volume Medicare and/or Medicaid physicians defined as those spending an aggregate of >50% of their time caring for Medicare or Medicaid patients. Respondents were identified and recruited by Research Now-Survey Sampling International using their voluntary physician panel derived from state licensing and professional association data. Physicians were randomly sampled and sent an email invitation to opt-in to participate in the survey (respondents received a 35 USD to 45 USD honorarium upon completion). Physicians were first required to complete a set of 'screener' questions to determine whether they met the study's *a priori* inclusion criteria, including: (1) being a licensed, practicing physician >2 years but <30 years post-residency and/or fellowship; (2) practicing in a general, internal or family medicine or specialist setting; (3) spending \geq 40% of their work time providing direct patient care and (4) receiving a non-medical switch request for at least one patient during the prior 12 months and spending an aggregate of >50% of their time caring for Medicare or Medicaid patients. Each physician deemed eligible after completing the screener questions were invited to complete the full online survey. The survey was administered using the Decipher online survey platform (FocusVision, New York, NY, USA) and was fielded between November and December 2018. Investigators were blinded to all respondents to remain compliant with the Health Insurance Portability and Accountability Act. An independent institutional review board (Solutions IRB, Yarnell, AZ, USA) approved this study and reporting of results follow American Association for Public Opinion Research (AAPOR) guidance [7].

We asked qualifying physicians 2 questions (15 total items) to assess their perceptions regarding the impact non-medical switching has on their patients' medication-related outcomes and health-care utilization (**eAppendix 1**). Survey questions were framed as either 5-point ('Very Frequently', 'Frequently', 'Occasionally', 'Rarely', 'Never') or 7-point ('Agree Strongly', 'Agree Very Much', 'Agree Somewhat', 'Neither Agree Nor Disagree', 'Disagree Strongly', 'Disagree Very Much',

'Disagree Somewhat') ordinal Likert scales. For each question, we transformed the native ordinal Likert scale response into binary responses by merging responses at the highest ends of the scales. Data regarding physicians' demographics and professional/practice characteristics were also collected. Analysis of data was descriptive in nature, with percentage of physician responses reported for each item. Analysis was conducted using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

Results

Between November and December 2018, email invitations to consent to participate were sent to 13,117 randomly sampled physicians of which 1,818 opened the email and followed the embedded survey link to participate. A total of 1010 physicians ($n = 606$ primary care and $n = 404$ specialists) who passed the screener met all study inclusion criteria and completed the survey (response rate = 55.5% of physicians receiving an email invitation and clicking the embedded opt-in link). Of these, 350 respondents (34.6%) reported spending >50% of their time caring for Medicare and/or Medicaid patients and were included in this analysis.

Respondent physicians' demographics, professional background and practice characteristics are detailed in eTable 1. Physicians reported spending a median (25%, 75% range) of 20% (10%, 30%) of their care time treating Medicaid and 40% (30%, 50%) of their time treating Medicare patients. Median age of the respondents was nearly 50 years, they were in practice for a median of 16 years and spent 90% of their time providing direct patient care. Approximately two-thirds of respondents were male, ~40% were specialists, the most common practice settings were private practice (46.3%) followed by hospital-affiliated care (28.0% community hospital, 24.0% hospital-affiliated outpatient care, 23.4% teaching hospital). The majority (59.1%) of physician respondents were salaried. Only 140 (or 40.0%) had heard the terminology 'non-medical switching' prior to participation in the survey.

Upon querying physicians regarding the impact of non-medical switching on patients' medication-related outcomes, most felt the practice, to some degree, increased side-effects (54.0%), medication errors (56.0%) and abandonment of medication (60.3%) (Table 1). Nearly one-half of physicians believed non-medical switching increased patients' out-of-pocket costs. Few physicians (\leq 13.4% for all) felt NMS have a positive impact on treatment effectiveness, medication adherence or patients'/physicians' confidence in the quality-of-care provided.

Table 1. Percent responding increases greatly, very much or somewhat.

	N = 350 n (%)
What effect has non-medical switch had on your patients:	
Effectiveness of treatment	43 (12.3)
Side effects	189 (54.0)
Medication adherence	47 (13.4)
Out-of-pocket medication costs	171 (48.9)
Abandonment of treatment	211 (60.3)
Frequency of medication errors	196 (56.0)
Confidence in you as their physician	44 (12.6)
Trust in your abilities to effectively practice medicine	46 (13.1)

Table 2. Percent responding very frequently or frequently.

How often does non-medical switch increase the number of each of the following?	N = 350 n (%)
Office visits	119 (34.0)
Non-office visit contacts (eg, phone, email)	227 (64.9)
Emergency room visits	45 (12.9)
Lab tests	76 (21.7)
Hospitalizations	39 (11.1)
Additional medications (for added effect or to manage side effects)	75 (21.4)
Calls to/from pharmacy	233 (66.6)

Respondents reported non-office visit and prescriber-pharmacy (pharmacist) contact were very frequently or frequently increased when non-medical switching occurred (Table 2). One-third of physicians also felt office visits were very frequently/frequently increased due to non-medical switching, and ~ 1 in every 5 respondents believed laboratory testing and additional medication use frequently increased following a non-medical switch. About 1 in 10 physicians felt non-medical switching very frequently/frequently increased the utilization of emergency department or in-hospital care.

Discussion

The present, online, cross-sectional survey study of high-volume Medicare and/or Medicaid physician providers providing direct patient care and with at least some experience with non-medical switching in prior 12 months suggests they perceive negative influences of non-medical switching on both medication-related outcomes and health-care utilization. Often respondents felt non-medical switching increased medication side-effects, errors, and treatment abandonment, as well as patients' out-of-pocket medication costs. Moreover, physician reported non-medical switching increased the frequency of non-office, office and prescriber-pharmacy contact, and to a lesser extent, increased laboratory testing, additional medication utilization and emergency department or hospital visits. Few responding physicians felt non-medical switching was associated with a positive impact on treatment

effectiveness, medication adherence or patient or physician confidence in overall quality-of-care.

We focused on high-volume Medicare and/or Medicaid physician providers in this analysis because the populations they care for are likely to have substantial vulnerability to non-medical switching practices due to their larger number of chronic medical conditions, subsequent need for multiple prescriptions and lack of economic security (difficulty affording any additional out-of-pocket medication costs) [4–6]. According to analysis of Medical Expenditure Panel Survey (MEPS) from the Agency of Healthcare Research and Quality (AHRQ), >80% of Medicare-aged (65 years or older) adults have multiple chronic conditions compared to just 42% of all US adults regardless of age [6]. This high prevalence of comorbid disease states in an individual has been associated with increased medication use (up to a mean of 51 prescriptions filled per patient per year when 5+ chronic conditions are present [6]; 40.7% taking 5+ medications in the past 30 days) [5], overall health-care expenditures (\$17,640 per patient per year when 5+ chronic conditions are present) and out-of-pocket costs (\$1,792 per patient per year when 5 + chronic conditions are present) [6]. Moreover, only about one-quarter of the Medicare population is considered economically secure [5]. Similarly, a high prevalence of chronic conditions among low-income, non-elderly adult Medicaid beneficiaries has been reported [8]. Health care spending trends for Medicaid patients appear to be similar (ranging from 4,107 USD to 20,763 USD) to Medicare patients when stratified by the presence of 1–2, 3–4 or 5+ chronic conditions; albeit with slightly lower out-of-pocket costs (ranging from 242 USD to 808 USD) [6].

A substantial body of evidence suggests a negative association between non-medical switching and medication-related outcomes and health-care utilization [6]. Nguyen and colleagues identified 29 studies published between January 2000 and November 2015 that evaluated the impact of non-medical switching on health outcomes (60.4% clinical, 21.9% resource utilization, 13.5% economic and 4.2% medication-taking behaviour outcomes), and subsequent analysis found outcomes following non-medical switching were more frequently negative (33.3%) or neutral (55.2%) in nature than positive (11.5%). Primary care physicians and specialists have previously reported frequently having reservations about the practice of non-medical switching; citing concerns regarding negatively impacted care, medical ethics and the administrative burden it imposes on their practice and staff [9,10]. Moreover, physicians have indicated their belief that insurers' current level of communication regarding nonmedical switching is suboptimal [11].

Despite their likely high vulnerability, there appears to be a relative paucity of data evaluating the impact of non-medical switching specifically in Medicare and/or Medicaid patients. The systematic review by Nguyen and colleagues [6] identified only a single study, which evaluated drug and total medical costs associated with non-medical switching of statins (atorvastatin to an alternative statin) in a multistate-managed Medicaid program [12]. Compared to the 12-month period before the non-medical switch off of atorvastatin (saving 11.7% in statin acquisition costs, $p < 0.001$), statin-associated laboratory (+31.5% change, $p < 0.001$), office visit (+44.8%, $p = 0.001$) and total medical costs (+38.6%, $p < 0.001$) during the 12 months after the non-medical switch each increased [9]. Additional studies evaluating the impact of non-medical switching specifically in Medicare and Medicaid patients are needed and would constitute a valuable addition to the literature.

Our study has several limitations worth discussing. First, as with any self-reported response survey, social desirability bias (whereby respondents answer questions in a manner that they feel will be viewed positively by others) may exist [13]. Next, our study did not focus on a specific therapeutic indication and we cannot rule out that physicians' opinions regarding non-medical switching vary by medication type. We did attempt to survey a broad set of physicians in this study including those practicing in different primary care settings as well as across multiple medical specialties. Finally, to avoid respondent burden [14], we restricted the number of questions asked and did not offer respondents the opportunity to provide an explanation or more nuanced response.

In summary, this cross-section survey study suggests high-volume Medicare and/or Medicaid physician providers perceive negative influences of non-medical switching on both medication-related outcomes and health-care utilization.

Author contributions

Drs. Coleman, Patel, Duhig and Cameron had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Coleman, Patel, Bookhart, Voelker.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Coleman, Patel.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Coleman, Duhig.

Obtained funding: Patel, Bookhart.

Administrative, technical, or material support: Coleman, Patel.

Supervision: Coleman, Patel.

Disclosure statement

T.S. has disclosed that she is employed by the American College of Physicians and was a consultant to Janssen on this study.

A.D. and A.C. have disclosed that they are employees of Xcenda which received funding for this study from Janssen.

A.P., J.V. and B.B. have disclosed that they are employees and shareholders of Janssen.

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Role of funder/sponsor

In their role as coauthors, Drs Patel, Voelker and Mr. Bookhart of the funding body contributed to design and conduct of the study; management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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