Exploring the Roots of Poor Medication Adherence

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ABSTRACT

Background. Approximately one-half of U.S. adults do not take their medications as prescribed. This increases healthcare costs, reduces patient health, and gives rise to safety concerns.

Objectives. We assessed patient medication adherence and identified the most common barriers for this.

Methods. We called Medicare Part D beneficiaries from University of Arizona SinfoniaRx Medication Management Center. Subjects qualified to participate in the study if they were identified as nonadherent. Nonadherence was identified using patient self-reports and prescription refill data which defined nonadherence as proportion of days covered (PDC) less than 80%. Data were collected from March 2018 and April 2018.

Results. When a gap in drug refill history is found, SinfoniaRx’s computer system creates an alert in a patient’s profile. The sample included 85 calls and 42 adherence alerts were observed. Of 42 alerts, 52.4% of alerts were denied by the subjects, and 95.3% of subjects reported adherence issues unrelated to the triggered alert. No alerts were identified for 56 subjects, and 72 adherence issues were identified via self-report only. The two most common reasons for nonadherence were cost (19.75%) and poor health literacy (22.2%).

Conclusions. Medication nonadherence is an important public health crisis because it reduces health and wellbeing as well as increases the risk for life-threatening events. Noncompliance also increases healthcare costs. Cost and poor health literacy were the most frequent barriers to compliance in our small study. Furthermore, most subjects were not aware of their
noncompliance. To address noncompliance, we suggested lower cost drug alternatives and provided patient education.

INTRODUCTION

Here, we present findings about medication nonadherence researched from the sampling of telephone calls at SinfoniaRx between February 2018 and April 2018. We investigated common reasons cited for nonadherence and potential solutions for such noncompliance.

SinfoniaRx

SinfoniaRx, an institute of the University of Arizona College of Pharmacy (formerly the Medication Management Center), is a call center that provides Medication Therapy Management (MTM) services to Medicare Part D beneficiaries. Medicare Prescription Drug Plans (Part D) include prescription drug coverage and are offered by private insurance companies approved by Medicare. Many Medicare Part D patients are eligible to qualify for the MTM program. Additional qualifications include having multiple chronic conditions, taking multiple Part D drugs, and spending a certain threshold of annual out-of-pocket costs. MTM is a medical service provided by pharmacists to improve therapy and optimize patient therapeutic outcomes. Over the telephone, pharmacists target nonadherence, gaps in care, cost-saving opportunities, safety concerns such as therapeutic duplications or drug-drug interactions, and medication questions. SinfoniaRx provides MTM services on behalf of various insurance companies it is contracted with. Data were collected at SinfoniaRx by researchers listening to the calls. During a call, the caller reviews the patient’s medications, inquiring if the drug is being taken and how often. At the end of the call, the patient is transferred to a pharmacist who reviews the list of medications again to ensure no problems and to answer remaining patient questions.
Medication Nonadherence: The Silent Epidemic

Medication adherence is the extent to which patients take their medicines as prescribed by their healthcare providers.\textsuperscript{2–5} Often, the simple act of taking a medication according to directions is, to some adults, a complex task.\textsuperscript{2} Medication adherence is more than reading the directions on a label, but it is an intricate interaction that involves a social environment, the patient, his/her disease, and the healthcare professionals.\textsuperscript{3,6} Examples of nonadherence include but are not limited to skipping drug doses, taking drugs at the wrong time, or failing to fill prescriptions.\textsuperscript{2} Two categories of medication nonadherence are recognized: primary nonadherence by which the patient fails to initially fill a written prescription and secondary nonadherence by which the patient fails to follow directions or refill prescriptions.\textsuperscript{2,5} A patient may decide to be non-adherent purposefully, or the patient may be unintentionally non-adherent. Three phases of medication adherence exist: 1) the patient fills the prescription written by a healthcare provider (initiation); 2) the patient takes the drug according to instructions (implementation) and 3) continues to take the drug appropriately with no premature cessation (discontinuation).\textsuperscript{7} Nonadherence may occur at any one of these three phases.

Approximately half of the 3.2 billion annual prescriptions in the U.S. are not taken as directed.\textsuperscript{2,8} This is a concern because medication nonadherence can harm the patient and increase general healthcare burdens. Because drugs are the most common type of therapy used in healthcare, maximizing their use is required for populations who rely on long-term pharmacotherapy.\textsuperscript{9} Noncompliance reduces treatment efficacy, limits chronic disease management, and increases costs due to poorer health outcomes.\textsuperscript{6–7,10} Annually, an estimated 125,000 deaths in the U.S. are due to medication nonadherence and poor adherence is thought to account for \textasciitilde10\% of hospitalizations and \textasciitilde64\% of hospital readmissions within 30 days.\textsuperscript{2,10} Noncompliance causes
revenue losses for pharmaceutical companies and pharmacies when prescriptions are not filled, and when prescriptions are filled but not used, drug wastage is significant. These costs total $100 billion annually so that drug adherence experts declared this problem a public health crisis.

METHODS

Measuring Medication Adherence

Various tools are used to measure adherence, both directly and indirectly as well as quantitatively and qualitatively. Direct methods include use of biomarkers, determination of the concentration of a drug in blood or urine, dried blood spot analysis (DBS), and direct observed therapy (whereby a healthcare provider watches people take their medications). Indirect methods to measure adherence are pill counts, prescription refill rates, electronic monitors (which consist of a microprocessor placed in a medication container which records the date and time the bottle was opened), and patient self-report (which includes medication diaries, patient questionnaires, and patient interviews). Some examples of standardized questionnaires are the Morisky Medication Adherence Scale (MMAS), Medication Adherence Questionnaire (MAQ), and the Medication Adherence Report Scale (MARS).

Technologically advanced measurement methods include mobile phone alerts and monitoring, electronic cap event monitoring (MEMS caps), smart pills, computerized logbooks, and ingestible medication markers. However, these methods take time to get approval from the FDA and are generally too expensive for the average patient to utilize. From refill rates and pill counts, adherence can be numerically calculated in many ways for claims-based adherence measurement. Medication possession ratio (MPR) is calculated by dividing days’ supply
obtained by the refill interval, and the proportion of days covered (PDC) calculation is defined as the number of medication-available days divided by the number of days in a specified time period.\textsuperscript{1,12–13}

\textit{Disadvantages of Methods}

There is no perfect standard to measure adherence because each method has its disadvantages.\textsuperscript{1} Self-report, although easy and inexpensive to perform, has been found to overestimate adherence because patients often say what they believe their healthcare provider would like to hear.\textsuperscript{9,14} In addition, self-report relies on patients’ perception of their behavior and is thus subject to recall and reporting bias.\textsuperscript{8} Prescription refill records and pill counts do not verify whether a patient is actually taking their medication and whether they are doing so correctly.\textsuperscript{8} Electronic devices may not always be precise and do not indicate the amount of medicine ingested.\textsuperscript{14} Indirect methods are more common because they are generally easier to conduct, less expensive, and noninvasive but often less accurate and do not provide all the required information to measure adherence.\textsuperscript{8,15} Direct methods are generally more costly, more time-consuming, and more invasive but more accurate.\textsuperscript{11} Many require the patient to go to a healthcare clinic, which is particularly difficult for the elderly who are disproportionately affected by physical limitations.\textsuperscript{2,16}

\textit{Data Collection}

SinfoniaRx has access to drug refill histories so gaps can be identified. Once a gap is found, the computer system automatically creates an alert in the patient’s profile and each alert identifies one medication. The gaps in refills are calculated using the PDC method with nonadherence defined as PDC less than 80\%.\textsuperscript{1} Both refills and patient self-reports of Medicare Part D participants who are offered MTM services from SinfoniaRx were sampled to measure
adherence. Alerts indicated a gap in refill history (quantitative data), and the subject’s conversation was self-reported qualitative data. Data were recorded when an alert was triggered and when a participant verbalized concern(s) about taking or having access to a medicine. Direct quotes were also recorded. All participants verbalized consent to be recorded and monitored.

RESULTS

Reasons for Nonadherence

Many factors affect medication adherence. Factors include patient, treatment, or healthcare system factors. Patient aspects include forgetfulness, personal beliefs on medications, physical limitations, health literacy, demographic factors such as race or education, limited English proficiency, poor social support network, behavioral/psychological factors such as depression, and socioeconomic factors. Treatment factors consist of regimen complexity (number of medications and intake frequency), actual or perceived side effects, duration of therapy, changes in medication regimen, and severity of symptoms. Healthcare system factors include a weak provider-patient relationship, poor provider communication skills or poor information provision, high drug costs and copayments, limited access to care, insurance complications, and pharmacy refill issues. For this study, factors raised in subject phone calls were recorded. Thus, 14 factors were developed and these appear in Table 2.
Findings

Data appear in Tables 1 and 2. Adherent patients with gaps in refill history were due to hospitalizations during which medications are provided by the hospital, use of samples sourced from a healthcare provider and as such will not appear in refill history, and a change in dose or medication whereby the patient stops the previous regimen as directed by their provider, causing a gap for the previous regimen. We identified 18 subjects with 1 alert, 9 subjects with 2 alerts, and 2 subjects with 3 alerts. The most frequent adherence barriers are depicted in Table 2. Thus, based on this study, cost and poor health literacy were the most common reasons for nonadherence. Past research of the Medicare Part D beneficiary population suggests that cost and side effects were the most common barriers. However, forgetfulness is also cited as a common cause of noncompliance. The most frequent obstacles to adherence differ among populations. For example, some minority groups are more likely to be non-adherent due to language barriers or cultural beliefs about medicines. Cost-related nonadherence may disproportionately affect elderly individuals who have limited income.

<table>
<thead>
<tr>
<th>Table 1 Adherence Issues Identified from Calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of calls</td>
</tr>
<tr>
<td>Total number of alerts in system</td>
</tr>
<tr>
<td>Adherence issues detected with no alerts in system</td>
</tr>
<tr>
<td>Alerts with adherent patients</td>
</tr>
<tr>
<td>Patients with no alerts</td>
</tr>
<tr>
<td>Hospitalized (H); Use of Samples (UOS), Change in Dose or Medication (CDOM)</td>
</tr>
</tbody>
</table>
Table 2 Adherence Issues

<table>
<thead>
<tr>
<th>Adherence Issue</th>
<th>Occurrences</th>
<th>Direct Quotes</th>
<th>Solutions Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forget</td>
<td>5 (6.2%)</td>
<td>“I won’t say that I haven’t missed one every now and then.”</td>
<td>Suggest patient to use a pill box, alarm, sticky note, or calendar. Keep medications easily visible.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“I can’t afford that kind of money.”</td>
<td>Suggest patient to get medications via mail order, get longer supplies, get the generic instead of the brand, pay their deductible, get samples, try alternatives (call insurance, talk to prescriber, talk to pharmacist).</td>
</tr>
<tr>
<td>Cost</td>
<td>16 (19.75%)</td>
<td>They’ll get every nickel they can from me.”</td>
<td>Suggest patient to get medications via mail order, get longer supplies, get the generic instead of the brand, pay their deductible, get samples, try alternatives (call insurance, talk to prescriber, talk to pharmacist).</td>
</tr>
<tr>
<td>Personal Beliefs</td>
<td>5 (6.2%)</td>
<td>“I don’t like ’em but I know I got to take ’em.”</td>
<td>Suggest patient to talk to prescriber before stopping medication(s). Transfer patient to pharmacist.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“I won’t take them tablets.”</td>
<td></td>
</tr>
<tr>
<td>Physical Limits</td>
<td>4 (4.9%)</td>
<td>“I don’t get out often cause they took my car from me.”</td>
<td>Suggest patient to get caregiver(s), easy open caps, pharmacy delivery service.</td>
</tr>
<tr>
<td>Poor Health Literacy</td>
<td>18 (22.2%)</td>
<td>“I just take it. I don’t pay attention to what it is.”</td>
<td>Inform and educate patient.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“I’m dying of liver cancer, that’s my only concern.”</td>
<td></td>
</tr>
<tr>
<td>Behavioral/Psychological</td>
<td>6 (7.4%)</td>
<td>“My having fun is going to the doctor’s office.”</td>
<td>Provide empathy.</td>
</tr>
<tr>
<td>Physician Factors</td>
<td>8 (9.9%)</td>
<td>“Nobody ever give me an explanation.”</td>
<td>Suggest patient to talk to prescriber.</td>
</tr>
<tr>
<td>Lack of or Poor Social Support Network</td>
<td>1 (1.2%)</td>
<td>(jokingly) “They’re only helping me cause of my will.”</td>
<td>Suggest patient to get caregiver(s).</td>
</tr>
</tbody>
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</thead>
<tbody>
<tr>
<td>Regimen Complexity</td>
<td>2 (2.5%)</td>
<td>“I just can’t handle taking four more pills.”</td>
<td>Explain the importance of taking medication(s). Suggest patient to ask pharmacist for help.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Suggest patient to talk to prescriber if having side effects with medicines before changing the dosage on their own or stopping the regimen.</td>
</tr>
<tr>
<td>Side Effects</td>
<td>5 (6.2%)</td>
<td>*NQO</td>
<td>Educate patient on importance of taking medication(s). Suggest alternatives and talking to a pharmacist.</td>
</tr>
<tr>
<td>Change in Symptoms</td>
<td>2 (2.5%)</td>
<td>“I didn’t feel like it was helping.”</td>
<td>Educate patient on importance of taking medication(s). Suggest patient to talk to prescriber if having issues with medicines before changing the dosage on their own or stopping the regimen.</td>
</tr>
<tr>
<td>Pharmacy Issue/Refill</td>
<td>5 (6.2%)</td>
<td>*NQO</td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insurance Problem</td>
<td>1 (1.2%)</td>
<td>“What’s the difference between copay and insurance?”</td>
<td>Suggest patient to call insurance and prescriber for help.</td>
</tr>
<tr>
<td>Limited English Proficiency</td>
<td>3 (3.7%)</td>
<td>“No speak English”</td>
<td>Language services are provided. Use a sheet saying how to say “one moment please” in several different languages, then transfer patient.</td>
</tr>
<tr>
<td>Unable to Recall</td>
<td>22</td>
<td>*NQO</td>
<td>NA</td>
</tr>
</tbody>
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<tr>
<td>No Reason</td>
<td>3</td>
<td>*NQO</td>
<td>NA</td>
</tr>
</tbody>
</table>

*NQO: No Quote Obtained

DISCUSSION

Cost: Healthcare System Factor

Nonadherence due to high cost is a healthcare system factor and this may be due to low income, limited insurance coverage for outpatient medications, and/or increased out-of-pocket costs.\(^{10}\) When copayments increase, patients with chronic illnesses are likely to skip or stop taking their drugs.\(^{2}\) Sometimes patients enter the ‘donut hole’, a coverage gap that occurs once the patient has reached the drug plan coverage limit. Copayments drastically rise in the donut hole and two subjects in this study expressed concerns about this. SinfoniaRx has interventions to help people pay for their medicines such as using mail order, samples from a provider, and three-month versus one-month supplies. Patients are also encouraged to use generic versions which are less expensive. Two patients were advised to file an appeal to their insurance to get a coverage rule waived for them. Finally, patients are advised to obtain lower cost alternatives by talking with their provider or a pharmacist. Communication is vital with nonadherence; patients are often advised to discuss their issue(s) with their physician.
"I can’t afford that kind of money."

"They’ll get every nickel they can from me."

**Poor Health Literacy: Patient Factor**

Another common cause of medication nonadherence is poor health literacy which is a patient factor. Health literacy is the ability to understand health information and services to make appropriate health decisions.\(^{17}\) Patients must read and understand medical information and each is expected to self-manage chronic conditions using basic literacy skills such as listening, speaking, writing, reading, and numeracy. Health literacy requires general knowledge of health topics as well as the nature and causes of one’s chronic condition(s).\(^{2,17}\) Poor health literacy is evidenced by unawareness of the need for a medication or inability to understand dosage instructions when they have been explained by a healthcare provider.\(^{15}\)

"I just take it. I don’t pay attention to what it is."

"I didn’t know that. I’m glad I’m reading that!"

Many instruments are developed to measure health literacy such as the Short Test of Functional Health Literacy in Adults and the Rapid Estimates of Adult Literacy in Medicine.\(^{18}\) According to the National Assessment of Adult Literacy conducted in 2003, 77 million U.S. adults (35%) have basic or below basic health literacy, whereas only 26.4 million (12%) have proficient health literacy.\(^{15,19}\) Poor health literacy is most common in immigrants, racial/ethnic minorities, older patients, and those with less education.\(^{19}\)

At SinfoniaRx, interventions are implemented to educate the patient using pictorial and audiovisual educational material instead of written instructions and creating a ‘shame-free
environment’ which may increase the likelihood of an admission of limited literacy.\textsuperscript{2} Other solutions may empower patients to ask questions such as the teach-back method which allows healthcare providers to confirm patient understanding by asking him/her to explain in his/her own words what they need to know or do.\textsuperscript{15} Given that 13.5 million Americans were identified to have limited English proficiency (LEP) in 2011, providing information in the patient’s native language can secure medication comprehension for these patients.\textsuperscript{20} SinfoniaRx has translators to provide verbal information in a native language when a patient has LEP and this may address medication nonadherence issues for these patients.

\textit{Denying Gaps in Adherence}

\begin{quote}
“Yes I’m taking my medicines; I want to live!”
\end{quote}

Of the 42 alerts that appeared in the system, 52.4\% were denied by the subjects. Only 4.7\% of patients reported adherence issues related to the triggered alert; the other issues were not related to the alert. This frequent failure to recognize nonadherence is consistent with the results of a previous study performed at SinfoniaRx.\textsuperscript{1} Subjects deny nonadherence for many reasons so open-ended questions are used to generate discussion.\textsuperscript{11} For example, asking “Do you take your medication as prescribed?” is a closed-ended question and typically generates binary and false answers compared to open-ended questions “How often do you take your medication?”\textsuperscript{8} Normalizing the likelihood of nonadherence increases the accuracy of self-reported medication use.\textsuperscript{8} For example, asking “How often do you forget to take your medicine?” may cause patients to overestimate their adherence.\textsuperscript{11} Phrasing the question, “People often forget to take their medicines; in the past week, how many days did you forget to take your medicine?” can result in more accurate responses.\textsuperscript{2,11} The second question reduces potential guilt patients may feel
because they view nonadherence as normal and not entirely their fault when missing doses. Thus, medication adherence measured via self-reports requires question phrasing to minimize response bias. At SinfoniaRx, staff used different wording to address alerts and this variety in phrasing may account for some of the patient denials.

In addition, nonadherence gaps may be due to cash-paid prescriptions because these are not recorded in drug refill histories, but this can be addressed by the patient during the telephone conversation. Furthermore, beneficiaries of MTM services must often manage multiple chronic conditions and several medications; thus, missing a few doses every week is likely and may indicate poor management of conditions. As a result, patients with comorbidities may not notice their own gaps in therapy.

LIMITATIONS

This study has several limitations. Assessing adherence qualitatively is difficult because nonadherence is typically not straightforward but is due to complex interactions of multiple factors. Next, the methods of the study were limited to self-reporting and refill history. Self-reporting is subject to bias, and consistent question phrasing was not used. Alerts were frequent, but because only 4 of 85 subjects recognized their refill gap, little quantitative data were obtained. As a result, this study largely depended on self-reporting to evaluate adherence. However, subjects rarely clearly stated they were non-adherent with a medicine but they implied it or vaguely referred to it. Because the call was not performed by the author, subjects could not be asked to clarify adherence and it was not possible to use structured questionnaires to measure adherence, which may have produced more accurate results. Unfortunately, ambiguous cases
were frequent. At times the patient did not know if they were taking a medication or claimed their physician told them to take a lower dosage of the drug. Some patients had a complicated story for the reason for refill gap(s), which for the sake of time could not be pursued in depth.

CONCLUSION

Medication nonadherence is an important public health issue because it lowers quality of health and causes avoidable costs to the healthcare system.\textsuperscript{2,10} Unfortunately, nonadherence is often overlooked which can be addressed by offering adherence training for providers.\textsuperscript{15} However, providers cannot shoulder this burden entirely. Rather, drug recipients should be aware of the medication benefits they have. Many called in this study knew little about the MTM program for which they were qualified. We must provide better benefit information to patients so that these resources can be more frequently used.

Our results confirmed that cost and poor health literacy are the most common causes of nonadherence in a Medicare Part D beneficiary population. Based on previous research, cost, side effects, and forgetfulness are other common reasons for U.S. adults.\textsuperscript{2,10} The most common barriers to adherence differ with different populations such as racial/ethnic minorities; healthcare providers should consider this phenomenon to identify adherence issues more effectively.

At SinfoniaRx, the interventions for cost concerns and poor health literacy include finding lower cost alternatives and educating patients. General interventions include providing written action plans and written instructions for patients, reducing regimen complexity such as creating the simplest dosing schedule, and individually delivering provider-to-patient interventions.\textsuperscript{2,8} In this way, patient-centered communication can be achieved, and individual adherence issues can be
identified and resolved. Finally, because medication adherence is a multifaceted issue, it requires interventions at multiple levels of the healthcare system.³

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REFERENCES


