Case Study of the Effects of Office-Based Generic Drug Sampling on Antibiotic Drug Costs and First-Line Antibiotic Prescribing Ratios

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ABSTRACT

BACKGROUND: Health plans and members benefit from the substitution of lower-cost drug therapies that achieve the same clinical outcomes as higher-cost drugs. Previous research suggests that generic sampling programs produce drug cost savings overall, but the effects attributable to acute therapies are unknown. Encouraging physicians to prescribe less expensive, first-line antibiotics may help reduce direct drug costs associated with prescribing potentially unnecessary, and more expensive, second-line agents.

OBJECTIVES: To determine the effects of an automated, office-based generic drug sampling kiosk on (a) prescribing of first-line oral antibiotic agents as a ratio of total antibiotic prescribing and (b) average antibiotic drug cost per claim.

METHODS: This managed care organization of 2.3 million members with pharmacy benefits collaborated with a vendor that developed an automated generic drug kiosk that allows for the dispensing of samples of generic medications within the provider’s office. Among the samples contained in the kiosk were 6 generic, first-line oral antibiotics, representing 6 unique drug-strength options. Drug costs were defined as the ingredient cost of the drug claim, which includes plan cost, member cost share, and any dispensing fees or administrative program costs associated with the sampling program. In a difference-in-difference analysis, changes in outcome measures (antibiotic drug cost per claim and dispensing rates of first-line antibiotics) from 2003 (baseline year) to 2005 (post-implementation year) were compared among kiosk prescribers (n=179) and nonkiosk prescribers who were part of the same provider network (n=7,236). A cross-sectional analysis of the same outcome measures compared kiosk (n=396) and nonkiosk prescribers (n=10,267) in 2006. All statistical analyses were performed using t-tests of log-transformed data.

RESULTS: The mean cost per claim dropped by $4.14 (12.3%) from $33.56 in 2003 to $29.42 in 2005 for the kiosk prescribers and by $3.35 (8.8%) from $38.26 in 2003 to $34.91 in 2005 for nonkiosk prescribers, but the mean change from 2003 to 2005 in the difference-in-difference analysis was not statistically significant (P=0.123). The first-line antibiotic prescribing ratio declined by 2.1 absolute points from 49.1% in 2003 to 47.0% in 2005 for the kiosk prescribers and by 3.4 points from 46.0% to 42.6% in 2005 for the nonkiosk prescribers, but the difference-in-difference analysis showed that the change was not statistically significant (P=0.901). A cross-sectional analysis of 2006 data revealed significant differences between the kiosk prescribers versus their nonkiosk network counterparts for both first-line antibiotic prescribing rates (42.0% vs. 41.4%, respectively; P=0.028) and antibiotic cost per claim ($28.44 and $32.40, respectively; P<0.001). While the results of the cross-sectional analysis are statistically significant, the practical significance of the results is less evident.

CONCLUSIONS: The benefits of including short-term medications such as first-line antibiotics in a generic drug sampling program are difficult to quantify, and the cost outcomes are unlikely on their own to justify generic drug sampling. However, acute (short-term) medications may be an effective part of an overall program to promote generic prescribing for all conditions.
Antibiotics represent a therapeutic category in which there is an opportunity to affect such utilization because many products are commercially available at varied costs with relatively predictable treatment outcomes.

Despite the existence of clinical guidelines that outline appropriate circumstances under which an antibiotic should be prescribed and which agent may be the agent of choice, data suggest that antibiotics are still prescribed inappropriately for a variety of diagnoses. The unnecessary prescribing of antibiotics contributes to antibiotic resistance and increased health care costs. Inappropriate antibiotic prescribing increases costs for patients as well as for payers and society. If burdened with high-cost drug regimens, some groups of patients, including those who are elderly or low-income, may forego treatment for their chronic disease states or for their infection if they are unable to afford their medication. Most first-line antibiotics are available generically and offer a significant cost savings over their branded, broader-spectrum counterparts. Hanson and colleagues have developed guidelines for prescribing low-cost antibiotics in outpatient settings that call for the use of first-line antibiotics for many common infections. Many of these proposed treatments provide therapeutic value for less than $15 per prescription to cash-paying (uninsured) patients.

Interventions that have sought to change antibiotic prescribing patterns have their roots in inpatient or institutional settings and largely focused on decreasing antimicrobial resistance. The Infectious Diseases Society of America outlines recommendations for the implementation of such interventions. These recommendations include interactive, web-based, or other prescriber education interventions; the development of practice guidelines or protocols that may assign responsibility to the prescriber; and the reduction of pharmaceutical promotion directly to prescribers. Additionally, the use of an interdisciplinary “antimicrobial team” has been suggested to be effective in monitoring antimicrobial prescribing and intervening in cases of suboptimal prescribing. More recently, interventions that aim to manage antibiotic prescribing have been implemented and evaluated in outpatient or community settings. Examples of community-based programs that have sought to influence antibiotic prescribing habits include confidential prescriber feedback and education and clinical decision support systems based in either the prescriber office or in community pharmacies. From a payer perspective, health plans can implement multi-tier copayment designs, based around sound formulary decision making, to further promote the utilization of more cost effective therapies. In general, such an intervention can be applied to a formulary, to a targeted therapeutic category (e.g., antibiotics), or to certain types of drug products (e.g., generics).

The managed care organization (MCO) in this study is a regional Blue Cross/Blue Shield plan located in Pennsylvania that provided prescription drug coverage for 2.2 million members in 2005 and 2.3 million members in 2006. In August 2003, the MCO partnered with MedVantx, a privately held corporation that provides generic drug samples, including first-line antibiotics, directly to physician offices via an automated dispensing kiosk. Information about this managed care intervention and its effect on the overall (all drug) generic dispensing ratio (GDR) in this MCO was published previously. The previous study found a 1.2-point higher GDR (55.3% vs. 54.1%) in the first year for prescribers participating in a generic drug sampling program (kiosk prescribers) compared with nonkiosk prescribers within the plan’s physician network. In the second year, the GDR difference narrowed to 0.8 points, 59.9% versus 59.1%. Direct drug cost savings for the program were $1,321 per kiosk prescriber in year 1 (2005) and $719 in year 2 (2006).

Recognizing the need to promote and provide a simple tool that would allow prescribers to change their prescribing habits, the MCO sought to examine an existing program that could provide prescribers with generic first-line oral antibiotic samples in their offices. Antibiotic samples were initially included in the kiosk program as part of a larger effort to change the prescriber’s mindset around generic drug prescribing in general, encompassing both long-term and short-term therapies. Anecdotal evidence had suggested that physicians preferred having access to samples of antibiotics as part of the sampling program, whether because of a perception of increased patient compliance or a broader approach to generic prescribing; thus, the antibiotic samples were believed to provide an intangible benefit to the program. The antibiotic samples were specifically selected for this analysis because of uncertainty about both the financial impact of their inclusion in the program and their specific impact on antibiotic prescribing practices. The present study sought to identify the effect of the generic dispensing kiosks on the prescribing of first-line versus second-line antibiotics and whether or not changes in such practices translate into drug cost savings on a per claim basis.

Methods

Generic Sampling Program

In August 2003 the MCO partnered with the vendor to implement a program by which network prescribers would be provided with a generic drug sampling kiosk in their office. The program began as a pilot study in 10 select physician practices that were targeted due to high-volume prescribing (>5,000 prescriptions per year) and/or a below-average GDR compared with their network peers. As of November 2008, the program has more than 800 providers participating in the kiosk generic drug sampling program.

The kiosk is a free-standing unit approximately the size of a bank automated teller machine and has the ability to dispense generic samples in a 30-day supply or sufficient quantity of antibiotics for a complete treatment cycle. There are 21 unique medications from 10 different therapeutic categories, representing 36 options based on dosage strength. Specifically, the kiosk contains...
samples of 6 unique oral antibiotic medications, representing 8 unique options by dose and strength (Table 1). The cost of the drug samples is automatically billed to the MCO, and no cost is incurred by the physician practice. Further, the program provides the generic samples at no cost ($0 copayment) to the member. Samples can be dispensed to any of a kiosk prescriber’s patients. Multiple health plans participate in the MedVantx program, but each MCO pays only for those samples provided to its members.

The office-based generic dispensing kiosk was complemented by an academic detailing service that is provided by a clinical pharmacist who is a full-time employee of the MCO. Academic detailing provides the prescribers involved in the program a variety of services, including education on benefit structures, feedback on prescribing patterns, and discussions on the impact of prescribing habits on member out-of-pocket cost, compliance, and adherence. Specific to the promotion of prescribing first-line antibiotics, the academic detailing focuses on the unique concerns surrounding opportunities for therapeutic substitution and the impact of antibiotic resistance on cost and quality outcomes. The academic detailing service was provided to all physician practices participating in the generic sampling program, but also was provided for large physician practices that were not participating in the program. Approximately 40% of the MCO’s network receives academic detailing services.

Study Groups
Kiosk prescribers (intervention group) are physicians or other health care professionals with prescribing rights who operate out of network primary care (family practice or internal medicine) physician practices that have been targeted by the MCO, based upon their prescribing practices, to engage in the program. Program participation is voluntary and is coordinated at the physician practice level (i.e., all prescribers within a participating practice are considered to be kiosk prescribers). Nonkiosk prescribers (comparison group) are any other primary care (family practice or internal medicine) physicians or other health care professionals with prescribing rights who are in the MCO’s physician network. The same criteria applied for both the first (2005) and second (2006) study years.

First-Line Antibiotics
For purposes of this study, the oral antibiotic agents in the generic drug sampling kiosk were determined to represent first-line therapeutic options. This determination was made based on their inclusion in clinical practice guidelines, evidence provided in peer-reviewed publications, and recommendations in professional reference literature as first-line drugs of choice for common diagnoses seen in the community setting such as upper respiratory tract infections or uncomplicated urinary tract infections. Understanding that the antibiotic samples provided by the sampling program do not constitute all of the available first-line oral antibiotics, we developed a comprehensive list of first-line antibiotics including other agents such as first-generation cephalosporins, penicillins, first-generation macrolides, and tetracyclines at the national drug code (NDC) level, which allows for the inclusion of all strengths and dosage forms. Inclusion of antibiotic agents on this list was based upon support from peer-reviewed and reference literature. The list of second-line agents was comprised of all other oral antibiotics, including fluoroquinolones, second- and third-generation cephalosporins, amoxicillin/clavulanate, and second-generation macrolides.

Statistical Analysis
Prescribing rates and drug costs were calculated for first- and second-line antibiotics using MCO drug claims data on file. Drug cost was defined as the ingredient cost for each drug claim, which includes plan cost, member cost share, and any dispensing fees or administrative program costs associated with the sampling program. For each prescriber, drug costs per claim (total cost of drugs prescribed divided by total number of claims) and first-line antibiotic prescribing rates (number of first-line antibiotic claims divided by number of all antibiotic claims) were calculated for 2005 (post-implementation) and 2003 (baseline). Only those kiosk or nonkiosk prescribers who had claims data in both 2003 and 2005 were included in the analysis.

### Table 1: First-Line Antibiotics

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Strength</th>
<th>Dose Form</th>
<th>Package Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>250mg</td>
<td>Capsule</td>
<td>30</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>500mg</td>
<td>Capsule</td>
<td>30</td>
</tr>
<tr>
<td>Cephalaxin</td>
<td>250mg</td>
<td>Capsule</td>
<td>28</td>
</tr>
<tr>
<td>Cephalaxin</td>
<td>500mg</td>
<td>Capsule</td>
<td>28</td>
</tr>
<tr>
<td>Doxycycline hydrochloride</td>
<td>100mg</td>
<td>Capsule</td>
<td>14</td>
</tr>
<tr>
<td>Penicillin VK</td>
<td>500mg</td>
<td>Tablet</td>
<td>40</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>250mg</td>
<td>Capsule</td>
<td>40</td>
</tr>
<tr>
<td>Sulfamethoxazole/trimethoprim</td>
<td>800mg/160mg</td>
<td>Tablet</td>
<td>20</td>
</tr>
</tbody>
</table>

Other first-line oral antibiotic medications:

- Amoxicillin
- Ampicillin
- Cefadroxil
- Cefazolin
- Cephalaxin
- Declozicillin
- Dicloxacillin
- Erythromycin
- Geocillin
- Minocycline
- Penicillin
- Sulfamethoxazole/trimethoprim
- Tetracycline

- National Drug Code numbers for branded versions of generic first-line antibiotics were also included as first-line antibiotics.
and 2005 were included in the analysis. Each prescriber was assigned a weight based upon his or her 2005 prescribing volume (number of claims multiplied by a constant so that sample size remained unchanged by weighting); thus, each prescriber's mathematical contribution to the study results was proportionate to his or her volume of claims. This calculation produced results equivalent to standard industry measures (e.g., aggregated total costs divided by aggregated total claims) but allowed for statistical testing. To perform a difference-in-difference analysis, 2003 outcomes were subtracted from 2005 outcomes, and the study groups (kiosk vs. nonkiosk) were compared using two-sided t-tests.

Because of a substantial increase in program participation from 2005 to 2006, direct comparisons could not be made between the samples of kiosk prescribers from year 1 of the program (2005) and year 2 (2006). Therefore, an additional by-group cross-sectional comparison was conducted to assess the drug cost per claim and first-line antibiotic prescribing rates for kiosk versus nonkiosk prescribers for 2006 alone. A distinct weight was invoked for these analyses based upon 2006 claims volume per prescriber, again multiplied by a constant to keep sample size unchanged. Again, two-sided t-tests were employed.

To account for skewness, all values (first-line prescribing rates and costs per claim for all 3 study years) were log-transformed (after adding 1 to each value to account for values of zero [0] because there is no natural logarithm of 0) for statistical testing. However, because of the descriptive and exploratory nature of the study, we did not retransform the values; instead, untransformed values are shown in the tables and text for ease of reading.

Analyses were performed using SPSS version 17.0 (SPSS, Chicago, IL) using an a priori significance level of 0.05.

## Results

For kiosk prescribers (n=179), the mean first-line antibiotic prescribing rate decreased from 49.1% in 2003 to 47.0% in 2005, an absolute 2.1% decrease (median=-2.32%, SD=13.02%; Table 2). For nonkiosk prescribers (n=7,236), the first-line antibiotic prescribing rate decreased from 46.0% in 2003 to 42.6% in 2005, an absolute 3.4% decrease (median=-3.5%, SD=14.59%). The difference between kiosk and nonkiosk prescribers (testing the change in log-transformed values from 2003 to 2005) was not statistically significant (P=0.901). Mean antibiotic cost per claim decreased from $33.56 in 2003 to $29.42 in 2005 for kiosk prescribers, a $4.14 decrease (median=-$2.84, SD=8.19). Nonkiosk network prescribers saw their mean antibiotic cost per claim decrease by $3.35 (median=-$2.84, SD=16.77), from $38.26 in 2003 to $34.91 in 2005. The difference between kiosk and nonkiosk prescribers (again testing the change in log-transformed values from 2003 to 2005) was also not statistically significant (P=0.123).

In 2006, kiosk providers (n=396) exhibited significant differences in both mean first-line antibiotic prescribing and mean antibiotic cost per claim compared with nonkiosk providers (n=10,267; Table 2). Kiosk prescribers prescribed first-line antibiotics 42.0% of the time (median=41.7%, SD=14.1%). By comparison, their nonkiosk counterparts prescribed first-line antibiotics 41.4% of the time (median=40.1%, SD=17.5%; P=0.028). The mean cost per claim for antibiotics written by kiosk prescribers was $28.44 (median=27.42, SD=8.43) compared with $32.40 (median=29.59, SD=28.84) for their nonkiosk counterparts (P<0.001).

## Discussion

A difference-in-difference analysis of changes in first-line antibiotic prescribing rates and mean antibiotic cost per claim from baseline through the first full year of participation in a generic drug sampling program did not reveal a significant difference among kiosk providers as compared with their nonkiosk network counterparts. However, a cross-sectional analysis of the same outcome measures, conducted 2 years after program implementation, identified significantly greater first-line prescribing rates and lower average costs per claim for prescribers who participated in the program than for those who did not. Kiosk physicians prescribed first-line antibiotics 0.6% more often and had a mean antibiotic cost per claim of $3.96 less than their nonkiosk counterparts.

While the 2006 results were statistically significant, their practical significance, especially that of the first-line antibiotic prescribing rate difference (0.6%), is less evident. A previous study of the same generic sampling program identified a larger overall GDR among kiosk prescribers (59.9% vs. 59.1% for non-kiosk prescribers) and estimated a return on investment of 3:1.
for the duration of the original study period, suggesting that the program, overall, is successful and sustainable. The results of this analysis suggest that the availability of full-course antibiotic samples likely contributes little to the overall cost outcomes of the program. However, the results also suggest that the antibiotic samples are unlikely to be financially detrimental, as kiosk prescribers exhibited positive cost outcome differences compared with nonkiosk prescribers in 2006. A longer-term analysis of the program would clarify the ongoing financial risks or benefits of providing short-term antibiotic samples as part of a generic drug sampling program.

In addition to a positive overall financial return for the program, the continued increase in prescriber participation serves as a measure of prescriber acceptance of the program. As of November 2008, generic sampling kiosks are located in 217 practice sites across Pennsylvania that allow over 800 prescribers access to generic samples for their patients. To date, 37,735 samples have been dispensed to members of the MCO in 2008, representing a significant cost savings to members who obtained the samples at no cost, without a trip to the pharmacy. To accommodate the increased participation in the program, the MCO has since hired additional clinical staff to support this program as part of the academic detailing initiative.

Anecdotal evidence provided by kiosk prescribers suggests that they were satisfied with being able to provide their patients with antibiotic samples, stating that the samples may improve patient compliance by improving patient convenience, allowing the member to leave the office with the drug therapy in hand. Other prescribers have commented that the presence of antibiotics in the kiosk was the primary reason that compelled them to participate in the program. Additional health plan data suggest that antibiotics, in many cases, were utilized more frequently than were other samples upon a prescriber’s initial participation in the program. Such anecdotal evidence suggests that an intangible benefit exists for the inclusion of antibiotic samples as part of a generic drug sampling program. The absolute value of the apparent benefit of including antibiotics in a generic drug sampling intervention must be determined by each health plan after examining the needs of its membership and network providers.

An additional potential benefit of including antibiotics in the sampling kiosks that is not readily quantifiable in the analysis conducted for this study is that the generic drug sampling program acts as a complementary program to the academic detailing services provided by the health plan. The kiosk helps facilitate the practical application of the detailing message (appropriate prescribing) that is delivered by the clinical consultants and clinical pharmacists who interact with the network prescribers. Future research examining the effects of improved antibiotic prescribing practices on outcomes such as treatment success rates and antibiotic resistance rates would be valuable to health plans and communities alike.

After careful consideration of the data and perceived intangible benefits, the MCO concluded that antibiotics should be included only in a generic drug sampling program whose primary objective is the promotion of generic drug samples for the treatment of chronic conditions. The dispensing of samples for the treatment of short-term (i.e., less than 1 month) conditions with no anticipated additional treatment is not supported by substantial positive cost outcomes data and appears to have a limited impact on prescribing practices but may provide intangible benefits as a value-added service when part of a larger program. At the time of this writing, the antibiotic samples continue to be part of the kiosk-based generic drug sampling program to help maintain a broad approach to generic sampling and to complement the academic detailing interventions performed by the MCO.

The addition of full-course antibiotic therapies to a generic drug sampling program represents one type of intervention that a health plan can undertake to affect a change in antibiotic prescribing practices, and it is likely that a multimodal approach would be the most effective means of promoting appropriate antibiotic prescribing. Physician education, member communications, incentive-laden tiered formulary benefit structures, pay-for-performance initiatives, and other interventions, such as a kiosk-based generic drug sampling program have the potential to provide incremental benefits when combined.

Limitations
The foremost limitation of this research was that it was a practical business application and not subjected to scientifically rigorous methods such as the use of randomization or a matched comparison group. The prescribers that comprised the intervention group in the present study were targeted specifically by the investigators or volunteered to participate in the program and were not meant to be a representative sample of the MCO’s network physicians. As such, the kiosk prescribers are likely to be more engaged in understanding their prescribing practices or motivated to dispense generics (or first-line antibiotics) than their nonkiosk counterparts. Additionally, the generalizability of the study results to populations outside of the specific MCO is limited. Regional prescribing practices may further limit generalizability of the study.

Second, this intervention involved more than the generic drug sampling program, and the contribution of an academic detailing service confounds the results in a manner that we cannot determine. However, approximately 40% of the prescribers not participating in the generic sampling program received the same academic detailing service. Still, there may be a confounding effect in comparing the intervention group and the comparison group, since academic detailing was not uniformly performed among all nonparticipants.

Third, other confounding variables must be taken into account when interpreting the results of the study. Market changes that are largely outside the control of the investigators or the MCO may affect the impact of a health care business initiative. Such changes include the publication of new scientific evidence or professional
guidelines that advocate for specific clinical practices, increased community awareness through the media, or other local public health initiatives. However, the authors did not identify a specific factor that affected kiosk prescribers more or less than their non-kiosk network counterparts.

The impact of the kiosk intervention on medical utilization patterns such as revisit rates or emergency department visits was not addressed. However, since clinically significant differences in study outcomes were not found between the study groups, it would be unlikely that the groups would exhibit significant medical utilization pattern differences that could be attributed directly to the kiosk intervention. Finally, per-member and per-patient antibiotic utilization rates were not evaluated. Future research should examine the complex relationship of antibiotic use and disease-specific medical resource utilization, including the possibility that increased access to low-cost antibiotics increases utilization of antibiotics.

Conclusions

Study findings suggest that a generic drug sampling program should not be limited exclusively to short-term medications such as antibiotics due to a lack of substantial positive cost outcomes data. The return on investment from a generic drug sampling program lies in savings accrued by promoting the use of generic medications to treat chronic disease states. The long-term benefits of dispensing generic medications, such as first-line antibiotics, for short-term use are difficult to quantify. However, a generic sampling program for short-term use medications may be an effective part of a program whose primary purpose is to promote generic prescribing for all drugs.

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DISCLOSURES

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Study concept and design were primarily the work of Culley, with input from Conklin and O’Donnell. Data collection was performed by O’Donnell with assistance from Conklin. Conklin interpreted the data with the assistance of Culley and O’Donnell, and wrote the manuscript with the assistance of Culley. Revision of the manuscript was shared equally by Conklin and Culley.

REFERENCES

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