Behind-the-Counter Statins: A Silver Bullet for Reducing Costs and Increasing Access?

Neeraj Sood, Eric Sun, and Xiaohui Zhuo

Objective. To examine how the 2004 introduction of behind-the-counter (BTC) simvastatin in the United Kingdom affected utilization, prices, and expenditures.

Data Sources/Study Setting. Secondary data on simvastatin utilization, prices, and expenditures between 1997 and 2007 in the United Kingdom and four other countries.

Study Design. We used a difference-in-differences approach to estimate how the introduction of BTC simvastatin affected utilization, prices, and expenditures. This approach compares outcomes in the United Kingdom before and after the introduction of BTC simvastatin, using outcomes in countries where the drug remained prescription only to control for possible confounders.

Data Collection/Extraction Methods. Data on simvastatin utilization, prices, and expenditures between 1997 and 2007 in the United Kingdom and four other countries were obtained from an outside vendor.

Principal Findings. The introduction of BTC simvastatin in the United Kingdom led to a significant increase in utilization of simvastatin and a significant decline in expenditures for simvastatin purchases. Our results are robust to alternate model specifications.

Conclusions. Behind-the-counter statins have the potential to simultaneously increase use of statins and lower expenditures.

Key Words. Simvastatin, United Kingdom, behind-the-counter drugs

Finding ways to improve access to pharmaceuticals has received much attention from policy makers and researchers, with significant effort being devoted toward examining how financial barriers such as insurance status and cost-sharing affect access, health, and medical costs (for a review, see Goldman, Joyce, and Zheng 2007). However, besides financial barriers, patients must contend with other obstacles to access, such as regulatory barriers. For example, in the United States, the vast majority of drugs are available only with a physician's prescription. By contrast, patients may freely purchase

over-the-counter (OTC) drugs from many outlets such as pharmacies and grocery stores.

The requirement for a physician's prescription has many potential benefits. Fundamentally, it places their use under the supervision of a physician, which may prevent misuse of prescription drugs and reduce the potential for adverse events. Indeed, the notion that many drugs cannot be used safely in the absence of physician supervision is why many countries require prescriptions to begin with. However, a prescription also imposes additional time and monetary costs on the patient, such as the direct costs of an office visit as well as transportation costs, which may reduce access to potentially beneficial therapies. As a result, many countries have implemented a third category, called behind-the-counter (BTC) drugs. Like their OTC counterparts, BTC drugs can be purchased in pharmacies without a physician's prescription. However, unlike OTC drugs, these drugs are not freely available on the pharmacy's shelves. Rather, a patient can only obtain the drug upon consultation with a pharmacist. Thus, in theory, placing a drug on BTC status allows for freer access while ensuring supervision over its use from a health care professional.¹

By eliminating the time and expense of acquiring a physician's prescription, moving a prescription drug to BTC status could improve patient health by increasing access to beneficial therapies, particularly to the degree that pharmacists can provide adequate supervision and monitoring. And indeed, given their extensive training in management of drug therapy, there is good reason to believe that pharmacists can provide adequate supervision. Several observational studies and randomized clinical trials document that pharmacists can play an important role in medication management, especially for chronic conditions such as hyperlipidemia (high cholesterol and triglycerides), hypertension, and diabetes (Tsuyuki, Johnson, and Teo 2002; Cranor, Bunting, and Christensen 2003; McConnell et al. 2006). For example, a randomized controlled trial found that increased supervision by community pharmacists can significantly improve cholesterol management in patients with high risk of cardiovascular disease (Tsuyuki, Johnson, and Teo 2002).

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Similarly, the economic effects of switching a drug to BTC are complex. As discussed earlier, BTC status will likely increase utilization and drug expenditures by removing the time and expense of receiving a prescription. These demand effects would likely be more pronounced for consumers who have easy access to grocery stores and other retail outlets that sell BTC products but not prescription drugs. However, BTC status might prompt insurers to drop coverage or increase co-pays for these drugs, in part because they might find it difficult to control utilization of drugs that are available without a prescription. Therefore, while BTC drugs may reduce expenditures for insurers, they have the potential to reduce access by increasing the prices patients pay. For example, when loratidine switched from prescription-only to OTC status, insurers chose not to cover the drug and as a consequence patients paid more for the drug, because its OTC price was higher than their co-payments for the drug (Freudenheim 2003). However, after a few years due to increased market competition from generics, the price of loratidine fell to the extent that it was lower than the copayment insured patients would have paid for the drug (Sullivan 2005). Finally, in addition to changes in prices for consumers, BTC status might also influence the level and type of marketing, consequently affecting utilization of drugs. In summary, it is difficult to predict *a priori* how BTC drugs would affect utilization, expenditures, and patient health. The scant literature to date uses a pre- to post-BTC introduction design and finds little effect of BTC status on utilization in the case of H₂ receptor antagonists (Furler et al. 2002) and proton pump inhibitors (Dhippayom and Walker 2006).

On May 12, 2004, the United Kingdom allowed the BTC purchase of low dose (10 mg) simvastatin (Nash and Nash 2004) for patients at moderate risk for coronary heart disease, for whom prescription strength statins were not indicated. The introduction of BTC simvastatin in the United Kingdom is particularly interesting for several reasons. First, statins are a widely used class of drug with important clinical benefits (Kapur and Musunuru 2008). Second, the introduction of BTC simvastatin was not without controversy, with an editorial in *The Lancet* criticizing the policy on clinical grounds and arguing that the introduction of BTC simvastatin was mainly done in order to shift costs from public payers to patients ("OTC Statins..." 2004). Finally, the United Kingdom became the first country to introduce BTC simvastatin, which is notable given that prior efforts to introduce OTC versions of low-dose pravastatin and lovastatin in the United States failed secondary to the FDA's concerns about the efficacy and safety of these drugs in an OTC setting.

In this article, we provide a first step toward examining the welfare effects of BTC simvastatin by examining how its introduction affected sales, prices,

and utilization. Our analysis builds on prior work by Filion et al. (2007), who find the utilization of prescription statins fell following the introduction of BTC simvastatin. However, the authors focus only on *prescriptions* for statins and do not address the issue of whether increases in the utilization of BTC statins outweighed any drop in prescriptions. We consider the effect of BTC simvastatin on total utilization of prescription and nonprescription statins, as well as additional outcomes, such as expenditures and price. Moreover, the analysis by Filion et al. (2007) is primarily a comparison of outcomes before and after the switch and is potentially vulnerable to bias from unobserved factors that might affect statin utilization. By contrast, we use a difference-in-differences (DD) approach, utilizing the sales experience of simvastatin in countries where the drug remained prescription only, to control for these unobserved factors. In addition, we utilize additional controls for other market factors, such as the introduction of generics. Our results suggest that the introduction of BTC significantly increased utilization reduced drug expenditures. At a first glance, then, our results suggest that the introduction of BTC simvastatin was successful in both increasing access and lowering expenditures.

This article is outlined as follows. The next section presents our data and methods, and the following section presents the results. We conclude with a discussion of results.

DATA AND METHODS

Data

We examined the effect of BTC simvastatin on sales, utilization, and prices using annual data on sales, utilization, and prices obtained from IMS Health, Inc. (Norwalk, CT, USA). Our data are from the MIDAS database and provide expenditures and utilization (quantities) through retail and hospital channels. Using these data, we calculated the price as revenue divided by quantity. Our data span the time period from 1997 to 2007 and include outcomes for the United Kingdom, the United States, Canada, Australia, and New Zealand. A descriptive snapshot of the data for three study years is provided in Appendix A1 (section B).

Methods

We use a DD approach to estimate the effect of BTC conversion of simvastatin in the United Kingdom on the three outcomes of interest—utilization,

expenditures, and prices. Our treatment group is the experience of simvastatin in the United Kingdom, where the drug was switched to BTC status in 2004, while the control group is the experience of simvastatin in the remaining countries in our sample (the United States, Canada, Australia, and New Zealand), where the drug remained prescription only. The DD approach essentially uses the experience of simvastatin in control countries to predict the counterfactual in the treatment country: what would have happened to simvastatin utilization and expenditures in the United Kingdom if simvastatin did not convert to BTC status. The model also controls for difference in timing of patent expiration of simvastatin in the treatment and control countries. Patent expiration and the introduction of generics is an important confounder as simvastatin's switch to BTC status in 2004 was immediately preceded by the introduction of generic versions of the drug in the second quarter of 2003. In control countries patent expiration and introduction of generics happened in later years, with the simvastatin patent expiring in 2004 in Canada and 2006 in the United States. We implement the difference in difference approach using the following model:

$$\text{Log}(\text{Outcome}_{it}) = \alpha + \beta_1 \text{BTC}_{it} + \beta_2 \text{OffPatent}_{it} + c_i + \tau_t + \epsilon_{it} \quad (1)$$

where outcome_{it} represents one of our outcomes (utilization, expenditures, or prices) for simvastatin in country i at time t . c_i is a country fixed effect and controls for all time invariant differences in pharmaceutical markets across countries. τ_t is a year fixed effect and controls for secular time trends or time varying factors common across all countries. BTC_{it} is a dummy variable which equals 1 in each year in the United Kingdom after the drug was switched to BTC status and 0 otherwise. OffPatent_{it} is a dummy variable which equals 1 in each year in each country when the drug was off patent and faced generic competition. β_1 is our parameter of interest and represents the effect of BTC switches on drug sales, prices, and expenditures.

Robustness Analyses

A crucial assumption of our approach is that simvastatin outcomes in the control countries provide a useful estimate of what simvastatin outcomes in United Kingdom would have been in the absence of a switch. This assumption will not hold if it is the case that drug sales, prices, and expenditures across countries are generally uncorrelated over time. One way of addressing this possibility, which we consider, is to examine if outcome trends in the treatment and

control groups appear similar prior to switch. We do so and discuss our findings in the Results section. Another approach is to examine the robustness of our results to inclusion of a richer set of covariates. We estimate two such alternate models. In the first set of alternate models, we test the sensitivity of our results by including a series of dummy variables that control for changes in outcomes over the lifecycle of the drug. In particular, we include the following indicator variables for different periods of the life cycle of simvastatin: (1) 0 or 1 year after patent expiration, (2) 2 or more years after patent expiration, (3) 1 or 2 years before patent expiration, and (4) 3 or 4 years before patent expiration. The reference group is more than 4 years before patent expiration.

$$\begin{aligned} \text{Log}(\text{Outcome}_{it}) = & \alpha + \beta_1 \text{BTC}_{it} + \beta_2 \text{After01}_{it} + \beta_3 \text{After2}_{it} + \beta_4 \text{Before12}_{it} \\ & + \beta_5 \text{Before34}_{it} + c_i + \tau_t + \epsilon_{it} \end{aligned} \quad (2)$$

In the second set of alternate models, to account for any residual confounding, we include country-specific linear time trends in addition to the above covariates to control for preexisting differences in trends.

$$\begin{aligned} \text{Log}(\text{Outcome}_{it}) = & \alpha + \beta_1 \text{BTC}_{it} + \beta_2 \text{After01}_{it} + \beta_3 \text{After2}_{it} + \beta_4 \text{Before12}_{it} \\ & + \beta_5 \text{Before34}_{it} + c_i + \tau_t + c_i * t + \epsilon_{it} \end{aligned} \quad (3)$$

We also conduct sensitivity tests to check if our results are being driven by the inclusion of specific countries in the analysis. In particular, we reestimate our empirical models by dropping one control country at a time and check whether the results are statistically different than the results from models that include all control countries. Finally, to investigate potential bias due to misclassification of BTC status, we investigate the change in our results across two specifications: (1) 2004 is treated as pre-BTC introduction year (base specification) and (2) 2004 is treated as post-BTC introduction year.

RESULTS

Overall Trends in Simvastatin Utilization, Prices, and Expenditures

As a first step, we examine the plausibility of our empirical approach by comparing outcomes in our treatment and control groups in the preswitch periods. Figure 1 plots the level of utilization, expenditures, and prices relative to their 1997 levels for the treatment group (the United Kingdom) and

Figure 1: Simvastatin Utilization, Prices, and Expenditures, 1997–2007

the control group (the United States, Canada, New Zealand, and Canada) For the non-U.K. countries, we graph the utilization-weighted average for each outcome across all countries. In the case of expenditures and prices, it is encouraging to note that trends in the treatment and control groups closely mirror each other prior to 2004 and diverge afterward. With utilization, sales in the United Kingdom closely mirrored sales in the control countries until roughly 2002, when the trends diverged slightly most likely due to patent expiration of simvastatin in the United Kingdom; however, it is interesting to note that after 2004, sales of simvastatin in the United Kingdom increased sharply, in contrast to the control countries, which saw a smoother increase over this time. Overall, Figure 1 supports the validity of our DD approach by suggesting that simvastatin utilization, prices, and expenditures followed similar trends in the United Kingdom and in the control countries prior to its 2004 switch to BTC status.

Difference-in-Differences Estimates

Table 1 presents the effects of introducing BTC simvastatin on simvastatin utilization in the United Kingdom. Specifically, Table 1 presents our estimates of β_1 from equations (1–3) above. We find our coefficient estimates

Table 1: Effect of Introducing BTC Simvastatin on Utilization

	<i>Model 1</i>	<i>Model 2</i>	<i>Model 3</i>
Estimated effect	0.518* (0.228)	0.779* (0.331)	0.555* (0.204)
<i>N</i>	55	55	55
<i>R</i> ²	0.927	0.929	0.988

Notes. This table shows the estimated effect of introducing behind-the-counter (BTC) simvastatin in the United Kingdom on drug utilization. The full regression model result is provided in Table A1 (Appendix A1). The dependent variable is log(units sold). Covariates in model 1 include a dummy variable for patent expiration, country fixed effects, and time fixed effects. Model 2 adds a series of dummy variables for 0–1 years after patent expiration, 2 or more years after patent expiration, 1–2 years before patent expiration, and 3–4 years before patent expiration. Model 3 adds country specific linear time trends to model 2. Robust standard errors shown in parentheses.

* $p < .05$.

** $p < .10$.

of the utilization effects of BTC simvastatin are robust to alternate model specifications. The results from model 1 show that the introduction of BTC simvastatin increased utilization of simvastatin by 64 percent ($p < .05$).² Similarly, results from model 2 suggest that the introduction of BTC simvastatin approximately doubled simvastatin utilization. Even though the point estimates from model 2 are somewhat larger, they are not statistically different from the point estimates from models 1 and 3. It is also important to note that our data do not distinguish between the 10 mg strength of simvastatin which switched to BTC status and other strengths that remained prescription only. In spite of the fact that the 10 mg strength simvastatin and prescription-only simvastatin are indicated for patients with different risks of cardiac disease, it is still possible that sales of prescription-only simvastatin strengths declined with the introduction of BTC 10 mg simvastatin. Our estimates capture the net effect of change in BTC status on overall simvastatin utilization and suggest that the increase in utilization of the 10 mg strength more than offset any decline in utilization of other strengths.

Table 2 presents the effects of introducing BTC simvastatin on simvastatin expenditures in the United Kingdom. As before, Table 2 presents our estimates of β_1 from equations (1–3) above with log of expenditures on simvastatin as the dependent variable. The results suggest that introduction of BTC simvastatin significantly reduced expenditures on simvastatin. The estimates from model 1 indicate that the introduction of BTC simvastatin reduced expenditures on simvastatin by 61 percent ($p < .05$). Similarly, results from models 2 and 3 suggest that the introduction of BTC simvastatin

Table 2: Effect of Introducing BTC Simvastatin on Expenditures

	<i>Model 1</i>	<i>Model 2</i>	<i>Model 3</i>
Estimated effect	−0.925* (0.197)	−0.724* (0.281)	−1.104* (0.252)
<i>N</i>	55	55	55
<i>R</i> ²	0.972	0.973	0.988

Notes. Table 1 shows the estimated effect of introducing behind-the-counter (BTC) simvastatin in the United Kingdom on drug utilization. The full regression model result is provided in Table A2 (Appendix A1). The dependent variable is log(expenditure). Covariates in model 1 include a dummy variable for patent expiration, country fixed effects, and time fixed effects. Model 2 adds a series of dummy variables for 0–1 years after patent expiration, 2 or more years after patent expiration, 1–2 years before patent expiration, and 3–4 years before patent expiration. Model 3 adds country-specific linear time trends to model 2. Robust standard errors shown in parentheses.

**p* < .05.

***p* < .10.

decreased expenditures on simvastatin by 53 and 68 percent, respectively. These point estimates from different models are not statistically different and show that our estimates of the effect of BTC simvastatin on expenditures are fairly robust across alternate model specifications.

Juxtaposing the results from Tables 1 and 2 suggests that the introduction of BTC simvastatin simultaneously increased utilization and decreased expenditures on simvastatin. This implies that the introduction of BTC simvastatin must have significantly lowered the cost of a unit of simvastatin (price). Table 3 presents the results from empirical models for this outcome. Again, the results are insensitive to model specification. The results from model 1 suggest that the introduction of BTC simvastatin reduced prices by

Table 3: Effect of Introducing BTC Simvastatin on Expenditures per Unit (Price)

	<i>Model 1</i>	<i>Model 2</i>	<i>Model 3</i>
Estimated effect	−1.442* (0.202)	−1.503* (0.207)	−1.659* (0.277)
<i>N</i>	55	55	55
<i>R</i> ²	0.849	0.852	0.950

Notes. Table 1 shows the estimated effect of introducing behind-the-counter (BTC) simvastatin in the United Kingdom on drug utilization. The full regression model result is provided in Table A3 (Appendix A1). The dependent variable is log(expenditure). Covariates in model 1 include a dummy variable for patent expiration, country fixed effects, and time fixed effects. Model 2 adds a series of dummy variables for 0–1 years after patent expiration, 2 or more years after patent expiration, 1–2 years before patent expiration, and 3–4 years before patent expiration. Model 3 adds country-specific linear time trends to model 2. Robust standard errors shown in parentheses.

**p* < .05.

***p* < .10.

77 percent. Similarly, the results from model 3 suggest that prices declined by about 82 percent after the introduction of BTC simvastatin. As discussed earlier, our data do not distinguish between the 10 mg strength of simvastatin and other strengths. In particular, these price effects reflect changes in the price of simvastatin averaged across all strengths, and therefore they could reflect changes in strengths of simvastatin sold after the introduction of BTC simvastatin, notably the significant increase in sales of the 10 mg strength of simvastatin.

To address concerns that our results are being driven by inclusion of a specific country in the control group, we estimate alternate models that exclude each control country one at a time from the analysis. None of the coefficients in these alternate models are statistically different from the baseline model with all control countries included. For example, the coefficient on BTC with $\log(\text{price})$ as the outcome variable and BTC, patent expiration, year fixed effects, and country fixed effects range from -1.33 (when Australia is excluded) to -1.57 (when New Zealand is excluded). The coefficient on BTC when all control countries are included is -1.44 as reported in model 1 in Table 3.

Finally, we also investigated whether classifying the 2004 as pre- or post-BTC introduction year affected our results. We found that the utilization, price and expenditure effects of BTC introduction were somewhat smaller when we classified 2004 as a post-BTC introduction year, but the change is not statistically significant.

DISCUSSION

In this study, we analyzed how the introduction of BTC simvastatin affected utilization, expenditures, and prices. Using a DD approach to control for potential confounders, we find that BTC simvastatin significantly increased overall simvastatin utilization. We also find that BTC simvastatin significantly reduced expenditures. The quality of our results depends on the feasibility of our DD approach, and in particular, whether trends in simvastatin prices, sales, and expenditures in countries where it remained prescription only serve as useful indicators of what outcomes in the United Kingdom would have been if simvastatin had remained prescription only. To address this issue, we examined utilization, price, and expenditure trends prior to the introduction of BTC simvastatin in 2004 and found that these trends were similar in the United Kingdom and in other countries. Moreover, our results

are robust to alternative specifications that take into account changes in outcomes over the life cycle of drugs and that allow for country-specific linear trends.

The results of this study should be viewed in light of its limitations. First, the conversion of simvastatin to BTC status in the United Kingdom occurred about a year after generic entry of simvastatin. However, since simvastatin went off patent in our control countries in different years (United States 2006, Canada 2004, Australia 2005, and New Zealand 2005) during our study period we use data from these countries to isolate the effect of patent expiration. In other words, we use the experience in other countries with patent expiration to create the counterfactual of what would have happened to simvastatin sales and prices in the United Kingdom if simvastatin lost patent protection but did not switch to BTC status. We would overstate the effects of BTC status to the extent that generic competition in United Kingdom was stronger than generic competition in our control countries.

Second, it is important to note that our data do not distinguish between the different strengths of simvastatin. Therefore, we can only estimate the effect of BTC status on overall simvastatin utilization and expenditures. We cannot isolate effects for the 10 mg strength that switched to BTC status or estimate the degree to which BTC status caused a substitution from higher strength prescription statins to lower strength BTC statins. Nonetheless, these effects are interesting and policy relevant as they suggest that the increase in utilization of 10 mg simvastatin dominated any decline in utilization of prescription-only simvastatin. Third, the drug sales do not include any rebates from manufacturers to insurers, which are common for prescription drugs but are unlikely to occur with BTC drugs. Therefore, our results may overstate the potential price effects. Finally, a full analysis of the costs and benefits of BTC drugs should also consider the potential health effects and effects on physician visits, which presents a useful subject for further research.

These results suggest that the introduction of BTC statins in the United States, especially the 10 mg strength, could increase overall statin utilization. In the United States, these effects could be quite large. For example, one study estimates that nearly 44 percent of eligible patients do not receive statin therapy (Mitka 2003). Moreover, since statins account for a large amount of expenditures—\$19.7 billion in 2005 (Stagnitti 2008)—the introduction of BTC statins, especially the lower strength form, could also significantly reduce expenditures. In addition to spending on statins directly, BTC statins could also reduce expenditures on physician office visits. Using the National

Ambulatory Medical Care Survey, a nationally representative sample of office visits, we estimated the number of physician office visits where a statin was prescribed, either as an initial prescription or as a renewal. Our estimates suggest that between 2000 and 2005, there were roughly 78 million office visits in which a prescription for simvastatin was written, and roughly 295 million office visits in which a prescription for any statin was written. Thus, with an average price of \$155 and a median price of \$72 per office visit (Machin and Carper 2007), the introduction of BTC statins has the potential to save hundreds of millions of dollars annually. In sum, our analysis finds the introduction of BTC statins dramatically increased utilization and reduced expenditures in the United Kingdom. If these effects were to carry over to the United States, the potential for savings could be tremendous. To the degree that increased statin utilization is appropriate and addresses underutilization of statins rather than substitution from higher strength prescription-only version to lower strength BTC version, our results suggest that BTC statins could reduce expenditures while improving health. On the other hand, if increases in utilization are inappropriate, for example, increased use by persons with no cardiovascular risk factors, the introduction of BTC statins could make patients worse off, even if expenditures fall. Future research should examine the potential health effects of introducing BTC statins.

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NOTES

1. In the United Kingdom, BTC drugs are known as Pharmacy Only (P) drugs, in contrast to General Sales List (OTC) and Prescription-Only (prescription medications), whereas in Australia, New Zealand, and Canada, BTC drug are known as schedule 3 drugs, in contrast to schedule 2 (prescription) and unscheduled (OTC) drugs.

2. We convert the estimates in Table 1 into percentage changes in outcomes using the method outlined in Kennedy (1981).

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Appendix A1: Descriptive Statistics.

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