

The Sustainability Of Healthcare Systems:

A Summary Of Existing Economic Evidence



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EXECUTIVE SUMMARY

Self-medication involves the use of nonprescription products to treat common health conditions or symptoms without the need for medical supervision. As populations are growing older and healthcare costs have continued to escalate in many countries, the need for accessible and affordable healthcare solutions is now more important than ever. Increasing access and availability to nonprescription products enables patients to take control of their health, and it reduces the need for costly medical services. The purpose of this report was to identify methodologies applied to determine the economic value of nonprescription medicines for conditions amenable to self-medication.

Two main study designs are commonly used. Multiple studies grouped conditions together in their analyses, while others involved a more targeted analysis of singular conditions/symptoms or type of self-medication (e.g. oral contraceptives).

These studies showed that the use of nonprescription products alone or in combination with prescription drugs for the treatment of various conditions resulted in an overall cost savings to the healthcare system and consumers. Furthermore, self-medication can deliver a reduction in work impairment or healthcare resource utilization, such as physician visits, thus freeing up time for more urgent or serious conditions. Several models estimated the impact of switching prescription drugs to nonprescription status, as well as the cost increments associated with reclassifying nonprescription medicines to prescription drug status.

Both approaches showed a significant cost-benefit associated with more medications having nonprescription status. By demonstrating these benefits, it is clear that nonprescription products easily provide a cost beneficial treatment option.

LIST OF ABBREVIATION

| | |
|----------------|--|
| CAD | Canadian Dollar |
| CVD | Cardiovascular Disease |
| CWHP | Center for Workforce Health Performance |
| DXM | Dextromethorphan |
| EC | Emergency Contraceptive |
| EU | European Union |
| FCHP | Fallon Community Health Plan |
| FDA | Food and Drug Administration |
| GP | General Practitioner |
| HCRU | Healthcare Resource Use |
| IMS | Intercontinental Marketing Services |
| MUCHE | Macquarie University Centre for Health Economy |
| NHWS | National Health and Wellness Survey |
| NA | Non-Sedating Antihistamines |
| OTC | Over-The-Counter |
| Omega EPA +DHA | Omega 3 Eicosapentaenoic Acid and Docosahexaenoic Acid |
| SF-36 | Short Form Health Survey 36 |
| SGA | Second Generation Antihistamines |
| SPS | Standard Presenteeism Scale |
| SSN | Sistema Sanitario Nazionale |
| UK | United Kingdom |
| US | United States |
| WLQ | Work Limitation Questionnaire |

INTRODUCTION

Self-medication is the use of nonprescription products to manage symptoms and treat health conditions without medical supervision or prescription. Examples of conditions and symptoms suitable for self-medication include pain, nausea, allergies, skin conditions, fungal infections, fever, and other respiratory conditions. Throughout the literature, a number of terms are used when referring to conditions and symptoms that can be treated by patients without supervision by a physician. For the purposes of this report, self-medication will be used to describe the class of products being examined.

The benefits of self-medication are substantial, but we will focus on two major themes:

1. Improved patient access
2. Reductions in cost associated with resource use, medication costs, and productivity. Patient access to healthcare, whether it be to healthcare professional services or pharmaceuticals, has consistently been shown to improve outcomes. Self-medication encompasses the broadest form of access with the ability of patients to obtain medications with limited or no requirements for involving a physician. With this increased access comes the benefit of shared decision making between patients and healthcare professionals. Patients are empowered to learn about what is available and either treat themselves or, if they have questions, bring those questions to a physician or pharmacist for advice.

As the world's population ages, healthcare systems are becoming more concerned with cost containment (Deloitte, 2016). Self-medication reduces the need for visits to the doctor's office, thereby off-setting physician time directed to more urgent or severe cases. In systems where there is a backlog for physician visits and procedures, self-medication allows for many conditions to be addressed without time spent in a formal healthcare setting. Physician visits avoided can also benefit the patient and the broader economy in terms of cost, time and productivity. The cost of physician visits may be borne by the patient or the public healthcare system. Even when there is no payment by the patient there is certainly opportunity cost associated with traveling to a clinic and potentially missing work.

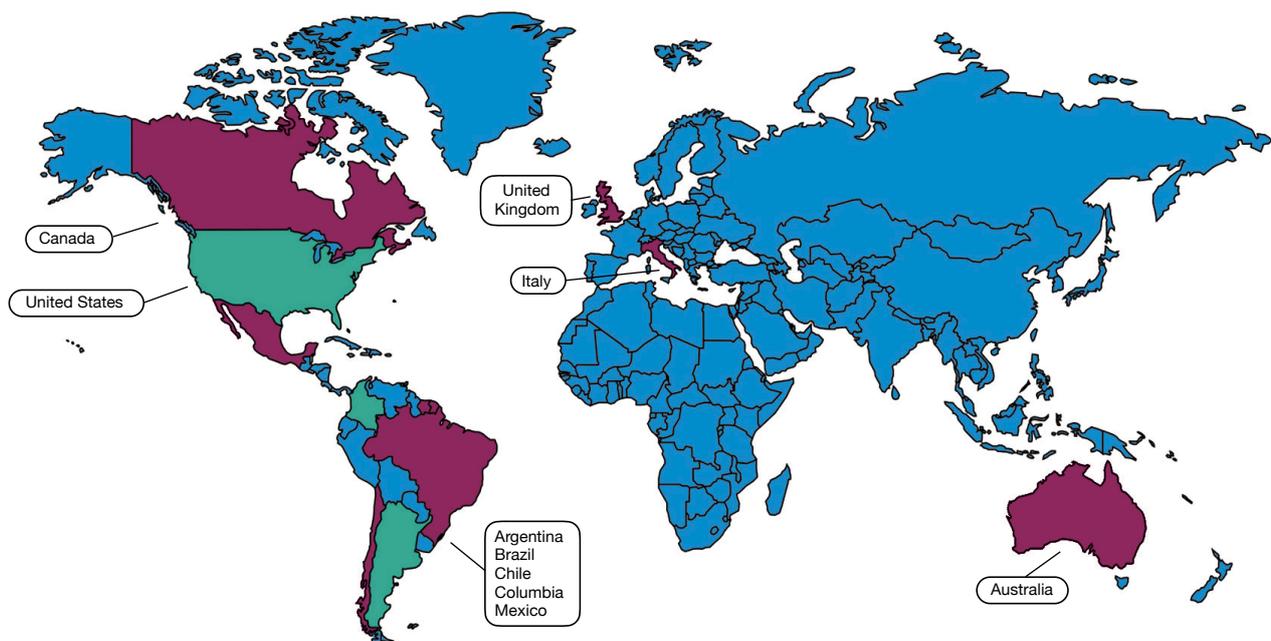
In spite of all the evidence demonstrating the economic benefits of self-medication, it is still not used to the extent possible. There remains debate regarding which compounds should be available, how accessible these products should be, and the exact cost savings associated with self-medication.



METHODS AND MODELS

Literature describing the economics of self-medication from countries around the world has been reviewed. This process included reviews of published research, white papers, and unpublished research studies that were received from members of the Global Self-Care Federation (GSCF) across various countries to illustrate research their organizations have developed. In addition, standard professional publication search methods were used to identify articles, and included searches of Pubmed.gov, EBSCOhost, and Google Scholar. Each of the selected articles were reviewed in a three-step selection process including title, abstract, and finally, full article review.

SELF-CARE ECONOMIC STUDIES SYSTEM BASED



To present such a broad array of information in a cohesive manner, the articles have been organized into research design types and specific conditions suitable for self-medication that fell within them.

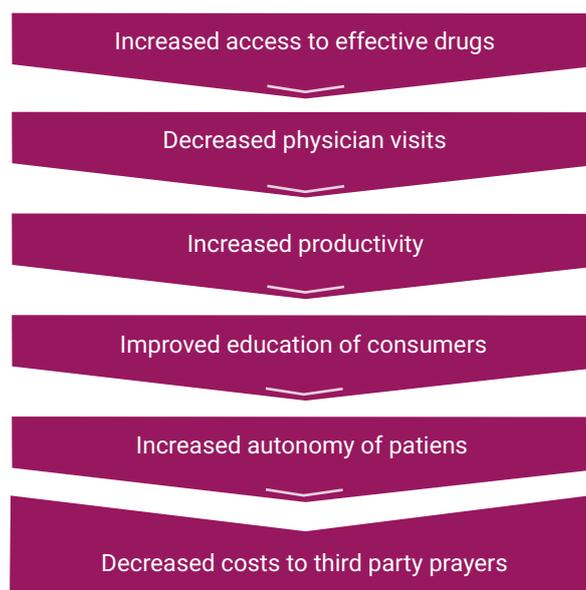
Models represent an estimation of what will happen in the future after

1. Some change is implemented or
2. A past change where specific data is unavailable. In most of the cases discussed here, a model is being used to predict the financial and healthcare services shift that will occur with a prescription becoming nonprescription or vice versa. Studies reviewed in this paper fall into two categories. First, there are studies that examine multiple switches and focus on the total value of these broader data sets. Second, and more common, are those studies that look at specific category or product switches and the economic value of making these changes in status.

MULTIPLE CLASS STUDIES

Several studies have looked at the economic effect of moving prescription drugs to nonprescription status (Rx-OTC switch). The main benefits measured in most of these cases are laid out in Figure 1. In a systematic review of research on the value of selfcare products, Cohen and his colleagues concluded that “switches may produce cost savings to public and private payers” (Cohen, Millier, Karry, & Toumi, 2013). Their review included many of the citations found in this paper and their conclusions are borne out in the following cases.

FIGURE 1: POTENTIAL BENEFITS OF SWITCHING PRESCRIPTION DRUGS TO NONPRESCRIPTION STATUS

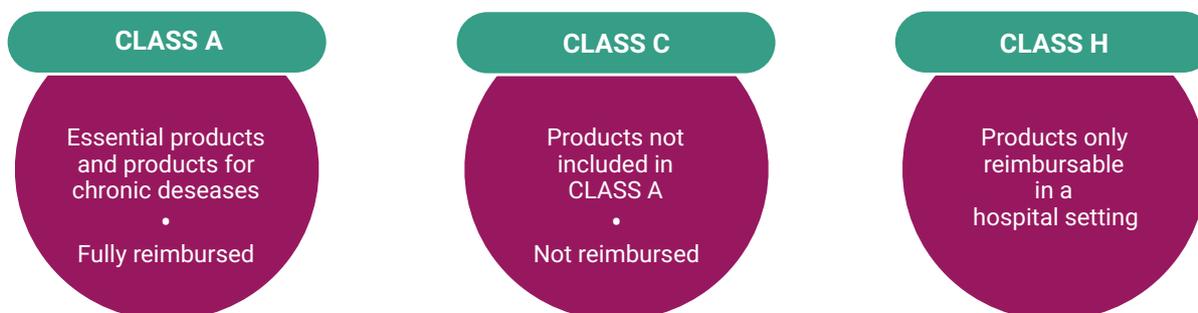


Retrospective research is often used to capture the impact of a change after that change has occurred. Retrospective data is commonly placed into categories of medical records, claims, registries, sales, and surveys. Each of these categories may exist independently or overlap (i.e. a registry may include a survey) in a given locality depending on how the data is compiled. Many of the studies reported herein utilize the retrospective methodology.

ITALY

Jommi et al (2008) studied two scenarios in Italy where a proportion of compounds from drug categories A (reimbursed) and C (not reimbursed, Figure 2) are reclassified to nonprescription status and the other, demonstrating a hypothetical scenario if all regions used self-medication medicines in a fashion closer to the national average. For scenario one, compounds used for the treatment of mild respiratory disorders, digestive disorders, and pain were reclassified as nonprescription medicines. Under this assumption, Italy's national healthcare service, the Sistema Sanitario Nazionale (SSN) would save approximately €49 million in one year. Some cost would be moved from the SSN to the city municipalities, but even including this cost, the total savings for the nation would be approximately €50 million. For the regional analysis, if nonprescription products were used in all regions exactly like the national average scenario, the healthcare system would save between €223 and €255 million. This regional difference is in large part attributed to limited nonprescription product use in the southern portion of Italy compared to that of the northern regions (Jommi, C; Otto, M; Vuolo, E, 2008).

FIGURE 2: PHARMACEUTICAL CLASSES IN ITALY



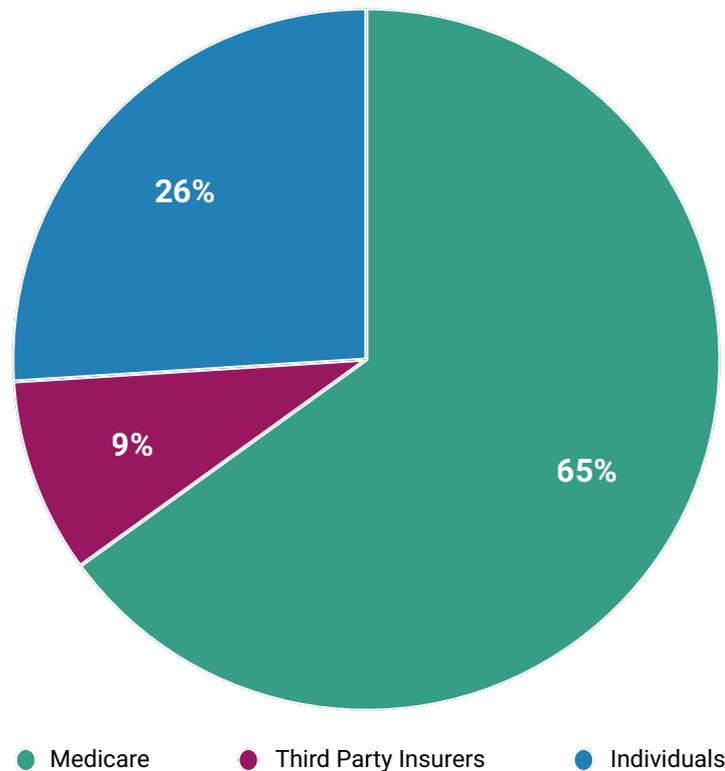
In a second study, Jommi et al (2010) focused solely on drugs treating mild respiratory diseases and digestive disorders calculating overall cost savings. The results of the study showed that the SSN would save approximately €16.6 million, but patients would spend an extra €11.76 million giving a net savings of €4.83 million. A major point of discussion following these results was the reduced price of compounds that have been reclassified to nonprescription status as well as the impact that shifting these compounds would have on other diseases. If these two factors are taken into account, the cost savings range from €40 to €110 million (Jommi, Otto, & Luca, 2010).

A further paper published by Otto et al (Otto, Pillarella, & Jommi, 2018) analysed the potential economic impact of switching drugs from prescription-only to over the counter status, using Italy as a case-study. These results showed that switching policy provided a societal savings ranging from 1 to 2.11 billion Euro.

AUSTRALIA

In an Australian study, the Macquarie University Centre for the Health Economy (MacQuarie University Centre for the Health Economy, 2014) demonstrated that in a hypothetical scenario of 8 categories of common self-medication medicines being switched to prescription status, 52-70% of respondents would choose to visit a doctor for their medication. Thus, it was estimated that this would cost \$3.8 billion in doctor's visits, of which Medicare would pay out an additional \$2.5 billion, health insurers \$360 million, and individuals \$1 billion (Figure 3). Conversely, in a separate scenario wherein 11 categories of common prescription drugs were switched to Schedule 3 (pharmacist only) status, Medicare would save \$730 million, health insurance \$110 million, and individuals \$300 million. Further supporting this evidence, was a report by Shanahan and Lorimier (2014), which showed that adoption of complementary medicine as a preventative regimen in osteoporosis, osteopenia, cardiovascular disease, age-related macular degeneration, and moderate major depression resulted in notable reductions in healthcare costs and improvements in productivity (Shanahan & de Lorimier, 2014).

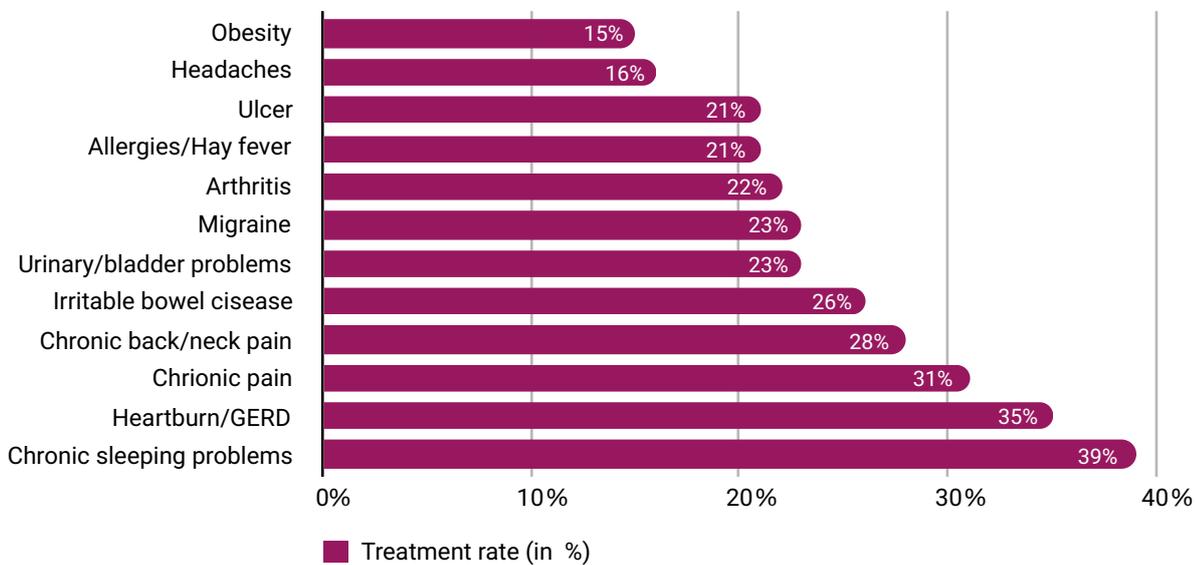
FIGURE 3. INCREASED COSTS ASSOCIATED WITH EIGHT CATEGORIES OF NONPRESCRIPTION MEDICATIONS BEING MOVED BACK TO PRESCRIPTION STATUS IN BILLIONS (AUSTRALIA)



UNITED STATES

In the United States, the Center for Workforce Health and Performance (Jinett, 2016) estimated absence, job performance, and lost productivity costs associated with 26 chronic conditions and symptoms by utilizing Integrated Benefits Institute’s Full Cost Estimator modeling tool. The Health and Performance Select database was used to evaluate self-reported prevalence and treatment rates for each of these conditions. It was estimated that chronic conditions account for approximately \$165 billion annually in lost-productivity costs in the US and only 28%, on average, of employee’s conditions are treated overall. Of the 26 conditions, 12 have an FDA-approved nonprescription drug available. Those 12 conditions have self-reported rates that range from 15-39% (Figure 4) and net lost-productivity costs that range from \$3.4 to \$44.9 billion (Table 1). The conditions associated with the highest net lost-productivity costs and lost work days included allergies/hay fever (\$44.9 billion, 130.9 days), chronic back/neck pain (\$42.4 billion, 128.1 days), and heartburn/GERD (\$30.5 billion, 92.6 days).

FIGURE 4: TREATMENT RATES FOR CONDITIONS WITH FDA-APPROVED NONPRESCRIPTION MEDICATIONS (US)



Taking a global look at the impacts of minor illness on work, data show that more than half of employees say their health issue have impacted their motivation to go to work, their concentration and their mood. These are impressive numbers and demonstrate the rather high impacts of both those present at work but less motivated and focused as well as the more severe absenteeism issue. (Sanofi, 2018).

Another U.S. study (Consumer Healthcare Products Association, 2019) conducted on the availability of OTC medicine to treat nine categories showed substantial value for the U.S. healthcare system, totaling approximately \$146 billion in savings per year from drug costs savings and clinical visit cost savings when compared to alternatives. Most of these savings were generated by OTC medicine value as a less expensive option compared to prescription medicines and an alternative to seeing a physician for mild conditions, creating \$52 billion and \$95 billion in savings respectively. Selfcare as examined in this study, increased treatment access to over 27 million consumers and reduced losses in productivity which created additional savings of approximately \$5 billion and \$34 billion respectively.

Collins and his colleagues (Collins, et al., 2005) assessed the impact of chronic health conditions on work performance, absence and total economic impact for employers through a two-part study. In part one, Dow Chemical Company full time employees completed an online health survey. Based on survey results from 7,797 respondents, the most frequently reported primary health conditions were allergies (18.9%), arthritis/joint pain or stiffness (9.0%), heart or circulatory problems (7.1%), and back/neck disorders (7.0%). Absenteeism and work impairment (in the past 4 weeks) varied from 0.9 to 5.9 hours and 17.8% to 36.4%, respectively. The second part of this study included a medical and pharmaceutical claims analysis of company records for demographics, job category, payroll absence data, plant location and annual health costs (sum of medical treatment costs, absenteeism costs, and presenteeism costs). Among those employees that reported at least one condition, having depression, anxiety or emotional disorders as a primary health condition had the highest total costs per worker per year (\$18,864 in 2002 USD), while allergies accounted for the lowest (\$6947 in 2002 USD). After weighting for survey prevalence of all conditions reported in the Dow survey, the average costs per employee amounted to \$6,721 from work impairment, \$2,278 for medical care, and \$661 from absenteeism (in 2002 USD).

**TABLE 1: ABSENTEEISM AND PRESENTEEISM COSTS BY CHRONIC CONDITION:
ESTIMATED COSTS FOR US WORKFORCE**

| CONDITION OR SYMPTOM | PERCENTAGE WITH CONDITION ^x | AVERAGE NUMBER OF OTHER CONDITIONS ^x | NET LOST WORKDAYS (ABSENCE + PRESENTEEISM) IN MILLIONS ^y | NET LOST-PRODUCTIVITY COSTS \$ BILLIONS ^y |
|---------------------------|--|---|---|--|
| Allergies/hay fever | 39.5% | 3.0 | 130.9 | \$44.9 |
| Chronic back/neck pain | 14.3% | 4.9 | 128.1 | \$42.4 |
| Heartburn/GERD | 13.6% | 4.6 | 92.6 | \$30.5 |
| Obesity | 11.1% | 4.6 | 92.1 | \$31.6 |
| Chronic sleeping problems | 6.5% | 5.7 | 89.8 | \$30.0 |
| Chronic pain | 5.6% | 6.1 | 60.6 | \$20.0 |
| Arthritis | 13.5% | 4.6 | 57.4 | \$19.7 |
| Irritable bowel disorder | 6.0% | 5.3 | 56.7 | \$18.9 |
| Headaches | 8.9% | 5.1 | 53.3 | \$19.1 |
| Migraine | 8.9% | 4.8 | 48.8 | \$16.7 |
| Urinary/bladder problems | 4% | 5.4 | 33.8 | \$11.2 |
| Ulcer | 2.0% | 6.0 | 9.9 | \$3.4 |

^x Among workers with condition ^y Compared with employees with condition

LATIN AMERICA

In a detailed analysis of five Latin American countries (Argentina, Brazil, Chile, Columbia and Mexico), the researchers discovered that there were significant cost savings for the formal healthcare system when OTC products are utilized for self-manageable conditions. These results are summarized in Table 2 (Buzzo & Mollinedo, 2019).

TABLE 2: HEALTHCARE SAVINGS FROM SELF-CARE

| COUNTRY | HEALTHCARE SAVINGS PER DOLLAR SPENT ON OTC MEDICINES |
|-----------|--|
| Argentina | \$7.6 |
| Brazil | \$2.0 (R) |
| Chile | \$2.2 |
| Columbia | \$3.9 |
| Mexico | \$10.5 |

EUROPEAN UNION

In a similar analysis, Pelise and Serra Reported that *“switching drugs for mild conditions may be a solution with positive societal net effects.”* Their research was based on testing the economic value from the shift of 5% of current prescription drugs to selfcare status over a five-year period. The valuation for this level of switch resulted in a 3.125 million Euros effect on healthcare costs that would be achieved by improving quality of primary health care (2.258 million Euros), improving labor productivity, reduction in productivity and a reduction of public expenditure on publicly reimbursed medication (Pellise & Serra, 2015).

UNITED KINGDOM

In the United Kingdom, estimates of the opportunity costs of failing to empower people to selfcare stretch up to £2.3bn (Proprietary Association of Great Britain, 2018). Looking at the costs of interactions with the health service (A&E attendances, GP appointments and prescriptions for over-the-counter medicines) that could reasonably be dealt with elsewhere, it is estimated that in total over £1.5bn could be saved each year and reinvested into the NHS if more people were empowered to take care of their own health and self-treat. In an earlier analysis carried out by IMS Health, it was estimated that primary self treatable conditions were responsible for 19.1% of attendances in England accounting for 3.7M attendances at a cost of £290M (IMS, 2015).

At a more local level savings can be significant as well. A UK study on the Greater Manchester area (Proprietary Association of Great Britain, 2019) found that 22 million pounds could be save annually from diverting emergency room visits for minor ailment to selfcare (16 million), cutting prescriptions for self-manageable illness (5 million) and redirecting help line calls to selfcare (1 million).

In the United Kingdom, a paper that examined the impact on physician visits for minor illness evidence suggested that significant amounts of people are attending GP appointments for self-treatable conditions. This was based on

a report from the IMS Health Disease Analyzer which broke out the number of general practice visits associated with conditions suitable for self-medication.

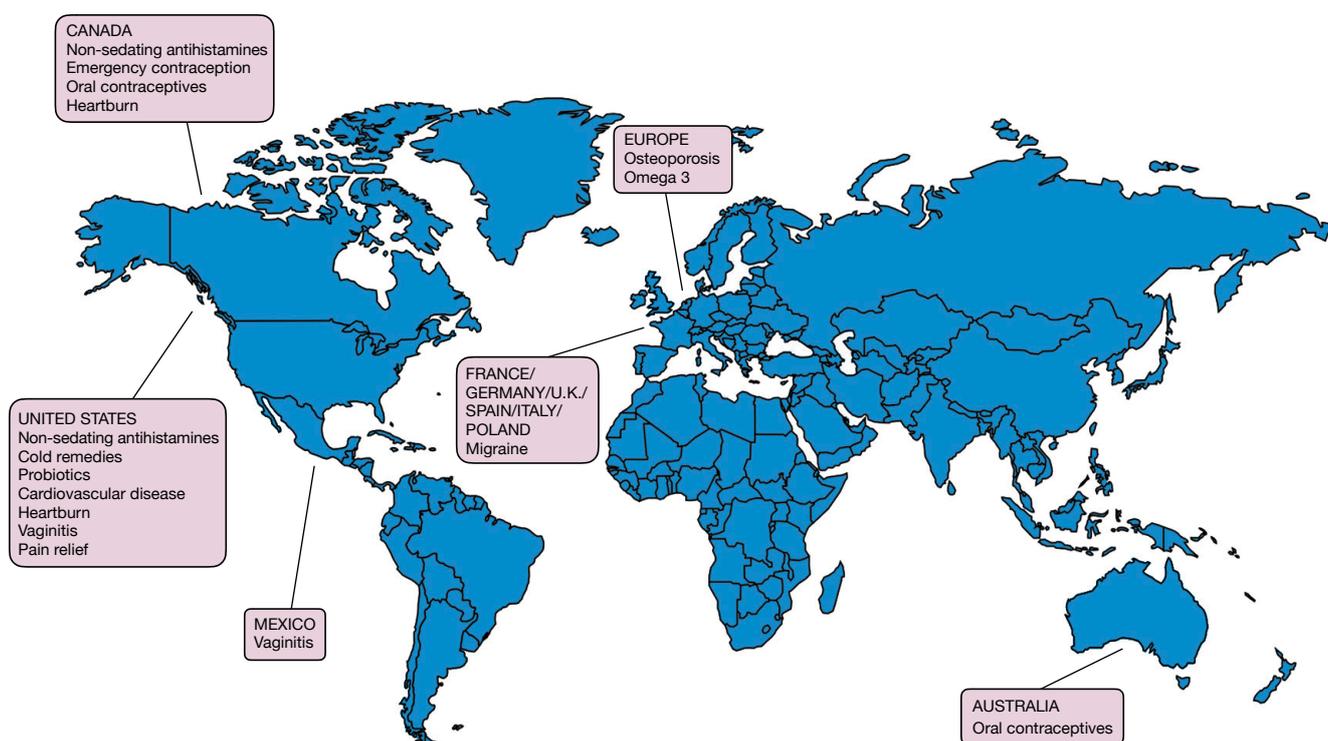
As a de-identified patient records database including diagnosis, prescription, admission and referrals, the IMS Health Disease Analyzer allows researchers to designate physician visits by patient condition. It was seen in the years 2006-2007 that there were 57 million physician visits per year involving conditions appropriate for self-medication, of which 51.4 million were solely for the purpose of seeking care for these conditions. To place this number in context, there were 290 million total physician visits during that time, meaning 20% of total visits involve conditions suitable for self-medication and 18% were solely for such conditions. 91% of the visits involving these conditions resulted in the writing of prescriptions at a cost of £370 million. If the cost of physician time is included in the calculation, approximately £2 billion are spent annually in the treating these conditions. The top ten conditions include, but are not limited to, colds, indigestion, and muscle aches, all of which could be reasonably treated with nonprescription medications (Proprietary Association of Great Britain, 2019).



THERAPEUTIC CATEGORY SERVICE

The primary consideration in reclassifying medicines from prescription to nonprescription status is safety. Most countries have established processes and guidelines for the data which has to be provided to demonstrate that an ingredient which is prescription only can safely be used without medical input. The process of reclassification can take several years and a considerable financial investment so there is an interest in establishing whether the switch makes economic sense for the manufacturer. Similarly, health authorities and 3rd party payers have an interest in establishing whether switching saves money for the user and the healthcare system which justifies the effort required to evaluate and switch the ingredient. A number of studies have been carried out to explore these issues.

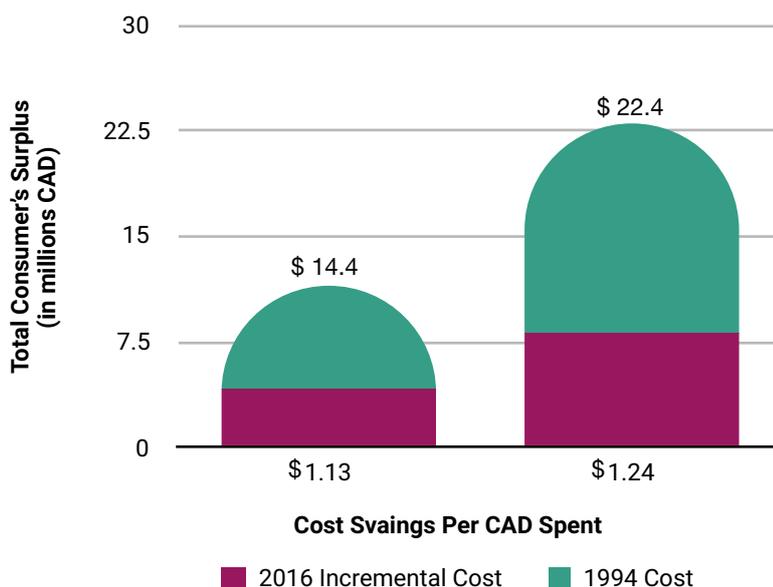
ECONOMICS OF WIDENING AVAILABILITY OF NEW INGREDIENTS AND NEW CATEGORIES OF SELF-CARE



ALLERGIC RHINITIS AND CHRONIC URTICARIA

Nonsedating antihistamines (NA) are used globally to treat histamine related conditions including allergic rhinitis and chronic urticaria. Two generations of NA have now widely been reclassified from prescription only to nonprescription status, and the impact of this reclassification was modeled in Canada using a decision model developed by the Queen’s Health Policy Center (1995). The model calculated the consumer surplus provided by NA’s being without prescription in terms of monetary and time benefits. It has been estimated that for every \$1 spent by consumers on NA’s, \$1.13 to \$1.24 was received in benefits depending on the model run. On a national level this equated to \$8.1 million to \$14.9 million in 1994 CAD, or \$12.2 to \$22.4 million in 2016 CAD. The opportunity cost savings associated with not having to go see a physician for the NA prescription was priced at \$4.4 million in 1994 CAD or \$6.6 million in 2016 CAD (Figure 5). Sensitivity analyses showed that the average prescription cost would equal that of self-medication with NA only when estimates are varied around physician services (all costing \$16.25, no follow ups), pharmacist fees (\$10, no follow ups), doubling costs of concomitant medication, and assuming only half the number of people going to a physician who would not otherwise have (Queens Health Policy, 1995). The cost savings seen in this analysis were corroborated by Tasch et al (1996) in a model predicting cost differences for the move of Famotidine, an NA, to nonprescription status. Tasch predicted costs to a third party payer, such as the provincial governments, would decrease per user by \$6 CAD (Tasch, Goeree, Henke, & O’Brien, 1996).

FIGURE 5: COST SAVINGS FROM NA BEING MOVED TO NONPRESCRIPTION STATUS (CANADA)



In the United States in a model by Sullivan et al (2003), the impacts of reclassifying second generation antihistamines (SGA) from prescription only to nonprescription availability was estimated. The results of the model showed that the transition to self-medication would save \$100 per individual with allergic rhinitis or approximately \$4 billion. When calculating the additional savings associated with the lost work productivity, an additional \$854 million contributed to the total economic impact of approximately \$4.85 billion (Sullivan, Follin, & Nichol, 2003).

OSTEOPOROSIS

Osteoporosis is the most prevalent bone disease in the European Union, with more than €24 billion being spent on the treatment of osteoporosis-attributed fractures alone, plus an additional €10 billion in long-term care costs related to osteoporosis-attributed disability. These costs do not include informal costs related to the loss of mobility and independence, and a general reduction in a patient's quality of life. The authors of this study note that if Europeans over the age of 55 diagnosed with osteoporosis, used 1,000 mg calcium + 15 µg vitamin D as a risk reduction strategy, there would be more than € 2.8 billion per year saved because of avoided osteoporosis-attributed fractures. This equates to nearly €101.63 per target user in healthcare cost savings typically payable by government or private insurance companies (Frost and Sullivan, 2017).

COLD

Approximately \$2 billion per year is spent (by patients) in the United States on self-medication products to treat cough symptoms. Many of these nonprescription cough medications contain dextromethorphan (DXM) as an active ingredient. When used as directed, DXM is a safe and effective agent for treating the common cold. Through a cost-minimization analysis, researchers at Charles River Associates (2016) evaluated the benefits associated with DXM being available for self-medication in regards to both avoided physician visits and lower drug prices. Overall, it was estimated that prescription only access to DXM would cost an additional \$22-31 billion for the time period of 2016 to 2025 vs DXM being available as a nonprescription medicine (Rankin, Tsvetkova, Estus, & Nah, 2016).

In the U.S., Lenoir-Wijnkoop and colleagues (Lenoir-Wijnkoop, et al., 2019) examined the economic impact of probiotic use for respiratory tract infections (RTI). Using data from meta-analyses conducted by the York Health Economics Consortium (YHEC) and Cochrane they demonstrated that generalized probiotic intake in the US population for 2017–2018 would have allowed cost savings for the health care payer of 4.6 million USD based on the YHEC scenario and 373 million USD for the Cochrane scenario. These savings accrue from averting 19 million and 54.5 million RTI sick days, respectively, compared to no probiotics. Antibiotic prescriptions decreased with 1.39–2.16 million courses, whereas absence from work decreased by 3.58–4.2 million days when applying the YHEC and Cochrane data, respectively. When productivity loss is included, total savings for society represented 784 million or 1.4 billion USD for the YHEC and Cochrane scenarios, respectively.

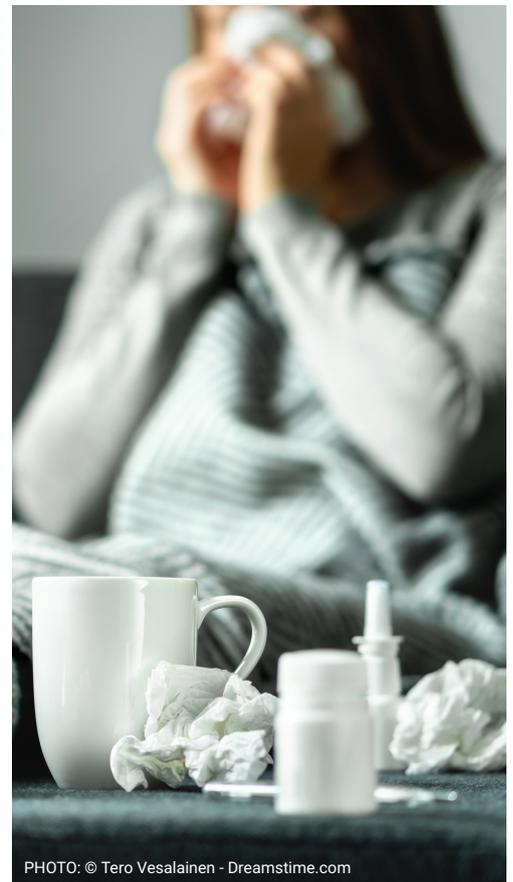


PHOTO: © Tero Vesalainen - Dreamstime.com

PREGNANCY

Emergency contraception (EC) has had more limited uptake than NA, but models from Canada, and Australia have projected changes in utilization and the cost savings associated with EC use. Trussell et al (2001) calculated the cost savings per dollar spent on two different drugs for pregnancies averted and pregnancies delayed in Canada. Pregnancies delayed attempts to account for women who are using ECs and yet still intend to have children at some point. The model also accounted for comparisons to various other contraceptive methods and accounted for less than ideal use of each method. In the averted birth model, ECs save between \$2.09 and \$2.35 CAD per dollar spent on the drug. Even under the costlier assumption that the women would eventually have planned child births, EC saved between \$1.19 and \$1.35 CAD per dollar spent on contraceptives (Trussell, Wiebe, Shochet, & Guilbert, 2001).

The Conference Board of Canada (Gagnon-Arpin, 2017) examined the savings from the reclassification of oral contraceptives from prescription only to nonprescription status by using an adapted logic model developed by Laura Pellisé and Miquel Serra (Pellise, L; Serra, M, 2015). The model focuses on estimating the time savings due to fewer primary care visits, which leads to increased efficiency in the health care system and improved workplace productivity. The analysis also models changes to the cost burden of paying for medications from the perspective of public and private drug plans and individuals. Overall, the economic gains of switching oral contraceptive to over the counter were estimated at \$222.2 million (Canadian dollars) over one year. Forty-four per cent (\$98.2 million) of this value would result from efficiency and productivity gains from fewer primary care visits, and 55.8 per cent (\$124.1 million) from a change in the cost burden of oral contraceptives

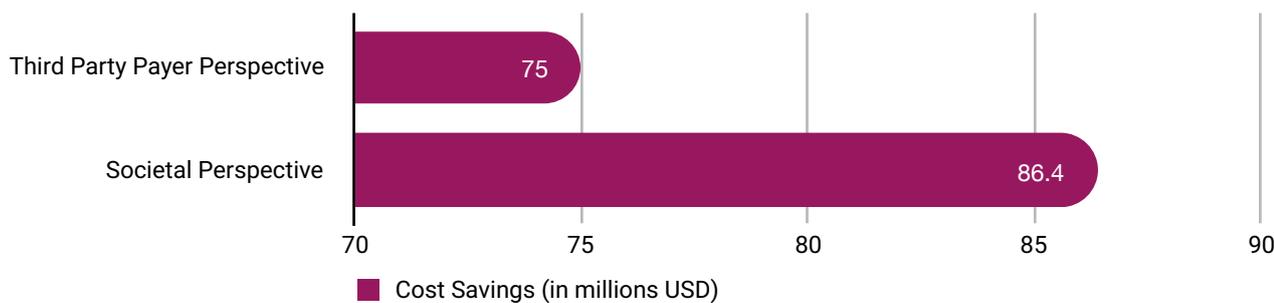
An Australian study (Gumbie, Parkinson, Cutler, Gauld, & Mumford, 2019) found that reclassifying oral contraceptives resulted in 85.70 million quality-adjusted life-years experienced and costs of \$46,910.14 million over 35 years, vs. 85.68 million quality-adjusted life-years experienced and costs of \$50,274.95 million with oral contraceptives remaining prescription-only. Thus, reclassification was more effective and cost saving for the healthcare system.



MIGRAINE

In 2006, two medications for migraine treatment which fall into the triptan class were approved as nonprescription drugs in Germany (naratriptan 2.5mg) and the UK (sumatriptan 50mg). In a study across six European countries Millier et al (Millier, Cohen, & Toumi, 2013) reported that migraine attack management is responsible for approximately €582 million in overall direct spending each year across 6 EU member states (France, UK, Spain, Italy, Germany, and Poland). In a study modeling the impact of switching triptans from prescription to nonprescription availability across 6 EU member states, an estimated €75 million in third party payer savings would be achieved after only one year of triptan nonprescription availability (assuming 20% of patients switch to self-medication). From the societal perspective, total cost savings amounted to €86.4 million annually (Figure 6). Followed by drug acquisition costs, the largest savings following the switch was due to GP visits avoided, decreases in productivity loss due to GP visits, and less time off work. As some EU member states, such as Poland, do not reimburse triptans as of 2013, a significant benefit would result from switching from prescription to nonprescription status. For example, early access to effective treatment may prevent an attack from progressing, improve outcomes, enhance productivity, lower drug prices, and avoid GP and/or emergency room visits.

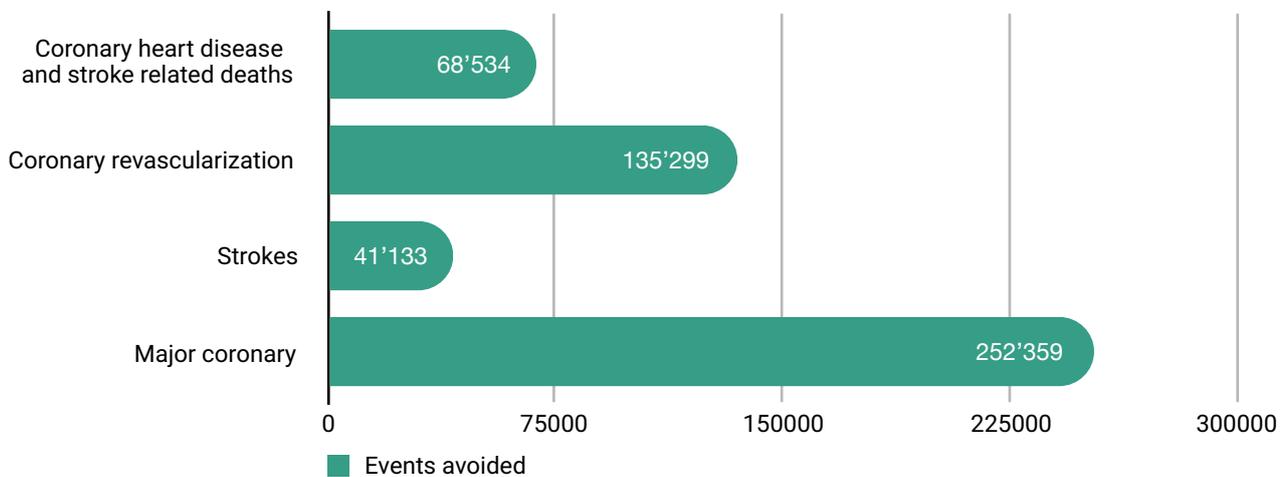
FIGURE 6: COST SAVINGS FROM PRESCRIPTION MEDICATIONS BEING MOVED TO NONPRESCRIPTION STATUS ACROSS 6 EU MEMBER STATES (FRANCE, UK, SPAIN, ITALY, GERMANY, AND POLAND)



CARDIOVASCULAR DISEASE

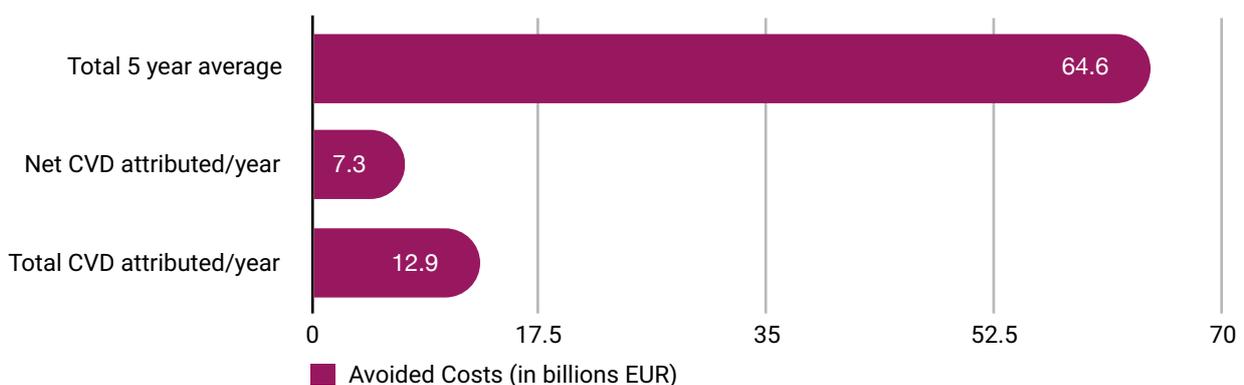
It is well understood that statin use can reduce the incidence of heart disease and stroke, as well as reduce mortality in heart disease and stroke patients. Conversely, 45% of patients who meet the criteria for statin treatment are still not receiving the them. Given that statins have been described as one of the most successful prescription drugs and have the potential to increase savings tremendously if reclassified to nonprescription availability, Stromberg et al (Stromberg, Albaugh, Shiffman, & Sood, 2016) developed a model to estimate the costs and benefits of self-medication with statins in the US. Over a 10-year time horizon, nonprescription statins would result in avoidance of 252,359 major coronary events, 41,133 strokes, 135,299 coronary revascularization procedure, as well as 68,534 coronary heart disease and stroke related deaths (Figure 7). Avoiding these events would result in a savings of \$10.8 billion. The authors stated that nonprescription statins, with appropriate labeling and patient education, would provide a cost-effective avenue for cardiovascular disease prevention.

FIGURE 7. PREDICTED NUMBER OF EVENTS AVOIDED ACROSS 10 YEARS AFTER MOVING STATINS TO NONPRESCRIPTION STATUS (US MODEL)



In addition to statins, other cardiovascular treatments have been proposed as prime self-medication targets. A European study evaluating changes in relative risk and costs with the use of omega-3 EPA + DHA found that relative risk is reduced by 4.9% in an individual CVD patient when taking 1,000 mg/day of omega-3 EPA + DHA. If extrapolating this risk reduction into avoided hospital events, over a 5-year time horizon, 1.5 million hospital events will be avoided in adults in the EU age 55 years and older. Furthermore, assuming 100% of the EU population 55 years and older is taking omega-3 EPA + DHA, avoidable costs would amount to €12.9 billion total CVD-attributed costs/year, €7.3 billion net CVD-attributed costs/year, €188 net CVD-attributed costs per person/year, at a total net benefit/cost ratio of €2.29 (€ avoided CVD-attributed costs per €1 spent on omega-3 EPA + DHA). For the entire EU population 55 years of age or older, supplementation would save an average of more than €64.6 billion over the next 5 years (Figure 8) (Shanahan C. , 2016).

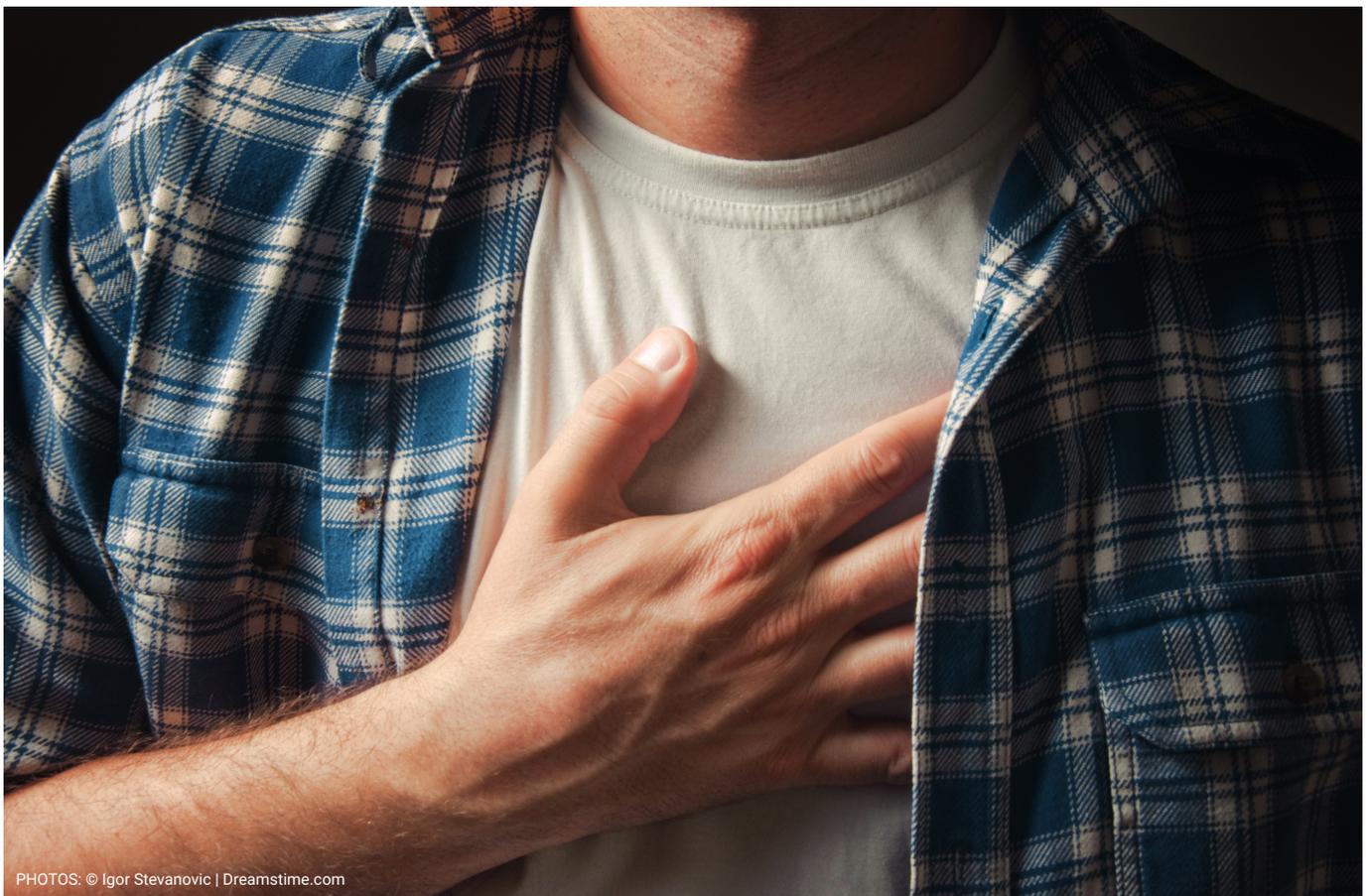
FIGURE 8: AVOIDED COSTS DUE TO PATIENTS TAKING OMEGA-3 EPA+DHA (EU)



HEARTBURN

While a variety of heartburn medications are available for self-medication, studies evaluating the costs and benefits of these medicines are not well described. In the United States, Mansfield et al (Mansfield & Callahan, 2008) conducted a study to quantify cost savings associated with nonprescription use for heartburn. Part one of the study determined that patients taking prescription heartburn drugs visited their doctor to discuss symptoms a ratio of 1.62 more times than patients using a nonprescription product. It was determined that if patients were not taking nonprescription heartburn medications, physician appointments would amount to approximately 6 million visits. At a rate of \$121 per physician visit, an increase of 6 million appointments would amount to approximately \$757 million in healthcare costs. From the patient perspective, self-medication provides an approximate annual savings of \$174 and \$160 in physician visits and medications, respectively.

In Canada, Gagnon-Arpin reported on the value of switching proton pump inhibitors from prescription status to self-medication (Gagnon-Arpin, 2017). The authors reported that the economic value of such a switch was estimated at \$709.9 million (Canadian dollars) over one year. Thirty-nine per cent (\$278.8 million) of this value would result from increased efficiency and productivity gains from fewer primary care visits, 40.1 per cent (\$284.8 million) from changes in the cost burden, and 20.6 per cent (\$146.3 million) from increased labour productivity due to earlier treatment.

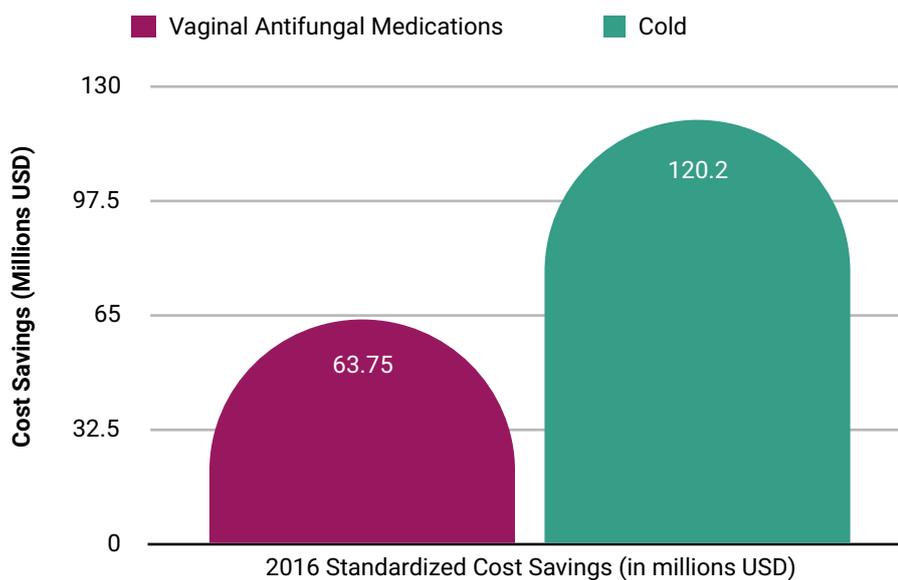


VAGINITIS

An analysis of the reclassification of vaginal antifungal products in the United States was completed by the Fallon Community Health Plan (FCHP), now Reliant Medical Group, in 1992 (Gurwitz, McLuaghlin, & Fish, 1995). FCHP is an integrated delivery network, which is a large healthcare delivery organization that provides healthcare services, including inpatient and outpatient care as well as health insurance, to patients. Because of this, FCHP was ideally suited to see the impact of this switch in terms of health service, prescriptions used, and lab tests. In the one year following the switch to nonprescription status, FCHP saw a reduction in physician visits of 0.66 per 100 members which equated to between \$12,768 and \$25,729 in savings. Additionally, there were considerable savings associated with less medication being dispensed of \$42,528 for the plan (Figure 9). The savings in physician and medication services comes to a total of between \$55,296 and \$68,257 in 1992 dollars or \$94,926 and \$117,176 in 2016 dollars.

This analysis was corroborated in a study by Lipsky and Waters which showed a 15% decrease in vaginitis related physician visits between 1991 and 1994. Using an approximate cost of \$61 per visit, this equates to a direct savings of \$45 million, with an additional \$18.75 million in savings associated with patient time (Lipsky, Lipsky, & Waters, 1999).

FIGURE 9. 2016 STANDARDIZED COST SAVINGS FROM MOVING TREATMENT OF VAGINITIS AND COLDS TO NONPRESCRIPTION STATUS (US)



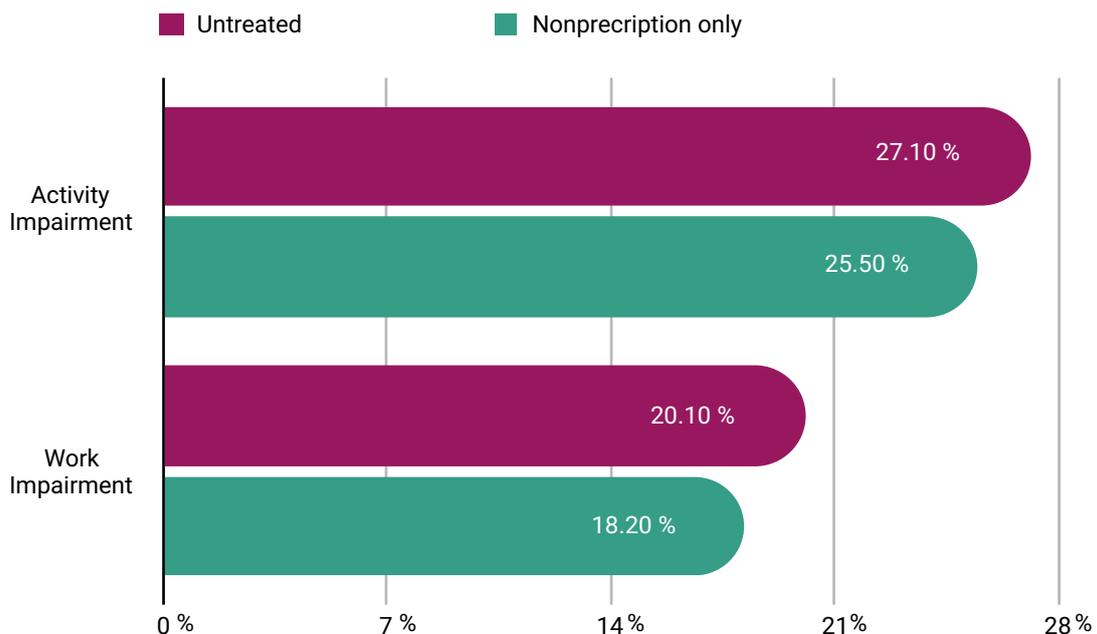
The potential economic value of making prescription vaginitis products available for self-medication in Mexico was assessed (Asociación de Fabricantes de Medicamentos de Libre Acceso, 2018). The study looked at the costs of attending a physicians office as well as productivity loss from absenteeism when compared with self-management of candidiasis. The authors concluded that the Health system would save 100 million (MXP) per 100,000 occurrences of the infection. The report estimates that there are 482,000 cases each year attended to by a doctor and covered by the health care system.

PAIN

At a global level, pain is one of the most common afflictions that impact people’s daily lives. According to one report (GlaxoSmithKline, 2017), 95% of people experience body pain during their lifetime while 86% report head pain. This report also found that the average worker takes 2.6 days off each year to cope with their pain which cost the global economy approximately \$245 billion annually.

In an analysis by Lee et al (Lee, DiBonaventura, Kudel, Schepart, & Kellstein, 2016) evaluating 2013 NHWS data, 25,851 respondents (34.5%; total respondents = 75,000) reported pain in the past 12 months, of which 15.1% were taking nonprescription medicine plus a prescription drug, 19.0% used a prescription drug only, 51.3% took a non-prescription medicine only, and 14.6% were untreated. Nonprescription product use was associated with significantly less work impairment (18.2% vs. 20.1%, $p = 0.0046$) and activity impairment (25.5% vs. 27.1%, $p = 0.0006$) in comparison with the untreated group (Figure 10). Similar trends were seen in activity impairment vs. prescription only group (42.8% vs. 46.1%, $p = 0.0002$). In the previous 6 months, those only taking a nonprescription medicine experienced fewer hospitalizations (0.09) vs. those untreated (0.13, $p < 0.0001$). When compared with those taking nonprescription medicine plus a prescription drug, the nonprescription only group had significantly less health resource utilization (3.5 vs. 5.6 provider visits, 0.19 vs. 0.40 ER visits, 0.09 vs. 0.21 hospitalizations; $p < 0.0001$ for all).

FIGURE 10: WORK AND ACTIVITY IMPAIRMENT AMONG PATIENTS REPORTING PAIN



COLD

In the United States, Temin (Temin, 1992) used data from the IMS (now IMSQuintiles) to track the reduction in physician visits associated with the switch of cold medicines over a 14-year period. It was seen in the study that the number of general practitioner visits related to common colds fell by approximately 110,000 per year. In the final year of analysis, there were 1.65 million fewer visits, and at a price of \$42 per visit, this equates to a savings of \$70 million. As this article was published in 1992, the costs associated with the physician visit would obviously have increased from the \$30 set and the \$2 for public transportation plus \$10 for an hour of a patient's time. Even assuming these costs are still equal, at a yearly savings of \$70 million this equates to \$120.2 million per year in 2016 dollars (Figure 9) (Soller, 1998).

A Mexican report described the potential cost savings associated with a cold or influenza (Association de Fabricantes de Medicamentos de Libre Acceso, 2018). Here the average cost of dealing with these common ailments runs at 1,025 (MXP) per event through the formal health system while the average costs associated with self-medication is only 32 (MXP). When the productivity losses due to these illnesses is taken into account the reported savings to the Mexican health authorities would be 993 million (MXP) for every million occurrences. Given there are nearly 7.5 million reported cases (in addition to those where self-care is already practiced to manage the illness), the impact is considerable.

Looking specifically at a single cough ingredient (dextromethorphan), Rankin and his colleagues examined various costs that would result if products with DXM were converted from OTC status to prescription only (Rankin, P J; Tsvetkova, I V; Estus, E; Nah, N; Senne, B, 2016). This type of research explores the economic consequences of losing a selfcare medicine. By proxy this provides an estimate of the current value of a selfcare product and the researchers assessed multiple scenarios and included full costing for key elements such as presenteeism, lost productivity, acquisition costs etc. They reported that the 10-year cost-savings estimates from over-the-counter availability of dextromethorphan would be \$21.1 billion (US). Based on assumptions they derived from the prescription-only access scenario they estimated such a reverse switch would create additional costs in the range of \$22 billion and \$31 billion for the period 2016 – 2025. Sensitivity testing showed that the value for the 10-year period examined would be between \$21 billion and \$29 billion.

TECHNOLOGY

The use of technology to improve the value fo selfcare is an emerging area of interest. Digital platforms for educating consumers and other stakeholders on how to best manage their health have added to the health literacy tools for people seeking to get healthy and stay healthy. One study that examined the impact of technology found that there was considerable potential for saving healthcare costs and improving outcomes (Proprietary Association of Great Britain, 2019).

The report notes that apps and wearables are moving from monitoring activity and encouraging healthy living to providing personalised advice. The potential for self care was illustrated by a few facts. First, there were an estimated 18 million GP appointments for self-treatable conditions in 2016 (Proprietary Association of Great Britain, 2019). Some of these included: 5.2 million visits to a GP for blocked nasal passages, over a million visits for backache and 40,000 appointments for dandruff. The authors point out that *"apps and wearables have the potential to help reverse this trend, changing the behaviour of users, directing them to self care where appropriate and encouraging greater use of their local community pharmacists."*

DISCUSSION

Around the world, multiple research efforts have highlighted the benefits of self-medication in reducing healthcare costs. Studies across countries encompassed a variety of designs, ranging from theoretical models to retrospective studies of medical records and surveys. Further, conditions suitable for self-medication evaluated ranged from analyses of grouped conditions to more specific conditions including allergic rhinitis/chronic urticaria, cold, pregnancy, migraine, cardiovascular disease, heartburn, vaginitis, and pain. As a result of this research, there are clear implications and areas where further research can be done.

The first implication is in the clear reduction in physician visits. In multiple studies it was evident that when a prescription medication is reclassified to nonprescription status, or when self-medication is used instead of prescription drugs, self-medicating patients require fewer primary care physician visits. Patients are able to obtain medication for self-medication without needing a healthcare professional to intervene. While self-medication often doesn't require a physician visit, studies included in this report have shown that a large proportion of patients seek medical care in a physician setting for conditions suitable for self-medication, most of which are unnecessary. As every healthcare system around the world deals with scarce resources and lengthy wait times, the benefits associated with fewer physician visits may reach far outside even treating these conditions.

The second implication is in cost savings to the government payer or third party payers. Not surprisingly, nonprescription availability of medications results in a reduction in costs borne by the payer. Part of this cost decrease may be associated with the reduction in physician visits if the general practitioners are not salaried employees. Other cost savings come in the form of reductions in prescription costs. If the payer is a third party entity, there are reductions in pharmacy cost. If the payer is a government that sets standard rates for prescriptions, there are less drugs to have on reimbursed formularies. As seen in the research above, in either situation, this cost savings can be significant (up to \$2 billion in one study), which may allow payers to reduce premiums or governments to use money in other sectors (Proprietary Association of Great Britain, 2019).

Other implications exist, such as reductions in patient time burden and productivity. These effects are usually studied in tandem with other implications such as the two discussed above, but the benefit they present is still important. These effects are more tangible to the patient themselves and their employers, making their lives easier. As patient centeredness and advocacy has come to the forefront of discussion around the world, these topics will move from their current status as a secondary focus to a primary focus.



FUTURE RESEARCH

Moving forward, there is still much that can be done to expand on this research. As stated previously, more research is needed in regards to patient burden and productivity differences between self-medication and the use of prescription drugs, but additional attention is needed in two other areas:

1. More targeted research on commonly used nonprescription products for self-medication
2. An identified, systematic process for performing research studies on conditions amenable to self-medication.

First, many nonprescription products have received little attention in terms of research analyses. For example, in the United States, outside of an opinion article, orlistat has received very little attention, even though there is a large market and need for proven weight-loss medications. Further, commonly used nonprescription products that have been on the market for many years or even decades have not been extensively evaluated. These compounds include rehydration salts for dehydration associated with acute diarrhea and vomiting, anti-diarrhea tablets, other heart-burn medications (antacids, alginates), among others.

Second, as new compounds are being discussed, there should be a steady process for research. Preliminary discussion around moving prescription drugs to nonprescription status should involve an accepted model to demonstrate both the therapeutic benefits as well as the economic value of the switch. After a prescription drug is switched to non-prescription status, retrospective research in the form of database analyses (claims, emergency medical records, etc.) could be done to show what the actual impact has been. In conjunction, research surveys and prospective research designs can be used to highlight patient satisfaction and how increased access has affected the market. Finally, conditions for which nonprescription products are currently available vary significantly from country to country. Different political and regional differences are inevitable, but from the research done in this report, it's clear that certain medications would deliver economic benefits if moved to nonprescription status.



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