RISKS OF UNREGULATED ACCESSIBILITY

Clinicians play a key role in assessing a patient's need for statins by considering blood test results in an overall risk assessment. They also educate patients on managing other risk factors such as physical inactivity and blood pressure. Without this intervention, individuals may misinterpret blood test results or forego cholesterol testing prior to their drug purchase. Hence, the use of statins by individuals at low risk of CVD might unnecessarily elevate the risk of side effects. A multi-centre study conducted in the United States in 2004 simulated an OTC setting to investigate potential consumer activity following the introduction of OTC statins. The results revealed that 20% of people purchasing statins were low-risk, while 25% did not undergo cholesterol testing.[12]

High-risk patients are equally susceptible to statin misuse. Since low-dose OTC statins can only effectively treat intermediate-risk patients, high-risk patients should continue using their prescription statins and avoid using low-dose OTC statins. The aforementioned study showed 23% of low-dose statin consumers were either high-risk or had too high cholesterol levels to be effectively treated by low-dose statins.[12] High-risk patients may substitute prescription statins for their OTC counterparts because they are cheaper and more accessible to the public. Since OTC statins' dosages are too low to effectively reduce their risk of CVD, they may actually cause more harm than good due to side effects and ineffective treatment.[3] Secondary prevention measures are also often required alongside prescription statins to manage the risk of CVD, indicating the need for direct physician-patient interaction.

Since OTC statins are used as a preventative therapy, they also raise the concern of low adherence. Current OTC drugs are intended for acute care, in which symptom relief is easily recognizable, encouraging people to use the drugs effectively to become healthy. Conversely, the benefit of OTC statins can only be tracked through regular blood tests. This inconvenience, combined with the lack of incentive to treat a potentially life-long asymptomatic disease, predicts low adherence to OTC statins.[9]

While they have wide safety margins, OTC statins also make it harder for physicians to track the medications their patients take and thus increases the possibility of adverse drug interactions. The risk of statin-induced rhabdomyolysis, a syndrome characterized by muscle necrosis, may increase significantly if statins are taken along with fibrates, another class of medication that reduces the risk of CVD.[13] Patients may be incentivized to take OTC statins along with fibrates for a potential additive effect if they deem fibrates to be inadequate for treatment. The possibility of adverse drug interactions is already high with physician involvement. In fact, a study of statin prescriptions in hospitals found that 26. 1% of patients received co-prescriptions of statins with other medications known to cause dangerous interactions.[13] Without physician involvement, the risk of adverse drug interactions may be even higher. The risks of misuse, low adherence, and additional adverse drug interactions may be potentially reduced through physician involvement in a patient's statin therapy.

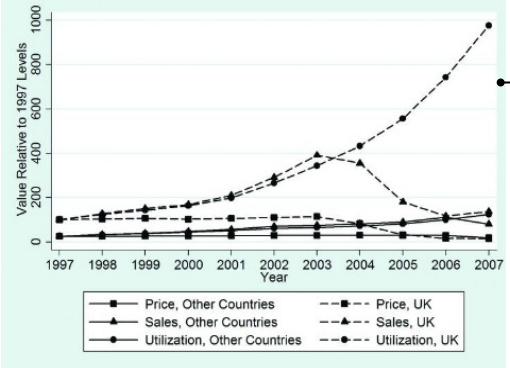

FIGURE 1: Change in Price, Sales and Utilization of Simvastatin in the UK compared to control countries from 1997-2007. The control countries used were the US, Canada and New Zealand. BTC Simvastatins were introduced in 2004. Following BTC approval of Simvastatin in the UK, statin use increased ten-fold from 1997 while its price and sales dropped.[14]

CONCLUSION

The prevention and management of CVD risk requires bridging the marked treatment gap in the Canadian population. Although OTC statins present a valid solution, the ability of patients to manage their own preventative care remains a predominant concern. It is crucial for statin consumers to understand the importance of clinician intervention so as to avoid possible misuse. There are safer alternatives to narrowing the gap, which include an introduction of patient education programs and stricter adherence to guidelines for physician prescription, both subject matters for future consideration.

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REVIEWED BY DR. EVA LONN

EDITED BY TAKHLIQ AMIR

Dr. Eva Lonn is Senior Scientist at the Population Health Research Institute, as well as Primary Panelist and Co-author of the Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult. Her research interests include clinical trials in the primary and secondary prevention of cardiovascular diseases, the study of cardiovascular risk factors, and cardiovascular epidemiology. She is also a Professor in the Division of Cardiology in the Department of Medicine at McMaster University.