CPA SUBMISSION

Off-label Prescribing in Psychiatry

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What is off-label prescribing? It is the use of licensed medication outside of the condition or indication for which the licence was issued. Pharmaceutical companies apply for approval to promote medications for specific conditions. These licensing regulations are designed to regulate the claims pharmaceutical companies can make about their medications. Although it is illegal for pharmaceutical companies to promote the use of medications for off-label conditions, it is legal for physicians to prescribe medications off-label.

Off-label prescribing is common in all medical practice and is often required to help patients who suffer with residual symptoms. Although many clinicians consider whether the medication is licensed for treating the condition, they rely more heavily on the clinical practice guidelines, systematic reviews and clinical experience.

The Canadian Medical Protective Association has issued recommendations to physicians on the off-label use of medications and devices. They suggest that physicians should review the medical literature and consider if the proposed off-label use of the medication has gained enough acceptance among peers, that they should take reasonable precautions to ensure that the off-label use is appropriate for the patient’s condition, that they should advise the patients that the drug is not approved for their particular condition and, finally, that they should obtain and document informed consent before using the off-label medication.

Turning to mental disorders, what are the reasons for off-label use for mental disorders? Off-label prescribing is very common and essential in medical practice in treating mental disorders, and there are some key reasons.

First, with the reduction in stigma over last number of years, there is an increased willingness to seek treatment for mental health problems. Mental disorders often present with complex symptoms that affect multiple brain systems. Most medications approved for common mental disorders are associated with only a partial reduction of the symptoms, so off-label prescribing is used to treat residual symptoms and improve functioning.

Second, off-label prescribing of antidepressants and antipsychotics in children and the elderly has been increasing over last 10 years. Pharmaceutical companies often do not seek approval for medications for children and the elderly due to financial concerns. Studies in these groups are difficult to do and outcomes are difficult to measure. Clinicians will often use medications that have been approved for the condition in an adult in children and the elderly. However, there is an urgent need for research in children and the elderly on the safety of off-label medication use.
Third, the majority of people treated for mental disorders in Canada are treated by their family physician who does not have the time or the training to provide psychotherapy. Long waiting lists for psychiatric assessments and limited availability of psychotherapy mean that patients often receive medications to treat their disorder and do not get the additional psychotherapy.

Finally, there is little data to guide clinicians on the length of treatment that a person requires. This means patients often receive multiple medications, some on-label and some off-label, to reduce their symptoms. To obtain approval, pharmaceutical companies usually conduct short-term studies, usually six weeks to a year. However, the appropriate length of required treatment and the long-term safety of medications often remain unknown.

What are the suggestions for future research and policy? First, a strong investment in research that aims to understand the underlying causes of mental disorders is required. Until we discover the cause of the illness, medications will continue to target the reduction of symptoms rather than curing the actual illness. Similar to the heavy investments in research in cardiovascular disease, cancer and AIDS that have led to important discoveries and better treatment of these conditions, there needs to be a similar increase in funding to support understanding the underlying causes of mental disorders. Furthermore, investment in innovative ways to treat mental health problems is also urgently needed.

Second, governments rely too heavily on pharmaceutical companies to conduct research on medications. We need to create an independent, non-biased research capacity to conduct trials on medications after they have gained approval. This research should focus on the long-term safety and efficacy of these medications and specifically target youth and the elderly.

Finally, Canada needs to invest in unbiased physician education focused on the benefits and risks of medications. In the last 20 years, most physician education has been sponsored by pharmaceutical companies and has been criticized for being biased. There have been substantial policy changes to reduce the potential bias in educating physicians. Nonetheless, there remains a need for education and best practices that are not profit-driven. This education should take a comprehensive approach that includes medications and psychotherapy.

In summary, the off-label use of medication is an essential tool in treating people suffering from severe and disabling mental disorders. Governments cannot rely on pharmaceutical companies to conduct research on long-term safety and efficacy of medications. They must invest in education and research into the causes and appropriate treatments of mental disorders. This investment will improve treatment and reduce the burden of mental illness for Canadian society.

For a complete transcript see: http://www.parl.gc.ca/Content/SEN/Committee/411/soci/32ev-49992-e.htm?Language=E&Parl=41&Ses=1&comm_id=47